Supplemental Update Report

CR Number: 2021308001 **Implementation Date:** 11-Oct-22 Related CR: 2021308001

Change Requested	Link HLT to another HLGT	Final Disposition	Final Placement	MedDRA Code #
Proposed HLT	*Cholecystitis and cholelithiasis*	Rejected After Suspension		
From HLGT	*Gallbladder disorders*			
To HLGT	*Hepatic and hepatobiliary disorders*			

MSSO Comment: The proposal to move the HLT Cholecystitis and cholelithiasis from HLGT Gallbladder disorders to another HLGT Hepatic and hepatobiliary disorders is not approved after suspension. Cholelithiasis is generally defined as the presence or formation of gallstones either in the gallbladder or in the bile ducts. However, MedDRA was constructed to separate out the anatomical locations such that the gallbladder and bile ducts are classified separately. Specifically, terms relating to stones in the gallbladder are in HLT Cholecystitis and cholelithiasis in HLGT Gallbladder disorders and terms for stones in the bile ducts are in HLT Obstructive bile duct disorders (excl neoplasms) in HLGT Bile duct disorders.

CR Number: 2021330008 **Implementation Date:** 20-Jul-22 Related CR: 2021330008

Change Requested	Add a New HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed HLT	*Surgical implant allergy*	Rejected After Suspension		
To HLGT	*Allergic conditions*			

MSSO Comment: The proposal to add a new HLT Surgical implant allergy to HLGT Allergic conditions is not approved after suspension. The PTs proposed for inclusion under a proposed HLT Surgical implant allergy (PT Allergy to metals, PT Allergy to surgical sutures, PT Bone cement allergy, PT Device allergy and PT Polymers allergy) are not specific to surgical implants and represent broader concepts. For example, PT Allergy to metals is not specific to implants and may represent contact dermatitis and PT Device allergy is a very broad concept which refers to all types of devices, not just surgical implants. Furthermore, what constitutes a surgical implant is not well defined. A separate grouping of these concepts is therefore not warranted within MedDRA.

CR Number: 2021364460 **Implementation Date:** 11-Oct-22 Related CR: 2021364460

Change Requested	Rename HLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Urinary tract lithiasis (excl renal)*	Approved Not as Requested After Suspension	Proposed HLT	
Replacement term	*Urinary tract lithiasis NEC*		*Urinary tract lithiasis NEC*	10088574
			To HLGT	
			Urolithiases	10046708

MSSO Comment: The proposal to rename the HLT Urinary tract lithiasis (excl renal) to Urinary tract lithiasis NEC is approved but not as requested after suspension. The MSSO will add a new HLT Urinary tract lithiasis NEC to HLGT Urolithiases. In a related change, existing HLT Urinary tract lithiasis (excl renal) will be merged under new HLT Urinary tract lithiasis NEC. LLT Urolithiasis and LLT Urolith, and the more general PT Calculus urinary under which both LLTs reside, refers to the whole urinary tract. These terms are not well represented under the HLT Urinary tract lithiasis (excl renal) because of the exclusion of kidney, which is also part of the urinary tract. Replacing HLT Urinary tract lithiasis (excl renal) with new HLT Urinary tract lithiasis NEC solves the problem.

Supplemental Update Report

CR Number: 2022284090 **Implementation Date:** 11-Oct-22 Related CR: 2021364460

Change Requested	Merge HLT	Final Disposition	Final Placement	MedDRA Code #
HLT to merge	*Urinary tract lithiasis (excl renal)*	Approved as Requested	HLT to merge	
			Urinary tract lithiasis (excl renal)	10046579
To HLT	*Urinary tract lithiasis NEC*		To HLT	
			Urinary tract lithiasis NEC	10088574

MSSO Comment:

CR Number: 2022109010 **Implementation Date:** 11-Oct-22 Related CR: 2022109010

Change Requested	Rename HLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Fertility analyses*	Approved Not as Requested After Suspension	Proposed HLT	
			Fertility analyses and other reproductive function procedures	10088575
Replacement term	*Fertility analyses and other reproductive function procedures*		To HLGT	
			Reproductive organ and breast investigations (excl hormone analyses)	10038592

MSSO Comment: The proposal to rename the HLT Fertility analyses to Fertility analyses and other reproductive function procedures is approved but not as requested after suspension. The MSSO will add new HLT Fertility analyses and other reproductive function procedures to HLGT Reproductive organ and breast investigations (excl hormone analyses). In a related change, existing HLT Fertility analyses will be merged under new HLT Fertility analyses and other reproductive function procedures. Additionally, PT Intracavernosal injection test will be moved from HLT Physical examination procedures and organ system status to new HLT Fertility analyses and other reproductive function procedures for better placement. Apart from imaging and histological investigations, functional reproductive investigations other than fertility analysis did not have a specific place presently in MedDRA. This is the case of tests performed to evaluate organic causes of erectile dysfunction. This change widens the current scope of HLT Fertility analyses to accommodate "functional-non fertility related" investigations, both male and female.

CR Number: 2022284091 **Implementation Date:** 11-Oct-22 Related CR: 2022109010

Change Requested	Merge HLT	Final Disposition	Final Placement	MedDRA Code #
HLT to merge	*Fertility analyses*	Approved as Requested	HLT to merge	
			Fertility analyses	10016462
To HLT	*Fertility analyses and other reproductive function procedures*		To HLT	
			Fertility analyses and other reproductive function procedures	10088575

MSSO Comment:

Supplemental Update Report

CR Number: 2022284092 **Implementation Date:** 11-Oct-22 Related CR: 2022109010

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Intracavernosal injection test*	Approved as Requested	Proposed PT	
From HLT	*Physical examination procedures and organ system status*		*Intracavernosal injection test*	10087710
To HLT	*Fertility analyses and other reproductive function procedures*		From HLT	
			Physical examination procedures and organ system status	10071941
			To HLT	
			Fertility analyses and other reproductive function procedures	10088575

MSSO Comment:

CR Number: 2022153001 **Implementation Date:** 06-Jul-22 Related CR: 2022153001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Diabetic myonecrosis*	Approved as Requested	Proposed PT	
			Diabetic myonecrosis	10087983
			HLT primary	
			Myopathies	10028640
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395
			HLT secondary	
			Diabetic complications NEC	10012655
			SOC secondary	
			Endocrine disorders	10014698

MSSO Comment: The proposal to add a new term Diabetic myonecrosis is approved as requested. Diabetic myonecrosis, also known as diabetic muscle infarction is a rare complication of diabetes mellitus usually associated with longstanding suboptimal glycaemic control. Diabetic myonecrosis will be added as PT to primary HLT Myopathies and secondary HLT Diabetic complications NEC.

Supplemental Update Report

CR Number: 2022153002 **Implementation Date:** 06-Jul-22 Related CR: 2022153002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Anti-liver pancreas antibody*	Approved as Requested	Proposed LLT		
To PT	*Anti-soluble liver antigen/liver pancreas antibody*		*Anti-liver pancreas antibody*	10087986	Current
			To PT		
			Anti-soluble liver antigen/liver pancreas antibody	10087984	

MSSO Comment: The proposal to add a new LLT Anti-liver pancreas antibody to PT Anti-soluble liver antigen/liver pancreas antibody is approved as requested. LLT Anti-liver pancreas antibody is a synonym of the PT Anti-soluble liver antigen/liver pancreas antibody, added in change request 2022153005.

CR Number: 2022153003 **Implementation Date:** 06-Jul-22 Related CR: 2022153003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Anti-SLA/LP antibody*	Approved as Requested	Proposed LLT		
To PT	*Anti-soluble liver antigen/liver pancreas antibody*		*Anti-SLA/LP antibody*	10087987	Current
			To PT		
			Anti-soluble liver antigen/liver pancreas antibody	10087984	

MSSO Comment: The proposal to add a new LLT Anti-SLA/LP antibody to PT Anti-soluble liver antigen/liver pancreas antibody is approved as requested. LLT Anti-SLA/LP antibody is a synonym of the PT Anti-soluble liver antigen/liver pancreas antibody, added in change request 2022153005.

CR Number: 2022153004 **Implementation Date:** 06-Jul-22 Related CR: 2022153004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Anti-soluble liver antigen antibody*	Approved as Requested	Proposed LLT		
To PT	*Anti-soluble liver antigen/liver pancreas antibody*		*Anti-soluble liver antigen antibody*	10087985	Current
			To PT		
			Anti-soluble liver antigen/liver pancreas antibody	10087984	

MSSO Comment: The proposal to add a new LLT Anti-soluble liver antigen antibody to PT Anti-soluble liver antigen/liver pancreas antibody is approved as requested. LLT Anti-soluble liver antigen antibody is a synonym of PT Anti-soluble liver antigen/liver pancreas antibody, added in change request 2022153005.

Supplemental Update Report

CR Number: 2022153005 **Implementation Date:** 06-Jul-22 Related CR: 2022153005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anti-soluble liver antigen/liver pancreas antibody*	Approved as Requested	Proposed PT	
HLT primary	*Autoimmunity analyses*		*Anti-soluble liver antigen/liver pancreas antibody*	10087984
SOC primary	*Investigations*		HLT primary	
			Autoimmunity analyses	10003828
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Anti-soluble liver antigen/liver pancreas antibody to primary HLT Autoimmunity analyses in SOC Investigations is approved as requested. Antibodies to soluble liver antigen (SLA)/liver pancreas (LP) are generally considered as highly specific diagnostic markers of type 1 auto-immune hepatitis (AIH-1), and are particularly useful in patients without conventional antibodies.

CR Number: 2022153006 **Implementation Date:** 06-Jul-22 Related CR: 2022153006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Bilaterally superficial cervical plexus block*	Approved Not as Requested	Proposed LLT	
			Bilateral superficial cervical plexus block	10087992 Current
			To PT	
			Cervical plexus block	10087988

MSSO Comment: The proposal to add a new term Bilaterally superficial cervical plexus block is approved but not as requested. Deep and superficial cervical plexus blocks can be used in a variety of surgical procedures, including superficial surgery on the neck and shoulders and thyroid surgery. The requested term, modified to Bilateral superficial cervical plexus block, will be added as sub-concept LLT to a new PT Cervical plexus block which will be added in a related change to HLT Anaesthesia and allied procedures.

CR Number: 2022187002 **Implementation Date:** 06-Jul-22 Related CR: 2022153006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cervical plexus block*	Approved as Requested	Proposed PT	
HLT primary	*Anaesthesia and allied procedures*		*Cervical plexus block*	10087988
SOC primary	*Surgical and medical procedures*		HLT primary	
			Anaesthesia and allied procedures	10002092
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment:

Supplemental Update Report

CR Number: 2022153007 **Implementation Date:** 06-Jul-22 Related CR: 2022153007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Cavernous sinus meningioma*	Approved as Requested	Proposed LLT		
			Cavernous sinus meningioma	10087991	Current
			To PT		
			Meningioma	10027191	

MSSO Comment: The proposal to add a new term Cavernous sinus meningioma is approved as requested. Meningiomas represent 41% of all cavernous sinus tumours. Cavernous sinus meningioma will be added as anatomical sub-concept LLT to PT Meningioma.

CR Number: 2022153008 **Implementation Date:** 06-Jul-22 Related CR: 2022153008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*MR enterography*	Approved as Requested	Proposed LLT		
			MR enterography	10087990	Current
			To PT		
			Magnetic resonance imaging abdominal	10083126	

MSSO Comment: The proposal to add a new term MR enterography is approved as requested. Magnetic resonance enterography is an imaging test which produces detailed pictures of the small intestine to diagnose Crohn's disease and other conditions involving inflammation, bleeding and obstruction. MR enterography will be added as sub-concept LLT to PT Magnetic resonance imaging abdominal.

Supplemental Update Report

CR Number: 2022153009 **Implementation Date:** 06-Jul-22 Related CR: 2022153009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Demodex blepharitis*	Approved as Requested	Proposed PT	
			Demodex blepharitis	10087989
			HLT primary	
			Ectoparasitic infestations	10014143
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Lid, lash and lacrimal infections, irritations and inflammations	10024445
			SOC secondary	
			Eye disorders	10015919

MSSO Comment: The proposal to add a new term Demodex blepharitis is approved as requested. Demodex mites have been implicated in anterior and posterior blepharitis, blepharoconjunctivitis, blepharokeratitis, and beyond. Demodex blepharitis will be added as PT to primary HLT Ectoparasitic infestations and secondary HLT Lid, lash and lacrimal infections, irritations and inflammations.

CR Number: 2022153010 **Implementation Date:** 06-Jul-22 Related CR: 2022153010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Nanoparticle toxicity*	Approved as Requested	Proposed PT	
			Nanoparticle toxicity	10087993
			HLT primary	
			Poisoning and toxicity	10035777
			SOC primary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new term Nanoparticle toxicity is approved as requested. Nanoparticles may cause serious health effects when exposed to the body through ingestion, inhalation, and skin contact without caution. The general mechanisms by which it causes toxicity lie on its capability to initiate the formation of reactive species, cytotoxicity, genotoxicity, and neurotoxicity, among others. Nanoparticle toxicity will be added as PT to HLT Poisoning and toxicity.

Supplemental Update Report

CR Number: 2022153011 **Implementation Date:** 06-Jul-22 Related CR: 2022153011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Prostate specific membrane antigen positron emission tomogram*	Approved as Requested	Proposed LLT	
			Prostate specific membrane antigen positron emission tomogram	10087995 Current
			To PT	
			Positron emission tomogram prostate	10087994

MSSO Comment: The proposal to add a new term Prostate specific membrane antigen positron emission tomogram is approved as requested. Prostate specific membrane antigen positron emission tomogram is a new imaging technique for prostate cancer that locates cancer lesions. Prostate specific membrane antigen positron emission tomogram will be added as LLT to a new PT Positron emission tomogram prostate which will be added in a related change and linked to HLT Reproductive organ and breast imaging procedures.

CR Number: 2022187003 **Implementation Date:** 06-Jul-22 Related CR: 2022153011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Positron emission tomogram prostate*	Approved as Requested	Proposed PT	
HLT primary	*Reproductive organ and breast imaging procedures*		*Positron emission tomogram prostate*	10087994
SOC primary	*Investigations*		HLT primary	
			Reproductive organ and breast imaging procedures	10038602
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022154001 **Implementation Date:** 06-Jul-22 Related CR: 2022154001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Dental flipper*	Approved Not as Requested	Proposed LLT	
			Dental flipper placement	10087996 Current
			To PT	
			Dental prosthesis placement	10052944

MSSO Comment: The proposal to add a new term Dental flipper is approved but not as requested. Dental flipper is a removable partial denture generally used as a temporary tooth replacement. The requested term will be modified for clarification as a procedure and added as LLT Dental flipper placement to PT Dental prosthesis placement. In a related change, the descriptive synonym LLT Removable partial denture placement will also be added to PT Dental prosthesis placement.

Supplemental Update Report

CR Number: 2022187004 **Implementation Date:** 06-Jul-22 Related CR: 2022154001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Removable partial denture placement*	Approved as Requested	Proposed LLT		
To PT	*Dental prosthesis placement*		*Removable partial denture placement*	10087997	Current
			To PT		
			Dental prosthesis placement	10052944	

MSSO Comment:

CR Number: 2022154002 **Implementation Date:** 06-Jul-22 Related CR: 2022154002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Testosterone deficiency syndrome*	Approved as Requested	Proposed PT	
			Testosterone deficiency syndrome	10087998
			HLT primary	
			Male gonadal function disorders	10013322
			SOC primary	
			Endocrine disorders	10014698
			HLT secondary	
			Male sex hormone abnormalities	10000193
			SOC secondary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new term Testosterone deficiency syndrome is approved as requested. Testosterone deficiency occurs when the body is unable to make enough testosterone. It is sometimes called hypogonadism. Testosterone deficiency can significantly affect a man's health and quality of life. Testosterone deficiency syndrome will be added as PT to primary HLT Male gonadal function disorders and to secondary HLT Male sex hormone abnormalities. In a related change, PT Late onset hypogonadism syndrome will be merged under the new PT Testosterone deficiency syndrome as a sub-concept LLT. .

Supplemental Update Report

CR Number: 2022187006 **Implementation Date:** 06-Jul-22 Related CR: 2022154002

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*Late onset hypogonadism syndrome*	Approved as Requested	PT to merge		
To PT	*Testosterone deficiency syndrome*		*Late onset hypogonadism syndrome*	10072742	Current
			To PT		
			Testosterone deficiency syndrome	10087998	

MSSO Comment:

CR Number: 2022154003 **Implementation Date:** 06-Jul-22 Related CR: 2022154003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Basaloid squamous cell carcinoma of lung*	Approved as Requested	Proposed LLT		
			Basaloid squamous cell carcinoma of lung	10087999	Current
			To PT		
			Squamous cell carcinoma of lung	10041826	

MSSO Comment: The proposal to add a new term Basaloid squamous cell carcinoma of lung is approved as requested. Basaloid squamous cell carcinoma of lung, a rare subtype of lung squamous cell carcinoma, will be added as an LLT to PT Squamous cell carcinoma of lung.

CR Number: 2022157001 **Implementation Date:** 06-Jul-22 Related CR: 2022157001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Black Urine Disease*	Approved Not as Requested	Proposed LLT		
To PT	*Alkaptonuria*		*Black urine disease*	10088000	Current
			To PT		
			Alkaptonuria	10001689	

MSSO Comment: The proposal to add a new LLT Black Urine Disease to PT Alkaptonuria is approved but not as requested. The condition is usually diagnosed in adults and causes dark skin pigmentation (ochronosis) and arthritis. Urine turns dark when exposed to air because of oxidation products of homogentisic acid. Diagnosis of alkaptonuria is by finding elevated urinary levels of homogentisic acid. Proposed term, which is a colloquial synonym, will be modified for MedDRA capitalization conventions and added as LLT Black urine disease under PT Alkaptonuria.

Supplemental Update Report

CR Number: 2022157002 **Implementation Date:** 06-Jul-22 Related CR: 2022157002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Penetrating trauma*	Approved as Requested	Proposed LLT		
			Penetrating trauma	10088001	Current
			To PT		
			Injury	10022116	

MSSO Comment: The proposal to add a new term Penetrating trauma is approved as requested. Penetrating trauma will be added as sub-concept LLT to PT Injury.

CR Number: 2022157003 **Implementation Date:** 06-Jul-22 Related CR: 2022157003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Spondylocostal dysostosis*	Approved as Requested	Proposed PT	
			Spondylocostal dysostosis	10088002
			HLT primary	
			Musculoskeletal and connective tissue disorders of spine congenital	10028383
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Musculoskeletal and connective tissue disorders of spine congenital	10028383
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new term Spondylocostal dysostosis is approved as requested. Spondylocostal dysostosis, also known as Jarcho-Levin syndrome (JLS), is a rare, heritable axial skeleton growth disorder. It is characterized by widespread and sometimes severe malformations of the vertebral column and ribs, shortened thorax, and moderate to severe scoliosis and kyphosis. Spondylocostal dysostosis will be added as PT to bi-axial HLT Musculoskeletal and connective tissue disorders of spine congenital, with link to primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders. In a related change, synonym LLT Jarcho-Levin syndrome will be added to newly added PT Spondylocostal dysostosis.

Supplemental Update Report

CR Number: 2022187007 **Implementation Date:** 06-Jul-22 Related CR: 2022157003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Jarcho-Levin syndrome*	Approved as Requested	Proposed LLT		
To PT	*Spondylocostal dysostosis*		*Jarcho-Levin syndrome*	10088003	Current
			To PT		
			Spondylocostal dysostosis	10088002	

MSSO Comment:

CR Number: 2022157004 **Implementation Date:** 06-Jul-22 Related CR: 2022157004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Retinal vascular tortuosity*	Approved as Requested	Proposed LLT		
			Retinal vascular tortuosity	10088004	Current
			To PT		
			Retinal vascular disorder	10038901	

MSSO Comment: The proposal to add a new term Retinal vascular tortuosity is approved as requested. Retinal vascular tortuosity (arteriolar or venular) may be related to several underlying pathologies. Retinal vascular tortuosity will be added as LLT to PT Retinal vascular disorder aligned with LLT Retinal vein tortuosity.

Supplemental Update Report

CR Number: 2022157011 **Implementation Date:** 06-Jul-22 Related CR: 2022157011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Carotid blowout syndrome*	Approved as Requested	Proposed PT	
HLT primary	*Central nervous system haemorrhages and cerebrovascular accidents*		*Carotid blowout syndrome*	10088005
SOC primary	*Nervous system disorders*		HLT primary	
			Central nervous system haemorrhages and cerebrovascular accidents	10007948
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Nervous system haemorrhagic disorders	10008206
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT Carotid blowout syndrome to primary HLT Central nervous system haemorrhages and cerebrovascular accidents in SOC Nervous system disorders is approved as requested. Carotid blowout syndrome refers to the rupture of the carotid artery and its branches. Carotid blowout syndrome is a dangerous medical emergency typically resulting from complications of treatments for head and neck cancer. Carotid blowout syndrome will be added as PT to primary HLT Central nervous system haemorrhages and cerebrovascular accidents and secondary HLT Nervous system haemorrhagic disorders and secondary HLT Cardiac and vascular procedural complications.

CR Number: 2022187008 **Implementation Date:** 06-Jul-22 Related CR: 2022157011

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Carotid blowout syndrome*	Approved as Requested	Proposed PT	
To HLT	*Cardiac and vascular procedural complications*		*Carotid blowout syndrome*	10088005
			To HLT	
			Cardiac and vascular procedural complications	10007602

MSSO Comment:

Supplemental Update Report

CR Number: 2022158001 **Implementation Date:** 06-Jul-22 Related CR: 2022158001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*GORD*	Approved as Requested	Proposed LLT	
To PT	*Gastrooesophageal reflux disease*		*GORD*	10088006 Current
			To PT	
			Gastrooesophageal reflux disease	10017885

MSSO Comment: The proposal to add a new LLT GORD to PT Gastrooesophageal reflux disease is approved as requested aligned with an other synonym LLT GERD.

CR Number: 2022158002 **Implementation Date:** 06-Jul-22 Related CR: 2022158002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Adhesive small bowel obstruction*	Approved as Requested	Proposed LLT	
			Adhesive small bowel obstruction	10088007 Current
			To PT	
			Small intestinal obstruction	10041101

MSSO Comment: The proposal to add a new term Adhesive small bowel obstruction is approved as requested. Adhesive small bowel obstruction (ASBO) is a common surgical emergency, causing high morbidity and even some mortality. The adhesions causing such bowel obstructions are typically the footprints of previous abdominal surgical procedures. Adhesive small bowel obstruction will be added as sub-concept LLT to PT Small intestinal obstruction.

Supplemental Update Report

CR Number: 2022158003 **Implementation Date:** 06-Jul-22 Related CR: 2022158003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Adenomyoepithelioma*	Approved Not as Requested	Proposed PT	
			Adenomyoepithelioma of breast	10088008
			HLT primary	
			Breast neoplasms unspecified malignancy	10006292
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Benign and malignant breast neoplasms	10006289
			SOC secondary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new term Adenomyoepithelioma is approved but not as requested. Adenomyoepithelioma of the breast is an uncommon tumor characterized by dual differentiation into luminal cells and myoepithelial cells. Although most tumors have a benign clinical course, local recurrences, malignant transformations, and distant metastases have been reported. The requested term will be modified for clarity and added as PT Adenomyoepithelioma of breast to primary HLT Breast neoplasms unspecified malignancy and to secondary HLT Benign and malignant breast neoplasms.

CR Number: 2022159001 **Implementation Date:** 06-Jul-22 Related CR: 2022159001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Catheter associated urinary tract infection*	Rejected		
To PT	*Urinary tract Infection*			

MSSO Comment: The proposal to add a new LLT Catheter associated urinary tract infection to PT Urinary tract Infection is not approved. The proposed term implies a causal relationship between two concepts, and therefore represents a combination term. The MSSO refrains from adding such terms as to avoid overpopulation of MedDRA. (Example: The MSSO considers this concept to be represented in MedDRA by e.g. LLT Urinary tract infection, and LLT Catheter related infection.) Please note that Section 3.5.4 of the MedDRA Term Selection: Points to Consider document provides the option for splitting and coding verbatim terms of a ‘due to’ nature.

Supplemental Update Report

CR Number: 2022159002 **Implementation Date:** 06-Jul-22 Related CR: 2022159002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Intestinal umbilical fistula*	Approved Not as Requested	Proposed PT	
			Congenital umbilico-enteric fistula	10088009
			HLT primary	
			Gastrointestinal tract disorders congenital NEC	10027679
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Gastrointestinal fistulae	10017952
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Intestinal umbilical fistula is approved but not as requested. Failure to obliterate the vitelline duct may produce different malformations, and involve a wide spectrum of anatomical structures and associated symptoms. Enteric fistula results from a completely patent vitelline duct, and is the least common of these anomalies. The requested term will be reworded for clarity and added as PT Congenital umbilico-enteric fistula to primary HLT Gastrointestinal tract disorders congenital NEC and secondary HLT Gastrointestinal fistulae.

CR Number: 2022159006 **Implementation Date:** 06-Jul-22 Related CR: 2022159006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Intra-abdominal pressure*	Rejected		

MSSO Comment: The proposal to add a new term Intra-abdominal pressure is not approved. The requested term is ambiguous and depending upon the intended meaning, the proposed concept may be represented by existing LLT/PT Intra-abdominal pressure increased or LLT/PT Intra-abdominal pressure monitoring.

Supplemental Update Report

CR Number: 2022159007 **Implementation Date:** 06-Jul-22 Related CR: 2022159007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Bacterial meningitis test*	Rejected		

MSSO Comment: The proposal to add a new LLT Bacterial meningitis test is not approved. Terms under SOC Investigations are represent concrete analytical, histological or imaging diagnostic procedures. Concepts resulting from the combination of a given pathogen or pathogen class with the word “test” are vague and may be endless, leading to the overpopulation of this SOC. Moreover, there are already existing terms in MedDRA which can be used to represent the requested concept, such as LLTs CSF bacteria test or CSF bacteria identified, with or without the complementary LLT Lumbar puncture, and LLT Bacterial meningitis as the indication for the test.

CR Number: 2022159008 **Implementation Date:** 06-Jul-22 Related CR: 2022159008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Viral meningitis test*	Rejected		

MSSO Comment: The proposal to add a new LLT Viral meningitis test is not approved. Terms under SOC Investigations are meant to represent concrete analytical, histological or imaging diagnostic procedures. Concepts resulting from the combination of a given pathogen or pathogen class with the word “test” are vague and may be endless, leading to the overpopulation of this SOC. Moreover, there are already existing terms in MedDRA which can be used to represent the requested concept, such as LLTs CSF virus or CSF virus identified, with or without the complementary LLT Lumbar puncture, and LLT Viral meningitis as indication for the test.

CR Number: 2022160001 **Implementation Date:** 06-Jul-22 Related CR: 2022160001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Radiation pharyngitis*	Approved Not as Requested	Proposed LLT	
HLT primary	*Radiation injuries*		*Radiation pharyngitis*	10088010 Current
SOC primary	*Injury, poisoning and procedural complications*		To PT	
			Pharynx radiation injury	10071734

MSSO Comment: The proposal to add a new PT Radiation pharyngitis to primary HLT Radiation injuries in SOC Injury, poisoning and procedural complications is approved but not as requested. Radiation pharyngitis is typically an adverse effect that develops in individuals receiving radiation cancer therapy, most commonly for breast, lung, and other lymphomas. Radiation pharyngitis will be added as a sub-element LLT to PT Pharynx radiation injury.

Supplemental Update Report

CR Number: 2022160002 **Implementation Date:** 06-Jul-22 Related CR: 2022160002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pus culture*	Approved as Requested	Proposed LLT	
To PT	*Culture*		*Pus culture*	10088011 Current
			To PT	
			Culture	10061447

MSSO Comment: The proposal to add a new LLT Pus culture to PT Culture is approved as requested. In pus culture, a sample of pus is added to a substance which promotes the growth of microorganisms. If microorganisms grow, the culture is said to be positive.

CR Number: 2022160003 **Implementation Date:** 06-Jul-22 Related CR: 2022160003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Mechanical purpura*	Approved as Requested	Proposed LLT	
			Mechanical purpura	10088012 Current
			To PT	
			Purpura	10037549

MSSO Comment: The proposal to add a new term Mechanical purpura is approved as requested. Mechanical purpura results from extravasation of the red cells caused by local physical pressure which exceeds the limit of capillary strength. Mechanical purpura will be added as sub-concept LLT under PT Purpura.

CR Number: 2022160004 **Implementation Date:** 06-Jul-22 Related CR: 2022160004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Immune-mediated perimyocarditis*	Approved as Requested	Proposed LLT	
			Immune-mediated perimyocarditis	10088013 Current
			To PT	
			Immune-mediated myocarditis	10082606

MSSO Comment: The proposal to add a new LLT Immune-mediated perimyocarditis is approved as requested. Perimyocarditis is acute inflammation of the pericardium and the underlying myocardium, most commonly of viral aetiology, specifically the coxsackie B virus. However, it can also be caused by conditions in which common inflammatory pathways lead to inflammation triggered by a dysregulation of the normal immune response. Immune-mediated perimyocarditis will be added to PT Immune-mediated myocarditis.

Supplemental Update Report

CR Number: 2022160005 **Implementation Date:** 06-Jul-22 Related CR: 2022160005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Autoimmune perimyocarditis*	Approved as Requested	Proposed LLT *Autoimmune perimyocarditis*	10088014 Current
			To PT *Autoimmune myocarditis*	10064539

MSSO Comment: The proposal to add a new LLT Autoimmune perimyocarditis is approved as requested. Perimyocarditis is acute inflammation of the pericardium and the underlying myocardium. Autoimmune myocarditis is an autoimmune disease characterized by inflammation of the myocardium without an exact underlying cause, occurring when the immune system mistakenly attacks healthy myocardial tissue. Autoimmune perimyocarditis will be added as LLT to PT Autoimmune myocarditis.

CR Number: 2022160006 **Implementation Date:** 06-Jul-22 Related CR: 2022160006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Hepatic angiography*	Approved as Requested	Proposed LLT *Hepatic angiography*	10088016 Current
			To PT *Hepatic angiogram*	10088015

MSSO Comment: The proposal to add a new term Hepatic angiography is approved as requested. Catheter angiography is the gold standard for vascular evaluation of the liver prior to tumor resection. At present, catheter angiography is performed for therapeutic liver tumor embolization and to assess complex vascular anatomy demonstrated on CT or MRI. Hepatic angiography will be placed as LLT to a new PT Hepatic angiogram, which will be added to HLT Hepatobiliary imaging procedures. In a related change, PT Arteriogram liver will be merged under new PT Hepatic angiogram as a sub-concept LLT.

CR Number: 2022187009 **Implementation Date:** 06-Jul-22 Related CR: 2022160006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hepatic angiogram*	Approved as Requested	Proposed PT *Hepatic angiogram*	10088015
HLT primary	*Hepatobiliary imaging procedures*		HLT primary *Hepatobiliary imaging procedures*	10019808
SOC primary	*Investigations*		SOC primary *Investigations*	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2022187010 **Implementation Date:** 06-Jul-22 Related CR: 2022160006

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Arteriogram liver*	Approved as Requested	PT to merge	
To PT	*Hepatic angiogram*		*Arteriogram liver*	10072872 Current
			To PT	
			Hepatic angiogram	10088015

MSSO Comment:

CR Number: 2022161002 **Implementation Date:** 06-Jul-22 Related CR: 2022161002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Immune-mediated thyroid disorder*	Rejected		

MSSO Comment: The proposal to add a new term Immune-mediated thyroid disorder is not approved. Different forms of thyroid immune-mediated conditions are already represented in existing LLTs Immune-mediated thyroiditis, Immune-mediated hyperthyroidism and Immune-mediated hypothyroidism.

CR Number: 2022164001 **Implementation Date:** 06-Jul-22 Related CR: 2022164001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Linear IgA/IgG bullous dermatosis*	Approved as Requested	Proposed LLT	
To PT	*Linear IgA disease*		*Linear IgA/IgG bullous dermatosis*	10088017 Current
			To PT	
			Linear IgA disease	10024515

MSSO Comment: The proposal to add a new LLT Linear IgA/IgG bullous dermatosis to PT Linear IgA disease is approved as requested. Linear IgA bullous dermatosis (LABD) is an autoimmune, blistering disease characterized by linear deposits of IgA along the basement membrane. In cases of concurrent deposits of IgG, the disease is considered a distinct subtype of LABD called linear IgA/IgG bullous dermatosis (LAGBD).

Supplemental Update Report

CR Number: 2022164002 **Implementation Date:** 06-Jul-22 Related CR: 2022164002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Taste astringent*	Approved as Requested	Proposed LLT	
To PT	*Dysgeusia*		*Taste astringent*	10088018 Current
			To PT	
			Dysgeusia	10013911

MSSO Comment: The proposal to add a new LLT Taste astringent to PT Dysgeusia is approved as requested. Apart from the drying and constricting effect on tissues, astringency also refers to the dry, puckering mouthfeel caused by the tannins in unripe fruits which deters eating.

CR Number: 2022164003 **Implementation Date:** 06-Jul-22 Related CR: 2022164003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Taste pungent*	Approved as Requested	Proposed LLT	
To PT	*Dysgeusia*		*Taste pungent*	10088019 Current
			To PT	
			Dysgeusia	10013911

MSSO Comment: The proposal to add a new LLT Taste pungent to PT Dysgeusia is approved as requested. Taste pungent refers to a taste very strong and sharp, often with an acrid aftertaste.

CR Number: 2022164004 **Implementation Date:** 06-Jul-22 Related CR: 2022164004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tardive Tourette-Like Syndrome*	Approved Not as Requested	Proposed LLT	
HLT primary	*Tic disorders*		*Tardive Tourette-like syndrome*	10088020 Current
SOC primary	*Psychiatric disorders*		To PT	
			Secondary tic	10076702

MSSO Comment: The proposal to add a new PT Tardive Tourette-Like Syndrome to primary HLT Tic disorders in SOC Psychiatric disorders and secondary HLT Poisoning and toxicity in SOC Injury, poisoning and procedural complications is approved but not as requested. The proposed term will be modified according to MedDRA capitalization naming conventions and added as an LLT Tardive Tourette-like syndrome under PT Secondary tic. In a related change, the secondary HLT for PT Secondary tic will be changed from HLT Neurological signs and symptoms NEC to HLT Dyskinesias and movement disorders NEC for more specific representation.

Supplemental Update Report

CR Number: 2022187011 **Implementation Date:** 06-Jul-22 Related CR: 2022164004

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Secondary tic*	Approved as Requested	Proposed PT	
From HLT	*Neurological signs and symptoms NEC*		*Secondary tic*	10076702
To HLT	*Dyskinesias and movement disorders NEC*		From HLT	
			Neurological signs and symptoms NEC	10029306
			To HLT	
			Dyskinesias and movement disorders NEC	10013929

MSSO Comment:

CR Number: 2022164005 **Implementation Date:** 06-Jul-22 Related CR: 2022164005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Barium X-ray*	Approved as Requested	Proposed PT	
			Barium X-ray	10088021
			HLT primary	
			Gastrointestinal and abdominal imaging procedures	10017963
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Barium X-ray is approved as requested. Barium X-ray is a type of radiography used to see the outline of the several segments of the gastrointestinal tract. This broad term will be added as PT Barium X-ray under HLT Gastrointestinal and abdominal imaging procedures to offer a coding alternative for those cases where the gastrointestinal segment explored is not specified.

Supplemental Update Report

CR Number: 2022165001 **Implementation Date:** 07-Jul-22 Related CR: 2022165001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Menstration on (hormonal) IUD*	Approved Not as Requested	Proposed PT	
			Unexpected vaginal bleeding on hormonal IUD	10088030
			HLT primary	
			Menstruation and uterine bleeding NEC	10027335
			SOC primary	
			Reproductive system and breast disorders	10038604
			HLT secondary	
			Reproductive complications associated with device	10069787
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new LLT Menstration on (hormonal) IUD is approved but not as requested. The proposed term will be modified to Unexpected vaginal bleeding on hormonal IUD and will be added as a PT to primary HLT Menstruation and uterine bleeding NEC, to secondary HLT Reproductive complications associated with device and to secondary HLT Reproductive system haemorrhages.

CR Number: 2022188004 **Implementation Date:** 07-Jul-22 Related CR: 2022165001

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Unexpected vaginal bleeding on hormonal IUD*	Approved as Requested	Proposed PT	
To HLT	*Reproductive system haemorrhages*		*Unexpected vaginal bleeding on hormonal IUD*	10088030
			To HLT	
			Reproductive system haemorrhages	10052743

MSSO Comment:

Supplemental Update Report

CR Number: 2022165003 **Implementation Date:** 07-Jul-22 Related CR: 2022165003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Oxygen combining power decreased*	Approved as Requested	Proposed PT	
			Oxygen combining power decreased	10088031
			HLT primary	
			Blood gas and acid base analyses	10005536
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Oxygen combining power decreased is approved as requested. The oxygen content of blood may either be measured directly or derived from the oxygen capacity of hemoglobin. Oxygen capacity of hemoglobin can be measured using carbon monoxide. Oxygen combining power decreased will be added as a new PT to HLT Blood gas and acid base analyses.

CR Number: 2022165004 **Implementation Date:** 07-Jul-22 Related CR: 2022165004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Deoxyhemoglobin increased*	Approved as Requested	Proposed LLT	
			Deoxyhemoglobin increased	10088032 Current
			To PT	
			Oxygen saturation decreased	10033318

MSSO Comment: The proposal to add a new term Deoxyhemoglobin increased is approved as requested. Any disorder causing hypoxemia may generate sufficient deoxyhemoglobin in the blood causing hemoglobin desaturation and leaving the heart to produce central cyanosis. Typical etiologies are pulmonary edema, pneumonia, and intracardiac right-to-left shunts. Deoxyhemoglobin increased will be added as LLT to PT Oxygen saturation decreased. In a related change, British English counterpart LLT Deoxyhaemoglobin increased will be added to PT Oxygen saturation decreased.

CR Number: 2022188005 **Implementation Date:** 07-Jul-22 Related CR: 2022165004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Deoxyhaemoglobin increased*	Approved as Requested	Proposed LLT	
To PT	*Oxygen saturation decreased*		*Deoxyhaemoglobin increased*	10088033 Current
			To PT	
			Oxygen saturation decreased	10033318

MSSO Comment:

Supplemental Update Report

CR Number: 2022165005 **Implementation Date:** 07-Jul-22 Related CR: 2022165005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Target temperatue management*	Approved Not as Requested	Proposed LLT	
			Target temperature management	10088034 Current
			To PT	
			Therapeutic hypothermia	10059485

MSSO Comment: The proposal to add a new term Target temperatue management is approved but not as requested. Targeted temperature management previously known as therapeutic hypothermia or protective hypothermia is an active treatment that tries to achieve and maintain a specific body temperature in a person for a specific duration of time in an effort to improve health outcomes during recovery after a period of stopped blood flow to the brain. The requested term will be modified to correct spelling and added as LLT Targeted temperature management to PT Therapeutic hypothermia.

CR Number: 2022166001 **Implementation Date:** 07-Jul-22 Related CR: 2022166001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Dubreuilh's melanoma*	Approved as Requested	Proposed LLT	
			Dubreuilh's melanoma	10088038 Current
			To PT	
			Lentigo maligna	10024218

MSSO Comment: The proposal to add a new term Dubreuilh's melanoma is approved as requested. Dubreuilh's melanoma will be added as a synonym LLT to PT Lentigo maligna.

CR Number: 2022166002 **Implementation Date:** 08-Jul-22 Related CR: 2022166002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Status dystonicus*	Approved Not as Requested	Proposed PT	
To PT	*Dystonia*		*Status dystonicus*	10088053
			HLT primary	
			Dystonias	10013985
			SOC primary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new LLT Status dystonicus to PT Dystonia is approved but not as requested. Status dystonicus is characterized by the development of increasingly frequent or continuous severe episodes of generalized dystonic spasms and requires urgent hospital management. Status dystonicus will be added as a PT to HLT Dystonias.

Supplemental Update Report

CR Number: 2022166003 **Implementation Date:** 08-Jul-22 Related CR: 2022166003

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pigmentary maculopathy*	Approved as Requested	Proposed LLT	
From PT	*Maculopathy*		*Pigmentary maculopathy*	10054856
HLT primary	*Retinal structural change, deposit and degeneration*		From PT	
			Maculopathy	10025425
			HLT primary	
			Retinal structural change, deposit and degeneration	10038896
			SOC primary	
			Eye disorders	10015919
			HLT secondary	
			Poisoning and toxicity	10035777
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to promote the LLT Pigmentary maculopathy from PT Maculopathy to primary HLT Retinal structural change, deposit and degeneration in SOC Eye disorders is approved as requested. Despite of its possible use in the context of the pigmentary changes in the macula due other pathologies, specially as an early feature of age-related macular degeneration, LLT Pigmentary maculopathy will be promoted to the PT level in consideration of is recent relevance in relation to drug toxicity, especially with the use of pentosan polysulfate sodium in interstitial cystitis. Pigmentary maculopathy will be primarily linked to HLT Retinal structural change, deposit and degeneration and secondarily linked to HLT Poisoning and toxicity

CR Number: 2022166004 **Implementation Date:** 07-Jul-22 Related CR: 2022166004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Portacath replacement*	Approved as Requested	Proposed LLT	
			Portacath replacement	10088039 Current
			To PT	
			Central venous catheterisation	10053377

MSSO Comment: The proposal to add a new term Portacath replacement is approved as requested. When an implanted port-catheter system can no longer be used, but vascular patency is required for the infusion of chemotherapy, removal and replacement of the port-catheter system are recommended. Portacath replacement will be added as an LLT under PT Central venous catheterisation.

Supplemental Update Report

CR Number: 2022166005 **Implementation Date:** 07-Jul-22 Related CR: 2022166005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Mechanical arthropathy*	Approved as Requested	Proposed LLT		
			Mechanical arthropathy	10088040	Current
			To PT		
			Arthropathy	10003285	

MSSO Comment: The proposal to add a new term Mechanical arthropathy is approved as requested. Degenerative or mechanical arthropathy refers to a group of conditions that mainly involve damage to the cartilage that covers the ends of the bones. Mechanical arthropathy will added as an LLT under PT Arthropathy.

CR Number: 2022166006 **Implementation Date:** 06-Jul-22 Related CR: 2022166006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with excess blasts*	Approved as Requested	Proposed PT	
			Myelodysplastic syndrome with excess blasts	10088023
			HLT primary	
			Myelodysplastic syndromes	10028536
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104

MSSO Comment: The proposal to add a new PT Myelodysplastic syndrome with excess blasts is approved as requested. The new revised WHO classification (2016) introduced refinements in the cytopenia and morphological changes, and also the influence of genetic information in myelodysplastic syndrome diagnosis and classification. Proposed term will be added as new PT Myelodysplastic syndrome with excess blasts under HLT Myelodysplastic syndromes. In a related change, the PT Refractory anaemia with an excess of blasts will be merged under this new PT Myelodysplastic syndrome with excess blasts.

CR Number: 2022187012 **Implementation Date:** 06-Jul-22 Related CR: 2022166006

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*Refractory anaemia with an excess of blasts*	Approved as Requested	PT to merge		
To PT	*Myelodysplastic syndrome with excess blasts*		*Refractory anaemia with an excess of blasts*	10038270	Current
			To PT		
			Myelodysplastic syndrome with excess blasts	10088023	

MSSO Comment:

Supplemental Update Report

CR Number: 2022166007 **Implementation Date:** 06-Jul-22 Related CR: 2022166007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with excess blasts 1*	Approved Not as Requested	Proposed LLT	
			Myelodysplastic syndrome with excess blasts 1	10088028 Current
			To PT	
			Myelodysplastic syndrome with excess blasts	10088023

MSSO Comment: The proposal to add a new PT Myelodysplastic syndrome with excess blasts 1 is approved but not as requested. The new revised WHO classification (2016) introduced refinements in the cytopenia and morphological changes, and also the influence of genetic information in myelodysplastic syndrome diagnosis and classification. Proposed term will be added as new LLT Myelodysplastic syndrome with excess blasts 1 under new PT Myelodysplastic syndrome with excess blasts added in change request 2022166006.

CR Number: 2022166008 **Implementation Date:** 06-Jul-22 Related CR: 2022166008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with excess blasts 2*	Approved Not as Requested	Proposed LLT	
			Myelodysplastic syndrome with excess blasts 2	10088027 Current
			To PT	
			Myelodysplastic syndrome with excess blasts	10088023

MSSO Comment: The proposal to add a new PT Myelodysplastic syndrome with excess blasts 2 is approved but not as requested. The new revised WHO classification (2016) introduced refinements in the cytopenia and morphological changes, and also the influence of genetic information in myelodysplastic syndrome diagnosis and classification. Proposed term will be added as new LLT Myelodysplastic syndrome with excess blasts 2 under new PT Myelodysplastic syndrome with excess blasts added in change request 2022166006.

CR Number: 2022166009 **Implementation Date:** 06-Jul-22 Related CR: 2022166009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with ringed sideroblasts*	Approved as Requested	Proposed PT	
			Myelodysplastic syndrome with ringed sideroblasts	10088024
			HLT primary	
			Myelodysplastic syndromes	10028536
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104

MSSO Comment: The proposal to add a new PT Myelodysplastic syndrome with ringed sideroblasts is approved as requested. The new revised WHO classification (2016) introduced refinements in the cytopenia and morphological changes, and also the influence of genetic information in myelodysplastic syndrome diagnosis and classification. Proposed term will be added as new PT Myelodysplastic syndrome with ringed sideroblasts under HLT Myelodysplastic syndromes. In a related change, the PT Refractory anaemia with ringed sideroblasts will be merged under this new PT Myelodysplastic syndrome with ringed sideroblasts.

Supplemental Update Report

CR Number: 2022187013 **Implementation Date:** 06-Jul-22 Related CR: 2022166009

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*Refractory anaemia with ringed sideroblasts*	Approved as Requested	PT to merge		
			Refractory anaemia with ringed sideroblasts	10038272	Current
To PT	*Myelodysplastic syndrome with ringed sideroblasts*		To PT		
			Myelodysplastic syndrome with ringed sideroblasts	10088024	

MSSO Comment:

CR Number: 2022166010 **Implementation Date:** 06-Jul-22 Related CR: 2022166010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with multilineage dysplasia*	Approved as Requested	Proposed PT	
			Myelodysplastic syndrome with multilineage dysplasia	10088022
			HLT primary	
			Myelodysplastic syndromes	10028536
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104

MSSO Comment: The proposal to add a new PT Myelodysplastic syndrome with multilineage dysplasia is approved as requested. The new revised WHO classification introduced refinements in the cytopenia and morphological changes, and also the influence of genetic information in myelodysplastic syndrome diagnosis and classification. Proposed term will be added as new PT Myelodysplastic syndrome with multilineage dysplasia under HLT Myelodysplastic syndromes. In a related change the PT Refractory cytopenia with multilineage dysplasia will be merged under this new PT Myelodysplastic syndrome with multilineage dysplasia. Further, a new PT Myelodysplastic syndrome with single lineage dysplasia will be added to HLT Myelodysplastic syndromes and PT Refractory cytopenia with unilineage dysplasia will be merged under new PT Myelodysplastic syndrome with single lineage dysplasia.

Supplemental Update Report

CR Number: 2022187014 **Implementation Date:** 06-Jul-22 Related CR: 2022166010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with single lineage dysplasia*	Approved as Requested	Proposed PT *Myelodysplastic syndrome with single lineage dysplasia*	10088025
HLT primary	*Myelodysplastic syndromes*		HLT primary *Myelodysplastic syndromes*	10028536
SOC primary	*Blood and lymphatic system disorders*		SOC primary *Blood and lymphatic system disorders*	10005329

MSSO Comment:

CR Number: 2022187015 **Implementation Date:** 06-Jul-22 Related CR: 2022166010

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*Refractory cytopenia with multilineage dysplasia*	Approved as Requested	PT to merge *Refractory cytopenia with multilineage dysplasia*	10067959	Current
To PT	*Myelodysplastic syndrome with multilineage dysplasia*		To PT *Myelodysplastic syndrome with multilineage dysplasia*	10088022	

MSSO Comment:

CR Number: 2022187016 **Implementation Date:** 06-Jul-22 Related CR: 2022166010

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*Refractory cytopenia with unilineage dysplasia*	Approved as Requested	PT to merge *Refractory cytopenia with unilineage dysplasia*	10072684	Current
To PT	*Myelodysplastic syndrome with single lineage dysplasia*		To PT *Myelodysplastic syndrome with single lineage dysplasia*	10088025	

MSSO Comment:

Supplemental Update Report

CR Number: 2022166011 **Implementation Date:** 06-Jul-22 Related CR: 2022166011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed PT	*Myelodysplastic syndrome progression*	Approved Not as Requested	Proposed LLT		
			Myelodysplastic syndrome progression	10088029	Current
			To PT		
			Myelodysplastic syndrome	10028533	

MSSO Comment: The proposal to add a new PT Myelodysplastic syndrome progression is approved but not as requested. Studies with advanced sequencing technologies have shown that a small population of cells in the hematopoietic stem cells compartment drive myelodysplastic syndrome progression. Proposed term will be added as sub-concept LLT Myelodysplastic syndrome progression under PT Myelodysplastic syndrome.

CR Number: 2022166012 **Implementation Date:** 06-Jul-22 Related CR: 2022166012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed PT	*Myelodysplastic syndrome progression to higher risk*	Approved Not as Requested	Proposed LLT		
			Myelodysplastic syndrome progression to higher risk	10088026	Current
			To PT		
			Myelodysplastic syndrome	10028533	

MSSO Comment: The proposal to add a new PT Myelodysplastic syndrome progression to higher risk is approved but not as requested. Studies with advanced sequencing technologies have shown that a small population of cells in the hematopoietic stem cells compartment drive myelodysplastic syndrome progression, as defined by The International Prognostic Scoring Sytem (IPSS), which is an important standard for assessing prognosis of primary untreated adult patients with myelodysplastic syndromes. Proposed term will be added as subconcept LLT Myelodysplastic syndrome progression to higher risk under PT Myelodysplastic syndrome.

CR Number: 2022166013 **Implementation Date:** 11-Jul-22 Related CR: 2022166013

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Anti-PM/SCL antibody*	Approved Not as Requested	Proposed PT	
			Anti-PM/Scl antibody	10088094
			HLT primary	
			Autoimmunity analyses	10003828
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Anti-PM/SCL antibody is approved but not as requested. Anti-PM/Scl antibodies represent a specific serological marker for a subset of patients with scleroderma (Scl) and polymyositis (PM), and especially with the PM/Scl overlap syndrome (PM/Scl). Proposed term will be modified to the most commonly form found in literature and added as new PT Anti-PM/Scl antibody under HLT Autoimmunity analyses.

Supplemental Update Report

CR Number: 2022166014 **Implementation Date:** 11-Jul-22 Related CR: 2022166014

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Anti-nucleosome antibody*	Approved as Requested	Proposed PT	
			Anti-nucleosome antibody	10088095
			HLT primary	
			Autoimmunity analyses	10003828
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Anti-nucleosome antibody is approved as requested. Detection of anti-nucleosome antibodies (anti-nuc) in patients with systemic lupus erythematosus has been well established and it is claimed that their presence is associated with disease activity. Proposed term will be added as PT Anti-nucleosome antibody under HLT Autoimmunity analyses.

CR Number: 2022166015 **Implementation Date:** 11-Jul-22 Related CR: 2022166015

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Anti-PCNA antibody*	Approved as Requested	Proposed PT	
			Anti-PCNA antibody	10088096
			HLT primary	
			Autoimmunity analyses	10003828
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Anti-PCNA antibody is approved as requested. Although Anti-PCNA antibodies were specifically detected in only 2-5% of the patients with systemic lupus erythematosus, anti-PCNA antibodies are useful as a clinical marker, for example, PCNA positive SLE patients showed a high frequency of renal and central nerve system (CNS) involvements and thrombocytopenia. Proposed term will be added as PT Anti-PCNA antibody under HLT Autoimmunity analyses. In a related change, the spelled out of the acronym Anti-proliferating cell nuclear antigen antibody will also be added as an LLT to new PT Anti-PCNA antibody.

CR Number: 2022192006 **Implementation Date:** 11-Jul-22 Related CR: 2022166015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Anti-proliferating cell nuclear antigen antibody*	Approved as Requested	Proposed LLT		
To PT	*Anti-PCNA antibody*		*Anti-proliferating cell nuclear antigen antibody*	10088097	Current
			To PT		
			Anti-PCNA antibody	10088096	

MSSO Comment:

Supplemental Update Report

CR Number: 2022166016 **Implementation Date:** 07-Jul-22 Related CR: 2022166016

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Splenic Tenderness*	Approved Not as Requested	Proposed LLT	
HLT primary	*Spleen disorders*		*Splenic tenderness*	10088041 Current
SOC primary	*Blood and lymphatic system disorders*		To PT	
			Abdominal pain upper	10000087

MSSO Comment: The proposal to add a new PT Splenic Tenderness to primary HLT Spleen disorders in SOC Blood and lymphatic system disorders is approved but not as requested. Spleen pain or tenderness is usually felt as a pain behind your left ribs. It may be tender when you touch the area. This can be a sign of a damaged, ruptured or enlarged spleen. Proposed term will be modified for MedDRA capitalization conventions and added as LLT Splenic tenderness under PT Abdominal pain upper. In a related change, LLT Spleen pain will be moved from PT Abdominal pain to PT Abdominal pain upper for better alignment.

CR Number: 2022188009 **Implementation Date:** 07-Jul-22 Related CR: 2022166016

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Spleen pain*	Approved as Requested	Proposed LLT	
From PT	*Abdominal pain*		*Spleen pain*	10050997 Current
To PT	*Abdominal pain upper*		From PT	
			Abdominal pain	10000081
			To PT	
			Abdominal pain upper	10000087

MSSO Comment:

CR Number: 2022166019 **Implementation Date:** 07-Jul-22 Related CR: 2022166019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*BREAST DILATOR PLACEMENT*	Rejected		

MSSO Comment: The proposal to add a new LLT BREAST DILATOR PLACEMENT is not approved. The proposed term is too granular as one of many possible devices used in surgical procedures.

Supplemental Update Report

CR Number: 2022167003 **Implementation Date:** 07-Jul-22 Related CR: 2022167003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Facial tic*	Approved as Requested	Proposed LLT	
To PT	*Tic*		*Facial tic*	10088042 Current
			To PT	
			Tic	10043833

MSSO Comment: The proposal to add a new LLT Facial tic to PT Tic is approved as requested. A facial tic is a repeated spasm, often involving the eyes and muscles of the face.

CR Number: 2022167004 **Implementation Date:** 07-Jul-22 Related CR: 2022167004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Neuroischaemic ulcer*	Approved Not as Requested	Proposed LLT	
To PT	*Diabetic foot*		*Diabetic neuroischaemic ulcer*	10088036 Current
			To PT	
			Diabetic foot	10060734

MSSO Comment: The proposal to add a new LLT Neuroischaemic ulcer to PT Diabetic foot is approved but not as requested. Diabetic neuroischaemic ulcer is a diabetic foot ulcer in which feet with ischemia is associated with neuropathy. The neuroischaemic foot is a cool and pulseless, with a thin and shiny skin and often without hair. There is also atrophy of the subcutaneous tissue, and intermittent claudication and rest pain may be absent because of neuropathy. The proposed term will be modified to Diabetic neuroischaemic ulcer and added as sub-type LLT to PT Diabetic foot. In a related change, the American English counterpart LLT Diabetic neuroischemic ulcer will also be added to PT Diabetic foot. Furthermore, PT Diabetic ulcer and PT Diabetic neuropathic ulcer will both be demoted under PT Diabetic foot to an LLT level.

CR Number: 2022188006 **Implementation Date:** 07-Jul-22 Related CR: 2022167004

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Diabetic ulcer*	Approved as Requested	PT to merge	
To PT	*Diabetic foot*		*Diabetic ulcer*	10056340 Current
			To PT	
			Diabetic foot	10060734

MSSO Comment:

Supplemental Update Report

CR Number: 2022188007 **Implementation Date:** 07-Jul-22 Related CR: 2022167004

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Diabetic neuropathic ulcer*	Approved as Requested	PT to merge	
			Diabetic neuropathic ulcer	10012679 Current
To PT	*Diabetic foot*		To PT	
			Diabetic foot	10060734

MSSO Comment:

CR Number: 2022188008 **Implementation Date:** 07-Jul-22 Related CR: 2022167004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Diabetic neuroischemic ulcer*	Approved as Requested	Proposed LLT	
			Diabetic neuroischemic ulcer	10088037 Current
To PT	*Diabetic foot*		To PT	
			Diabetic foot	10060734

MSSO Comment:

CR Number: 2022167005 **Implementation Date:** 07-Jul-22 Related CR: 2022167005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Peripheral blood mononuclear cell apheresis*	Approved as Requested	Proposed PT	
			Peripheral blood mononuclear cell apheresis	10088035
HLT primary	*Blood and blood product treatment*		HLT primary	
			Blood and blood product treatment	10019028
SOC primary	*Surgical and medical procedures*		SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Peripheral blood mononuclear cell apheresis to primary HLT Blood and blood product treatment in SOC Surgical and medical procedures is approved as requested. Adaptive cellular immunotherapy is one of the fastest growing fields in cancer therapy. It includes donor lymphocyte infusion, chimeric antigen receptor T cells, natural killer cells, and cancer vaccine using dendritic cells. Peripheral blood mononuclear cell collection by apheresis is the first step for all these treatments.

Supplemental Update Report

CR Number: 2022167006 **Implementation Date:** 11-Jul-22 Related CR: 2022167006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Congenital trigeminal anaesthesia*	Approved as Requested	Proposed PT	
			Congenital trigeminal anaesthesia	10088099
			HLT primary	
			Neurological disorders congenital NEC	10029300
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Trigeminal disorders	10044645
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Congenital trigeminal anaesthesia is approved as requested. Congenital trigeminal anaesthesia is a rare paediatric condition characterised by a congenital deficit involving all or part of the sensory component of the trigeminal nerve in children. It usually presents with painless keratopathy in a young child. Proposed term will be added as new PT Congenital trigeminal anaesthesia under primary HLT Neurological disorders congenital NEC and secondary HLT Trigeminal disorders. In a related change, the American English spelled counterpart LLT Congenital trigeminal anesthesia will also be added under PT Congenital trigeminal anaesthesia.

CR Number: 2022192007 **Implementation Date:** 11-Jul-22 Related CR: 2022167006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Congenital trigeminal anesthesia*	Approved as Requested	Proposed LLT		
To PT	*Congenital trigeminal anaesthesia*		*Congenital trigeminal anesthesia*	10088100	Current
			To PT		
			Congenital trigeminal anaesthesia	10088099	

MSSO Comment:

Supplemental Update Report

CR Number: 2022167007 **Implementation Date:** 11-Jul-22 Related CR: 2022167007

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Acquired trigeminal anaesthesia*	Approved Not as Requested	Proposed PT *Trigeminal anaesthesia*	10088098
		HLT primary *Trigeminal disorders*	10044645
		SOC primary *Nervous system disorders*	10029205

MSSO Comment: The proposal to add a new term Acquired trigeminal anaesthesia is approved but not as requested. In acquired trigeminal anaesthesia, the acquired lesions are usually due to neoplastic, vascular, or inflammatory conditions of the hindbrain. The proposed term will be added without the qualifier as new PT Trigeminal anaesthesia under HLT Trigeminal disorders. In a related change, the American English spelled counterpart LLT Trigeminal anesthesia will also be added under PT Trigeminal anaesthesia.

CR Number: 2022192008 **Implementation Date:** 11-Jul-22 Related CR: 2022167007

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New LLT			
Proposed LLT *Trigeminal anesthesia*	Approved as Requested	Proposed LLT *Trigeminal anesthesia*	10088101 Current
To PT *Trigeminal anaesthesia*		To PT *Trigeminal anaesthesia*	10088098

MSSO Comment:

CR Number: 2022168001 **Implementation Date:** 07-Jul-22 Related CR: 2022168001

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Dubreuilhs melanosis*	Rejected		

MSSO Comment: The proposal to add a new term Dubreuilhs melanosis is not approved. The proposed concept has been addressed with the addition of LLT Dubreuilh's melanoma to PT Lentigo maligna in change request 2022166001.

Supplemental Update Report

CR Number: 2022168002 **Implementation Date:** 11-Jul-22 Related CR: 2022168002

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Pediatric croup with covid-19*	Rejected		

MSSO Comment: The proposal to add a new term Pediatric croup with covid-19 is not approved. Proposed term is a combination concept term which the MSSO typically refrains from adding to the terminology. Please refer to MedDRA Term Selection: Points to Consider, section 3.5 Combination Reports for coding guidance.

CR Number: 2022168003 **Implementation Date:** 11-Jul-22 Related CR: 2022168003

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Nucleic acid amplification tests*	Rejected		

MSSO Comment: The proposal to add a new term Nucleic acid amplification tests is not approved. Proposed concept is already represented with LLT Nucleic acid test which was added in change request 2019224003 in MedDRA version 23.0.

CR Number: 2022168004 **Implementation Date:** 11-Jul-22 Related CR: 2022168004

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Covid-19 breathalyzer*	Approved Not as Requested	Proposed PT	
		COVID-19 breath test	10088102
		HLT primary	
		Virus identification and serology	10047490
		SOC primary	
		Investigations	10022891

MSSO Comment: The proposal to add a new term Covid-19 breathalyzer is approved but not as requested. The COVID-19 breath test uses a technique called gas chromatography gas mass-spectrometry to separate and identify chemical mixtures and rapidly detect five Volatile Organic Compounds associated with SARS-CoV-2 infection in exhaled breath. Proposed term will be modified for better alignment and added as new PT COVID-19 breath test under HLT Virus identification and serology.

Supplemental Update Report

CR Number: 2022168005 **Implementation Date:** 11-Jul-22 Related CR: 2022168005

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Non vital tooth*	Approved as Requested	Proposed LLT	
		Non vital tooth	10088106 Current
		To PT	
		Pulpless tooth	10082273

MSSO Comment: The proposal to add a new term Non vital tooth is approved as requested. When the nerves in the pulp of the tooth, which is the inner layer, become damaged, such as by injury or decay, they can stop providing blood to the tooth. That can cause an infection and cause the nerve to die. This is also sometimes known as a non-vital tooth. Proposed term will be added as Non vital tooth will be added as an LLT to PT Pulpless tooth aligned with the synonym LLT Tooth devitalised.

CR Number: 2022168006 **Implementation Date:** 11-Jul-22 Related CR: 2022168006

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Dead tooth*	Approved as Requested	Proposed LLT	
		Dead tooth	10088108 Current
		To PT	
		Pulpless tooth	10082273

MSSO Comment: The proposal to add a new term Dead tooth is approved as requested. Dead tooth, the colloquial expression for devitalized tooth, will be added as an LLT to PT Pulpless tooth.

CR Number: 2022168007 **Implementation Date:** 11-Jul-22 Related CR: 2022168007

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Ictal central apnea*	Approved as Requested	Proposed LLT	
		Ictal central apnea	10088107 Current
		To PT	
		Ictal central apnoea	10088103

MSSO Comment: The proposal to add a new term Ictal central apnea is approved as requested. Desaturations and ictal central apnea occurred most frequently in seizures arising from the temporal lobe and the longer the duration of the seizure, the higher the degree of desaturation. Proposed term will be added as the American English spelled LLT Ictal central apnea to PT Ictal central apnoea which will be added, in a related change, to primary HLT Seizures and seizure disorders NEC and to secondary HLT Breathing abnormalities.

Supplemental Update Report

CR Number: 2022192009 **Implementation Date:** 11-Jul-22 Related CR: 2022168007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ictal central apnoea*	Approved as Requested	Proposed PT	
HLT primary	*Seizures and seizure disorders NEC*		*Ictal central apnoea*	10088103
SOC primary	*Nervous system disorders*		HLT primary	
			Seizures and seizure disorders NEC	10039912
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Breathing abnormalities	10006334
			SOC secondary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment:

CR Number: 2022168008 **Implementation Date:** 11-Jul-22 Related CR: 2022168008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Lymphangioma circumscriptum*	Approved as Requested	Proposed LLT	
			Lymphangioma circumscriptum	10088105 Current
			To PT	
			Lymphatic malformation	10087901

MSSO Comment: The proposal to add a new term Lymphangioma circumscriptum is approved as requested. Lymphangioma circumscriptum is a cutaneous and more superficial type of lymphangioma usually a microcystic lymphatic malformation. Lymphangioma circumscriptum and the more current term Microcystic lymphatic malformation will both be added as LLTs to the newly promoted PT Lymphatic malformation. In a related change, PT Venolymphatic malformation will be swapped with LLT Lymphatic malformation. Furthermore, PT Cystic lymphangioma will be demoted under new PT Lymphatic malformation. In addition the primary HLT for newly promoted PT Lymphatic malformation will be moved from HLT Vascular anomalies congenital NEC to HLT Lymphatic system disorders congenital.

Supplemental Update Report

CR Number: 2022192010 **Implementation Date:** 11-Jul-22 Related CR: 2022168008

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Venolymphatic malformation*	Approved as Requested	Proposed PT	
With LLT	*Lymphatic malformation*		*Venolymphatic malformation*	10079880 Current
			With LLT	
			Lymphatic malformation	10087901

MSSO Comment:

CR Number: 2022192011 **Implementation Date:** 11-Jul-22 Related CR: 2022168008

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Cystic lymphangioma*	Approved as Requested	PT to merge	
To PT	*Lymphatic malformation*		*Cystic lymphangioma*	10058949 Current
			To PT	
			Lymphatic malformation	10087901

MSSO Comment:

CR Number: 2022192012 **Implementation Date:** 11-Jul-22 Related CR: 2022168008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Microcystic lymphatic malformation*	Approved as Requested	Proposed LLT	
To PT	*Lymphatic malformation*		*Microcystic lymphatic malformation*	10088104 Current
			To PT	
			Lymphatic malformation	10087901

MSSO Comment:

Supplemental Update Report

CR Number: 2022192013 **Implementation Date:** 11-Jul-22 Related CR: 2022168008

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Lymphatic malformation*	Approved as Requested	Proposed PT	
From HLT	*Vascular anomalies congenital NEC*		*Lymphatic malformation*	10087901
To HLT	*Lymphatic system disorders congenital*		From HLT	
			Vascular anomalies congenital NEC	10047047
			To HLT	
			Lymphatic system disorders congenital	10025232

MSSO Comment:

CR Number: 2022168009 **Implementation Date:** 07-Jul-22 Related CR: 2022168009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Esophagus fundus ventricularis varication(食管胃底静脉曲张)*	Rejected		

MSSO Comment: The proposal to add a new term Esophagus fundus ventricularis varication(食管胃底静脉曲张) is not approved. The proposed term can be represented by existing LLT Gastroesophageal varices. Please note change requests are only to be submitted in English.

CR Number: 2022168010 **Implementation Date:** 07-Jul-22 Related CR: 2022168010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Amylase test*	Rejected		

MSSO Comment: The proposal to add a new term Amylase test is not approved. An amylase test measures the amount of amylase in blood or urine. Proposed term already exists as PT Amylase under SOC Investigations.

Supplemental Update Report

CR Number: 2022170001 **Implementation Date:** 11-Jul-22 Related CR: 2022170001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*SUBMUCOSAL CYST*	Rejected		

MSSO Comment: The proposal to add a new LLT SUBMUCOSAL CYST is not approved. The term without an anatomical qualifier is vague.

CR Number: 2022171001 **Implementation Date:** 07-Jul-22 Related CR: 2022171001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Lyme arthritis*	Approved Not as Requested	Proposed PT	
			Lyme arthritis	10088043
			HLT primary	
			Borrelial infections	10006038
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Infectious arthritis	10021904
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new LLT Lyme arthritis is approved but not as requested. Lyme arthritis is a late complication of Lyme disease, often beginning months after the causative tick bite. Lyme arthritis will be added as a PT with primary link to HLT Borrelial infections and secondary link to HLT Infectious arthritis.

CR Number: 2022171002 **Implementation Date:** 07-Jul-22 Related CR: 2022171002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hernioplasty*	Approved as Requested	Proposed LLT	
To PT	*Hernia repair*		*Hernioplasty*	10088044 Current
			To PT	
			Hernia repair	10062003

MSSO Comment: The proposal to add a new LLT Hernioplasty to PT Hernia repair is approved as requested. Hernioplasty is a type of hernia repair surgery where a mesh patch is sewn over the weakened region of tissue.

Supplemental Update Report

CR Number: 2022171004 **Implementation Date:** 07-Jul-22 Related CR: 2022171004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Mechanopostural low back pain*	Rejected		

MSSO Comment: The proposal to add a new term Mechanopostural low back pain is not approved. The proposed term is a combination of a symptom and causality.

CR Number: 2022172003 **Implementation Date:** 07-Jul-22 Related CR: 2022172003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Epiglottic nodule*	Rejected		

MSSO Comment: The proposal to add a new LLT Epiglottic nodule is not approved. As per the Introductory Guide MedDRA Version 25.0, in general, new terms containing “nodule” are not added to MedDRA, except when a nodule represents a full diagnostic expression.

CR Number: 2022172005 **Implementation Date:** 07-Jul-22 Related CR: 2022172005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Enterococcus faecalis pneumonia*	Rejected		

MSSO Comment: The proposal to add a new term Enterococcus faecalis pneumonia is not approved. Although enterococci can cause serious infections in multiple sites, they are a rare cause of pneumonia. It is not practical for MedDRA to contain terms for every type of pathogen which can possibly cause pneumonia. Please consider the broader PT Pneumonia bacterial and refer to MedDRA Term Selection: Points to Consider, section 3.8 Location-Specific vs. Microorganism-Specific Infection.

Supplemental Update Report

CR Number: 2022172076 **Implementation Date:** 07-Jul-22 Related CR: 2022172076

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Goniosynechialysis*	Approved as Requested	Proposed PT	
HLT primary	*Iris and ciliary body therapeutic procedures*		*Goniosynechialysis*	10088046
SOC primary	*Surgical and medical procedures*		HLT primary	
			Iris and ciliary body therapeutic procedures	10022947
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Goniosynechialysis to primary HLT Iris and ciliary body therapeutic procedures in SOC Surgical and medical procedures is approved as requested. Goniosynechialysis is a surgical technique that involves separation of the peripheral anterior synechiae adhesions that occur in the corners of the eyes.

CR Number: 2022172077 **Implementation Date:** 07-Jul-22 Related CR: 2022172077

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*FLANK ULTRASOUND*	Rejected		

MSSO Comment: The proposal to add a new LLT FLANK ULTRASOUND is not approved. The proposed term is represented by existing PT Ultrasound abdomen.

CR Number: 2022172078 **Implementation Date:** 07-Jul-22 Related CR: 2022172078

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Immunoturbidimetry*	Approved Not as Requested	Proposed PT	
To PT	*Immunonephelometry*		*Immunoturbidimetry*	10088048
			HLT primary	
			Immunoglobulin analyses	10021477
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new LLT Immunoturbidimetry to PT Immunonephelometry is approved but not as requested. Although immunoturbidimetry and immunonephelometry both measure the turbidity of a sample to determine the level of an analyte, there is a difference in technique. Immunoturbidimetry measures the absorbance of the light by the sample, immunonephelometry measures the light scattered at a fixed angle. Immunoturbidimetry will be added as PT under HLT Immunoglobulin analyses.

Supplemental Update Report

CR Number: 2022173001 **Implementation Date:** 07-Jul-22 Related CR: 2022173001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Drug administered outside healthcare facility*	Rejected		
To PT	*Product use in unapproved therapeutic environment*			

MSSO Comment: The proposal to add a new LLT Drug administered outside healthcare facility to PT Product use in unapproved therapeutic environment is not approved. The proposed term worded as such does not represent an issue as it often reflects a normal situation.

CR Number: 2022173002 **Implementation Date:** 07-Jul-22 Related CR: 2022173002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Medication administered by non healthcare provider*	Rejected		
To PT	*Product administered by wrong person*			

MSSO Comment: The proposal to add a new LLT Medication administered by non healthcare provider to PT Product administered by wrong person is not approved. The proposed term worded as such does not represent an issue as it often reflects a normal situation.

CR Number: 2022173003 **Implementation Date:** 06-Jul-22 Related CR: 2022173003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Alkalinuria*	Approved as Requested	Proposed PT	
			Alkalinuria	10087982
			HLT primary	
			Urinary abnormalities	10000196
			SOC primary	
			Renal and urinary disorders	10038359

MSSO Comment: The proposal to add a new PT Alkalinuria is approved as requested. Alkalinuria, a condition in which the urine (which is normally slightly acidic) is alkaline, will be added as PT to HLT Urinary abnormalities.

Supplemental Update Report

CR Number: 2022174001 **Implementation Date:** 07-Jul-22 Related CR: 2022174001

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *CUTANEOUS MELANOMA*	Approved Not as Requested	Proposed LLT *Cutaneous melanoma* To PT *Malignant melanoma*	10088049 Current 10025650

MSSO Comment: The proposal to add a new term CUTANEOUS MELANOMA is approved but not as requested. This term, which is a synonym for skin melanoma, will be rephrased to meet MedDRA capitalization conventions and will be added as an LLT Cutaneous melanoma to PT Malignant melanoma, aligned with the synonym LLT Skin melanoma.

CR Number: 2022174002 **Implementation Date:** 07-Jul-22 Related CR: 2022174002

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Mucosal Melanoma*	Rejected		

MSSO Comment: The proposal to add a new term Mucosal Melanoma is not approved. The proposed term is too vague without anatomical descriptor - Mucosal melanomas occur in the head and neck (55%), anorectal (24%) and vulvovaginal region (18%), and in the urinary tract (3%).

Supplemental Update Report

CR Number: 2022174006 **Implementation Date:** 07-Jul-22 Related CR: 2022174006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Uterine leiomyoma degeneration*	Approved Not as Requested	Proposed LLT	
HLT primary	*Uterine neoplasms benign*		*Degeneration of uterine leiomyoma*	10070866
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		From PT	
			Uterine leiomyoma	10046798
			HLT primary	
			Uterine neoplasms benign	10046806
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Uterine neoplasms	10046805
			SOC secondary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new PT Uterine leiomyoma degeneration to primary HLT Uterine neoplasms benign in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved but not as requested. Instead of creating a new PT Uterine leiomyoma degeneration, LLT Degeneration of uterine leiomyoma will promoted from PT Uterine leiomyoma to a PT level and linked to primary HLT Uterine neoplasms benign and to secondary HLT Uterine neoplasms. In a related change, the following LLTs will be moved from PT Uterine leiomyoma to the newly promoted PT Degeneration of uterine leiomyoma: LLT Degeneration of uterine fibroid, LLT Fibroid uterine degenerated, LLT Leiomyoma uterine degenerated and LLT Uterine fibroids degenerated.

CR Number: 2022188010 **Implementation Date:** 07-Jul-22 Related CR: 2022174006

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Degeneration of uterine fibroid*	Approved as Requested	Proposed LLT	
From PT	*Uterine leiomyoma*		*Degeneration of uterine fibroid*	10012158 Current
To PT	*Degeneration of uterine leiomyoma*		From PT	
			Uterine leiomyoma	10046798
			To PT	
			Degeneration of uterine leiomyoma	10070866

MSSO Comment:

Supplemental Update Report

CR Number: 2022188011 **Implementation Date:** 07-Jul-22 Related CR: 2022174006

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Fibroid uterine degenerated*	Approved as Requested	Proposed LLT	
From PT	*Uterine leiomyoma*		*Fibroid uterine degenerated*	10016626 Current
To PT	*Degeneration of uterine leiomyoma*		From PT	
			Uterine leiomyoma	10046798
			To PT	
			Degeneration of uterine leiomyoma	10070866

MSSO Comment:

CR Number: 2022188012 **Implementation Date:** 07-Jul-22 Related CR: 2022174006

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Leiomyoma uterine degenerated*	Approved as Requested	Proposed LLT	
From PT	*Uterine leiomyoma*		*Leiomyoma uterine degenerated*	10024187 Current
To PT	*Degeneration of uterine leiomyoma*		From PT	
			Uterine leiomyoma	10046798
			To PT	
			Degeneration of uterine leiomyoma	10070866

MSSO Comment:

CR Number: 2022188013 **Implementation Date:** 07-Jul-22 Related CR: 2022174006

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Uterine fibroids degenerated*	Approved as Requested	Proposed LLT	
From PT	*Uterine leiomyoma*		*Uterine fibroids degenerated*	10046785 Current
To PT	*Degeneration of uterine leiomyoma*		From PT	
			Uterine leiomyoma	10046798
			To PT	
			Degeneration of uterine leiomyoma	10070866

MSSO Comment:

Supplemental Update Report

CR Number: 2022174007 **Implementation Date:** 07-Jul-22 Related CR: 2022174007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Uterine leiomyoma necrosis*	Approved as Requested	Proposed PT	
HLT primary	*Uterine neoplasms benign*		*Uterine leiomyoma necrosis*	10088050
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		HLT primary	
			Uterine neoplasms benign	10046806
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Uterine neoplasms	10046805
			SOC secondary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new PT Uterine leiomyoma necrosis to primary HLT Uterine neoplasms benign in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved as requested. PT Uterine leiomyoma necrosis will also be linked to secondary HLT Uterine neoplasms. In a related change, the following LLTs will be moved from PT Uterine leiomyoma to new PT Uterine leiomyoma necrosis: LLT Necrotic leiomyoma, and LLT Necrotic uterine fibroid.

CR Number: 2022188014 **Implementation Date:** 07-Jul-22 Related CR: 2022174007

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Necrotic leiomyoma*	Approved as Requested	Proposed LLT		
From PT	*Uterine leiomyoma*		*Necrotic leiomyoma*	10073951	Current
To PT	*Uterine leiomyoma necrosis*		From PT		
			Uterine leiomyoma	10046798	
			To PT		
			Uterine leiomyoma necrosis	10088050	

MSSO Comment:

Supplemental Update Report

CR Number: 2022188015 **Implementation Date:** 07-Jul-22 Related CR: 2022174007

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Necrotic uterine fibroid*	Approved as Requested	Proposed LLT	
From PT	*Uterine leiomyoma*		*Necrotic uterine fibroid*	10073950 Current
To PT	*Uterine leiomyoma necrosis*		From PT	
			Uterine leiomyoma	10046798
			To PT	
			Uterine leiomyoma necrosis	10088050

MSSO Comment:

CR Number: 2022174008 **Implementation Date:** 07-Jul-22 Related CR: 2022174008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Uterine leiomyoma calcification*	Approved as Requested	Proposed PT	
HLT primary	*Uterine neoplasms benign*		*Uterine leiomyoma calcification*	10088052
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		HLT primary	
			Uterine neoplasms benign	10046806
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Uterine neoplasms	10046805
			SOC secondary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new PT Uterine leiomyoma calcification to primary HLT Uterine neoplasms benign in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved as requested. PT Uterine leiomyoma calcification will also be linked to secondary HLT Uterine neoplasms. In a related change, LLT Uterine fibroid calcification will be moved from PT Uterine leiomyoma to new PT Uterine leiomyoma calcification.

Supplemental Update Report

CR Number: 2022188016 **Implementation Date:** 07-Jul-22 Related CR: 2022174008

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Uterine fibroid calcification*	Approved as Requested	Proposed LLT	
From PT	*Uterine leiomyoma*		*Uterine fibroid calcification*	10085783 Current
To PT	*Uterine leiomyoma calcification*		From PT	
			Uterine leiomyoma	10046798
			To PT	
			Uterine leiomyoma calcification	10088052

MSSO Comment:

CR Number: 2022174009 **Implementation Date:** 07-Jul-22 Related CR: 2022174009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Secondary changes to uterine leiomyoma*	Rejected		
HLT primary	*Uterine neoplasms benign*			
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*			

MSSO Comment: The proposal to add a new PT Secondary changes to uterine leiomyoma to primary HLT Uterine neoplasms benign in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is not approved. The proposed term is an unspecific expression.

Supplemental Update Report

CR Number: 2022174010 **Implementation Date:** 07-Jul-22 Related CR: 2022174010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Uterine leiomyoma prolapse*	Approved as Requested	Proposed PT	
HLT primary	*Uterine neoplasms benign*		*Uterine leiomyoma prolapse*	10088051
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		HLT primary	
			Uterine neoplasms benign	10046806
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Uterine neoplasms	10046805
			SOC secondary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new PT Uterine leiomyoma prolapse to primary HLT Uterine neoplasms benign in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved as requested. PT Uterine leiomyoma prolapse will also be linked to secondary HLT Uterine neoplasms. In a related changes, the following LLTs will be moved from PT Uterine leiomyoma to new PT Uterine leiomyoma prolapse: LLT Prolapsed uterine fibroid, and LLT Uterine myoma prolapse.

CR Number: 2022188017 **Implementation Date:** 07-Jul-22 Related CR: 2022174010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Prolapsed uterine fibroid*	Approved as Requested	Proposed LLT	
From PT	*Uterine leiomyoma*		*Prolapsed uterine fibroid*	10085788 Current
To PT	*Uterine leiomyoma prolapse*		From PT	
			Uterine leiomyoma	10046798
			To PT	
			Uterine leiomyoma prolapse	10088051

MSSO Comment:

Supplemental Update Report

CR Number: 2022188018 **Implementation Date:** 07-Jul-22 Related CR: 2022174010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Uterine myoma prolapse*	Approved as Requested	Proposed LLT	
From PT	*Uterine leiomyoma*		*Uterine myoma prolapse*	10085899 Current
To PT	*Uterine leiomyoma prolapse*		From PT	
			Uterine leiomyoma	10046798
			To PT	
			Uterine leiomyoma prolapse	10088051

MSSO Comment:

CR Number: 2022175001 **Implementation Date:** 08-Jul-22 Related CR: 2022175001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Placental villous edema*	Approved as Requested	Proposed LLT	
			Placental villous edema	10088055 Current
			To PT	
			Placental oedema	10088054

MSSO Comment: The proposal to add a new term Placental villous edema is approved as requested. Placental edema consists of enlargement of the chorionic villi with edema fluid, abundant stroma, and persistence into late pregnancy of a bilayered trophoblast. Placental villous edema will be added as an LLT to a new PT Placental oedema which will be linked to HLT Placental abnormalities (excl neoplasms). In a related change, LLT Placental villous oedema and LLT Placental edema will both be added to new PT Placental oedema to have all American and British spelled terms available.

CR Number: 2022189011 **Implementation Date:** 08-Jul-22 Related CR: 2022175001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Placental oedema*	Approved as Requested	Proposed PT	
HLT primary	*Placental abnormalities (excl neoplasms)*		*Placental oedema*	10088054
SOC primary	*Pregnancy, puerperium and perinatal conditions*		HLT primary	
			Placental abnormalities (excl neoplasms)	10035130
			SOC primary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment:

Supplemental Update Report

CR Number: 2022189012 **Implementation Date:** 08-Jul-22 Related CR: 2022175001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Placental villous oedema*	Approved as Requested	Proposed LLT	
To PT	*Placental oedema*		*Placental villous oedema*	10088056 Current
			To PT	
			Placental oedema	10088054

MSSO Comment:

CR Number: 2022189013 **Implementation Date:** 08-Jul-22 Related CR: 2022175001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Placental edema*	Approved as Requested	Proposed LLT	
To PT	*Placental oedema*		*Placental edema*	10088057 Current
			To PT	
			Placental oedema	10088054

MSSO Comment:

CR Number: 2022175002 **Implementation Date:** 08-Jul-22 Related CR: 2022175002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Villous edema*	Rejected		

MSSO Comment: The proposal to add a new term Villous edema is not approved. The proposed term can be represented by the recently added LLT Placental villous edema added in change request 2022175001.

Supplemental Update Report

CR Number: 2022175003 **Implementation Date:** 08-Jul-22 Related CR: 2022175003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Anti IFN gamma autoantibody syndrome*	Approved as Requested	Proposed PT	
			Anti IFN gamma autoantibody syndrome	10088058
			HLT primary	
			Acquired immunodeficiency syndromes	10052740
			SOC primary	
			Immune system disorders	10021428

MSSO Comment: The proposal to add a new term Anti IFN gamma autoantibody syndrome is approved as requested. Adult-onset immunodeficiency with anti-interferon-gamma autoantibodies is an immunodeficiency disorder associated with susceptibility to disseminated infections (dispersed throughout the body) caused by organisms that typically affect only people with weakened immune systems (opportunistic pathogens). People with this disorder produce higher amounts of anti-interferon-gamma autoantibodies. Symptoms depend on the infection(s) present in each person. The cause of developing anti-interferon-gamma autoantibodies is unclear, but genetic factors are suspected to be involved. Anti IFN gamma autoantibody syndrome will be added as a PT to HLT Acquired immunodeficiency syndromes. In a related change, the frequently used term Adult onset immunodeficiency with anti-interferon-gamma autoantibodies will be added as an LLT to new PT Anti IFN gamma autoantibody syndrome.

CR Number: 2022189014 **Implementation Date:** 08-Jul-22 Related CR: 2022175003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Adult onset immunodeficiency with anti-interferon-gamma autoantibodies*	Approved as Requested	Proposed LLT	
			Adult onset immunodeficiency with anti-interferon-gamma autoantibodies	10088059 Current
To PT	*Anti IFN gamma autoantibody syndrome*		To PT	
			Anti IFN gamma autoantibody syndrome	10088058

MSSO Comment:

Supplemental Update Report

CR Number: 2022175004 **Implementation Date:** 07-Jul-22 Related CR: 2022175004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spinal cord hypoxia*	Approved as Requested	Proposed PT	
HLT primary	*Spinal cord and nerve root disorders NEC*		*Spinal cord hypoxia*	10088047
SOC primary	*Nervous system disorders*		HLT primary	
			Spinal cord and nerve root disorders NEC	10041544
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Cerebrovascular and spinal necrosis and vascular insufficiency	10008192
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT Spinal cord hypoxia to primary HLT Spinal cord and nerve root disorders NEC in SOC Nervous system disorders and secondary HLT Cerebrovascular and spinal necrosis and vascular insufficiency in SOC Vascular disorders is approved as requested. Spinal cord hypoxia, whether acute or chronic in nature, can produce profound tissue changes resulting in neurologic dysfunction.

CR Number: 2022175005 **Implementation Date:** 08-Jul-22 Related CR: 2022175005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Fungus stool test negative*	Approved as Requested	Proposed LLT	
			Fungus stool test negative	10088060 Current
			To PT	
			Fungal test negative	10070458

MSSO Comment: The proposal to add a new LLT Fungus stool test negative is approved as requested. Fungus stool test negative will be added as an LLT under PT Fungal test negative.

Supplemental Update Report

CR Number: 2022177001 **Implementation Date:** 08-Jul-22 Related CR: 2022177001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*KLEBSIELLA PNEUMONIAE URINARY TRACT INFECTION*	Approved Not as Requested	Proposed PT	
			Klebsiella urinary tract infection	10088061
			HLT primary	
			Klebsiella infections	10023455
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Genitourinary tract infections and inflammations NEC	10018191
			SOC secondary	
			Renal and urinary disorders	10038359

MSSO Comment: The proposal to add a new LLT KLEBSIELLA PNEUMONIAE URINARY TRACT INFECTION is approved but not as requested. The gram negative bacteria of Klebsiella pneumoniae is a common bacteria causing urinary tract infection. The proposed term will be modified to comply with MedDRA capitalization conventions and added as a PT Klebsiella urinary tract infection to primary HLT Klebsiella infections and secondary HLT Genitourinary tract infections and inflammations NEC.

CR Number: 2022178001 **Implementation Date:** 08-Jul-22 Related CR: 2022178001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tricuspid valve thrombus*	Approved Not as Requested	Proposed PT	
			Tricuspid valve thrombosis	10088062
			HLT primary	
			Tricuspid valvular disorders	10044637
			SOC primary	
			Cardiac disorders	10007541
			HLT secondary	
			Site specific embolism and thrombosis NEC	10052782
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new term Tricuspid valve thrombus is approved but not as requested. Native cardiac valve thrombus as a cause of peripheral embolization is rare. Most described cases are associated with a hyperthrombogenic state (e.g., antiphospholipid syndrome, protein S deficiency), systemic connective tissue disease (systemic lupus erythematosus), formation on diseased valves (e.g., calcifications, amyloidosis) or trauma (surgery, catheterization). The proposed term will be modified and added as PT Tricuspid valve thrombosis with a primary link to HLT Tricuspid valvular disorders and a secondary link to HLT Site specific embolism and thrombosis NEC.

Supplemental Update Report

CR Number: 2022178002 **Implementation Date:** 08-Jul-22 Related CR: 2022178002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Osteorrhaphy*	Approved as Requested	Proposed LLT *Osteorrhaphy* To PT *Internal fixation of fracture*	10088063 Current 10022576

MSSO Comment: The proposal to add a new LLT Osteorrhaphy is approved as requested. Osteorrhaphy which describes surgical suturing or joining of fragments of broken bone, will be added as an LLT to PT Internal fixation of fracture.

CR Number: 2022178003 **Implementation Date:** 08-Jul-22 Related CR: 2022178003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT To PT	*Pruritus Hiemalis* *Eczema asteatotic*	Approved Not as Requested	Proposed LLT *Pruritus hiemalis* To PT *Eczema asteatotic*	10088064 Current 10014190

MSSO Comment: The proposal to add a new LLT Pruritus Hiemalis to PT Eczema asteatotic is approved but not as requested. Pruritus hiemalis is a synonym of the existing LLT Winter itch, which is a type of subclinical dermatitis, that affects individuals during cold weather. Proposed term will be modified for MedDRA capitalization conventions and added as LLT Pruritus hiemalis under PT Eczema asteatotic.

CR Number: 2022179001 **Implementation Date:** 08-Jul-22 Related CR: 2022179001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Retrograde nephroureteral stent (RNUS)*	Approved Not as Requested	Proposed LLT *Retrograde nephroureteral stent* To PT *Ureteral stent insertion*	10088065 Non-Current 10050307

MSSO Comment: The proposal to add a new term Retrograde nephroureteral stent (RNUS) is approved but not as requested. Transileal conduit retrograde nephroureteral stent placement is safe and effective and may serve as definitive treatment for the management of postsurgical ureteral obstruction after noncontinent urinary diversion procedures. The requested term will be modified for clarification as a procedural concept and without the accronym and added as an LLT Retrograde nephroureteral stent to PT Ureteral stent insertion.

Supplemental Update Report

CR Number: 2022179002 **Implementation Date:** 11-Jul-22 Related CR: 2022179002

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Unspecified visual loss*	Rejected		
From PT	*Blindness*			
To PT	*Visual impairment*			

MSSO Comment: The proposal to move the LLT Unspecified visual loss from PT Blindness to PT Visual impairment is not approved. In MedDRA, blindness can range from a complete lack of perception of visual stimuli or total loss of the sense of light to a partial loss of useful sight. Therefore, with the exception two LLTs referring to partial vision loss (namely, Partial visual loss and Transient partial visual loss), terms referring to vision loss are considered to be better represented under the corresponding blindness PT.

CR Number: 2022179003 **Implementation Date:** 08-Jul-22 Related CR: 2022179003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Exercise induced myocardial ischemia*	Approved as Requested	Proposed LLT		
			Exercise induced myocardial ischemia	10088070	Current
			To PT		
			Myocardial ischaemia	10028600	

MSSO Comment: The proposal to add a new term Exercise induced myocardial ischemia is approved as requested. Exercise-induced myocardial ischemia is known to increase the risk of future coronary events not only in patients with coronary heart disease but also in individuals with no prior coronary heart disease. Exercise induced myocardial ischemia and the British English counterpart Exercise induced myocardial ischaemia will be added as LLTs to PT Myocardial ischaemia.

CR Number: 2022189015 **Implementation Date:** 08-Jul-22 Related CR: 2022179003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Exercise induced myocardial ischaemia*	Approved as Requested	Proposed LLT		
To PT	*Myocardial ischaemia*		*Exercise induced myocardial ischaemia*	10088071	Current
			To PT		
			Myocardial ischaemia	10028600	

MSSO Comment:

Supplemental Update Report

CR Number: 2022179004 **Implementation Date:** 08-Jul-22 Related CR: 2022179004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*INFECTIVE EXACERBATION OF ASTHMA*	Approved Not as Requested	Proposed PT	
			Infective exacerbation of asthma	10088066
			HLT primary	
			Lower respiratory tract and lung infections	10025101
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Bronchospasm and obstruction	10006484
			SOC secondary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new term INFECTIVE EXACERBATION OF ASTHMA is approved but not as requested. Acute exacerbations can be triggered by a variety of things including upper respiratory tract infections. The requested term will be modified according to MedDRA capitalisation conventions and added as PT Infective exacerbation of asthma to primary HLT Lower respiratory tract and lung infections and secondary HLT Bronchospasm and obstruction.

CR Number: 2022179005 **Implementation Date:** 08-Jul-22 Related CR: 2022179005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Hemihypesthesia*	Approved as Requested	Proposed LLT	
			Hemihypesthesia	10088069 Current
			To PT	
			Hemihypoaesthesia	10077193

MSSO Comment: The proposal to add a new term Hemihypesthesia is approved as requested. Hemihypesthesia is a reduction in sensitivity on one side of the body. A person with this condition may not be able to perceive being lightly touched on one side, but has normal function on the other side of the body. Hemihypesthesia and the British English counterpart Hemihypaesthesia will both be added as LLTs to PT Hemihypoaesthesia.

Supplemental Update Report

CR Number: 2022189016 **Implementation Date:** 08-Jul-22 Related CR: 2022179005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hemihypaesthesia*	Approved as Requested	Proposed LLT	
To PT	*Hemihypoaesthesia*		*Hemihypaesthesia*	10088072 Current
			To PT	
			Hemihypoaesthesia	10077193

MSSO Comment:

CR Number: 2022179006 **Implementation Date:** 08-Jul-22 Related CR: 2022179006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Abduction sling*	Approved Not as Requested	Proposed LLT	
			Abduction sling application	10088068 Current
			To PT	
			Joint stabilisation	10060788

MSSO Comment: The proposal to add a new term Abduction sling is approved but not as requested. A abduction sling provides comfortable support while immobilizing the shoulder following surgery or injury, including shoulder dislocations, subluxations, and rotator cuff repair. The requested term will be modified for clarity and added as LLT Abduction sling application to PT Joint stabilisation.

CR Number: 2022179007 **Implementation Date:** 08-Jul-22 Related CR: 2022179007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*STUMP PLASTY*	Approved Not as Requested	Proposed PT	
			Limb stump plasty	10088067
			HLT primary	
			Limb therapeutic procedures	10024502
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term STUMP PLASTY is approved but not as requested. After limp amputation, Stump-plasty aims to improve the amputees' prosthetic fit, mobility and health and to reduce the risk of neuroma formation. The requested term will be modified for clarification, to avoid confusion with penis stump plasty, and to comply with MedDRA capitalisation conventions and added as PT Limb stump plasty to HLT Limb therapeutic procedures.

Supplemental Update Report

CR Number: 2022179068 **Implementation Date:** 11-Jul-22 Related CR: 2022179068

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*S100 protein elevated*	Approved Not as Requested	Proposed PT *S100 protein increased* HLT primary *Protein analyses NEC* SOC primary *Investigations*	 10088109 10036998 10022891

MSSO Comment: The proposal to add a new term S100 protein elevated is approved but not as requested. The extracellular S100 proteins, serving as a danger signal, are crucial in regulating immune homeostasis, post-traumatic injury, and inflammation. Extracellular S100 proteins are also considered biomarkers for some specific diseases, such as coronary artery disease, autoimmune diseases or as a post-traumatic biomarker for predicting brain death in head trauma. The requested term will be modified according to MedDRA naming conventions at PT level and added as PT S100 protein increased to HLT Protein analyses NEC.

CR Number: 2022179069 **Implementation Date:** 08-Jul-22 Related CR: 2022179069

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Orthostatic tachycardia*	Approved as Requested	Proposed LLT *Orthostatic tachycardia* To PT *Postural orthostatic tachycardia syndrome*	 10088073 Current 10063080

MSSO Comment: The proposal to add a new term Orthostatic tachycardia is approved as requested. Orthostatic tachycardia will be added as a sub-concept LLT to PT Postural orthostatic tachycardia syndrome.

Supplemental Update Report

CR Number: 2022179070 **Implementation Date:** 11-Jul-22 Related CR: 2022179070

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ocular vaccinia virus infection*	Approved as Requested	Proposed PT	
HLT primary	*Orthopox viral infections*		*Ocular vaccinia virus infection*	10088113
SOC primary	*Infections and infestations*		HLT primary	
			Orthopox viral infections	10067228
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Ocular infections, inflammations and associated manifestations	10030045
			SOC secondary	
			Eye disorders	10015919

MSSO Comment: The proposal to add a new PT Ocular vaccinia virus infection to primary HLT Orthopox viral infections in SOC Infections and infestations and secondary HLT Ocular infections, inflammations and associated manifestations in SOC Eye disorders is approved as requested. Ocular vaccinia virus infections may occur after receiving smallpox vaccination or after contact with a recently immunized individual. PT Ocular vaccinia virus infection will also be linked to secondary HLT Vaccination related complications.

CR Number: 2022192014 **Implementation Date:** 11-Jul-22 Related CR: 2022179070

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ocular vaccinia virus infection*	Approved as Requested	Proposed PT	
To HLT	*Vaccination related complications*		*Ocular vaccinia virus infection*	10088113
			To HLT	
			Vaccination related complications	10068755

MSSO Comment:

Supplemental Update Report

CR Number: 2022179071 **Implementation Date:** 11-Jul-22 Related CR: 2022179071

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Congenital vaccinia virus infection*	Approved as Requested	Proposed PT	
HLT primary	*Viral infections congenital*		*Congenital vaccinia virus infection*	10088114
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Viral infections congenital	10047464
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Orthopox viral infections	10067228
			SOC secondary	
			Infections and infestations	10021881

MSSO Comment: The proposal to add a new PT Congenital vaccinia virus infection to primary HLT Viral infections congenital in SOC Congenital, familial and genetic disorders and secondary HLT Orthopox viral infections in SOC Infections and infestations is approved as requested. Fetal (congenital) vaccinia virus infections are a rare complication of smallpox vaccination in a pregnant woman. Fetal vaccinia usually results in stillbirth or death of the infant shortly after delivery. PT Congenital vaccinia virus infection will also be linked to secondary HLT Vaccination related complications and to secondary HLT Congenital neonatal infections (for consistency with other congenital infections regardless of fetal viability).

CR Number: 2022192015 **Implementation Date:** 11-Jul-22 Related CR: 2022179071

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Congenital vaccinia virus infection*	Approved as Requested	Proposed PT	
To HLT	*Congenital neonatal infections*		*Congenital vaccinia virus infection*	10088114
			To HLT	
			Congenital neonatal infections	10028929

MSSO Comment:

Supplemental Update Report

CR Number: 2022192016 **Implementation Date:** 11-Jul-22 Related CR: 2022179071

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Congenital vaccinia virus infection*	Approved as Requested	Proposed PT	
To HLT	*Vaccination related complications*		*Congenital vaccinia virus infection*	10088114
			To HLT	
			Vaccination related complications	10068755

MSSO Comment:

CR Number: 2022180001 **Implementation Date:** 07-Jul-22 Related CR: 2022180001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*PF-ILD*	Approved as Requested	Proposed LLT	
To PT	*Interstitial lung disease*		*PF-ILD*	10088045 Current
			To PT	
			Interstitial lung disease	10022611

MSSO Comment: The proposal to add a new LLT PF-ILD to PT Interstitial lung disease is approved as requested. PF-ILD is a widely accepted acronym for LLT Progressive fibrosing interstitial lung disease.

CR Number: 2022180002 **Implementation Date:** 07-Jul-22 Related CR: 2022180002

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vulvovaginitis allergic*	Approved Not as Requested	Proposed PT	
To HLT	*Allergies to foods, food additives, drugs and other chemicals*		*Vulvovaginitis allergic*	10080783
			To HLT	
			Allergic conditions NEC	10027654

MSSO Comment: The proposal to link the PT Vulvovaginitis allergic to the HLT Allergies to foods, food additives, drugs and other chemicals is approved but not as requested. PT Vulvovaginitis allergic will be linked to the broader secondary HLT Allergic conditions NEC.

Supplemental Update Report

CR Number: 2022180003 **Implementation Date:** 08-Jul-22 Related CR: 2022180003

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Collagenous gastritis*	Approved as Requested	Proposed PT	
		Collagenous gastritis	10088074
		HLT primary	
		Gastritis (excl infective)	10017854
		SOC primary	
		Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Collagenous gastritis is approved as requested. Collagenous gastritis is a rare disease characterized by the subepithelial deposition of collagen bands thicker than 10 µm and the infiltration of inflammatory mononuclear cells in the lamina propria. Collagenous gastritis will be added as PT to HLT Gastritis (excl infective).

CR Number: 2022180004 **Implementation Date:** 08-Jul-22 Related CR: 2022180004

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Lymphocytic duodenitis*	Approved as Requested	Proposed LLT	
		Lymphocytic duodenitis	10088075 Current
		To PT	
		Microscopic enteritis	10084313

MSSO Comment: The proposal to add a new term Lymphocytic duodenitis is approved as requested. Lymphocytic duodenitis is one of the possible manifestations of microscopic enteritis, which is characterized by abnormal infiltration of intraepithelial lymphocytes in intestinal mucosa. Its most frequent causes are gluten-related disorders, Helicobacter pylori infection and drug-related damages. Lymphocytic duodenitis will be added as LLT under PT Microscopic enteritis.

CR Number: 2022180005 **Implementation Date:** 07-Jul-22 Related CR: 2022180005

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *MyoSure*	Rejected		

MSSO Comment: The proposal to add a new term MyoSure is not approved. MyoSure® is a groundbreaking minimally invasive treatment for women who struggle with abnormal growths in their inner uterine lining. As MyoSure is a trade name of a procedure, therefore, out of scope of MedDRA, the term has already been modified to represent a non trademark procedure concept in a earlier change request (2022145020), added as PT Hysteroscopic tissue extraction under HLT Uterine therapeutic procedures and will be available for version 25.1.

Supplemental Update Report

CR Number: 2022180006 **Implementation Date:** 07-Jul-22 Related CR: 2022180006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ictus*	Rejected		

MSSO Comment: The proposal to add a new term Ictus is not approved. Ictus without any further qualifier is ambiguous and can refer to cerebrovascular accident or seizure, sometimes with regional variations in meaning.

CR Number: 2022180007 **Implementation Date:** 08-Jul-22 Related CR: 2022180007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Hill's procedure*	Approved Not as Requested	Proposed LLT		
To PT	*Gastrooesophageal reflux prophylaxis*		*Hill repair procedure*	10088076	Current
			To PT		
			Oesophagogastric fundoplasty	10048852	

MSSO Comment: The proposal to add a new LLT Hill's procedure to PT Gastrooesophageal reflux prophylaxis is approved but not as requested. The procedure known as the Hill repair is a procedure consisting of calibration of the lower esophageal sphincter and posterior fixation of the gastroesophageal junction to the median arcuate ligament. Proposed term will be modified for clarity and added as sub-concept LLT Hill repair procedure to PT Oesophagogastric fundoplasty.

CR Number: 2022181001 **Implementation Date:** 11-Jul-22 Related CR: 2022181001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Recalibration of the lumbar canal*	Approved Not as Requested	Proposed PT	
			Lumbar canal recalibration	10088110
			HLT primary	
			Spine and spinal cord therapeutic procedures	10041590
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Recalibration of the lumbar canal is approved but not as requested. Recalibration of the lumbar canal is a technique for widening the lumbar vertebral canal in the treatment of lumbar stenosis. This method, which preserves part of the posterior arches, has the aim of avoiding the instability which accompanies extensive laminectomies of the whole lumbar spine. Proposed term will be modified and added in the natural word order as PT Lumbar canal recalibration under HLT Spine and spinal cord therapeutic procedures.

Supplemental Update Report

CR Number: 2022181002 **Implementation Date:** 11-Jul-22 Related CR: 2022181002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Sinusectomy*	Rejected		

MSSO Comment: The proposal to add a new term Sinusectomy is not approved. The proposed term without an anatomical qualifier is vague.

CR Number: 2022181003 **Implementation Date:** 11-Jul-22 Related CR: 2022181003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Endoscopic balloon dilation*	Approved as Requested	Proposed LLT	
			Endoscopic balloon dilation	10088111 Current
			To PT	
			Gastrointestinal dilation procedure	10073232

MSSO Comment: The proposal to add a new term Endoscopic balloon dilation is approved as requested. Endoscopic balloon dilation is known to be an effective and safe intervention for intestinal strictures in Crohn's disease as well as for gastric outlet obstruction. Proposed term will be added as subconcept LLT Endoscopic balloon dilation under PT Gastrointestinal dilation procedure.

CR Number: 2022181004 **Implementation Date:** 08-Jul-22 Related CR: 2022181004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Palatal perforation*	Approved as Requested	Proposed PT	
			Palatal perforation	10088077
			HLT primary	
			Oral soft tissue disorders NEC	10031015
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Abdominal and gastrointestinal injuries NEC	10083613
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new term Palatal perforation is approved as requested. Palatal perforations may be seen due to infectious disease, granulomatous disease, drug abuse, collagen vascular diseases, neoplastic conditions and trauma. Palatal perforation will be added as a PT to primary HLT Oral soft tissue disorders NEC and secondary HLT Abdominal and gastrointestinal injuries NEC.

Supplemental Update Report

CR Number: 2022181005 **Implementation Date:** 08-Jul-22 Related CR: 2022181005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Penile pigmentation*	Approved Not as Requested	Proposed PT	
HLT primary	*Penile disorders NEC (excl erection and ejaculation)*		*Penile pigmentation*	10088078
SOC primary	*Reproductive system and breast disorders*		HLT primary	
			Penile disorders NEC (excl erection and ejaculation)	10034304
			SOC primary	
			Reproductive system and breast disorders	10038604
			HLT secondary	
			Hyperpigmentation disorders	10020713
			SOC secondary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new PT Penile pigmentation to primary HLT Penile disorders NEC (excl erection and ejaculation) in SOC Reproductive system and breast disorders and secondary HLT Pigmentation changes NEC in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Penile pigmentation is caused by melanin, one of the main pigments in the skin. Penile melanosis refers to a buildup of melanin and may also involve other pigment compounds in the skin, such as hemosiderin, lipofuscin, and ferrous sulfate. Proposed term will be added as new PT Penile pigmentation under primary HLT Penile disorders NEC (excl erection and ejaculation) and secondary HLT Hyperpigmentation disorders.

CR Number: 2022181006 **Implementation Date:** 08-Jul-22 Related CR: 2022181006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Oedema due to thermal burn*	Approved Not as Requested	Proposed PT	
			Burn oedema	10088079
			HLT primary	
			Oedema NEC	10030113
			SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Total fluid volume increased	10044085
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to add a new LLT Oedema due to thermal burn is approved but not as requested. Massive tissue edema after thermal injury is a well-recognized entity. The proposed term will be modified to Burn oedema and added as a PT to primary HLT Oedema NEC, to secondary HLT Total fluid volume increased and to secondary HLT Thermal burns. In a related change, the American English spelled counterpart LLT Burn edema will be added to new PT Burn oedema.

Supplemental Update Report

CR Number: 2022189017 **Implementation Date:** 08-Jul-22 Related CR: 2022181006

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Burn oedema*	Approved as Requested	Proposed PT	
To HLT	*Thermal burns*		*Burn oedema*	10088079
			To HLT	
			Thermal burns	10043418

MSSO Comment:

CR Number: 2022189018 **Implementation Date:** 08-Jul-22 Related CR: 2022181006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Burn edema*	Approved as Requested	Proposed LLT	
To PT	*Burn oedema*		*Burn edema*	10088080 Current
			To PT	
			Burn oedema	10088079

MSSO Comment:

CR Number: 2022181007 **Implementation Date:** 08-Jul-22 Related CR: 2022181007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Swelling due to thermal burn*	Rejected		

MSSO Comment: The proposal to add a new LLT Swelling due to thermal burn is not approved. The proposed term in context of thermal burns can be represented by PT Burn oedema, added in change request 2022181006.

Supplemental Update Report

CR Number: 2022181008 **Implementation Date:** 08-Jul-22 Related CR: 2022181008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pemphigoid antibody test*	Approved Not as Requested	Proposed PT	
			Pemphigoid antibody panel	10088081
			HLT primary	
			Autoimmunity analyses	10003828
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Pemphigoid antibody test is approved but not as requested. Pemphigoid antibody panel is the preferred antibody test for initial diagnostic assessment and disease monitoring in pemphigoid, epidermolysis bullosa acquisita, and linear IgA bullous dermatosis. The requested term will be modified to Pemphigoid antibody panel, a more frequent form of its denomination in literature, and added as PT to HLT Autoimmunity analyses.

CR Number: 2022181009 **Implementation Date:** 08-Jul-22 Related CR: 2022181009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Allergic reaction to plaster*	Rejected		

MSSO Comment: The proposal to add a new term Allergic reaction to plaster is not approved. The proposed concept exists in LLT Plaster allergy.

CR Number: 2022181010 **Implementation Date:** 08-Jul-22 Related CR: 2022181010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Glans mucositis*	Approved as Requested	Proposed LLT	
			Glans mucositis	10088082 Current
			To PT	
			Balanoposthitis	10004078

MSSO Comment: The proposal to add a new term Glans mucositis is approved as requested. Glans mucositis is a type of non-infectious balanitis resulting from chemotherapy treatment, which may present with erythema, scales or serous crusts. Glans mucositis will be added as LLT to PT Balanoposthitis.

Supplemental Update Report

CR Number: 2022182001 **Implementation Date:** 08-Jul-22 Related CR: 2022182001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Delirium Superimposed on Dementia*	Rejected		

MSSO Comment: The proposal to add a new term Delirium Superimposed on Dementia is not approved. The proposed term represents the coexistence of two distinct diagnoses both existing in MedDRA. The underlying disease dementia represents a risk for developing a delirium e.g. after surgical interventions with anesthesia or delirium may be a complication in dementia patients.

CR Number: 2022182002 **Implementation Date:** 08-Jul-22 Related CR: 2022182002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Mesenteric lymphadenitis/Mesenteric adenitis*	Approved Not as Requested	Proposed PT	
			Mesenteric lymphadenitis	10088083
			HLT primary	
			Lymphatic system disorders NEC	10025198
			SOC primary	
			Blood and lymphatic system disorders	10005329
			HLT secondary	
			Gastrointestinal inflammatory disorders NEC	10017921
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Mesenteric lymphadenitis/Mesenteric adenitis is approved but not as requested. Mesenteric lymphadenitis is inflammation of the lymph nodes in the abdomen. Symptoms include pain and tenderness in the abdomen, nausea and diarrhea. The requested term will be modified and added as PT Mesenteric lymphadenitis to primary HLT Lymphatic system disorders NEC and secondary HLT Gastrointestinal inflammatory disorders NEC. In a related change, LLT Nonspecific mesenteric lymphadenitis and Mesenteric adenitis will both be moved from PT Lymphadenitis to the new PT Mesenteric lymphadenitis for better alignment.

Supplemental Update Report

CR Number: 2022189019 **Implementation Date:** 08-Jul-22 Related CR: 2022182002

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Nonspecific mesenteric lymphadenitis*	Approved as Requested	Proposed LLT		
From PT	*Lymphadenitis*		*Nonspecific mesenteric lymphadenitis*	10029717	Current
To PT	*Mesenteric lymphadenitis*		From PT		
			Lymphadenitis	10025188	
			To PT		
			Mesenteric lymphadenitis	10088083	

MSSO Comment:

CR Number: 2022189020 **Implementation Date:** 08-Jul-22 Related CR: 2022182002

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Mesenteric adenitis*	Approved as Requested	Proposed LLT		
From PT	*Lymphadenitis*		*Mesenteric adenitis*	10027393	Current
To PT	*Mesenteric lymphadenitis*		From PT		
			Lymphadenitis	10025188	
			To PT		
			Mesenteric lymphadenitis	10088083	

MSSO Comment:

Supplemental Update Report

CR Number: 2022182003 **Implementation Date:** 08-Jul-22 Related CR: 2022182003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Marshall-White syndrome*	Approved as Requested	Proposed PT	
			Marshall-White syndrome	10088084
			HLT primary	
			Musculoskeletal and connective tissue disorders of face, neck and jaw congenital	10028380
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Musculoskeletal and connective tissue disorders of face, neck and jaw congenital	10028380
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new term Marshall-White syndrome is approved as requested. Marshall-White syndrome is a rare autosomal dominant genetic disorder caused by mutations in the COL11A1 gene. Major symptoms may include a distinctive face with a flattened nasal bridge and nostrils that are tilted upward, widely spaced eyes, nearsightedness, cataracts and hearing loss. Marshall-White syndrome will be added as PT to bi-axial HLT Musculoskeletal and connective tissue disorders of face, neck and jaw congenital with primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders, to secondary HLT Congenital eye disorders NEC and to secondary HLT Hearing losses.

CR Number: 2022189021 **Implementation Date:** 08-Jul-22 Related CR: 2022182003

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Marshall-White syndrome*	Approved as Requested	Proposed PT	
To HLT	*Congenital eye disorders NEC*		*Marshall-White syndrome*	10088084
			To HLT	
			Congenital eye disorders NEC	10010464

MSSO Comment:

Supplemental Update Report

CR Number: 2022189022 **Implementation Date:** 08-Jul-22 Related CR: 2022182003

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Marshall-White syndrome*	Approved as Requested	Proposed PT	
To HLT	*Hearing losses*		*Marshall-White syndrome*	10088084
			To HLT	
			Hearing losses	10011879

MSSO Comment:

CR Number: 2022182004 **Implementation Date:** 08-Jul-22 Related CR: 2022182004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Dermatophilosis*	Approved as Requested	Proposed LLT	
			Dermatophilosis	10088085 Current
			To PT	
			Actinomycotic skin infection	10000629

MSSO Comment: The proposal to add a new term Dermatophilosis is approved as requested. Dermatophilosis is a skin disease in animals and rarely seen in humans caused by the actinomycete Dermatophilus congolensis. Dermatophilosis will be added as sub-concept LLT to PT Actinomycotic skin infection.

CR Number: 2022182005 **Implementation Date:** 08-Jul-22 Related CR: 2022182005

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Autonomic dysreflexia*	Approved as Requested	Proposed PT	
Old Primary SOC	*Injury, poisoning and procedural complications*		*Autonomic dysreflexia*	10068196
			Old Primary SOC	
New Primary SOC	*Nervous system disorders*		*Injury, poisoning and procedural complications*	10022117
			New Primary SOC	
			Nervous system disorders	10029205

MSSO Comment: The proposal to reassign the primary SOC of PT Autonomic dysreflexia from current SOC Injury, poisoning and procedural complications to SOC Nervous system disorders is approved as requested. Besides traumatic etiology, autonomic dysreflexia is also seen e.g. in multiple sclerosis patients, Guillain-Barre syndrome or use of illegal stimulant drugs.

Supplemental Update Report

CR Number: 2022182006 **Implementation Date:** 08-Jul-22 Related CR: 2022182006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Widowmaker heart attack*	Approved as Requested	Proposed LLT	
			Widowmaker heart attack	10088087 Current
			To PT	
			Acute myocardial infarction	10000891

MSSO Comment: The proposal to add a new term Widowmaker heart attack is approved as requested. The left anterior descending artery is a branch of the left coronary artery whose blockage is often called the widow-maker infarction due to a high death risk. Widowmaker heart attack will be added as LLT to PT Acute myocardial infarction.

CR Number: 2022182007 **Implementation Date:** 08-Jul-22 Related CR: 2022182007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Retinal pigment epithelium granularity*	Approved as Requested	Proposed LLT	
			Retinal pigment epithelium granularity	10088086 Current
			To PT	
			Retinal degeneration	10038845

MSSO Comment: The proposal to add a new term Retinal pigment epithelium granularity is approved as requested. Granularity and thinning of the retinal pigment epithelium is a frequent finding in the evolution of retinal atrophy. Retinal pigment epithelium granularity will be added as an LLT to PT Retinal degeneration, together with existing LLT Retinal pigment epithelium atrophy.

CR Number: 2022185001 **Implementation Date:** 08-Jul-22 Related CR: 2022185001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Plate stabilization with bone rivets*	Approved as Requested	Proposed LLT	
			Plate stabilization with bone rivets	10088088 Current
			To PT	
			Internal fixation of fracture	10022576

MSSO Comment: The proposal to add a new term Plate stabilization with bone rivets is approved as requested. Bone rivets can be an alternative method to fasten plates during internal fixation of fractures when screw anchorage may be inadequate. Plate stabilization with bone rivets will be added as LLT to PT Internal fixation of fracture. In a related change, its British counterpart Plate stabilisation with bone rivets will also be added as LLT to the same PT Internal fixation of fracture.

Supplemental Update Report

CR Number: 2022189023 **Implementation Date:** 08-Jul-22 Related CR: 2022185001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Plate stabilisation with bone rivets*	Approved as Requested	Proposed LLT	
To PT	*Internal fixation of fracture*		*Plate stabilisation with bone rivets*	10088089 Current
			To PT	
			Internal fixation of fracture	10022576

MSSO Comment:

CR Number: 2022185002 **Implementation Date:** 12-Jul-22 Related CR: 2022185002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Interaction with Live vaccine*	Approved Not as Requested	Proposed LLT	
			Interaction with live vaccine	10088123 Current
			To PT	
			Vaccine interaction	10088119

MSSO Comment: The proposal to add a new LLT Interaction with Live vaccine is approved but not as requested. A growing number of clinical observations have indicated the possibility of interactions between vaccines and drugs, leading to changes in drug metabolism after vaccination. The proposed term will be modified according to MedDRA capitalization conventions and added as an LLT Interaction with live vaccine to a new PT Vaccine interaction which will be added and linked to HLT Interactions. Furthermore, the following LLTs will be added to the new PT Vaccine interaction: LLT Vaccine-vaccine interaction, and LLT Vaccine-drug interaction.

CR Number: 2022193003 **Implementation Date:** 12-Jul-22 Related CR: 2022185002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vaccine interaction*	Approved as Requested	Proposed PT	
HLT primary	*Interactions*		*Vaccine interaction*	10088119
SOC primary	*General disorders and administration site conditions*		HLT primary	
			Interactions	10022528
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment:

Supplemental Update Report

CR Number: 2022193004 **Implementation Date:** 12-Jul-22 Related CR: 2022185002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vaccine-vaccine interaction*	Approved as Requested	Proposed LLT	
To PT	*Vaccine interaction*		*Vaccine-vaccine interaction*	10088120 Current
			To PT	
			Vaccine interaction	10088119

MSSO Comment:

CR Number: 2022193005 **Implementation Date:** 12-Jul-22 Related CR: 2022185002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vaccine-drug interaction*	Approved as Requested	Proposed LLT	
To PT	*Vaccine interaction*		*Vaccine-drug interaction*	10088121 Current
			To PT	
			Vaccine interaction	10088119

MSSO Comment:

CR Number: 2022185003 **Implementation Date:** 12-Jul-22 Related CR: 2022185003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NSAID induced colopathy*	Rejected		

MSSO Comment: The proposal to add a new LLT NSAID induced colopathy is not approved. NSAID induced colopathy represents a combination concept with a causal relationship with a drug. The MSSO refrains from further adding drug-induced terms. However, in a related change, LLT Colopathy will be promoted from under PT Gastrointestinal disorder to a PT level to linked to HLT Gastrointestinal disorders NEC.

Supplemental Update Report

CR Number: 2022193006 **Implementation Date:** 12-Jul-22 Related CR: 2022185003

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Colopathy*	Approved as Requested	Proposed LLT	
From PT	*Gastrointestinal disorder*		*Colopathy*	10049897
HLT primary	*Gastrointestinal disorders NEC*		From PT	
			Gastrointestinal disorder	10017944
			HLT primary	
			Gastrointestinal disorders NEC	10017948
			SOC primary	
			Gastrointestinal disorders	10017947

MSSO Comment:

CR Number: 2022185004 **Implementation Date:** 12-Jul-22 Related CR: 2022185004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Platypnea-orthodeoxia syndrome*	Approved as Requested	Proposed LLT	
			Platypnea-orthodeoxia syndrome	10088122 Current
			To PT	
			Platypnoea-orthodeoxia syndrome	10088118

MSSO Comment: The proposal to add a new LLT Platypnea-orthodeoxia syndrome is approved as requested. Platypnea-orthodeoxia syndrome is a rare syndrome that is characterized by positional dyspnea (platypnea) and arterial desaturation (orthodeoxia) while in the upright position. Pathopysiologic underlying mechanisms are determined by an atrial right-to-left shunt. Platypnea-orthodeoxia syndrome will be added as LLT to the British spelled counterpart PT Platypnoea-orthodeoxia syndrome which will be added in a related change to primary HLT Dyspnoeas and to secondary HLT Conditions associated with abnormal gas exchange.

Supplemental Update Report

CR Number: 2022193007 **Implementation Date:** 12-Jul-22 Related CR: 2022185004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Platypnoea-orthodeoxia syndrome*	Approved as Requested	Proposed PT	
HLT primary	*Dyspnoeas*		*Platypnoea-orthodeoxia syndrome*	10088118
SOC primary	*Cardiac disorders*		HLT primary	
			Dyspnoeas	10013975
			SOC primary	
			Cardiac disorders	10007541
			HLT secondary	
			Conditions associated with abnormal gas exchange	10010268
			SOC secondary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment:

CR Number: 2022186001 **Implementation Date:** 08-Jul-22 Related CR: 2022186001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Infusion site bumps*	Rejected		

MSSO Comment: The proposal to add a new LLT Infusion site bumps is not approved. "Bumps" is a colloquial expression and imprecise term that may have different international interpretations. The MSSO generally refrains from adding "bump" terms unless they represent a specific concept such as LLT Goose bumps.

Supplemental Update Report

CR Number: 2022186002 **Implementation Date:** 08-Jul-22 Related CR: 2022186002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ear Dryness*	Approved Not as Requested	Proposed PT	
			Ear dryness	10088090
			HLT primary	
			Ear disorders NEC	10027666
			SOC primary	
			Ear and labyrinth disorders	10013993
			HLT secondary	
			Dermal and epidermal conditions NEC	10012424
			SOC secondary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new LLT Ear Dryness is approved but not as requested. Dry ears are frequently marked by a buildup of dry, dead skin flakes and itchiness in the ear canal. Dry ears can also be linked to skin allergies, and to other dry skin conditions such as eczema, psoriasis, and dermatitis. Proposed term will be modified for MedDRA capitalization standards and added as new PT Ear dryness under primary HLT Ear disorders NEC and secondary HLT Dermal and epidermal conditions NEC.

CR Number: 2022186004 **Implementation Date:** 08-Jul-22 Related CR: 2022186004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Inadvertent injection air bubble*	Approved Not as Requested	Proposed PT	
			Inadvertent injection air bubble	10088091
			HLT primary	
			Non-site specific procedural complications	10029559
			SOC primary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new LLT Inadvertent injection air bubble is approved but not as requested. A syringe or IV can accidentally inject air into your veins. Air can also enter your veins or arteries through a catheter that's inserted into them which may cause an air embolism. Proposed term, Inadvertent injection air bubble will be added as a new PT under HLT Non-site specific procedural complications.

Supplemental Update Report

CR Number: 2022186005 **Implementation Date:** 08-Jul-22 Related CR: 2022186005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Macula thinning*	Approved as Requested	Proposed LLT *Macula thinning*	10088092 Current
			To PT *Macular degeneration*	10025409

MSSO Comment: The proposal to add a new term Macula thinning is approved as requested. Macula thinning is a recognized concept and will be added as an LLT to PT Macular degeneration.

CR Number: 2022186007 **Implementation Date:** 08-Jul-22 Related CR: 2022186007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Otolaryngoscopy*	Approved Not as Requested	Proposed PT *Otolaryngoscopy*	10088093
			HLT primary *Imaging procedures NEC*	10021404
			SOC primary *Investigations*	10022891

MSSO Comment: The proposal to add a new LLT Otolaryngoscopy is approved but not as requested. Otolaryngoscopy, a modern method to help diagnose diseases of the ENT region, will be added as a PT to HLT Imaging procedures NEC.

Supplemental Update Report

CR Number: 2022187001 **Implementation Date:** 11-Jul-22 Related CR: 2022187001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Fibromyxoma*	Approved Not as Requested	Proposed PT	
HLT primary	*Benign musculoskeletal and connective tissue neoplasms*		*Fibromyxoma*	10088112
SOC primary	*Musculoskeletal and connective tissue disorders*		HLT primary	
			Soft tissue neoplasms benign NEC	10041295
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Benign musculoskeletal and connective tissue neoplasms	10004297
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Fibromyxoma to primary HLT Benign musculoskeletal and connective tissue neoplasms in SOC Musculoskeletal and connective tissue disorders is approved but not as requested. Fibromyxoma is classified as a specific type of myxoma with a higher fibrous/myxoid tissue ratio than myxoma. The fibromyxoid lesion may present loci of calcification or ossification and a higher amount of collagen fibres and vessels than a typical myxoma. Proposed term will be added as new PT Fibromyxoma under primary HLT Soft tissue neoplasms benign NEC and secondary HLT Benign musculoskeletal and connective tissue neoplasms.

CR Number: 2022187005 **Implementation Date:** 12-Jul-22 Related CR: 2022187005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Bladder prolapse repair*	Approved as Requested	Proposed LLT	
			Bladder prolapse repair	10088124 Current
			To PT	
			Cystocele repair	10064256

MSSO Comment: The proposal to add a new term Bladder prolapse repair is approved as requested. A prolapsed bladder, also called a cystocele or dropped bladder, is the bulging or dropping of the bladder into the vagina. The most common prolapsed bladder repair is an anterior vaginal repair, or anterior colporrhaphy. Bladder prolapse repair will be added as synonym LLT to PT Cystocele repair. In a related change, existing PT Bladder prolapse will be merged under PT Cystocele.

Supplemental Update Report

CR Number: 2022193008 **Implementation Date:** 12-Jul-22 Related CR: 2022187005

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Bladder prolapse*	Approved as Requested	PT to merge	
To PT	*Cystocele*		*Bladder prolapse*	10048475 Current
			To PT	
			Cystocele	10011803

MSSO Comment:

CR Number: 2022188001 **Implementation Date:** 12-Jul-22 Related CR: 2022188001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Gastric sleeve surgery*	Rejected		

MSSO Comment: The proposal to add a new term Gastric sleeve surgery is not approved. The proposed term can be represented by existing LLT Sleeve gastrectomy. However, in a related change, the LLT Sleeve gastrectomy will be promoted from PT Gastrectomy to a PT level and linked to HLT Gastric therapeutic procedures, aligned with other bariatric procedures.

CR Number: 2022193009 **Implementation Date:** 12-Jul-22 Related CR: 2022188001

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Sleeve gastrectomy*	Approved as Requested	Proposed LLT	
From PT	*Gastrectomy*		*Sleeve gastrectomy*	10070978
HLT primary	*Gastric therapeutic procedures*		From PT	
			Gastrectomy	10061965
			HLT primary	
			Gastric therapeutic procedures	10017813
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment:

Supplemental Update Report

CR Number: 2022188002 **Implementation Date:** 12-Jul-22 Related CR: 2022188002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*WNT4 deficiency*	Approved as Requested	Proposed PT	
			WNT4 deficiency	10088125
			HLT primary	
			Female reproductive tract disorders congenital	10016416
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Congenital female reproductive tract disorders	10010446
			SOC secondary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new term WNT4 deficiency is approved as requested. WNT4 deficiency is a rare genetic disorder, caused by mutations in the WNT4 gene, that affects females. It is characterized by the absence or underdevelopment of the uterus and sometimes absence or underdevelopment of the vagina in association with symptoms of hyperandrogenism. WNT4 deficiency will be added as PT with a primary link to HLT Female reproductive tract disorders congenital, and secondary links to HLT Congenital female reproductive tract disorders and HLT Female gonadal function disorders.

CR Number: 2022193010 **Implementation Date:** 12-Jul-22 Related CR: 2022188002

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*WNT4 deficiency*	Approved as Requested	Proposed PT	
To HLT	*Female gonadal function disorders*		*WNT4 deficiency*	10088125
			To HLT	
			Female gonadal function disorders	10013307

MSSO Comment:

Supplemental Update Report

CR Number: 2022188003 **Implementation Date:** 12-Jul-22 Related CR: 2022188003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Turcot syndrome*	Approved as Requested	Proposed LLT	
			Turcot syndrome	10088126 Current
			To PT	
			Adenomatous polyposis coli	10056981

MSSO Comment: The proposal to add a new term Turcot syndrome is approved as requested. Turcot syndrome is a rare inherited disorder characterized by the association of adenomatous polyps with tumors of the central nervous system. Like Gardner's syndrome, Turcot syndrome can be considered a subtype of familial polyposis coli, and will be added as LLT to PT Adenomatous polyposis coli.

CR Number: 2022188019 **Implementation Date:** 12-Jul-22 Related CR: 2022188019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Eyelid subcutaneous hemorrhage*	Rejected		
To PT	*Eye contusion*			

MSSO Comment: The proposal to add a new LLT Eyelid subcutaneous hemorrhage to PT Eye contusion is not approved. The proposed term can be represented by existing PT Eyelid contusion.

CR Number: 2022189001 **Implementation Date:** 12-Jul-22 Related CR: 2022189001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*INTESTINAL RUPTURE REPAIR*	Approved Not as Requested	Proposed LLT	
To PT	*Enterorrhaphy*		*Intestinal rupture repair*	10088127 Current
			To PT	
			Enterorrhaphy	10082396

MSSO Comment: The proposal to add a new LLT INTESTINAL RUPTURE REPAIR to PT Enterorrhaphy is approved but not as requested. Intestinal rupture repair modified according to MedDRA capitalization rules and will be added as an LLT to PT Enterorrhaphy, aligned with LLT Intestinal perforation repair.

Supplemental Update Report

CR Number: 2022189002 **Implementation Date:** 12-Jul-22 Related CR: 2022189002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*PERIANAL ABSCESS SURGERY*	Rejected		

MSSO Comment: The proposal to add a new term PERIANAL ABSCESS SURGERY is not approved. To avoid the overpopulation of the Surgical and medical procedures SOC, MedDRA cannot add a surgery treatment counterpart term for every possible pathologic condition. If deemed appropriate, existing terms like LLT Perianal abscess drainage, or LLTs such as Abscess management or Anorectal operation selected in combination with LLT Perianal abscess may be considered.

CR Number: 2022189003 **Implementation Date:** 12-Jul-22 Related CR: 2022189003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Food disgust*	Approved as Requested	Proposed LLT	
To PT	*Food aversion*		*Food disgust*	10088128 Current
			To PT	
			Food aversion	10049238

MSSO Comment: The proposal to add a new LLT Food disgust to PT Food aversion is approved as requested. Food disgust is used to represent an aversive emotion consisting in the refusal of food that is considered potentially harmful to health, and is often encountered in people with eating disorders.

CR Number: 2022189004 **Implementation Date:** 12-Jul-22 Related CR: 2022189004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tumor biopsy*	Approved Not as Requested	Proposed LLT	
To PT	*Biopsy*		*Tumor biopsy*	10088132 Current
			To PT	
			Tumour biopsy	10088129

MSSO Comment: The proposal to add a new LLT Tumor biopsy to PT Biopsy is approved but not as requested. Tumor biopsy samples represent the traditional and most direct tissue for evaluating molecular biomarker responses to cancer therapy. Tumor biopsy will be added as an LLT to the British English counterpart PT Tumour biopsy which will be linked to HLT Histopathology procedures NEC, in a related change.

Supplemental Update Report

CR Number: 2022193011 **Implementation Date:** 12-Jul-22 Related CR: 2022189004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tumour biopsy*	Approved as Requested	Proposed PT	
HLT primary	*Histopathology procedures NEC*		*Tumour biopsy*	10088129
SOC primary	*Investigations*		HLT primary	
			Histopathology procedures NEC	10020126
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022189005 **Implementation Date:** 12-Jul-22 Related CR: 2022189005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Liquid biopsy*	Approved Not as Requested	Proposed PT	
To PT	*Biopsy*		*Liquid biopsy*	10088130 Current
			HLT primary	
			Histopathology procedures NEC	10020126
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new LLT Liquid biopsy to PT Biopsy is approved but not as requested. A liquid biopsy is a simple and non-invasive alternative to surgical biopsies which enables to discover a range of information about a tumour through a simple blood sample. Liquid biopsy will be added as a PT to HLT Histopathology procedures NEC.

CR Number: 2022189006 **Implementation Date:** 12-Jul-22 Related CR: 2022189006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vacuum assisted biopsy*	Approved Not as Requested	Proposed LLT	
To PT	*Biopsy*		*Vacuum assisted biopsy*	10088131 Current
			To PT	
			Diagnostic aspiration	10072924

MSSO Comment: The proposal to add a new LLT Vacuum assisted biopsy to PT Biopsy is approved but not as requested. A vacuum assisted biopsy of the breast is a way of taking a sample of abnormal breast tissue to look at under the microscope. Vacuum assisted biopsy will be added as an LLT to the more appropriate PT Diagnostic aspiration.

Supplemental Update Report

CR Number: 2022189007 **Implementation Date:** 12-Jul-22 Related CR: 2022189007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Euthyroidism*	Rejected		
To PT	*Thyroid function test normal*			

MSSO Comment: The proposal to add a new LLT Euthyroidism to PT Thyroid function test normal is not approved. MedDRA does not generally include normal conditions, nor a condition related term (even if normal) under an investigation term.

CR Number: 2022189008 **Implementation Date:** 12-Jul-22 Related CR: 2022189008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Nstemi (non-st-segment elevation myocardial infarction)*	Approved Not as Requested	Proposed LLT	
			NSTEMI	10088133 Current
			To PT	
			Acute myocardial infarction	10000891

MSSO Comment: The proposal to add a new term Nstemi (non-st-segment elevation myocardial infarction) is approved but not as requested. Proposed term will be modified to the most common acronym for LLT Non ST segment elevation myocardial infarction, and added as LLT NSTEMI under PT Acute myocardial infarction.

CR Number: 2022189009 **Implementation Date:** 12-Jul-22 Related CR: 2022189009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Chest exloration*	Approved Not as Requested	Proposed LLT	
			Explorative thoracotomy	10088134 Current
			To PT	
			Thoracotomy	10043491

MSSO Comment: The proposal to add a new term Chest exloration is approved but not as requested. Chest exploration is performed after a thoractomy -an operation to open the chest, usually in order to gain access to the lungs or heart- for identifying bleeds and other gross pathologies. Proposed term will be modified for spelling and for clarity and added as sub-concept LLT Explorative thoracotomy under PT Thoracotomy.

Supplemental Update Report

CR Number: 2022189010 **Implementation Date:** 12-Jul-22 Related CR: 2022189010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Postoperative meningitis*	Approved Not as Requested	Proposed PT *Post procedural meningitis*	10088135
			HLT primary *Central nervous system and spinal infections*	10007935
			SOC primary *Infections and infestations*	10021881
			HLT secondary *Neurological and psychiatric procedural complications*	10029294
			SOC secondary *Injury, poisoning and procedural complications*	10022117

MSSO Comment: The proposal to add a new term Postoperative meningitis is approved but not as requested. Postoperative meningitis is a rare complication after spinal lumbar surgery and serious complication of craniotomy procedures, affecting some 1.5–4% of patients. Proposed term will be modified and added as PT Post procedural meningitis under primary HLT Central nervous system and spinal infections, secondary HLT Neurological and psychiatric procedural complications and to secondary HLT Meningitis NEC.

CR Number: 2022193012 **Implementation Date:** 12-Jul-22 Related CR: 2022189010

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Post procedural meningitis*	Approved as Requested	Proposed PT *Post procedural meningitis*	10088135
To HLT	*Meningitis NEC*		To HLT *Meningitis NEC*	10027187

MSSO Comment:

Supplemental Update Report

CR Number: 2022192001 **Implementation Date:** 12-Jul-22 Related CR: 2022192001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*PAPILLITIS GINGIVALIS*	Approved Not as Requested	Proposed LLT	
			Papillary gingivitis	10088136 Current
			To PT	
			Gingivitis	10018292

MSSO Comment: The proposal to add a new term PAPILLITIS GINGIVALIS is approved but not as requested. The rarely used Latin expression for interdental gingivitis will be modified to the English expression and added as LLT Papillary gingivitis to PT Gingivitis.

CR Number: 2022192002 **Implementation Date:** 12-Jul-22 Related CR: 2022192002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Camphylobacter bacteremia*	Approved Not as Requested	Proposed LLT	
			Campylobacter bacteremia	10088116 Current
			To PT	
			Campylobacter bacteraemia	10088115

MSSO Comment: The proposal to add a new term Camphylobacter bacteremia is approved but not as requested. Campylobacter infections typically cause self-limited diarrhea but occasionally cause bacteremia, with consequent endocarditis, osteomyelitis, or septic arthritis. The proposed term will be modified to correct spelling and added as LLT Campylobacter bacteremia to a new PT representing its British English counterpart spelling, Campylobacter bacteraemia, which will be added to HLT Campylobacter infections.

CR Number: 2022193002 **Implementation Date:** 12-Jul-22 Related CR: 2022192002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Campylobacter bacteraemia*	Approved as Requested	Proposed PT	
HLT primary	*Campylobacter infections*		*Campylobacter bacteraemia*	10088115
SOC primary	*Infections and infestations*		HLT primary	
			Campylobacter infections	10053136
			SOC primary	
			Infections and infestations	10021881

MSSO Comment:

Supplemental Update Report

CR Number: 2022192003 **Implementation Date:** 12-Jul-22 Related CR: 2022192003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Laparoscopic deroofing renal cyst*	Approved Not as Requested	Proposed LLT	
			Laparoscopic decortication of renal cyst	10088117 Current
			To PT	
			Renal cyst excision	10038425

MSSO Comment: The proposal to add a new term Laparoscopic deroofing renal cyst is approved but not as requested. Laparoscopic cyst decortication is an effective and durable treatment for symptomatic renal cysts due to its minimal invasiveness and greater success rate. The proposed term will be modified for greater clarity and added as an LLT Laparoscopic decortication of renal cyst under PT Renal cyst excision.

CR Number: 2022192004 **Implementation Date:** 12-Jul-22 Related CR: 2022192004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nocturnal hypoventilation*	Approved as Requested	Proposed PT	
HLT primary	*Breathing abnormalities*		*Nocturnal hypoventilation*	10088137
SOC primary	*Respiratory, thoracic and mediastinal disorders*		HLT primary	
			Breathing abnormalities	10006334
			SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738
			HLT secondary	
			Dyspnoeas	10013975
			SOC secondary	
			Cardiac disorders	10007541

MSSO Comment: The proposal to add a new PT Nocturnal hypoventilation to primary HLT Breathing abnormalities in SOC Respiratory, thoracic and mediastinal disorders and secondary HLT Dyspnoeas in SOC Cardiac disorders is approved as requested. While hypoventilation during sleep can occur in a range of disparate disorders, the feature in common is the rise in CO that occurs during sleep and the compensatory retention of bicarbonate by the kidney in response to this. These changes blunt central drive, generating further CO2 retention, so that eventually hypoventilation is present not just during sleep but during wakefulness as well. PT Nocturnal hypoventilation will also be linked to secondary HLT Sleep apnoeas.

Supplemental Update Report

CR Number: 2022193013 **Implementation Date:** 12-Jul-22 Related CR: 2022192004

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nocturnal hypoventilation*	Approved as Requested	Proposed PT	
To HLT	*Sleep apnoeas*		*Nocturnal hypoventilation*	10088137
			To HLT	
			Sleep apnoeas	10040978

MSSO Comment:

CR Number: 2022192005 **Implementation Date:** 12-Jul-22 Related CR: 2022192005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Mesenteric neoplasm removal*	Rejected		

MSSO Comment: The proposal to add a new term Mesenteric neoplasm removal is not approved. The MSSO refrains from adding "removal" terms for all possible neoplasms as this may lead to overpopulation of the terminology. Please consider to represent this concept with either two terms to represent the diagnosis, i.e. specific neoplasm, and the procedure separately or only with the underlying diagnosis. Please see MedDRA Term Selection: Points to Consider document for the recommended options in section 3.13.2 Procedure and diagnosis are reported.

CR Number: 2022192017 **Implementation Date:** 19-Jul-22 Related CR: 2022192017

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Prostate massage*	Approved as Requested	Proposed PT	
			Prostate massage	10088138
			HLT primary	
			Prostatic therapeutic procedures	10036967
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Prostate massage is approved as requested. Prostate massage, the practice of massaging the male prostate either for medical diagnostic or therapeutic reasons, will be added as PT to HLT Prostatic therapeutic procedures.

Supplemental Update Report

CR Number: 2022192018 **Implementation Date:** 19-Jul-22 Related CR: 2022192018

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Leukocyte reduced red blood transfusion*	Approved Not as Requested	Proposed LLT		
To PT	*Red blood cell transfusion*		*Leukocyte reduced red blood cell transfusion*	10088139	Current
			To PT		
			Red blood cell transfusion	10087283	

MSSO Comment: The proposal to add a new LLT Leukocyte reduced red blood transfusion to PT Red blood cell transfusion is approved but not as requested. Leukocyte removal filters are used to reduce complications associated with transfused white blood cells that are contained in units of red blood cells and platelets. The suggested term will be modified for clarity and added as LLT Leukocyte reduced red blood cell transfusion to PT Red blood cell transfusion.

CR Number: 2022193001 **Implementation Date:** 19-Jul-22 Related CR: 2022193001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*SOLUBLE TRANSFERRIN RECEPTOR INCREASED*	Approved Not as Requested	Proposed LLT		
			Soluble transferrin receptor increased	10088141	Current
			To PT		
			Transferrin receptor increased	10088140	

MSSO Comment: The proposal to add a new term SOLUBLE TRANSFERRIN RECEPTOR INCREASED is approved but not as requested. The requested term will be modified according to MedDRA capitalization conventions and added as LLT Soluble transferrin receptor increased to a new PT Transferrin receptor increased which will be added to HLT Mineral and electrolyte analyses. Soluble transferrin receptor conventionally refers to the cleaved extracellular portion of transferrin receptor 1 that is released into serum. Because it is insensitive to inflammation, it can detect anemia in patients with preexisting inflammatory states, and is particularly useful in distinguishing between the anemia of chronic disease and anemias caused by lack of iron intake.

CR Number: 2022200005 **Implementation Date:** 19-Jul-22 Related CR: 2022193001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Transferrin receptor increased*	Approved as Requested	Proposed PT	
HLT primary	*Mineral and electrolyte analyses*		*Transferrin receptor increased*	10088140
SOC primary	*Investigations*		HLT primary	
			Mineral and electrolyte analyses	10027637
			SOC primary	
			Investigations	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2022194002 **Implementation Date:** 19-Jul-22 Related CR: 2022194002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Basal cell carcinoma ear*	Approved as Requested	Proposed LLT *Basal cell carcinoma ear* To PT *Basal cell carcinoma*	 10088142 Current 10004146

MSSO Comment: The proposal to add a new term Basal cell carcinoma ear is approved as requested. Basal cell cancers are the most common ear tumors of the external ear. Usually, years of sun exposure causes basal cell tumors (cancers), particularly of the upper portion of the exposed ear. They are the most common cancers of any part of the face including the external ear. LLT Basal cell carcinoma ear will be added to PT Basal cell carcinoma.

CR Number: 2022194003 **Implementation Date:** 19-Jul-22 Related CR: 2022194003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Posterior circulation ischemic stroke*	Approved as Requested	Proposed LLT *Posterior circulation ischemic stroke* To PT *Vertebrobasilar stroke*	 10088143 Current 10082484

MSSO Comment: The proposal to add a new term Posterior circulation ischemic stroke is approved as requested. Posterior circulation ischaemic stroke is a clinical syndrome associated with ischaemia related to stenosis, in situ thrombosis, or embolic occlusion of the posterior circulation arteries—the vertebral arteries in the neck, the intracranial vertebral, basilar, and posterior cerebral arteries, and their branches. Posterior circulation ischemic stroke and the British English counterpart Posterior circulation ischaemic stroke will both be added as synonym LLTs to PT Vertebrobasilar stroke.

CR Number: 2022200003 **Implementation Date:** 19-Jul-22 Related CR: 2022194003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT To PT	*Posterior circulation ischaemic stroke* *Vertebrobasilar stroke*	Approved as Requested	Proposed LLT *Posterior circulation ischaemic stroke* To PT *Vertebrobasilar stroke*	 10088144 Current 10082484

MSSO Comment:

Supplemental Update Report

CR Number: 2022194004 **Implementation Date:** 19-Jul-22 Related CR: 2022194004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Fundus exudation*	Approved as Requested	Proposed LLT *Fundus exudation*	10088145 Current
			To PT *Retinal exudates*	10038862

MSSO Comment: The proposal to add a new LLT Fundus exudation is approved as requested. Fundus exudation will be added as a synonym LLT to PT Retinal exudates. Since retinal exudates are very often found in the diabetic eye, the PT Retinal exudates will be linked to HLT Diabetic complications ophthalmic as an associated change.

CR Number: 2022200006 **Implementation Date:** 19-Jul-22 Related CR: 2022194004

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Retinal exudates*	Approved as Requested	Proposed PT *Retinal exudates*	10038862
To HLT	*Diabetic complications ophthalmic*		To HLT *Diabetic complications ophthalmic*	10012657

MSSO Comment:

CR Number: 2022195001 **Implementation Date:** 19-Jul-22 Related CR: 2022195001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Fastig therapy*	Approved Not as Requested	Proposed LLT *Fasting therapy*	10088146 Current
To PT	*Medical diet*		To PT *Medical diet*	10027087

MSSO Comment: The proposal to add a new LLT Fastig therapy to PT Medical diet is approved but not as requested. The requested term will be added with corrected spelling as LLT Fasting therapy to PT Medical diet.

Supplemental Update Report

CR Number: 2022195002 **Implementation Date:** 09-Aug-22 Related CR: 2022195002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*TACE*	Approved After Suspension	Proposed LLT	
To PT	*Transcatheter arterial chemoembolisation*		*TACE*	10088295 Current
			To PT	
			Transcatheter arterial chemoembolisation	10076242

MSSO Comment: The proposal to add a new LLT TACE to PT Transcatheter arterial chemoembolisation is approved as requested after suspension. TACE is a commonly used acronym and will be added as an LLT to PT Transcatheter arterial chemoembolisation.

CR Number: 2022195003 **Implementation Date:** 09-Aug-22 Related CR: 2022195003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*PCI*	Rejected After Suspension		
To PT	*Percutaneous coronary intervention*			

MSSO Comment: The proposal to add a new LLT PCI to PT Percutaneous coronary intervention is not approved after suspension. PCI is not only used as an acronym in medicine for Abbreviation for percutaneous coronary intervention and therefore cannot be added. Even though less frequent, PCI also is used for e.g. Prostate Cancer Index, Prophylactic Cranial Irradiation and others.

CR Number: 2022195004 **Implementation Date:** 19-Jul-22 Related CR: 2022195004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Kneecap fracture*	Rejected	Proposed LLT	
To PT	*Patella fracture*			

MSSO Comment: The proposal to add a new LLT Kneecap fracture to PT Patella fracture is not approved. The requested term can be represented by LLT Broken knee cap.

Supplemental Update Report

CR Number: 2022195005 **Implementation Date:** 19-Jul-22 Related CR: 2022195005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Percutaneous nephrolithotomy*	Approved as Requested	Proposed LLT *Percutaneous nephrolithotomy* To PT *Renal stone removal*	10088147 Current 10038528

MSSO Comment: The proposal to add a new term Percutaneous nephrolithotomy is approved as requested. Percutaneous nephrolithotomy is a minimally-invasive procedure to remove stones from the kidney by a small puncture wound through the skin. It is accepted as the procedure of choice for the treatment of large or complex renal calculi. Percutaneous nephrolithotomy will be added as an LLT under PT Renal stone removal.

CR Number: 2022195006 **Implementation Date:** 19-Jul-22 Related CR: 2022195006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Chronic rhinosinusitis with fungal allergy*	Approved as Requested	Proposed LLT *Chronic rhinosinusitis with fungal allergy* To PT *Allergic fungal rhinosinusitis*	10088148 Current 10084709

MSSO Comment: The proposal to add a new term Chronic rhinosinusitis with fungal allergy is approved as requested. Allergic fungal rhinosinusitis is a distinct type of chronic rhinosinusitis, which is believed to result from chronic, intense allergic inflammation directed against colonizing fungi. Chronic rhinosinusitis with fungal allergy is a synonym expression of PT Allergic fungal rhinosinusitis and will be added as its LLT.

CR Number: 2022195007 **Implementation Date:** 19-Jul-22 Related CR: 2022195007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT To PT	*PSVT* *Supraventricular tachycardia*	Approved as Requested	Proposed LLT *PSVT* To PT *Supraventricular tachycardia*	10088149 Current 10042604

MSSO Comment: The proposal to add a new LLT PSVT to PT Supraventricular tachycardia is approved as requested. PSVT is a well recognized medical abbreviation which specifically represents Paroxysmal supraventricular tachycardia.

Supplemental Update Report

CR Number: 2022195008 **Implementation Date:** 19-Jul-22 Related CR: 2022195008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Intra aortic balloon counterpulsation*	Approved Not as Requested	Proposed LLT	
			Intra-aortic balloon counterpulsation	10088150 Current
			To PT	
			Intra-aortic balloon placement	10052989

MSSO Comment: The proposal to add a new LLT Intra aortic balloon counterpulsation is approved but not as requested. Intra aortic balloon counterpulsation consists of a cylindrical polyurethane balloon that sits in the aorta, inflating during diastole and aortic valve closure, improving coronary flow, to then actively deflate during systole. For consistency, the requested term will be hyphenated and added as LLT Intra-aortic balloon counterpulsation under PT Intra-aortic balloon placement.

CR Number: 2022195009 **Implementation Date:** 20-Jul-22 Related CR: 2022195009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Reverse cervical lordosis*	Approved Not as Requested	Proposed LLT	
To PT	*Lordosis*		*Reverse cervical lordosis*	10088165 Current
			To PT	
			Kyphosis	10023509

MSSO Comment: The proposal to add a new LLT Reverse cervical lordosis to PT Lordosis is approved but not as requested. Reverse cervical lordosis, reversal of the normal lordose curvature, means that part of the cervical spine develops a kyphotic profile, with the open end of the curve facing anteriorly. Reverse cervical lordosis will be added as LLT to PT Kyphosis aligned with the quasi-synonym LLT Cervical kyphosis.

CR Number: 2022196001 **Implementation Date:** 20-Jul-22 Related CR: 2022196001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NASOPHARYNGEAL SWAB - COVID TEST*	Rejected		

MSSO Comment: The proposal to add a new LLT NASOPHARYNGEAL SWAB - COVID TEST is not approved. The proposed term is already represented by LLT Nasopharyngeal swab and LLT COVID-19 virus test. To avoid the overpopulation of the terminology, MedDRA can not add combinations of a particular test with its obtaining method.

Supplemental Update Report

CR Number: 2022196002 **Implementation Date:** 20-Jul-22 Related CR: 2022196002

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Gland in neck*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Gland in neck to non-current is not approved. Gland in neck is in MedDRA since version 2.1 and understood in meaning as "swollen gland" - changing to non-current may have impact on legacy data.

CR Number: 2022196003 **Implementation Date:** 20-Jul-22 Related CR: 2022196003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Diamniotic twin pregnancy*	Approved as Requested	Proposed LLT	
To PT	*Twin pregnancy*		*Diamniotic twin pregnancy*	10088160 Current
			To PT	
			Twin pregnancy	10045188

MSSO Comment: The proposal to add a new LLT Diamniotic twin pregnancy to PT Twin pregnancy is approved as requested. Diamniotic twins are the product of a single fertilized ovum, resulting in genetically identical offspring. They share a single placenta but have separate amniotic sacs. In a related change, the additional sub-types Diamniotic monochorionic twin pregnancy and Diamniotic dichorionic twin pregnancy will be added as LLTs to PT Twin pregnancy.

CR Number: 2022201012 **Implementation Date:** 20-Jul-22 Related CR: 2022196003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Diamniotic monochorionic twin pregnancy*	Approved as Requested	Proposed LLT	
To PT	*Twin pregnancy*		*Diamniotic monochorionic twin pregnancy*	10088162 Current
			To PT	
			Twin pregnancy	10045188

MSSO Comment:

Supplemental Update Report

CR Number: 2022201013 **Implementation Date:** 20-Jul-22 Related CR: 2022196003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Diamniotic dichorionic twin pregnancy*	Approved as Requested	Proposed LLT		
To PT	*Twin pregnancy*		*Diamniotic dichorionic twin pregnancy*	10088163	Current
			To PT		
			Twin pregnancy	10045188	

MSSO Comment:

CR Number: 2022196004 **Implementation Date:** 20-Jul-22 Related CR: 2022196004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Monoamniotic monochorionic twin pregnancy*	Approved as Requested	Proposed LLT		
To PT	*Twin pregnancy*		*Monoamniotic monochorionic twin pregnancy*	10088157	Current
			To PT		
			Twin pregnancy	10045188	

MSSO Comment: The proposal to add a new LLT Monoamniotic monochorionic twin pregnancy to PT Twin pregnancy is approved as requested. A monochorionic monoamniotic twin pregnancy is a subtype of monozygotic twin pregnancy. These fetuses share a single chorionic sac, a single amniotic sac and, in general, a single yolk sac.

CR Number: 2022196005 **Implementation Date:** 20-Jul-22 Related CR: 2022196005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Therapeutic paracentesis*	Rejected		

MSSO Comment: The proposal to add a new LLT Therapeutic paracentesis is not approved. Therapeutic paracentesis without anatomical qualifier is of no benefit to the terminology. Existing PT Paracentesis may already represent the requested term. Paracentesis is a form of body fluid sampling procedure - either for diagnostic or therapeutic purposes or both.

Supplemental Update Report

CR Number: 2022196006 **Implementation Date:** 20-Jul-22 Related CR: 2022196006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Granulomatous lymphocytic interstitial lung disease*	Approved as Requested	Proposed LLT *Granulomatous lymphocytic interstitial lung disease* To PT *Interstitial lung disease*	10088161 Current 10022611

MSSO Comment: The proposal to add a new LLT Granulomatous lymphocytic interstitial lung disease is approved as requested. Granulomatous-lymphocytic interstitial lung disease is a specific kind of interstitial lung disease caused when granulomas, or small calcified nodules, form around the lung in response to chronic inflammation. Granulomatous lymphocytic interstitial lung disease will be added as LLT to PT Interstitial lung disease.

CR Number: 2022196007 **Implementation Date:** 20-Jul-22 Related CR: 2022196007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*EROSIVE PUSTULAR DERMATOSIS*	Approved Not as Requested	Proposed PT *Erosive pustular dermatosis* HLT primary *Dermatitis and eczema* SOC primary *Skin and subcutaneous tissue disorders*	10088153 10012435 10040785

MSSO Comment: The proposal to add a new PT EROSIVE PUSTULAR DERMATOSIS is approved but not as requested. Erosive pustular dermatosis of the scalp (EPDS) is an inflammatory dermatosis of unknown etiology. EPDS tends to spontaneously affect bald areas of the scalp in elderly individuals. EPDS is characterized by pustular, erosive, and crusted lesions on the affected area, most often scalp but can affect other skin areas such as legs as well. The requested term will be modified according to MedDRA capitalisation conventions and added as PT Erosive pustular dermatosis to HLT Dermatitis and eczema.

CR Number: 2022196008 **Implementation Date:** 20-Jul-22 Related CR: 2022196008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*REST REGIMEN*	Approved Not as Requested	Proposed PT *Rest regimen* HLT primary *Therapeutic procedures NEC* SOC primary *Surgical and medical procedures*	10088151 10027700 10042613
HLT primary	*Therapeutic procedures NEC*			
SOC primary	*Surgical and medical procedures*			

MSSO Comment: The proposal to add a new PT REST REGIMEN to primary HLT Therapeutic procedures NEC in SOC Surgical and medical procedures is approved but not as requested. In general, rest regimen refers to ordered decrease of overall physical activity. The requested term will be modified according to MedDRA capitalisation conventions and added as PT Rest regimen to HLT Therapeutic procedures NEC. In a related change, PT Bed rest will be demoted as sub-concept LLT to the new PT Rest regimen.

Supplemental Update Report

CR Number: 2022201014 **Implementation Date:** 20-Jul-22 Related CR: 2022196008

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Bed rest*	Approved as Requested	PT to merge	
To PT	*Rest regimen*		*Bed rest*	10050118 Current
			To PT	
			Rest regimen	10088151

MSSO Comment:

CR Number: 2022196009 **Implementation Date:** 20-Jul-22 Related CR: 2022196009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*HYPERTRIGLYCERIDEMIC WAIST PHENOTYPE*	Approved Not as Requested	Proposed LLT	
			Hypertriglyceridemic waist phenotype	10088164 Current
			To PT	
			Hypertriglycaeridemic waist phenotype	10088156

MSSO Comment: The proposal to add a new PT HYPERTRIGLYCERIDEMIC WAIST PHENOTYPE is approved but not as requested. The requested term will be modified accroding to MedDRA capitalisation conventions and added as LLT Hypertriglyceridemic waist phenotype to a new British English PT Hypertriglycaeridemic waist phenotype which will be added, in a related change, to HLT Lipid metabolism and deposit disorders NEC.

CR Number: 2022201015 **Implementation Date:** 20-Jul-22 Related CR: 2022196009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypertriglycaeridemic waist phenotype*	Approved as Requested	Proposed PT	
HLT primary	*Lipid metabolism and deposit disorders NEC*		*Hypertriglycaeridemic waist phenotype*	10088156
SOC primary	*Metabolism and nutrition disorders*		HLT primary	
			Lipid metabolism and deposit disorders NEC	10024581
			SOC primary	
			Metabolism and nutrition disorders	10027433

MSSO Comment:

Supplemental Update Report

CR Number: 2022196010 **Implementation Date:** 20-Jul-22 Related CR: 2022196010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Sprengel deformity*	Approved Not as Requested	Proposed LLT	
			Sprengel deformity	10088159 Current
			To PT	
			Congenital elevation of scapula	10010455

MSSO Comment: The proposal to add a new PT Sprengel deformity is approved but not as requested. Sprengel deformity (also known as high scapula or congenital high scapula) is a rare congenital skeletal abnormality where a person has one shoulder blade that sits higher on the back than the other. The deformity is due to a failure in early fetal development where the shoulder fails to descend to its normal position. Sprengel deformity will be added as synonym LLT to PT Congenital elevation of scapula.

CR Number: 2022196011 **Implementation Date:** 20-Jul-22 Related CR: 2022196011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vitamin test*	Approved as Requested	Proposed PT	
HLT primary	*Vitamin analyses*		*Vitamin test*	10088154
SOC primary	*Investigations*		HLT primary	
			Vitamin analyses	10047598
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Vitamin test to primary HLT Vitamin analyses in SOC Investigations is approved as requested to complement related vitamin test terms qualified as normal/abnormal.

CR Number: 2022196012 **Implementation Date:** 20-Jul-22 Related CR: 2022196012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hormone analysis*	Approved as Requested	Proposed PT	
			Hormone analysis	10088152
			HLT primary	
			Endocrine analyses and imaging NEC	10014693
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Hormone analysis is approved as requested. The unspecific term Hormone analysis will be added as PT to HLT Endocrine analyses and imaging NEC to facilitate coding of such broad reports in line with related PT Hormone level abnormal.

Supplemental Update Report

CR Number: 2022196013 **Implementation Date:** 20-Jul-22 Related CR: 2022196013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Chronic urinary tract infection*	Approved as Requested	Proposed LLT	
To PT	*Urinary tract infection*		*Chronic urinary tract infection*	10088158 Current
			To PT	
			Urinary tract infection	10046571

MSSO Comment: The proposal to add a new LLT Chronic urinary tract infection to PT Urinary tract infection is approved as requested in line with synonym LLT Chronic UTI and to facilitate autoencoding.

CR Number: 2022196014 **Implementation Date:** 20-Jul-22 Related CR: 2022196014

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Sun's procedure*	Approved Not as Requested	Proposed PT	
			Sun's procedure	10088155
			HLT primary	
			Aortic therapeutic procedures	10002903
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Sun's procedure is approved but not as requested. The Sun's procedure is a surgical technique proposed by Dr. Li-Zhong Sun in 2002 that integrates total aortic arch replacement using a tetrafurcated graft with implantation of a specially designed stented graft in the descending aorta. Sun's procedure will be added as PT to HLT Aortic therapeutic procedures.

CR Number: 2022196015 **Implementation Date:** 20-Jul-22 Related CR: 2022196015

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tinea axillaris*	Approved Not as Requested	Proposed LLT	
HLT primary	*Tinea infections*		*Tinea axillaris*	10088167 Current
SOC primary	*Infections and infestations*		To PT	
			Body tinea	10005913

MSSO Comment: The proposal to add a new PT Tinea axillaris to primary HLT Tinea infections in SOC Infections and infestations and secondary HLT Skin and subcutaneous tissue fungal infections in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Although axillary region is an unusual site for tinea infections, widespread tinea corporis and unguium may end up affecting one or both armpits. Tinea axillaris will be added as an LLT to PT Body tinea.

Supplemental Update Report

CR Number: 2022196016 **Implementation Date:** 20-Jul-22 Related CR: 2022196016

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Small and large bowel atresias*	Approved Not as Requested	PT to merge	
From PT	*Multiple gastrointestinal atresias*		*Multiple gastrointestinal atresias*	10028210 Current
To PT	*Intestinal atresia*		To PT	
			Intestinal atresia	10062022

MSSO Comment: The proposal to move the LLT Small and large bowel atresias from PT Multiple gastrointestinal atresias to PT Intestinal atresia is approved but not as requested. Multiple gastrointestinal atresias are virtually always intestinal (with very few exceptions presenting in the prepyloric region). In the classification of jejunoileal atresias, multiple intestinal atresias represent the more severe type IV, which consists in the presence of multiple atretic segments. Multiple gastrointestinal atresias will be demoted under PT Intestinal atresia. In a related change, and for a better alignment, PT Ileal atresia will also be demoted under PT Intestinal atresia.

CR Number: 2022201016 **Implementation Date:** 20-Jul-22 Related CR: 2022196016

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Ileal atresia*	Approved as Requested	PT to merge	
To PT	*Intestinal atresia*		*Ileal atresia*	10021298 Current
			To PT	
			Intestinal atresia	10062022

MSSO Comment:

CR Number: 2022196017 **Implementation Date:** 20-Jul-22 Related CR: 2022196017

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Acne scars*	Approved Not as Requested	Proposed LLT	
From PT	*Scar*		*Acne scars*	10000515 Current
To PT	*Skin lesion*		From PT	
			Scar	10039580
			To PT	
			Acne	10000496

MSSO Comment: The proposal to move the LLT Acne scars from PT Scar to PT Skin lesion is approved but not as requested. The LLT Acne scars will be moved from PT Scar to the general PT Acne in order to align it with other LLTs representing forms of acne associated with skin lesions, such LLT Acne comedonal.

Supplemental Update Report

CR Number: 2022196018 **Implementation Date:** 20-Jul-22 Related CR: 2022196018

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Calcified atherosclerotic plaque*	Approved as Requested	Proposed LLT	
To PT	*Arteriosclerosis*		*Calcified atherosclerotic plaque*	10088166 Current
			To PT	
			Arteriosclerosis	10003210

MSSO Comment: The proposal to add a new LLT Calcified atherosclerotic plaque to PT Arteriosclerosis is approved as requested. Calcification of differential amounts, sizes, shapes, and positions may play differential roles in plaque homeostasis, leading to new findings on the association between calcification and plaque vulnerability.

CR Number: 2022196019 **Implementation Date:** 20-Jul-22 Related CR: 2022196019

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Psychomotor hyperactivity*	Rejected		
Old Primary SOC	*Nervous system disorders*			
New Primary SOC	*Psychiatric disorders*			

MSSO Comment: The proposal to reassign the primary SOC of PT Psychomotor hyperactivity from current SOC Nervous system disorders to SOC Psychiatric disorders is not approved. Psychomotor hyperactivity is a symptom in various disorders and health conditions and it is characterized by unintentional and purposeless motions and restlessness, often but not always accompanied by emotional distress. It may occur as a manifestation of nervous system drug toxicity or neurological conditions. Recognizing the difficulty of which of the two SOCs in question does better represent this PT, we consider preferable to keep its current mapping in order to avoid disturbance of current legacy data.

CR Number: 2022196020 **Implementation Date:** 20-Jul-22 Related CR: 2022196020

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anterior chamber forming/reformation*	Approved Not as Requested	Proposed PT	
			Anterior chamber reformation	10088168
			HLT primary	
			Eye therapeutic procedures NEC	10027675
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Anterior chamber forming/reformation is approved but not as requested. Anterior chamber reformation refers to management of a flat anterior chamber - see PT Flat anterior chamber of eye - because of overfiltration in the early postoperative period after trabeculectomy. Anterior chamber reformation will be added as a PT to HLT Eye therapeutic procedures NEC.

Supplemental Update Report

CR Number: **2022196021** **Implementation Date:** 20-Jul-22 Related CR: 2022196021

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Foot Swelling / Swelling of foot*	Rejected		

MSSO Comment: The proposal to add a new LLT Foot Swelling / Swelling of foot is not approved. The concept is already represented by the LLT Swelling of feet, which do not have to be understood only in its plural meaning (as swelling of both feet) but also in its neutral signification, as a swelling localized in the region or location of feet, which incudes as well a unilateral swelling. However, based on subscriber's justification for reports of swollen foot on infusion site, please consider existing injection site /infusion site swelling terms in MedDRA.

CR Number: **2022196022** **Implementation Date:** 20-Jul-22 Related CR: 2022196022

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Taste buds changed / Taste buds not working / Taste buds desensitized / Taste buds impaired*	Rejected		

MSSO Comment: The proposal to add a new LLT Taste buds changed / Taste buds not working / Taste buds desensitized / Taste buds impaired is not approved. MedDRA can not add imprecise descriptive lay expressions, both to avoid terminology overpopulation and the inherent lack of medical accuracy of such type of terms. Please review PT under HLT Taste disorders for the closest coding option for these types of reports.

CR Number: **2022196023** **Implementation Date:** 20-Jul-22 Related CR: 2022196023

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Poor Venous Access*	Rejected		
Old Primary SOC	*Vascular disorders*			
New Primary SOC	*Injury, poisoning and procedural complications*			

MSSO Comment: The proposal to reassign the primary SOC of PT Poor Venous Access from current SOC Vascular disorders to SOC Injury, poisoning and procedural complications is not approved. Poor venous access may result in injury, but it is not an injury per se, but just an anatomical feature of clinical relevance for being an impediment for an easy venous access.

Supplemental Update Report

CR Number: 2022196024 **Implementation Date:** 20-Jul-22 Related CR: 2022196024

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vascular Access difficulty / Poor Vascular Access*	Rejected		

MSSO Comment: The proposal to add a new LLT Vascular Access difficulty / Poor Vascular Access is not approved. The use of the word "difficulty" in the proposed term "Vascular Access difficulty" is too vague and non-specific for inclusion in MedDRA. Please consider the broad PT Vascular access complication as a coding option.

CR Number: 2022196025 **Implementation Date:** 20-Jul-22 Related CR: 2022196025

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Mobius Syndrome*	Approved Not as Requested	Proposed LLT	
To PT	*Moebius II Syndrome*		*Mobius syndrome*	10088170 Current
			To PT	
			Congenital facial diplegia	10010466

MSSO Comment: The proposal to add a new LLT Mobius Syndrome to PT Moebius II Syndrome is approved but not as requested. The requested term will be modified accordingly to MedDRA capitalization conventions and added as LLT Mobius syndrome to the promoted PT Congenital facial diplegia. In a related change, the secondary HLT for PT Moebius II syndrome will be changed from HLT Congenital and hereditary neurological disorders NEC to HLT Facial cranial nerve disorders for better alignment. Furthermore, LLT Congenital facial diplegia will be swapped with PT Moebius II syndrome to have the broader concept at PT level. In addition, the correct spelled Moebius syndrome will also be added as an LLT to the newly promoted PT Congenital facial diplegia.

CR Number: 2022201017 **Implementation Date:** 20-Jul-22 Related CR: 2022196025

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Moebius II syndrome*	Approved as Requested	Proposed PT	
With LLT	*Congenital facial diplegia*		*Moebius II syndrome*	10027802 Current
			With LLT	
			Congenital facial diplegia	10010466

MSSO Comment:

Supplemental Update Report

CR Number: 2022201018 **Implementation Date:** 20-Jul-22 Related CR: 2022196025

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed PT	*Moebius II syndrome*	Approved as Requested	Proposed PT		
From HLT	*Congenital and hereditary neurological disorders NEC*		*Moebius II syndrome*	10027802	Current
To HLT	*Facial cranial nerve disorders*		From HLT		
			Congenital and hereditary neurological disorders NEC	10010333	
			To HLT		
			Facial cranial nerve disorders	10016054	

MSSO Comment:

CR Number: 2022201019 **Implementation Date:** 20-Jul-22 Related CR: 2022196025

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Moebius syndrome*	Approved as Requested	Proposed LLT		
To PT	*Congenital facial diplegia*		*Moebius syndrome*	10088169	Current
			To PT		
			Congenital facial diplegia	10010466	

MSSO Comment:

CR Number: 2022196026 **Implementation Date:** 20-Jul-22 Related CR: 2022196026

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed PT	*Peripheral Pulmonary Stenosis*	Approved Not as Requested	Proposed LLT		
			Peripheral pulmonary stenosis	10088171	Current
			To PT		
			Pulmonary artery stenosis congenital	10037339	

MSSO Comment: The proposal to add a new PT Peripheral Pulmonary Stenosis is approved but not as requested. Peripheral pulmonary stenosis is a rare congenital anomaly of the great arteries that may occur at single or multiple sites, in isolation or in association with other congenital heart defects. The requested term will be modified according to MedDRA capitalization conventions and added as LLT Peripheral pulmonary stenosis to PT Pulmonary artery stenosis congenital.

Supplemental Update Report

CR Number: 2022196027 **Implementation Date:** 03-Aug-22 Related CR: 2022196027

Change Requested	Add a New SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed SOC	*Dental and gingival disorders*	Rejected After Suspension		

MSSO Comment: The proposal to add a new SOC Dental and gingival disorders is not approved after suspension. The dental and gingival terms have a dedicated HLGT Dental and gingival conditions with 10 underlying HLTs for the purpose of coding and retrieval. The HLGT Dental and gingival conditions is appropriately placed in SOC Gastrointestinal disorders as the gastrointestinal tract is defined as encompassing structures from the mouth to the anus. A separate SOC for dental and gingival terms is not warranted in the defined structure of MedDRA.

CR Number: 2022198001 **Implementation Date:** 25-Jul-22 Related CR: 2022198001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Weakness nails*	Rejected		

MSSO Comment: The proposal to add a new term Weakness nails is not approved. Proposed term is imprecise and may mean either Onychomalacia or Onychoclasis depending on context and clinical scenario.

CR Number: 2022199001 **Implementation Date:** 25-Jul-22 Related CR: 2022199001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*COVID arm*	Rejected		

MSSO Comment: The proposal to add a new term COVID arm is not approved. The requested term is imprecise as it can refer to different pathologies. Please review existing terms such as LLT Delayed local vaccination site reaction, LLT Extensive swelling of vaccinated limb or LLT Vaccination site rash to see if they meet the reported scenario.

Supplemental Update Report

CR Number: 2022199002 **Implementation Date:** 25-Jul-22 Related CR: 2022199002

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Muscle weakness right-sided*	Rejected		
From PT	*Hemiparesis*			
To PT	*Muscular weakness*			

MSSO Comment: The proposal to move the LLT Muscle weakness right-sided from PT Hemiparesis to PT Muscular weakness is not approved. Hemiparesis is defined as muscular weakness or partial paralysis affecting one side of the body. As such, the existing link is appropriate. In addition, PT Muscular weakness is more appropriate for a generalized concept of weakness not limited to one side.

CR Number: 2022199003 **Implementation Date:** 25-Jul-22 Related CR: 2022199003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Apical Thrombus*	Approved Not as Requested	Proposed LLT	
			Apical thrombus	10088173 Current
			To PT	
			Intracardiac thrombus	10048620

MSSO Comment: The proposal to add a new term Apical Thrombus is approved but not as requested. Thrombus formation usually occurs in left ventricular apically. However, thrombus formation is not exclusively located apically; approximately 11% occurs at the septal wall and 3% at the inferoposterior wall. Proposed term will be modified for MedDRA capitalization conventions and added as anatomical sub-concept LLT Apical thrombus under PT Intracardiac thrombus.

Supplemental Update Report

CR Number: 2022199004 **Implementation Date:** 25-Jul-22 Related CR: 2022199004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Familial dilated cardiomyopathy*	Approved as Requested	Proposed PT	
			Familial dilated cardiomyopathy	10088172
			HLT primary	
			Cardiac disorders congenital NEC	10007542
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Cardiomyopathies	10007635
			SOC secondary	
			Cardiac disorders	10007541

MSSO Comment: The proposal to add a new term Familial dilated cardiomyopathy is approved as requested. There is accumulating evidence that genetic factors have an important role in the pathogenesis of DCM. However, although more than 100 genes have been implicated to date, the sensitivity of genetic testing, even in familial disease, is only 25-40%. As more patients are genotyped, nuanced information about disease phenotypes is emerging including variability in age of onset and penetrance of DCM, as well as additional cardiac and extra-cardiac features. Familial dilated cardiomyopathy will be added as a PT to primary HLT Cardiac disorders congenital NEC and to secondary HLT Cardiomyopathies. In a related change, PT Congestive cardiomyopathy will be swapped with LLT Dilated cardiomyopathy to have the most prevalent term at PT level.

CR Number: 2022206174 **Implementation Date:** 25-Jul-22 Related CR: 2022199004

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed PT	*Congestive cardiomyopathy*	Approved as Requested	Proposed PT		
With LLT	*Dilated cardiomyopathy*		*Congestive cardiomyopathy*	10056370	Current
			With LLT		
			Dilated cardiomyopathy	10056419	

MSSO Comment:

Supplemental Update Report

CR Number: 2022199005 **Implementation Date:** 25-Jul-22 Related CR: 2022199005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*COVID-19 convalescent plasma Therapy*	Rejected		

MSSO Comment: The proposal to add a new term COVID-19 convalescent plasma Therapy is not approved. In order to avoid overpopulation at PT level in MedDRA , it is not possible to represent the concept of convalescent plasma for every possible indication. Concept may be represented by LLT Convalescent plasma transfusion and relevant corresponding disease.

CR Number: 2022199006 **Implementation Date:** 25-Jul-22 Related CR: 2022199006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Canaloplasty*	Approved Not as Requested	Proposed PT	
			Eye Canaloplasty	10088174
			HLT primary	
			Iris and ciliary body therapeutic procedures	10022947
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Canaloplasty is approved but not as requested. Canaloplasty is a relatively new non-penetrating surgery for the reduction of intraocular pressure in patients affected by glaucoma. The proposed term will be modified for clarity and added as PT Eye Canaloplasty to HLT Iris and ciliary body therapeutic procedures. In a related change PT Viscocanalostomy will be moved from HLT Corneal and scleral therapeutic procedures to HLT Iris and ciliary body therapeutic procedures for better grouping.

CR Number: 2022206175 **Implementation Date:** 25-Jul-22 Related CR: 2022199006

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed PT	*Viscocanalostomy*	Approved as Requested	Proposed PT		
From HLT	*Corneal and scleral therapeutic procedures*		*Viscocanalostomy*	10077985	Current
To HLT	*Iris and ciliary body therapeutic procedures*		From HLT		
			Corneal and scleral therapeutic procedures	10010988	
			To HLT		
			Iris and ciliary body therapeutic procedures	10022947	

MSSO Comment:

Supplemental Update Report

CR Number: 2022199007 **Implementation Date:** 25-Jul-22 Related CR: 2022199007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Paratubal cystectomy*	Approved Not as Requested	Proposed LLT	
HLT primary	*Fallopian tube therapeutic procedures*		*Paratubal cystectomy*	10088175 Current
SOC primary	*Surgical and medical procedures*		To PT	
			Paraovarian cystectomy	10053329

MSSO Comment: The proposal to add a new PT Paratubal cystectomy to primary HLT Fallopian tube therapeutic procedures in SOC Surgical and medical procedures is approved but not as requested. Paratubal cystectomy will be added as sub-concept LLT under PT Paraovarian cystectomy.

CR Number: 2022200001 **Implementation Date:** 25-Jul-22 Related CR: 2022200001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Functional Visual Loss*	Approved Not as Requested	Proposed LLT	
To PT	*Visual acuity reduced*		*Functional visual loss*	10088176 Current
			To PT	
			Psychogenic blindness	10085007

MSSO Comment: The proposal to add a new LLT Functional Visual Loss to PT Visual acuity reduced is approved but not as requested. Functional visual loss is a decrease in visual acuity and/or visual field not caused by any organic lesion. It is therefore also called “nonorganic visual loss”. The proposed term will be modified for MedDRA capitalization standards and added as LLT Functional visual loss to PT Psychogenic blindness. In a related change, the alternate wording LLT Nonorganic visual loss will also be added to PT Psychogenic blindness.

CR Number: 2022206176 **Implementation Date:** 25-Jul-22 Related CR: 2022200001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Nonorganic visual loss*	Approved as Requested	Proposed LLT	
To PT	*Psychogenic blindness*		*Nonorganic visual loss*	10088177 Current
			To PT	
			Psychogenic blindness	10085007

MSSO Comment:

Supplemental Update Report

CR Number: 2022200002 **Implementation Date:** 25-Jul-22 Related CR: 2022200002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Magnetic resonance imaging larynx*	Approved as Requested	Proposed PT *Magnetic resonance imaging larynx*	10088178
			HLT primary *Respiratory tract and thoracic imaging procedures*	10006476
			SOC primary *Investigations*	10022891

MSSO Comment: The proposal to add a new term Magnetic resonance imaging larynx is approved as requested. Recent technical improvements have resulted in outstanding depiction of the laryngeal anatomy using MRI allowing superior definition of anatomy and tumor extent compared with CT scanning. Thus MRI has become the primary modality in imaging the larynx. Magnetic resonance imaging larynx will be added as a PT to HLT Respiratory tract and thoracic imaging procedures.

CR Number: 2022200004 **Implementation Date:** 25-Jul-22 Related CR: 2022200004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Device deficiency*	Rejected		

MSSO Comment: The proposal to add a new PT Device deficiency is not approved. Device deficiency does not represent a single concept as may refer to multiple characteristics such as identity, quality, durability, reliability, safety or performance, such as malfunction, misuse or use error and inadequate labeling. In a related change, the recently added LLT Device septum dislodgement will be moved from PT Device dislocation to PT Device issue aligned with LLT Device component detached.

CR Number: 2022206177 **Implementation Date:** 25-Jul-22 Related CR: 2022200004

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Device septum dislodgement*	Approved as Requested	Proposed LLT *Device septum dislodgement*	10087844 Current
From PT	*Device dislocation*		From PT *Device dislocation*	10064684
To PT	*Device issue*		To PT *Device issue*	10069868

MSSO Comment:

Supplemental Update Report

CR Number: 2022200007 **Implementation Date:** 25-Jul-22 Related CR: 2022200007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Puerperal Metritis*	Approved Not as Requested	Proposed LLT	
			Puerperal metritis	10088179 Current
			To PT	
			Puerperal infection	10072652

MSSO Comment: The proposal to add a new PT Puerperal Metritis is approved but not as requested. Puerperal infection may present as endometritis, myometritis, parametritis, pelvic abscess, salpingitis, septic pelvic thrombophlebitis or septicemia. The requested term will be modified according to MedDRA capitalisation conventions and added as LLT Puerperal metritis to PT Puerperal infection. In a related change PT Endometritis decidual will also be demoted under the umbrella PT Puerperal infection as sub-concept to avoid overgranularity of closely related concepts.

CR Number: 2022206178 **Implementation Date:** 25-Jul-22 Related CR: 2022200007

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Endometritis decidual*	Approved as Requested	PT to merge	
To PT	*Puerperal infection*		*Endometritis decidual*	10014792 Current
			To PT	
			Puerperal infection	10072652

MSSO Comment:

CR Number: 2022201001 **Implementation Date:** 25-Jul-22 Related CR: 2022201001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Renal insufficiency*	Rejected		
From PT	*Renal failure*			
To PT	*Renal injury*			

MSSO Comment: The proposal to move the LLT Renal insufficiency from PT Renal failure to PT Renal injury is not approved. As stated in point 5.1 GENERAL WORD USAGE of the Introductory Guide MedDRA Version 25.0, interpretations of the words “failure” and “insufficiency” can be problematic; some users may interpret the concepts as synonymous while others interpret them as similar, but differing in severity (with “insufficiency” being less severe than “failure”). In order to reconcile this, MSSO decided to make the terms essentially synonyms for the major body systems as described above. The MSSO realizes this means that many subscribers will have a different interpretation of these words, but this was the most practical solution for consistency in the terminology.

Supplemental Update Report

CR Number: 2022201002 **Implementation Date:** 01-Aug-22 Related CR: 2022201002

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with single lineage dysplasia*	Approved as Requested	Proposed PT	
			Myelodysplastic syndrome with single lineage dysplasia	10088025
Old Primary SOC	*Blood and lymphatic system disorders*		Old Primary SOC	
			Blood and lymphatic system disorders	10005329
New Primary SOC	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		New Primary SOC	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104

MSSO Comment: The proposal to reassign the primary SOC of PT Myelodysplastic syndrome with single lineage dysplasia from current SOC Blood and lymphatic system disorders to SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved as requested. All myelodysplastic syndrome concepts need to be consistently assigned to SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps)

CR Number: 2022201003 **Implementation Date:** 28-Jul-22 Related CR: 2022201003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*术后淋巴漏*	Rejected After Suspension		

MSSO Comment: The proposal to add a new LLT 术后淋巴漏 is not approved after suspension. With the help of our Chinese Medical Officer the requested term was translated to Postoperative Lymph leakage. The MSSO is cautious about adding any new post procedural/postoperative terms. The proposed term can be represented by LLT "Postoperative complication" and LLT "Lymph leakage". Please consider Section 3.5.4 "When to “split” into more than one MedDRA term" in the MTS:PTC document. In the future, kindly submit future requests in English to allow our international team the ability to understand and efficiently review your proposed request.

CR Number: 2022201004 **Implementation Date:** 25-Jul-22 Related CR: 2022201004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vertical banded gastroplasty*	Approved as Requested	Proposed LLT	
			Vertical banded gastroplasty	10088180 Current
To PT	*Gastric stapling*		To PT	
			Gastric stapling	10049167

MSSO Comment: The proposal to add a new LLT Vertical banded gastroplasty to PT Gastric stapling is approved as requested. LLT Vertical banded gastroplasty is a sub-concept of PT Gastric stapling.

Supplemental Update Report

CR Number: 2022201005 **Implementation Date:** 25-Jul-22 Related CR: 2022201005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Genyantritis*	Approved as Requested	Proposed LLT	
			Genyantritis	10088181 Current
			To PT	
			Sinusitis	10040753

MSSO Comment: The proposal to add a new term Genyantritis is approved as requested. Genyantritis is also called acute inflammation of the mucous membrane of the maxillary sinus or maxillary sinusitis. Proposed term will be added as synonym LLT Genyantritis of existing LLT Maxillary sinusitis under PT Sinusitis.

CR Number: 2022201020 **Implementation Date:** 25-Jul-22 Related CR: 2022201020

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*INCREASED BLOOD BILE ACIDS*	Approved Not as Requested	Proposed PT	
			Bile acids increased	10088182
			HLT primary	
			Hepatobiliary function diagnostic procedures	10087057
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term INCREASED BLOOD BILE ACIDS is approved but not as requested. The proposed term will be added without the specimen and added as PT Bile acids increased to HLT Hepatobiliary function diagnostic procedures. In a related change, PT Total bile acids increased will be demoted under the new, broader PT Bile acids increased. Furthermore, new PT Bile acids will also be added to HLT Hepatobiliary function diagnostic procedures and existing PT Total bile acids demoted under new PT Bile acids.

CR Number: 2022206179 **Implementation Date:** 25-Jul-22 Related CR: 2022201020

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Total bile acids increased*	Approved as Requested	PT to merge	
To PT	*Bile acids increased*		*Total bile acids increased*	10064558 Current
			To PT	
			Bile acids increased	10088182

MSSO Comment:

Supplemental Update Report

CR Number: 2022206180 **Implementation Date:** 25-Jul-22 Related CR: 2022201020

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Bile acids*	Approved as Requested	Proposed PT	
HLT primary	*Hepatobiliary function diagnostic procedures*		*Bile acids*	10088183
SOC primary	*Investigations*		HLT primary	
			Hepatobiliary function diagnostic procedures	10087057
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022206181 **Implementation Date:** 25-Jul-22 Related CR: 2022201020

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*Total bile acids*	Approved as Requested	PT to merge		
To PT	*Bile acids*		*Total bile acids*	10059962	Current
			To PT		
			Bile acids	10088183	

MSSO Comment:

CR Number: 2022202001 **Implementation Date:** 25-Jul-22 Related CR: 2022202001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Accessory pancreas*	Approved as Requested	Proposed LLT		
			Accessory pancreas	10088184	Current
			To PT		
			Congenital ectopic pancreas	10056987	

MSSO Comment: The proposal to add a new term Accessory pancreas is approved as requested. Accessory pancreas will be added as a synonym LLT to PT Congenital ectopic pancreas.

Supplemental Update Report

CR Number: 2022202002 **Implementation Date:** 25-Jul-22 Related CR: 2022202002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Thick toenail*	Rejected		
To PT	*Onychomycosis*			

MSSO Comment: The proposal to add a new LLT Thick toenail to PT Onychomycosis is not approved. The proposed term is ambiguous as it may refer to multiple nail pathologies.

CR Number: 2022202003 **Implementation Date:** 25-Jul-22 Related CR: 2022202003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Eruption cysts*	Approved Not as Requested	Proposed LLT	
			Eruption cyst	10088185 Current
			To PT	
			Odontogenic cyst	10063413

MSSO Comment: The proposal to add a new term Eruption cysts is approved but not as requested. Eruption cysts are benign cysts that appear on the mucosa of a tooth shortly before its eruption. They may disappear by themselves but if they hurt, bleed or are infected they may require surgical treatment to expose the tooth and drain the contents. The proposed term will be modified to its singular form and added as LLT Eruption cyst to PT Odontogenic cyst.

CR Number: 2022202004 **Implementation Date:** 25-Jul-22 Related CR: 2022202004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Emotional turmoil*	Rejected		

MSSO Comment: The proposal to add a new term Emotional turmoil is not approved. The requested term is too broad and colloquial and may represent different emotional conditions.

Supplemental Update Report

CR Number: 2022202005 **Implementation Date:** 28-Jul-22 Related CR: 2022202005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Inlays*	Approved Not as Requested	Proposed LLT	
			Dental inlay	10088187 Current
			To PT	
			Tooth restoration	10085637

MSSO Comment: The proposal to add a new term Inlays is approved but not as requested. An inlay in dentistry is a a filling shaped to fit a tooth cavity. Inlays and onlays can be made of ceramic, composite resin, gold, titanium or other metals. This is an alternative to a direct restoration, made out of composite, amalgam or glass ionomer. The requested term will be modified for clarity and added in singular form as LLT Dental inlay to PT Tooth restoration, aligned with LLT Dental fillings.

CR Number: 2022202006 **Implementation Date:** 28-Jul-22 Related CR: 2022202006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Onlays*	Approved Not as Requested	Proposed LLT	
			Dental onlay	10088186 Current
			To PT	
			Tooth restoration	10085637

MSSO Comment: The proposal to add a new term Onlays is approved but not as requested. An onlay is a type of cusp-covering dental restoration. Inlays and onlays can be made of ceramic, composite resin, gold, titanium or other metals. This is an alternative to a direct restoration, made out of composite, amalgam or glass ionomer. The requested term will be modified for clarity and added in singular form as LLT Dental onlay to PT Tooth restoration, aligned with LLT Dental fillings.

CR Number: 2022202007 **Implementation Date:** 28-Jul-22 Related CR: 2022202007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Paradental cyst*	Approved as Requested	Proposed LLT	
			Paradental cyst	10088188 Current
			To PT	
			Odontogenic cyst	10063413

MSSO Comment: The proposal to add a new term Paradental cyst is approved as requested. A paradental cyst is an odontogenic cyst of inflammatory origin, which occurs on either the buccal, distal, or (rarely) mesial aspects of partially erupted mandibular third molars, in most cases associated with a history of recurrent pericoronitis. Paradental cyst will be added as a sub-element LLT to PT Odontogenic cyst.

Supplemental Update Report

CR Number: 2022202008 **Implementation Date:** 28-Jul-22 Related CR: 2022202008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ultrashort wave therapy*	Approved as Requested	Proposed LLT	
			Ultrashort wave therapy	10088189 Current
			To PT	
			Magnetic therapy	10065343

MSSO Comment: The proposal to add a new term Ultrashort wave therapy is approved as requested. Ultrashort wave therapy is a type of electrotherapy involving the therapeutic use of an alternating electromagnetic field with a frequency ranging from 30 to 300 megahertz. In some studies, ultrashort wave therapy is said to improve local blood circulation, eliminate nerve edema, relieve nerve compression, and promote nerve function recovery. Ultrashort wave therapy will be added as sub-element LLT to PT Magnetic therapy, in line with existing LLT Electromagnetic therapy.

CR Number: 2022202009 **Implementation Date:** 28-Jul-22 Related CR: 2022202009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Lymphoma of the uterine cervix*	Approved Not as Requested	Proposed PT	
			Uterine cervix lymphoma	10088190
			HLT primary	
			Lymphomas unspecified NEC	10025324
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Cervix neoplasms	10029109
			SOC secondary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new term Lymphoma of the uterine cervix is approved but not as requested. Primary lymphomas of the cervix and uterus are rare with approximately 150 cases reported in the world literature to date. Appropriate diagnosis is often delayed until the post-operative setting as clinical and radiographic presentations are non-specific. Several sub-types of lymphoma arising primarily in the cervix or uterus have been reported with diffuse large B-Cell lymphoma (DLBCL) being the most frequent. The requested term will be modified and added in the natural word order as PT Uterine cervix lymphoma to primary HLT Lymphomas unspecified NEC and secondary HLT Cervix neoplasms.

Supplemental Update Report

CR Number: 2022202010 **Implementation Date:** 28-Jul-22 Related CR: 2022202010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Hypertrophic pharyngitis*	Approved as Requested	Proposed LLT *Hypertrophic pharyngitis* To PT *Pharyngitis*	10088191 Current 10034835

MSSO Comment: The proposal to add a new term Hypertrophic pharyngitis is approved as requested. Chronic pharyngitis is a chronic inflammatory and/or irritative process, with no infectious component, of the pharyngeal mucosa. It can be simple, hypertrophic or atrophic. According to the clinical symptomatology, three types of chronic pharyngitis can be distinguished: simple chronic pharyngitis, hyperplastic chronic pharyngitis (granular) and dry chronic pharyngitis (atrophic). Hypertrophic pharyngitis will be added as sub-concept LLT to PT Pharyngitis aligned with LLT Chronic pharyngitis. In a related change, PT Atrophic pharyngitis will be merged under PT Pharyngitis to avoid overgranulation at PT level for related concepts.

CR Number: 2022209073 **Implementation Date:** 28-Jul-22 Related CR: 2022202010

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Atrophic pharyngitis*	Approved as Requested	PT to merge *Atrophic pharyngitis* To PT *Pharyngitis*	10078861 Current 10034835
To PT	*Pharyngitis*			

MSSO Comment:

CR Number: 2022202011 **Implementation Date:** 25-Jul-22 Related CR: 2022202011

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pseudophakia*	Approved Not as Requested	Proposed LLT *Pseudophakia* From PT *Intraocular lens implant* HLT primary *Lens structural change, deposit and degeneration (excl cataracts)* SOC primary *Eye disorders*	10048867 10067434 10024210 10015919
From PT	*Intraocular lens implant*			
To PT	*Pseudophakia*			

MSSO Comment: The proposal to move the LLT Pseudophakia from PT Intraocular lens implant to PT Pseudophakia is approved but not as requested. Pseudophakia refers to the condition resulting of having been implanted in an intraocular lens implant, rather than to the procedure itself. It is also used for pathological conditions where a degenerated crystalline lens is replaced by mesodermal, adipose or fibrous tissue. LLT Pseudophakia will be promoted from PT Intraocular lens implant to a PT level linked to HLT Lens structural change, deposit and degeneration (excl cataracts) for a more adequate placement in the terminology.

Supplemental Update Report

CR Number: 2022202012 **Implementation Date:** 28-Jul-22 Related CR: 2022202012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Coronary artery ectasia*	Approved as Requested	Proposed LLT	
To PT	*Coronary artery dilatation*		*Coronary artery ectasia*	10088194 Current
			To PT	
			Coronary artery dilatation	10065420

MSSO Comment: The proposal to add a new LLT Coronary artery ectasia to PT Coronary artery dilatation is approved as requested. Coronary artery ectasia or aneurismal coronary artery disease is dilatation of an arterial segment to a diameter at least 1.5 times that of the adjacent normal coronary artery.

CR Number: 2022202013 **Implementation Date:** 28-Jul-22 Related CR: 2022202013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Idiopathic Cardiomyopathy*	Approved Not as Requested	Proposed LLT	
To PT	*Congestive cardiomyopathy*		*Idiopathic cardiomyopathy*	10088193 Current
			To PT	
			Dilated cardiomyopathy	10056419

MSSO Comment: The proposal to add a new LLT Idiopathic Cardiomyopathy to PT Congestive cardiomyopathy is approved but not as requested. Idiopathic cardiomyopathy is also known as idiopathic dilated cardiomyopathy (DCM). The cause of DCM is not always known, but is thought to be triggered e.g. by Genetic , Alcohol and drug use, Cancer medications and others. The requested term will be modified according to MedDRA capitalisaiton conventions and added as LLT Idiopathic cardiomyopathy to PT Dilated cardiomyopathy, recently swapped with LLT Congestive cardiomyopathy in change request 2022206174.

CR Number: 2022202014 **Implementation Date:** 28-Jul-22 Related CR: 2022202014

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Nonsyndromic deafness*	Approved Not as Requested	Proposed LLT	
			Non-syndromic deafness	10088196 Current
			To PT	
			Deafness congenital	10011882

MSSO Comment: The proposal to add a new term Nonsyndromic deafness is approved but not as requested. Non-syndromic hearing loss and deafness is characterized by congenital non-progressive mild-to-profound hearing impairment, with no other associated medical findings present. The requested term will be modified and added as LLT Non-syndromic genetic deafness to PT Deafness congenital.

Supplemental Update Report

CR Number: 2022202015 **Implementation Date:** 28-Jul-22 Related CR: 2022202015

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Glutaric acidemia type I*	Approved as Requested	Proposed LLT	
			Glutaric acidemia type I	10088195 Current
			To PT	
			Glutaric acidaemia type I	10088192

MSSO Comment: The proposal to add a new term Glutaric acidemia type I is approved as requested. Glutaric acidemia type I (GA1) is a genetic metabolic disorder. People with GA1 don't make enough of one of the enzymes needed to break down certain amino acids found in the proteins we eat. Without enough of the enzyme, the breakdown products of these amino acids build up in tissues of the body. The buildup of these chemicals can damage the brain, especially the area of the brain called the basal ganglia. Glutaric acidemia type I will be added as LLT to the British English PT Glutaric acidaemia type I which will be added to primary HLT Inborn errors of metabolism NEC, bi-axial to primary SOC Congenital, familial and genetic disorders and secondary SOC Metabolism and nutrition disorders and secondary HLT Encephalopathies toxic and metabolic.

CR Number: 2022209074 **Implementation Date:** 28-Jul-22 Related CR: 2022202015

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Glutaric acidaemia type I*	Approved as Requested	Proposed PT	
HLT primary	*Inborn errors of metabolism NEC*		*Glutaric acidaemia type I*	10088192
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Inborn errors of metabolism NEC	10021606
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Inborn errors of metabolism NEC	10021606
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment:

Supplemental Update Report

CR Number: 2022209075 **Implementation Date:** 28-Jul-22 Related CR: 2022202015

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Glutaric acidaemia type I*	Approved as Requested	Proposed PT	
To HLT	*Encephalopathies toxic and metabolic*		*Glutaric acidaemia type I*	10088192
			To HLT	
			Encephalopathies toxic and metabolic	10014624

MSSO Comment:

CR Number: 2022202078 **Implementation Date:** 28-Jul-22 Related CR: 2022202078

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Basaloid squamous cell carcinoma*	Approved as Requested	Proposed LLT		
			Basaloid squamous cell carcinoma	10088197	Current
			To PT		
			Squamous cell carcinoma	10041823	

MSSO Comment: The proposal to add a new LLT Basaloid squamous cell carcinoma is approved as requested. Basaloid squamous cell carcinoma is a rare and aggressive variant of oral squamous cell carcinoma with a predilection for the tongue and in other locations, such as floor of the mouth, palate, retromolar trigone, and gingival mucosa. In accordance with the placement of other related terms representing this type of neoplasm, Basaloid squamous cell carcinoma will be added as LLT to PT Squamous cell carcinoma.

CR Number: 2022202079 **Implementation Date:** 28-Jul-22 Related CR: 2022202079

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Actinic esophagitis*	Approved as Requested	Proposed LLT		
			Actinic esophagitis	10088198	Current
			To PT		
			Radiation oesophagitis	10048899	

MSSO Comment: The proposal to add a new LLT Actinic esophagitis is approved as requested. Radiation-induced esophagitis is a consequence of radiotherapy toxicity over the esophagus resulting in both acute or chronic complications. Actinic esophagitis will be added as synonym LLT of PT Radiation oesophagitis. In a related change, the counterpart term Actinic oesophagitis representing its British spelling will also be added to the PT Radiation oesophagitis.

Supplemental Update Report

CR Number: 2022209076 **Implementation Date:** 28-Jul-22 Related CR: 2022202079

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Actinic oesophagitis*	Approved as Requested	Proposed LLT	
To PT	*Radiation oesophagitis*		*Actinic oesophagitis*	10088199 Current
			To PT	
			Radiation oesophagitis	10048899

MSSO Comment:

CR Number: 2022202080 **Implementation Date:** 28-Jul-22 Related CR: 2022202080

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Adrenomyeloneuropathy*	Approved as Requested	Proposed LLT	
			Adrenomyeloneuropathy	10088201 Current
			To PT	
			Adrenoleukodystrophy	10051260

MSSO Comment: The proposal to add a new term Adrenomyeloneuropathy is approved as requested. Adrenomyeloneuropathy (AMN) is an inherited metabolic disorder characterized by the degeneration of the adrenal gland and the loss of fatty covering on brain nerves. It is a form of X-linked adrenoleukodystrophy. AMN patients typically experience symptoms including spinal cord dysfunction, weakness, weight loss, skin changes, vomiting, and coma. Brain function may also be affected, depending on the type of AMN. Adrenomyeloneuropathy will be added as sub-concept LLT to PT Adrenoleukodystrophy.

CR Number: 2022202081 **Implementation Date:** 28-Jul-22 Related CR: 2022202081

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Acute Hepatic Porphyria*	Approved Not as Requested	Proposed LLT	
			Acute hepatic porphyria	10088202 Current
			To PT	
			Porphyria acute	10036182

MSSO Comment: The proposal to add a new term Acute Hepatic Porphyria is approved but not as requested. Acute hepatic porphyria, also known as Acute porphyria, refers to a family of rare genetic diseases characterized by potentially life-threatening attacks and, for some people, chronic pain and other symptoms that interfere in their ability to live normal lives. The requested term will be modified according to MedDRA capitalisation conventions and added as synonym LLT Acute hepatic porphyria to PT Porphyria acute.

Supplemental Update Report

CR Number: 2022202082 **Implementation Date:** 28-Jul-22 Related CR: 2022202082

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Infantile neuroaxonal dystrophy*	Approved as Requested	Proposed PT	
			Infantile neuroaxonal dystrophy	10088200
			HLT primary	
			Central nervous system disorders congenital NEC	10009713
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Hereditary muscle disorders	10019888
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Infantile neuroaxonal dystrophy is approved as requested. Infantile neuroaxonal dystrophy (INAD) is a rare inherited neurological disorder. It affects axons, the part of a nerve cell that carries messages from the brain to other parts of the body, and causes progressive loss of vision, muscular control, and mental skills. Infantile neuroaxonal dystrophy will be added as PT to primary HLT Central nervous system disorders congenital NEC and secondary HLT Hereditary muscle disorders and secondary HLT Visual impairment and blindness (excl colour blindness).

CR Number: 2022209077 **Implementation Date:** 28-Jul-22 Related CR: 2022202082

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Infantile neuroaxonal dystrophy*	Approved as Requested	Proposed PT	
			Infantile neuroaxonal dystrophy	10088200
To HLT	*Visual impairment and blindness (excl colour blindness)*		To HLT	
			Visual impairment and blindness (excl colour blindness)	10080708

MSSO Comment:

Supplemental Update Report

CR Number: 2022203001 **Implementation Date:** 28-Jul-22 Related CR: 2022203001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Cytotoxic Chemotherapy*	Approved Not as Requested	Proposed LLT		
			Cytotoxic chemotherapy	10088206	Current
			To PT		
			Chemotherapy	10061758	

MSSO Comment: The proposal to add a new term Cytotoxic Chemotherapy is approved but not as requested. Cytotoxic chemotherapy are drugs used to destroy cancer cells. Proposed term will be modified based on MedDRA capitalization conventions and added as LLT Cytotoxic chemotherapy to PT Chemotherapy.

CR Number: 2022203002 **Implementation Date:** 28-Jul-22 Related CR: 2022203002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Fumarase deficiency*	Approved as Requested	Proposed PT	
			Fumarase deficiency	10088204
			HLT primary	
			Inborn errors of metabolism NEC	10021606
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Inborn errors of metabolism NEC	10021606
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to add a new term Fumarase deficiency is approved as requested. Fumarase deficiency (or fumaric aciduria) is a rare autosomal recessive metabolic disorder in the Krebs cycle, characterized by a deficiency of the enzyme fumarate hydratase, which causes a buildup of fumaric acid in the urine and a deficiency of malate. Fumarase deficiency will be added as a PT with a link to the bi-axial HLT Inborn errors of metabolism NEC (primary SOC Congenital, familial and genetic disorders and secondary SOC Metabolism and nutrition disorders) and to HLT Encephalopathies NEC.

Supplemental Update Report

CR Number: 2022209078 **Implementation Date:** 28-Jul-22 Related CR: 2022203002

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Fumarase deficiency*	Approved as Requested	Proposed PT	
To HLT	*Encephalopathies NEC*		*Fumarase deficiency*	10088204
			To HLT	
			Encephalopathies NEC	10014632

MSSO Comment:

CR Number: 2022203003 **Implementation Date:** 28-Jul-22 Related CR: 2022203003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Macular hypoplasia*	Approved as Requested	Proposed PT	
			Macular hypoplasia	10088203
			HLT primary	
			Retinal disorders congenital	10038855
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Retinal structural change, deposit and degeneration	10038896
			SOC secondary	
			Eye disorders	10015919

MSSO Comment: The proposal to add a new term Macular hypoplasia is approved as requested. Macular hypoplasia is a retinal congenital disorder in which there is a lack of full development of the morphology of the fovea. Macular hypoplasia will be added as PT with a primary link to HLT Retinal disorders congenital, and a secondary link to HLT Retinal structural change, deposit and degeneration.

Supplemental Update Report

CR Number: 2022203004 **Implementation Date:** 28-Jul-22 Related CR: 2022203004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Vascular rings and slings*	Approved as Requested	Proposed PT	
			Vascular rings and slings	10088205
			HLT primary	
			Great vessel disorders congenital	10018717
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Oesophageal stenosis and obstruction	10030196
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Vascular rings and slings is approved as requested. Vascular rings and slings refer to the congenital vascular encirclement of the esophagus and/or trachea by anomalous/aberrant vessels. Vascular rings and slings will be added as a PT with a primary link to HLT Great vessel disorders congenital and secondary links to HLT Oesophageal stenosis and obstruction, HLT Tracheal disorders (excl infections and neoplasms) and HLT Vascular malformations and acquired anomalies.

CR Number: 2022209079 **Implementation Date:** 28-Jul-22 Related CR: 2022203004

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular rings and slings*	Approved as Requested	Proposed PT	
To HLT	*Tracheal disorders (excl infections and*		*Vascular rings and slings*	10088205
			To HLT	
			Tracheal disorders (excl infections and neoplasms)	10044288

MSSO Comment:

Supplemental Update Report

CR Number: 2022209080 **Implementation Date:** 28-Jul-22 Related CR: 2022203004

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular rings and slings*	Approved as Requested	Proposed PT	
To HLT	*Vascular malformations and acquired anomalies*		*Vascular rings and slings*	10088205
			To HLT	
			Vascular malformations and acquired anomalies	10047091

MSSO Comment:

CR Number: 2022203005 **Implementation Date:** 28-Jul-22 Related CR: 2022203005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ototubaritis*	Approved as Requested	Proposed LLT	
			Ototubaritis	10088207 Current
			To PT	
			Otosalpingitis	10033102

MSSO Comment: The proposal to add a new LLT Ototubaritis is approved as requested. Ototubaritis, inflammation of the mucous membrane of the eustachian tube, is a rarely used synonym of and will be added as LLT to PT Otosalpingitis, aligned with another synonym LLT Eustachitis.

CR Number: 2022203006 **Implementation Date:** 28-Jul-22 Related CR: 2022203006

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Malignant ascites*	Approved as Requested	Proposed PT	
Old Primary SOC	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		*Malignant ascites*	10025538
			Old Primary SOC	
New Primary SOC	*Gastrointestinal disorders*		*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*	10029104
			New Primary SOC	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to reassign the primary SOC of PT Malignant ascites from current SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) to SOC Gastrointestinal disorders is approved as requested. PTs in the HLGT Oncologic complications and emergencies, which have a site of manifestation are generally assigned with primary link to the SOC representative of that site and a secondary link to the SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps).

Supplemental Update Report

CR Number: 2022203007 **Implementation Date:** 28-Jul-22 Related CR: 2022203007

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pericarditis malignant*	Approved as Requested	Proposed PT	
Old Primary SOC	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		*Pericarditis malignant*	10034491
New Primary SOC	*Cardiac disorders*		Old Primary SOC	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			New Primary SOC	
			Cardiac disorders	10007541

MSSO Comment: The proposal to reassign the primary SOC of PT Pericarditis malignant from current SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) to SOC Cardiac disorders is approved as requested. PTs in the HLGT Oncologic complications and emergencies, which have a site of manifestation are generally assigned with primary link to the SOC representative of that site and a secondary link to the SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps).

CR Number: 2022206001 **Implementation Date:** 28-Jul-22 Related CR: 2022206001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*PERIHEPATIC EFFUSION*	Approved Not as Requested	Proposed LLT	
			Perihepatic effusion	10088208 Current
			To PT	
			Ascites	10003445

MSSO Comment: The proposal to add a new LLT PERIHEPATIC EFFUSION is approved but not as requested. Perihepatic effusion is an effusion and accumulation of serous fluid near or around the liver. Proposed term will be modified in accordance with MedDRA capitalization conventions and added as sub-concept LLT Perihepatic effusion under PT Ascites.

CR Number: 2022206002 **Implementation Date:** 28-Jul-22 Related CR: 2022206002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Paracentesis Drainage*	Approved Not as Requested	Proposed PT	
To PT	*Drainage*		*Paracentesis*	10061905
			To HLT	
			Therapeutic procedures NEC	10027700

MSSO Comment: The proposal to add a new LLT Paracentesis Drainage to PT Drainage is approved but not as requested. Paracentesis is a form of body fluid extraction procedure. Instead of modifying paracentesis with drainage to specify as procedure PT Paracentesis will be moved from SOC Investigations to SOC Surgical and medical procedures in a series of moves. First, PT Paracentesis will be linked to HLT Therapeutic procedures NEC. Second, the primary SOC for PT Paracentesis will be re-assigned from SOC Investigations to SOC Surgical and medical procedures. Finally, HLT Investigations NEC will be unlinked from PT Paracentesis.

Supplemental Update Report

CR Number: 2022209081 **Implementation Date:** 28-Jul-22 Related CR: 2022206002

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Paracentesis*	Approved as Requested	Proposed PT	
			Paracentesis	10061905
Old Primary SOC	*Investigations*		Old Primary SOC	
			Investigations	10022891
New Primary SOC	*Surgical and medical procedures*		New Primary SOC	
			Surgical and medical procedures	10042613

MSSO Comment:

CR Number: 2022209082 **Implementation Date:** 28-Jul-22 Related CR: 2022206002

Change Requested	Unlink a PT from a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Paracentesis*	Approved as Requested	Proposed PT	
			Paracentesis	10061905
From HLT	*Investigations NEC*		From HLT	
			Investigations NEC	10022892

MSSO Comment:

CR Number: 2022207001 **Implementation Date:** 28-Jul-22 Related CR: 2022207001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*DERMATOME*	Rejected		

MSSO Comment: The proposal to add a new LLT DERMATOME is not approved. A dermatome indicates an anatomical area of skin that send signals to the brain through the spinal nerves. Dermatome, without indicating specific symptom such as pain, does not represent a concept within the scope of MedDRA.

Supplemental Update Report

CR Number: 2022207002 **Implementation Date:** 28-Jul-22 Related CR: 2022207002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Fibroma Pendulum*	Approved Not as Requested	Proposed LLT *Fibroma pendulum*	10088209 Current
			To PT *Fibroma*	10016629

MSSO Comment: The proposal to add a new LLT Fibroma Pendulum is approved but not as requested. The requested term will be modified according to MedDRA capitalisaiton conventions and added as sub-concept LLT Fibroma pendulum to PT Fibroma.

CR Number: 2022207003 **Implementation Date:** 28-Jul-22 Related CR: 2022207003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New PT				
Proposed PT	*CORONARY SYNDROME*	Rejected		

MSSO Comment: The proposal to add a new PT CORONARY SYNDROME is not approved. The dynamic nature of the Coronary artery disase process results in various clinical presentations, which can be conveniently categorized as either acute coronary syndromes (ACS) or chronic coronary syndromes (CCS) but medical literature and guidelines from international societies for cardiology do not use Coronary syndrome without being qualified with either acute or chronic.

CR Number: 2022207004 **Implementation Date:** 28-Jul-22 Related CR: 2022207004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Continuous venovenous hemodialysis*	Rejected		

MSSO Comment: The proposal to add a new LLT Continuous venovenous hemodialysis is not approved. Based on subscribers justification mentioning the acronym CVVHD, the concept is represented by LLT Continuous venovenous haemodiafiltration.

Supplemental Update Report

CR Number: 2022207005 **Implementation Date:** 29-Jul-22 Related CR: 2022207005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Hereditary gingival fibromatosis*	Approved as Requested	Proposed PT	
			Hereditary gingival fibromatosis	10088210
			HLT primary	
			Oral cavity disorders congenital NEC	10030967
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Gingival disorders, signs and symptoms NEC	10082211
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Hereditary gingival fibromatosis is approved as requested. Hereditary gingival fibromatosis is a rare disorder characterized by a benign, non-hemorrhagic, fibrous gingival overgrowth that can appear in isolation or as part of a syndrome. Though more research needs to be done, it is mostly agreed that a mutation in SOS1, son-of-sevenless gene, is responsible for this disease. Hereditary gingival fibromatosis will be added as a PT with a primary link to HLT Oral cavity disorders congenital NEC and a secondary link to HLT Gingival disorders, signs and symptoms NEC.

CR Number: 2022207006 **Implementation Date:** 29-Jul-22 Related CR: 2022207006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Mulberry molars*	Approved as Requested	Proposed LLT	
			Mulberry molars	10088211 Current
			To PT	
			Tooth malformation	10044046

MSSO Comment: The proposal to add a new term Mulberry molars is approved as requested. Mulberry molars are a dental condition usually associated with congenital syphilis, characterized by multiple rounded rudimentary enamel cusps on the permanent first molars. Mulberry molars will be added as LLT to PT Tooth malformation, where the related LLT Hutchinson's teeth, also consequence of congenital syphilis, can also be found.

Supplemental Update Report

CR Number: 2022207007 **Implementation Date:** 29-Jul-22 Related CR: 2022207007

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Gingival cyst of newborn*	Approved as Requested	Proposed LLT	
		Gingival cyst of newborn	10088212 Current
		To PT	
		Gingival cyst	10055018

MSSO Comment: The proposal to add a new term Gingival cyst of newborn is approved as requested. Odontogenic cysts originate in the epithelial components of the odontogenic apparatus or from its remnants, which are entrapped within the bone or the peripheral gingival tissues. Gingival cyst of newborn will be added as sub-concept LLT to PT Gingival cyst, aligned with the synonym LLT Epstein pearls.

CR Number: 2022207008 **Implementation Date:** 29-Jul-22 Related CR: 2022207008

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Talon cusp*	Approved as Requested	Proposed LLT	
		Talon cusp	10088213 Current
		To PT	
		Tooth malformation	10044046

MSSO Comment: The proposal to add a new term Talon cusp is approved as requested. Talon cusp is a rare developmental extra cusp-like projection on the cingulum area of affected anterior teeth that may cause various functional and aesthetic problems. A cusp can develop on a baby tooth (also known as primary teeth) but more commonly develops on a permanent tooth. Talon cusp will be added as a sub-concept LLT to PT Tooth malformation.

CR Number: 2022207009 **Implementation Date:** 29-Jul-22 Related CR: 2022207009

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Macrodontia*	Approved as Requested	Proposed PT	
		Macrodontia	10088214
		HLT primary	
		Dental developmental disorders and anomalies	10012321
		SOC primary	
		Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Macrodontia is approved as requested. Macrodontia is a developmental disorder characterized by increase in the size of the teeth; it may affect a single tooth or all of the teeth. Proposed term will be added as new PT Macrodontia under HLT Dental developmental disorders and anomalies.

Supplemental Update Report

CR Number: 2022207010 **Implementation Date:** 29-Jul-22 Related CR: 2022207010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Microdontia*	Approved as Requested	Proposed PT	
			Microdontia	10088215
			HLT primary	
			Dental developmental disorders and anomalies	10012321
			SOC primary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Microdontia is approved as requested. Microdontia is a developmental disorder characterized by abnormal smallness of the teeth; it may affect a single tooth or all of the teeth. Proposed term will be added as new PT Microdontia under HLT Dental developmental disorders and anomalies.

CR Number: 2022207011 **Implementation Date:** 29-Jul-22 Related CR: 2022207011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cerebral folate deficiency*	Approved as Requested	Proposed PT	
			Cerebral folate deficiency	10088217
			HLT primary	
			Cerebral disorders congenital	10052634
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Leukodystrophies	10068202
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Cerebral folate deficiency is approved as requested. Cerebral folate deficiency is a disorder that develops from a shortage of the B-vitamin folate in the brain. Delays in development may be noted including slow head growth, low muscle tone, ataxia, loss of voluntary movement, constant contracted muscles, speech complications, and epilepsy. Cerebral folate deficiency will be added as a PT to primary HLT Cerebral disorders congenital, to secondary HLT Leukodystrophies and to secondary HLT Water soluble vitamin deficiencies.

Supplemental Update Report

CR Number: 2022210008 **Implementation Date:** 29-Jul-22 Related CR: 2022207011

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cerebral folate deficiency*	Approved as Requested	Proposed PT	
To HLT	*Water soluble vitamin deficiencies*		*Cerebral folate deficiency*	10088217
			To HLT	
			Water soluble vitamin deficiencies	10047842

MSSO Comment:

CR Number: 2022207012 **Implementation Date:** 29-Jul-22 Related CR: 2022207012

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cervical Teratoma*	Approved Not as Requested	Proposed LLT	
			Cervical teratoma	10088219 Current
			To PT	
			Extragonadal primary germ cell tumour	10073055

MSSO Comment: The proposal to add a new term Cervical Teratoma is approved but not as requested. Cervical teratomas are extremely rare germ cell tumors (neoplasm) that occur in the neck. Proposed term will be modified for MedDRA capitalization conventions and added as new LLT Cervical teratoma to PT Extragonadal primary germ cell tumour.

CR Number: 2022207013 **Implementation Date:** 29-Jul-22 Related CR: 2022207013

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Wandering spleen*	Approved Not as Requested	Proposed LLT	
			Acquired wandering spleen	10088218 Current
			To PT	
			Acquired hypermobile spleen	10087502

MSSO Comment: The proposal to add a new term Wandering spleen is approved but not as requested. Acquired wandering spleen is an uncommon clinical condition in which the spleen is relocated from its normal anatomical position to other parts of the abdomen. It is usually diagnosed in multiparous women of reproductive age. Proposed term will be modified for clarity and added as synonym LLT Acquired wandering spleen under PT Acquired hypermobile spleen (recently added in change request 2021364325).

Supplemental Update Report

CR Number: 2022207014 **Implementation Date:** 29-Jul-22 Related CR: 2022207014

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Urachal Cancer*	Rejected		
To PT	*Bladder cancer*			

MSSO Comment: The proposal to add a new LLT Urachal Cancer to PT Bladder cancer is not approved. The requested term can be represented by LLT Malignant neoplasm of urachus. MedDRA cannot provide the synonym cancer for existing malignant neoplasm as this may lead to redundancy on LLT level.

CR Number: 2022207015 **Implementation Date:** 29-Jul-22 Related CR: 2022207015

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Laryngotracheoplasty*	Approved as Requested	Proposed LLT	
			Laryngotracheoplasty	10088220 Current
			To PT	
			Tracheal plastic repair	10044298

MSSO Comment: The proposal to add a new term Laryngotracheoplasty is approved as requested. Laryngotracheplasty is used to treat tracheal stenosis or subglottic stenosis. It is a surgery to expand and repair an airway using pieces of cartilage taken from rib, ear, or thyroid. Laryngotracheoplasty will be added as sub-concept LLT to PT Tracheal plastic repair.

CR Number: 2022207016 **Implementation Date:** 29-Jul-22 Related CR: 2022207016

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Left ventricular outflow tract gradient increased*	Approved as Requested	Proposed LLT	
			Left ventricular outflow tract gradient increased	10088221 Current
			To PT	
			Transvalvular pressure gradient increased	10079128

MSSO Comment: The proposal to add a new LLT Left ventricular outflow tract gradient increased is approved as requested. Left ventricular outflow tract gradient in hypertrophic obstructive cardiomyopathy is usually measured from the apical five chamber view in echocardiography. Left ventricular outflow tract gradient increased will be added as an LLT to PT Transvalvular pressure gradient increased.

Supplemental Update Report

CR Number: 2022207017 **Implementation Date:** 29-Jul-22 Related CR: 2022207017

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*ALCOHOLIC MYELOPATHY*	Approved Not as Requested	Proposed PT	
			Alcoholic myelopathy	10088216
			HLT primary	
			Spinal cord and nerve root disorders NEC	10041544
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Alcohol related nutritional disorders	10001608
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to add a new LLT ALCOHOLIC MYELOPATHY is approved but not as requested. Myelopathy has been reported in patients with alcoholism. As portosystemic blood shunting associated with liver cirrhosis has been considered to be the major cause of myelopathy in chronic alcoholics. However, direct toxicity of ethanol or poor nutritional status, with vitamin deficiency can also be the cause in patients without substantial liver disease. The requested term will be modified to Alcoholic myelopathy in accordance with MedDRA capitalization conventions, and added as PT with a primary link to HLT Spinal cord and nerve root disorders NEC and a secondary link to HLT Alcohol related nutritional disorders.

CR Number: 2022207018 **Implementation Date:** 29-Jul-22 Related CR: 2022207018

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Wunderlich Syndrome*	Approved Not as Requested	Proposed LLT		
To PT	*Renal haemorrhage*		*Wunderlich syndrome*	10088222	Current
			To PT		
			Renal haemorrhage	10038460	

MSSO Comment: The proposal to add a new LLT Wunderlich Syndrome to PT Renal haemorrhage is approved but not as requested. Wunderlich syndrome is a rare condition in which spontaneous non-traumatic renal hemorrhage occurs into the subcapsular and perirenal spaces. Proposed term will be modified for MedDRA capitalization conventions and added as LLT Wunderlich syndrome to PT Renal haemorrhage.

Supplemental Update Report

CR Number: 2022207072 **Implementation Date:** 29-Jul-22 Related CR: 2022207072

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Radiation Tracheitis*	Approved Not as Requested	Proposed LLT	
HLT primary	*Radiation injuries*		*Radiation tracheitis*	10088223 Current
SOC primary	*Injury, poisoning and procedural complications*		To PT	
			Tracheal radiation injury	10071733

MSSO Comment: The proposal to add a new PT Radiation Tracheitis to primary HLT Radiation injuries in SOC Injury, poisoning and procedural complications and secondary HLT Tracheal disorders (excl infections and neoplasms) in SOC Respiratory, thoracic and mediastinal disorders is approved but not as requested. Radiation tracheitis is an adverse effect that develops in individuals receiving radiation cancer therapy, most commonly for breast, lung, and other structures in the thorax. The requested term will be modified according to MedDRA capitalisation conventions and added as LLT Radiation tracheitis to PT Tracheal radiation injury.

CR Number: 2022207073 **Implementation Date:** 29-Jul-22 Related CR: 2022207073

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Bronchiectasis infection*	Rejected		
HLT primary	*Lower respiratory tract and lung infections*			
SOC primary	*Infections and infestations*			

MSSO Comment: The proposal to add a new PT Bronchiectasis infection to primary HLT Lower respiratory tract and lung infections in SOC Infections and infestations is not approved. The requested term is represented by LLT/PT Infective exacerbation of bronchiectasis.

CR Number: 2022208001 **Implementation Date:** 01-Aug-22 Related CR: 2022208001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Sclerosing lipogranuloma*	Approved as Requested	Proposed LLT	
To PT	*Lipogranuloma*		*Sclerosing lipogranuloma*	10088224 Current
			To PT	
			Lipogranuloma	10049940

MSSO Comment: The proposal to add a new LLT Sclerosing lipogranuloma to PT Lipogranuloma is approved as requested. The term Sclerosing lipogranuloma represents a peculiar granulomatous reaction that occurs in subcutaneous fat tissue as a consequence of the injection of several - frequently illegal - injectable materials for volume augmentation. In a related change, PT Lipogranuloma will be linked to secondary HLT Granulomatous and deep cutaneous inflammatory conditions.

Supplemental Update Report

CR Number: 2022213012 **Implementation Date:** 01-Aug-22 Related CR: 2022208001

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Lipogranuloma*	Approved as Requested	Proposed PT	
			Lipogranuloma	10049940
To HLT	*Granulomatous and deep cutaneous inflammatory conditions*		To HLT	
			Granulomatous and deep cutaneous inflammatory conditions	10018699

MSSO Comment:

CR Number: 2022208003 **Implementation Date:** 01-Aug-22 Related CR: 2022208003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pulmonary Tractotomy*	Approved Not as Requested	Proposed PT	
			Pulmonary tractotomy	10088225
			HLT primary	
			Bronchial and pulmonary therapeutic procedures	10006412
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Pulmonary Tractotomy is approved but not as requested. A pulmonary tractotomy is a surgical technique to treat a penetrating lung injury. The tract of the lung injury is opened, and open bronchi and blood vessels are ligated. Proposed term will be modified for MedDRA capitalization conventions and added as new PT Pulmonary tractotomy under HLT Bronchial and pulmonary therapeutic procedures.

CR Number: 2022208004 **Implementation Date:** 01-Aug-22 Related CR: 2022208004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Chemotherapy induced nausea and vomiting*	Rejected		

MSSO Comment: The proposal to add a new LLT Chemotherapy induced nausea and vomiting is not approved. Proposed concept is already represented as two existing LLT's -LLT Vomiting post chemotherapy and LLT Nausea post chemotherapy.

Supplemental Update Report

CR Number: 2022208005 **Implementation Date:** 01-Aug-22 Related CR: 2022208005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anti-LP antibody*	Approved as Requested	Proposed LLT	
To PT	*Anti-soluble liver antigen/liver pancreas antibody*		*Anti-LP antibody*	10088226 Current
			To PT	
			Anti-soluble liver antigen/liver pancreas antibody	10087984

MSSO Comment: The proposal to add a new LLT Anti-LP antibody to PT Anti-soluble liver antigen/liver pancreas antibody is approved as requested. Anti-LP antibody is an acronym and synonym of Anti-soluble liver antigen/liver pancreas antibody, which is associated with the history of the discovery of this antibody.

CR Number: 2022209015 **Implementation Date:** 04-Aug-22 Related CR: 2022209015

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Alkalinuria*	Approved as Requested	Proposed PT	
To SMQ	*Hypokalaemia (SMQ)*		*Alkalinuria*	10087982
Term scope	*Broad*		To SMQ	
			Hypokalaemia (SMQ)	20000233
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Alkalinuria to Hypokalaemia (SMQ) as a broad term is approved as requested. This is a new term in Version 26.0. Alkalinuria is a condition in which the urine (which is normally slightly acidic) is alkaline. Uncomplicated hypokalaemia can produce a metabolic alkalosis which consequently results in an increase in urine pH. Due to the fact that alkalinization of the urine can have many causes, this term will be added to the broad search terms of this SMQ.

Supplemental Update Report

CR Number: 2022209016 **Implementation Date:** 04-Aug-22 Related CR: 2022209016

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Burn oedema*	Approved as Requested	Proposed PT *Burn oedema*	10088079
To SMQ	*Accidents and injuries (SMQ)*		To SMQ *Accidents and injuries (SMQ)*	20000135
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Burn oedema to Accidents and injuries (SMQ) as a narrow term is approved as requested. This is a new term in Version 26.0. Massive tissue edema after thermal injury is a well-recognized entity. Burn edema, which describes a specific type of burn injury, will be added to the narrow search terms of this SMQ.

CR Number: 2022209017 **Implementation Date:** 04-Aug-22 Related CR: 2022209017

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Carotid blowout syndrome*	Approved as Requested	Proposed PT *Carotid blowout syndrome*	10088005
To SMQ	*Conditions associated with central nervous system haemorrhages and cerebrovascular accidents (SMQ)*		To SMQ *Conditions associated with central nervous system haemorrhages and cerebrovascular accidents (SMQ)*	20000166
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Carotid blowout syndrome to Conditions associated with central nervous system haemorrhages and cerebrovascular accidents (SMQ) as a narrow term is approved as requested. This is a new term in version 26.0. Carotid blowout syndrome refers to the rupture of the carotid artery and its branches. Carotid blowout syndrome is a dangerous medical emergency typically resulting from complications of treatments for head and neck cancer. This PT will be added to the narrow search terms of this SMQ.

Supplemental Update Report

CR Number: 2022209018 **Implementation Date:** 04-Aug-22 Related CR: 2022209018

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ictal central apnoea*	Approved as Requested	Proposed PT *Ictal central apnoea*	10088103
To SMQ	*Convulsions (SMQ)*		To SMQ *Convulsions (SMQ)*	20000079
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Ictal central apnoea to Convulsions (SMQ) as a narrow term is approved as requested. This is a new term in Version 26.0. Respiratory desaturations and ictal central apnea most frequently occur in seizures arising from the temporal lobe. Since this term describes a phenomenon which can accompany a convulsive event, it will be added to the narrow search terms of this SMQ.

CR Number: 2022209019 **Implementation Date:** 04-Aug-22 Related CR: 2022209019

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spinal cord hypoxia*	Approved as Requested	Proposed PT *Spinal cord hypoxia*	10088047
To SMQ	*Central nervous system vascular disorders, not specified as haemorrhagic or ischaemic (SMQ)*		To SMQ *Central nervous system vascular disorders, not specified as haemorrhagic or ischaemic (SMQ)*	20000165
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Spinal cord hypoxia to Central nervous system vascular disorders, not specified as haemorrhagic or ischaemic (SMQ) as a narrow term is approved as requested. This is a new term in version 26.0. Spinal cord hypoxia, whether acute or chronic in nature, can produce profound tissue changes resulting in neurologic dysfunction. This term does not describe the specific nature of the underlying vascular disorder, only the physiologic outcome of tissue hypoxia. As with the related PT Cerebral hypoperfusion, this term will be added to the narrow search terms of this SMQ.

Supplemental Update Report

CR Number: 2022209020 **Implementation Date:** 04-Aug-22 Related CR: 2022209020

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Status dystonicus*	Approved as Requested	Proposed PT *Status dystonicus*	10088053
To SMQ	*Dystonia (SMQ)*		To SMQ *Dystonia (SMQ)*	20000098
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Status dystonicus to Dystonia (SMQ) as a narrow term is approved as requested. This is a new term in Version 26.0. Status dystonicus is characterized by the development of increasingly frequent or continuous severe episodes of generalized dystonic spasms. Since it describes a specific clinical presentation of dystonia, it will be added to the narrow search terms of this SMQ.

CR Number: 2022209021 **Implementation Date:** 04-Aug-22 Related CR: 2022209021

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Adenomyoepithelioma of breast*	Approved as Requested	Proposed PT *Adenomyoepithelioma of breast*	10088008
To SMQ	*Breast tumours of unspecified malignancy (SMQ)*		To SMQ *Breast tumours of unspecified malignancy (SMQ)*	20000199
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Adenomyoepithelioma of breast to Breast tumours of unspecified malignancy (SMQ) as a narrow term is approved as requested. New term for v26.0 which fits inclusion criteria as a narrow term. Although most tumors have a benign clinical course, local recurrences, malignant transformations, and distant metastases have been reported.

Supplemental Update Report

CR Number: 2022209022 **Implementation Date:** 04-Aug-22 Related CR: 2022209022

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with excess blasts*	Approved as Requested	Proposed PT *Myelodysplastic syndrome with excess blasts*	10088023
To SMQ	*Myelodysplastic syndrome (SMQ)*		To SMQ *Myelodysplastic syndrome (SMQ)*	20000217
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Myelodysplastic syndrome with excess blasts to Myelodysplastic syndrome (SMQ) as a narrow term is approved as requested. New term which fits inclusion criteria as narrow in scope. Former PT Refractory anaemia with an excess of blasts is now LLT to the new PT.

CR Number: 2022209023 **Implementation Date:** 04-Aug-22 Related CR: 2022209023

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with multilineage dysplasia*	Approved as Requested	Proposed PT *Myelodysplastic syndrome with multilineage dysplasia*	10088022
To SMQ	*Myelodysplastic syndrome (SMQ)*		To SMQ *Myelodysplastic syndrome (SMQ)*	20000217
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Myelodysplastic syndrome with multilineage dysplasia to Myelodysplastic syndrome (SMQ) as a narrow term is approved as requested. New term which fits inclusion criteria as narrow in scope. Former outdated PT Refractory cytopenia with multilineage dysplasia is now LLT to the new PT.

Supplemental Update Report

CR Number: 2022209024 **Implementation Date:** 04-Aug-22 Related CR: 2022209024

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with ringed sideroblasts*	Approved as Requested	Proposed PT *Myelodysplastic syndrome with ringed sideroblasts*	10088024
To SMQ	*Myelodysplastic syndrome (SMQ)*		To SMQ *Myelodysplastic syndrome (SMQ)*	20000217
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Myelodysplastic syndrome with ringed sideroblasts to Myelodysplastic syndrome (SMQ) as a narrow term is approved as requested. New term which fits inclusion criteria as narrow in scope. Former outdated PT Refractory anaemia with ringed sideroblasts is now LLT to the new PT.

CR Number: 2022209025 **Implementation Date:** 04-Aug-22 Related CR: 2022209025

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with single lineage dysplasia*	Approved as Requested	Proposed PT *Myelodysplastic syndrome with single lineage dysplasia*	10088025
To SMQ	*Myelodysplastic syndrome (SMQ)*		To SMQ *Myelodysplastic syndrome (SMQ)*	20000217
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Myelodysplastic syndrome with single lineage dysplasia to Myelodysplastic syndrome (SMQ) as a narrow term is approved as requested. New term for v26.0 which fits inclusion as a narrow term. Former outdated LT Refractory cytopenia with unilineage dysplasia is now LLT to the new PT.

Supplemental Update Report

CR Number: 2022209026 **Implementation Date:** 04-Aug-22 Related CR: 2022209026

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with excess blasts*	Approved as Requested	Proposed PT *Myelodysplastic syndrome with excess blasts*	10088023
To SMQ	*Blood premalignant disorders (SMQ)*		To SMQ *Blood premalignant disorders (SMQ)*	20000086
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Myelodysplastic syndrome with excess blasts to Blood premalignant disorders (SMQ) as a narrow term is approved as requested. New term for v26.0 which fits inclusion as a narrow term. Former outdated PT Refractory anaemia with an excess of blasts is now LLT to the new PT.

CR Number: 2022209027 **Implementation Date:** 04-Aug-22 Related CR: 2022209027

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with multilineage dysplasia*	Approved as Requested	Proposed PT *Myelodysplastic syndrome with multilineage dysplasia*	10088022
To SMQ	*Blood premalignant disorders (SMQ)*		To SMQ *Blood premalignant disorders (SMQ)*	20000086
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Myelodysplastic syndrome with multilineage dysplasia to Blood premalignant disorders (SMQ) as a narrow term is approved as requested. New term for v26.0 which fits inclusion as a narrow term. Former outdated PT Refractory cytopenia with multilineage dysplasia is now LLT to the new PT.

Supplemental Update Report

CR Number: 2022209028 **Implementation Date:** 04-Aug-22 Related CR: 2022209028

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with ringed sideroblasts*	Approved as Requested	Proposed PT	
To SMQ	*Blood premalignant disorders (SMQ)*		*Myelodysplastic syndrome with ringed sideroblasts*	10088024
Term scope	*Narrow*		To SMQ	
			Blood premalignant disorders (SMQ)	20000086
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Myelodysplastic syndrome with ringed sideroblasts to Blood premalignant disorders (SMQ) as a narrow term is approved as requested. New term for v26.0 which fits inclusion as a narrow term. Former outdated PT Refractory anaemia with ringed sideroblasts is now LLT to the new PT.

CR Number: 2022209029 **Implementation Date:** 04-Aug-22 Related CR: 2022209029

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with single lineage dysplasia*	Approved as Requested	Proposed PT	
To SMQ	*Blood premalignant disorders (SMQ)*		*Myelodysplastic syndrome with single lineage dysplasia*	10088025
Term scope	*Narrow*		To SMQ	
			Blood premalignant disorders (SMQ)	20000086
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Myelodysplastic syndrome with single lineage dysplasia to Blood premalignant disorders (SMQ) as a narrow term is approved as requested. New term for v26.0 which fits inclusion as a narrow term. Former outdated PT Refractory cytopenia with unilineage dysplasia is now LLT to the new PT.

Supplemental Update Report

CR Number: 2022209030 **Implementation Date:** 04-Aug-22 Related CR: 2022209030

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ocular vaccinia virus infection*	Approved as Requested	Proposed PT *Ocular vaccinia virus infection*	10088113
To SMQ	*Ocular infections (SMQ)*		To SMQ *Ocular infections (SMQ)*	20000183
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Ocular vaccinia virus infection to Ocular infections (SMQ) as a narrow term is approved as requested. New term for v26.0. Ocular vaccinia virus infections may occur after receiving smallpox vaccination or after contact with a recently immunized individual. See included broaded PT Keratitis viral.

CR Number: 2022209031 **Implementation Date:** 04-Aug-22 Related CR: 2022209031

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Infective exacerbation of asthma*	Approved as Requested	Proposed PT *Infective exacerbation of asthma*	10088066
To SMQ	*Asthma/bronchospasm (SMQ)*		To SMQ *Asthma/bronchospasm (SMQ)*	20000025
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Infective exacerbation of asthma to Asthma/bronchospasm (SMQ) as a narrow term is approved as requested. New term for v26.0 which fits inclusion criteria as narrow in scope. Acute exacerbations can be triggered by a variety of things including upper respiratory tract infections.

Supplemental Update Report

CR Number: 2022209032 **Implementation Date:** 04-Aug-22 Related CR: 2022209032

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Diabetic myonecrosis*	Approved as Requested	Proposed PT *Diabetic myonecrosis*	10087983
To SMQ	*Rhabdomyolysis/myopathy (SMQ)*		To SMQ *Rhabdomyolysis/myopathy (SMQ)*	20000002
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Diabetic myonecrosis to Rhabdomyolysis/myopathy (SMQ) as a narrow term is approved as requested. New term for v. 26.0 which fits criterion as a narrow term. Diabetic myonecrosis (Rhabdomyolysis) is a complication in diabetic patients with hyperosmolarity.

CR Number: 2022209033 **Implementation Date:** 04-Aug-22 Related CR: 2022209033

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tricuspid valve thrombosis*	Approved as Requested	Proposed PT *Tricuspid valve thrombosis*	10088062
To SMQ	*Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ)*		To SMQ *Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ)*	20000083
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Tricuspid valve thrombosis to Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria of this SMQ for terms relating to thrombosis. All terms in this SMQ are narrow scope.

Supplemental Update Report

CR Number: 2022209034 **Implementation Date:** 04-Aug-22 Related CR: 2022209034

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ictal central apnoea*	Approved as Requested	Proposed PT *Ictal central apnoea*	10088103
To SMQ	*Respiratory failure (SMQ)*		To SMQ *Respiratory failure (SMQ)*	20000222
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Ictal central apnoea to Respiratory failure (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria of this SMQ for terms indicating respiratory failure/depression/arrest. Similar apnea terms are included in the narrow scope.

CR Number: 2022209035 **Implementation Date:** 04-Aug-22 Related CR: 2022209035

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nocturnal hypoventilation*	Approved as Requested	Proposed PT *Nocturnal hypoventilation*	10088137
To SMQ	*Acute central respiratory depression (SMQ)*		To SMQ *Acute central respiratory depression (SMQ)*	20000116
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Nocturnal hypoventilation to Acute central respiratory depression (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria of this SMQ. Similar sleep apnea terms are included in the broad scope.

Supplemental Update Report

CR Number: 2022209036 **Implementation Date:** 04-Aug-22 Related CR: 2022209036

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nocturnal hypoventilation*	Approved as Requested	Proposed PT *Nocturnal hypoventilation*	10088137
To SMQ	*Respiratory failure (SMQ)*		To SMQ *Respiratory failure (SMQ)*	20000222
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Nocturnal hypoventilation to Respiratory failure (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria of this SMQ for terms for breathing abnormalities indicating respiratory failure. Similar hypoventilation terms are included as narrow scope terms.

CR Number: 2022209037 **Implementation Date:** 04-Aug-22 Related CR: 2022209037

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Lyme arthritis*	Approved as Requested	Proposed PT *Lyme arthritis*	10088043
To SMQ	*Arthritis (SMQ)*		To SMQ *Arthritis (SMQ)*	20000216
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Lyme arthritis to Arthritis (SMQ) as a narrow term is approved as requested. PT Lyme arthritis was added in V26.0 and meets the inclusion criterion "Terms for various forms of arthritis including ineffective, reactive and rheumatic disorders". PT Lyme arthritis will be added to Arthritis (SMQ) with narrow scope, in line with other already included PTs representing ineffective and inflammatory arthritis.

Supplemental Update Report

CR Number: 2022209038 **Implementation Date:** 04-Aug-22 Related CR: 2022209038

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Marshall-White syndrome*	Approved as Requested	Proposed PT *Marshall-White syndrome*	10088084
To SMQ	*Arthritis (SMQ)*		To SMQ *Arthritis (SMQ)*	20000216
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Marshall-White syndrome to Arthritis (SMQ) as a narrow term is approved as requested. PT Marshall-White syndrome was added in V26.0 and is an inherited condition characterized by a distinctive facial appearance, eye abnormalities, hearing loss, and early-onset arthritis, meeting the inclusion criterion "Terms for genetic syndromes affecting joints". PT Marshall-White syndrome is added with narrow scope, in line with already included PT COPA syndrome, PT Otospondylomegaepiphyseal dysplasia and PT Pyogenic sterile arthritis pyoderma gangrenosum and acne syndrome.

CR Number: 2022209039 **Implementation Date:** 04-Aug-22 Related CR: 2022209039

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with excess blasts*	Approved as Requested	Proposed PT *Myelodysplastic syndrome with excess blasts*	10088023
To SMQ	*Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)*		To SMQ *Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)*	20000028
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Myelodysplastic syndrome with excess blasts to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ) as a broad term is approved as requested. PT Myelodysplastic syndrome with excess blasts was added in V26.0 and represents a subtype of the myelodysplastic syndromes (MDS), a group of diverse clonal hematopoietic disorders characterized by ineffective hematopoiesis, manifested by morphologic dysplasia in hematopoietic cells and by bone marrow failure, refractory peripheral cytopenia(s) and by a risk of progression to acute myeloid leukemia. Cytopenia may affect 1-3 cell types in this MDS subtype and therefore, PT Myelodysplastic syndrome with excess blasts will be added with broad scope to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ).

Supplemental Update Report

CR Number: 2022209040 **Implementation Date:** 04-Aug-22 Related CR: 2022209040

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with multilineage dysplasia*	Approved as Requested	Proposed PT *Myelodysplastic syndrome with multilineage dysplasia*	10088022
To SMQ	*Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)*		To SMQ *Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)*	20000028
Term scope	*Broad*		Term scope *Broad* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Myelodysplastic syndrome with multilineage dysplasia to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ) as a broad term is approved as requested. PT Myelodysplastic syndrome with multilineage dysplasia was added in V26.0 and represents a subtype of the myelodysplastic syndromes (MDS), a group of diverse clonal hematopoietic disorders characterized by ineffective hematopoiesis, manifested by morphologic dysplasia in hematopoietic cells and by bone marrow failure, refractory peripheral cytopenias and by a risk of progression to acute myeloid leukemia. PT Myelodysplastic syndrome with multilineage dysplasia will be added with broad scope to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ).

CR Number: 2022209041 **Implementation Date:** 04-Aug-22 Related CR: 2022209041

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Palatal perforation*	Approved as Requested	Proposed PT *Palatal perforation*	10088077
To SMQ	*Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)*		To SMQ *Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)*	20000114
Term scope	*Narrow*		Term scope *Narrow* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Palatal perforation to Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ) as a narrow term is approved as requested. PT Palatal perforation was added in V26.0 and meets the inclusion criterion " lesions not clearly related to specific infections, neoplasms or allergic reactions but due to the following etiology: Injuries, Ulcers, Hypoesthesias, Hemorrhages, Unspecified disorders" of Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ). All PTs of this SMQ have a narrow scope.

Supplemental Update Report

CR Number: 2022209042 **Implementation Date:** 04-Aug-22 Related CR: 2022209042

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Otolaryngoscopy*	Approved as Requested	Proposed PT *Otolaryngoscopy*	10088093
To SMQ	*Hearing impairment (SMQ)*		To SMQ *Hearing impairment (SMQ)*	20000171
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Otolaryngoscopy to Hearing impairment (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ for terms relating to signs, symptoms, and procedures related to hearing impairment. Similar "procedure" terms such as PT Tympanoscopy and PT Otoendoscopy are already included. Terms for signs, symptoms, and procedures are generally included in broad search.

CR Number: 2022209043 **Implementation Date:** 04-Aug-22 Related CR: 2022209043

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Congenital trigeminal anaesthesia*	Approved as Requested	Proposed PT *Congenital trigeminal anaesthesia*	10088099
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Congenital trigeminal anaesthesia to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2022209044 **Implementation Date:** 04-Aug-22 Related CR: 2022209044

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Congenital umbilico-enteric fistula*	Approved as Requested	Proposed PT *Congenital umbilico-enteric fistula*	10088009
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Congenital umbilico-enteric fistula to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2022209045 **Implementation Date:** 04-Aug-22 Related CR: 2022209045

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Congenital vaccinia virus infection*	Approved as Requested	Proposed PT *Congenital vaccinia virus infection*	10088114
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Congenital vaccinia virus infection to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2022209046 **Implementation Date:** 04-Aug-22 Related CR: 2022209046

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Marshall-White syndrome*	Approved as Requested	Proposed PT *Marshall-White syndrome*	10088084
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Marshall-White syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2022209047 **Implementation Date:** 04-Aug-22 Related CR: 2022209047

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spondylocostal dysostosis*	Approved as Requested	Proposed PT *Spondylocostal dysostosis*	10088002
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Spondylocostal dysostosis to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2022209048 **Implementation Date:** 04-Aug-22 Related CR: 2022209048

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*WNT4 deficiency*	Approved as Requested	Proposed PT *WNT4 deficiency*	10088125
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT WNT4 deficiency to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2022209049 **Implementation Date:** 04-Aug-22 Related CR: 2022209049

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Mesenteric lymphadenitis*	Approved as Requested	Proposed PT *Mesenteric lymphadenitis*	10088083
To SMQ	*Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)*		To SMQ *Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)*	20000225
Term scope	*Broad*		Term scope *Broad*	
			Term_category *D*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Mesenteric lymphadenitis to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Lymphadenitis and PT Retroperitoneal lymphadenopathy are already included as broad scope terms.

Supplemental Update Report

CR Number: 2022209050 **Implementation Date:** 04-Aug-22 Related CR: 2022209050

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Carotid blowout syndrome*	Approved as Requested	Proposed PT *Carotid blowout syndrome*	10088005
To SMQ	*Haemorrhage terms (excl laboratory terms) (SMQ)*		To SMQ *Haemorrhage terms (excl laboratory terms) (SMQ)*	20000039
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Carotid blowout syndrome to Haemorrhage terms (excl laboratory terms) (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes terms that refer to rupture of blood vessels. Carotid blowout syndrome refers to the rupture of the carotid artery and its branches. Similar term such as PT Iliac artery rupture is already included as a narrow scope term.

CR Number: 2022209051 **Implementation Date:** 04-Aug-22 Related CR: 2022209051

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with single lineage dysplasia*	Approved as Requested	Proposed PT *Myelodysplastic syndrome with single lineage dysplasia*	10088025
To SMQ	*Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)*		To SMQ *Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)*	20000028
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Myelodysplastic syndrome with single lineage dysplasia to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ) as a broad term is approved as requested. PT Myelodysplastic syndrome with single lineage dysplasia was added in V26.0 and is characterized by morphologic dysplasia of a single myeloid lineage with associated one or two peripheral blood cytopenia(s). PT Myelodysplastic syndrome with single lineage dysplasia will be added with broad scope to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ).

Supplemental Update Report

CR Number: 2022209052 **Implementation Date:** 04-Aug-22 Related CR: 2022209052

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Demodex blepharitis*	Approved as Requested	Proposed PT	
To SMQ	*Ocular infections (SMQ)*		*Demodex blepharitis*	10087989
Term scope	*Narrow*		To SMQ	
			Ocular infections (SMQ)	20000183
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Demodex blepharitis to Ocular infections (SMQ) as a narrow term is approved as requested. New term for V26.0 which fits inclusion criterion "All terms directly related to or describing an eye infection – these are generally the narrow terms. This includes infections of the orbital and periorbital structures: conjunctiva, eyelids and lashes, lacrimal system, cornea, episclera, iris, retina and optic nerve".

CR Number: 2022209053 **Implementation Date:** 04-Aug-22 Related CR: 2022209053

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome with ringed sideroblasts*	Approved as Requested	Proposed PT	
To SMQ	*Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)*		*Myelodysplastic syndrome with ringed sideroblasts*	10088024
Term scope	*Broad*		To SMQ	
			Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)	20000028
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Myelodysplastic syndrome with ringed sideroblasts to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ) as a broad term is approved as requested. PT Myelodysplastic syndrome with ringed sideroblasts was added in V26.0 and represents a subtype of the myelodysplastic syndromes (MDS), a group of diverse clonal hematopoietic disorders characterized by ineffective hematopoiesis, manifested by morphologic dysplasia in hematopoietic cells and by bone marrow failure, refractory peripheral cytopenia(s) and by a risk of progression to acute myeloid leukemia. PT Myelodysplastic syndrome with ringed sideroblasts will be added with broad scope to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ), because in MDS, the lineage(s) manifesting morphological dysplasia frequently do not correlate with the specific cytopenia and also, single lineage dysplasia may lead to cytopenia of 1-3 cell types.

Supplemental Update Report

CR Number: 2022209054 **Implementation Date:** 04-Aug-22 Related CR: 2022209054

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myelodysplastic syndrome unclassifiable*	Approved as Requested	Proposed PT	
To SMQ	*Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)*		*Myelodysplastic syndrome unclassifiable*	10028535
Term scope	*Broad*		To SMQ	
			Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)	20000028
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Myelodysplastic syndrome unclassifiable to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ) as a broad term is approved as requested. PT Myelodysplastic syndrome unclassifiable belongs to a group of diverse clonal hematopoietic disorders characterized by ineffective hematopoiesis, manifested by morphologic dysplasia in hematopoietic cells and by bone marrow failure, refractory peripheral cytopenia(s) and by a risk of progression to acute myeloid leukemia. PT Myelodysplastic syndrome unclassifiable will be added with broad scope to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ), because in MDS, the lineage(s) manifesting morphological dysplasia frequently do not correlate with the specific cytopenia and also, single lineage dysplasia may lead to cytopenia of 1-3 cell types.

CR Number: 2022209055 **Implementation Date:** 04-Aug-22 Related CR: 2022209055

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Otolaryngoscopy*	Approved as Requested	Proposed PT	
To SMQ	*Vestibular disorders (SMQ)*		*Otolaryngoscopy*	10088093
Term scope	*Broad*		To SMQ	
			Vestibular disorders (SMQ)	20000172
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Otolaryngoscopy to Vestibular disorders (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ for terms relating to signs, symptoms, and procedures related to vestibular disorders. Similar "procedure" terms such as PT Tympanoscopy and PT Otoendoscopy are already included. Terms for signs, symptoms, and procedures are generally included in broad search.

Supplemental Update Report

CR Number: 2022209056 **Implementation Date:** 04-Aug-22 Related CR: 2022209056

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Campylobacter bacteraemia*	Approved as Requested	Proposed PT *Campylobacter bacteraemia*	10088115
To SMQ	*Sepsis (SMQ)*		To SMQ *Sepsis (SMQ)*	20000234
Term scope	*Broad*		Term scope *Broad* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Campylobacter bacteraemia to Sepsis (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Bacillus bacteraemia and PT Citrobacter bacteraemia are already included as broad scope terms.

CR Number: 2022209057 **Implementation Date:** 04-Aug-22 Related CR: 2022209057

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Placental oedema*	Approved as Requested	Proposed PT *Placental oedema*	10088054
To SMQ	*Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)*		To SMQ *Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)*	20000186
Term scope	*Narrow*		Term scope *Narrow* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Placental oedema to Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Placental insufficiency and PT Placental disorder are already included as narrow scope terms.

Supplemental Update Report

CR Number: 2022209058 **Implementation Date:** 04-Aug-22 Related CR: 2022209058

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Testosterone deficiency syndrome*	Approved as Requested	Proposed PT *Testosterone deficiency syndrome*	10087998
To SMQ	*Fertility disorders (SMQ)*		To SMQ *Fertility disorders (SMQ)*	20000210
Term scope	*Narrow*		Term scope *Narrow* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Testosterone deficiency syndrome to Fertility disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Blood testosterone abnormal and PT Hypogonadism male are already included as narrow scope terms.

CR Number: 2022209059 **Implementation Date:** 04-Aug-22 Related CR: 2022209059

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Placental oedema*	Approved as Requested	Proposed PT *Placental oedema*	10088054
To SMQ	*Haemodynamic oedema, effusions and fluid overload (SMQ)*		To SMQ *Haemodynamic oedema, effusions and fluid overload (SMQ)*	20000145
Term scope	*Narrow*		Term scope *Narrow* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Placental oedema to Haemodynamic oedema, effusions and fluid overload (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Pelvic fluid collection and PT Testicular swelling are already included as narrow scope terms.

Supplemental Update Report

CR Number: 2022209060 **Implementation Date:** 04-Aug-22 Related CR: 2022209060

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Unexpected vaginal bleeding on hormonal IUD*	Approved as Requested	Proposed PT	
To SMQ	*Haemorrhage terms (excl laboratory terms) (SMQ)*		*Unexpected vaginal bleeding on hormonal IUD*	10088030
Term scope	*Narrow*		To SMQ	
			Haemorrhage terms (excl laboratory terms) (SMQ)	20000039
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Unexpected vaginal bleeding on hormonal IUD to Haemorrhage terms (excl laboratory terms) (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Abnormal uterine bleeding and PT Vaginal haemorrhage are already included as narrow scope terms.

CR Number: 2022209061 **Implementation Date:** 04-Aug-22 Related CR: 2022209061

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Campylobacter bacteraemia*	Approved as Requested	Proposed PT	
To SMQ	*Opportunistic infections (SMQ)*		*Campylobacter bacteraemia*	10088115
Term scope	*Broad*		To SMQ	
			Opportunistic infections (SMQ)	20000235
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Campylobacter bacteraemia to Opportunistic infections (SMQ) as a broad term is approved as requested. Although campylobacter species are common food-borne pathogens that affect healthy and compromised people, C. jejuni, C. fetus and several other Campylobacter species (eg, C. coli and C. lari) typically cause bacteremia and systemic manifestations in adults; more often when underlying predisposing diseases, such as diabetes, cirrhosis, cancer, or HIV/AIDS are present. Like most bacteraemia terms, it should be added to the broad scope of this SMQ.

Supplemental Update Report

CR Number: 2022209062 **Implementation Date:** 04-Aug-22 Related CR: 2022209062

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*S100 protein increased*	Approved as Requested	Proposed PT *S100 protein increased*	10088109
To SMQ	*Immune-mediated/autoimmune disorders (SMQ)*		To SMQ *Immune-mediated/autoimmune disorders (SMQ)*	20000236
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT S100 protein increased to Immune-mediated/autoimmune disorders (SMQ) as a broad term is approved as requested. Several studies have explored the value S100A8/A9 as a predictive biomarker for autoimmune diseases. In rheumatoid arthritis, S100A8/A9 was suggested as a potential biomarker in predicting clinical response to monitor treatment. Some clinical investigations have indicated that S100A8/A9 levels might be a more sensitive predictor for monitoring synovial inflammation in rheumatoid arthritis patients when compared with other markers such as c-reactive protein levels. Despite being affected by a wide range of pathologies, is unlikely producing “noise” and is found suitable for the broad scope.

CR Number: 2022209063 **Implementation Date:** 04-Aug-22 Related CR: 2022209063

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Testosterone deficiency syndrome*	Approved as Requested	Proposed PT *Testosterone deficiency syndrome*	10087998
To SMQ	*Sexual dysfunction (SMQ)*		To SMQ *Sexual dysfunction (SMQ)*	20000238
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Testosterone deficiency syndrome to Sexual dysfunction (SMQ) as a narrow term is approved as requested. Adult age-related symptoms of male hypogonadism include various nonspecific symptoms such as decreased libido, erectile dysfunction, cognitive decline, decrease in percentage of lean body mass, sleep disturbances, and mood changes. Like the existing broader PT Hypogonadism, this new PT should be added to the narrow scope.

Supplemental Update Report

CR Number: 2022209064 **Implementation Date:** 04-Aug-22 Related CR: 2022209064

Change Requested	Change term status in a SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Sleeve gastrectomy*	Approved as Requested	Proposed PT *Sleeve gastrectomy*	10070978
To SMQ	*Gastrointestinal perforation, ulcer, haemorrhage, obstruction non-specific findings/procedures (SMQ)*		To SMQ *Gastrointestinal perforation, ulcer, haemorrhage, obstruction non-specific findings/procedures (SMQ)*	20000104
Status	*I*		Status *I*	

MSSO Comment: The proposal to change status of the term Sleeve gastrectomy in Gastrointestinal perforation, ulcer, haemorrhage, obstruction non-specific findings/procedures (SMQ) to Inactive is approved as requested. While the broad PT Gastrectomy is suitable for this unspecific SMQ, Sleeve gastrectomy is an specific treatment in bariatric surgery, which is out of the scope of this SMQ. The term should be made inactive.

CR Number: 2022209065 **Implementation Date:** 04-Aug-22 Related CR: 2022209065

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anti IFN gamma autoantibody syndrome*	Approved as Requested	Proposed PT *Anti IFN gamma autoantibody syndrome*	10088058
To SMQ	*Immune-mediated/autoimmune disorders (SMQ)*		To SMQ *Immune-mediated/autoimmune disorders (SMQ)*	20000236
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Anti IFN gamma autoantibody syndrome to Immune-mediated/autoimmune disorders (SMQ) as a broad term is approved as requested. Even if this syndrome presents clinically as an immunodeficiency, is pathogenesis is based on an autoimmune attack against gamma-interferon, evidenced by a high amounts of anti-interferon-gamma autoantibodies. The term qualifies for being added to the broad scope of this SMQ.

Supplemental Update Report

CR Number: 2022209066 **Implementation Date:** 04-Aug-22 Related CR: 2022209066

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*S100 protein increased*	Approved as Requested	Proposed PT *S100 protein increased*	10088109
To SMQ	*Systemic lupus erythematosus (SMQ)*		To SMQ *Systemic lupus erythematosus (SMQ)*	20000045
Term scope	*Broad*		Term scope *Broad*	
			Term_category *I*	
			Term_weight *3*	

MSSO Comment: The proposal to add PT S100 protein increased to Systemic lupus erythematosus (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Anti-neuronal antibody positive and PT Histone antibody positive are already included as broad scope terms.

CR Number: 2022209067 **Implementation Date:** 04-Aug-22 Related CR: 2022209067

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anti-PCNA antibody*	Approved as Requested	Proposed PT *Anti-PCNA antibody*	10088096
To SMQ	*Systemic lupus erythematosus (SMQ)*		To SMQ *Systemic lupus erythematosus (SMQ)*	20000045
Term scope	*Broad*		Term scope *Broad*	
			Term_category *I*	
			Term_weight *3*	

MSSO Comment: The proposal to add PT Anti-PCNA antibody to Systemic lupus erythematosus (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Double stranded DNA antibody and PT Double stranded DNA antibody positive are already included as broad scope terms.

Supplemental Update Report

CR Number: 2022209069 **Implementation Date:** 01-Aug-22 Related CR: 2022209069

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Gastroduodenal Perforation*	Approved Not as Requested	Proposed LLT		
To PT	*Upper gastrointestinal perforation*		*Gastroduodenal perforation*	10088230	Current
			To PT		
			Upper gastrointestinal perforation	10078413	

MSSO Comment: The proposal to add a new LLT Gastroduodenal Perforation to PT Upper gastrointestinal perforation is approved but not as requested. Gastroduodenal perforation may be spontaneous or traumatic and the majority of spontaneous perforation is due to peptic ulcer disease. Proposed term will be modified for MedDRA capitalization conventions and added as LLT Gastroduodenal perforation under PT Upper gastrointestinal perforation.

CR Number: 2022209070 **Implementation Date:** 01-Aug-22 Related CR: 2022209070

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Fundus photography*	Approved as Requested	Proposed LLT		
To PT	*Retinogram*		*Fundus photography*	10088229	Current
			To PT		
			Retinogram	10059661	

MSSO Comment: The proposal to add a new LLT Fundus photography to PT Retinogram is approved as requested. Eye fundus photography is a method of capturing images of the vitreous, retina, choroid, and optic nerve using a fundus camera, a specialized low power microscope with an attached camera.

CR Number: 2022209071 **Implementation Date:** 01-Aug-22 Related CR: 2022209071

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Image guided radiation therapy*	Approved as Requested	Proposed LLT		
To PT	*Radiotherapy*		*Image guided radiation therapy*	10088228	Current
			To PT		
			Radiotherapy	10037794	

MSSO Comment: The proposal to add a new LLT Image guided radiation therapy to PT Radiotherapy is approved as requested. Image guided radiation therapy is a procedure that uses a computer to create a picture of a tumor to help guide the radiation beam during radiation therapy. The pictures are made using CT, ultrasound, X-ray, or other imaging techniques.

Supplemental Update Report

CR Number: 2022209072 **Implementation Date:** 01-Aug-22 Related CR: 2022209072

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Whole body gamma measurement*	Approved as Requested	Proposed PT	
			Whole body gamma measurement	10088227
			HLT primary	
			Imaging procedures NEC	10021404
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Whole body gamma measurement is approved as requested. In health physics, whole-body counting refers to the measurement of radioactivity within the human body. The technique is primarily applicable to radioactive material that emits gamma rays and may be used to monitor people who had been injected with radium or in the context of the development of new radioactive anticancer drugs. Proposed term will be added as PT Whole body gamma measurement under HLT Imaging procedures NEC.

CR Number: 2022210001 **Implementation Date:** 04-Aug-22 Related CR: 2022210001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ventricular premature beats*	Approved as Requested	Proposed LLT	
			Ventricular premature beats	10088231 Current
			To PT	
			Ventricular extrasystoles	10047289

MSSO Comment: The proposal to add a new term Ventricular premature beats is approved as requested. A premature ventricular contraction is a common event where the heartbeat is initiated by Purkinje fibers in the ventricles rather than by the sinoatrial node. Ventricular premature beats will be added as a synonym LLT to PT Ventricular extrasystoles.

CR Number: 2022210002 **Implementation Date:** 04-Aug-22 Related CR: 2022210002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*PNEUMATIC DISPLACEMENT*	Approved Not as Requested	Proposed PT	
			Macular pneumatic displacement	10088232
			HLT primary	
			Retinal therapeutic procedures	10038890
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT PNEUMATIC DISPLACEMENT is approved but not as requested. Pneumatic displacement is a simple procedure, not too invasive and with a small risk of intraocular complications. The proposed term will be modified to Macular pneumatic displacement for greater clarity and added as PT under HLT Retinal therapeutic procedures.

Supplemental Update Report

CR Number: 2022210003 **Implementation Date:** 04-Aug-22 Related CR: 2022210003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Physiatry consultation*	Approved as Requested	Proposed LLT *Physiatry consultation* To PT *Specialist consultation*	10088233 Current 10076498

MSSO Comment: The proposal to add a new LLT Physiatry consultation is approved as requested. Physiatry physicians, also known as physiatrists, treat a wide variety of medical conditions affecting the brain, spinal cord, nerves, bones, joints, ligaments, muscles, and tendons. Physiatry consultation will be added as an LLT to PT Specialist consultation.

CR Number: 2022210004 **Implementation Date:** 04-Aug-22 Related CR: 2022210004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Monkeypox immunisation*	Approved as Requested	Proposed PT *Monkeypox immunisation*	10088234
HLT primary	*Immunisations*		HLT primary *Immunisations*	10021431
SOC primary	*Surgical and medical procedures*		SOC primary *Surgical and medical procedures*	10042613

MSSO Comment: The proposal to add a new PT Monkeypox immunisation to primary HLT Immunisations in SOC Surgical and medical procedures is approved as requested. The currently used vaccine for monkeypox immunisation is originally developed as a vaccine against smallpox, but has now been approved for use against monkeypox as well. In a related change, the American spelled LLT Monkeypox immunization will also be added to the new PT Monkeypox immunisation.

CR Number: 2022216001 **Implementation Date:** 04-Aug-22 Related CR: 2022210004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Monkeypox immunization*	Approved as Requested	Proposed LLT *Monkeypox immunization*	10088235 Current
To PT	*Monkeypox immunisation*		To PT *Monkeypox immunisation*	10088234

MSSO Comment:

Supplemental Update Report

CR Number: 2022210005 **Implementation Date:** 04-Aug-22 Related CR: 2022210005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Gestational alloimmune liver disease*	Approved as Requested	Proposed PT *Gestational alloimmune liver disease*	10088236
			HLT primary *Hepatobiliary abnormalities congenital*	10019803
			SOC primary *Congenital, familial and genetic disorders*	10010331
			HLT secondary *Neonatal hepatobiliary disorders*	10028942
			SOC secondary *Pregnancy, puerperium and perinatal conditions*	10036585

MSSO Comment: The proposal to add a new term Gestational alloimmune liver disease is approved as requested. Gestational alloimmune liver disease is initiated by maternal antibodies that attack fetal hepatocytes. The fetal immune response to the antibodies causes liver damage. Gestational alloimmune liver disease will be added as PT to primary HLT Hepatobiliary abnormalities congenital, secondary HLT Neonatal hepatobiliary disorders, to secondary HLT Hepatocellular damage and hepatitis NEC and to secondary HLT Hepatic autoimmune disorders.

CR Number: 2022216002 **Implementation Date:** 04-Aug-22 Related CR: 2022210005

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gestational alloimmune liver disease*	Approved as Requested	Proposed PT *Gestational alloimmune liver disease*	10088236
To HLT	*Hepatocellular damage and hepatitis NEC*		To HLT *Hepatocellular damage and hepatitis NEC*	10019833

MSSO Comment:

Supplemental Update Report

CR Number: 2022216003 **Implementation Date:** 04-Aug-22 Related CR: 2022210005

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gestational alloimmune liver disease*	Approved as Requested	Proposed PT	
To HLT	*Hepatic autoimmune disorders*		*Gestational alloimmune liver disease*	10088236
			To HLT	
			Hepatic autoimmune disorders	10003820

MSSO Comment:

CR Number: 2022210006 **Implementation Date:** 04-Aug-22 Related CR: 2022210006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Benign Macrocrania of Infancy (BMI)*	Approved Not as Requested	Proposed PT	
			Benign macrocrania of infancy	10088237
			HLT primary	
			Musculoskeletal and connective tissue disorders of skull congenital	10028382
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Hydrocephalic conditions	10020509
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new LLT Benign Macrocrania of Infancy (BMI) is approved but not as requested. Benign macrocrania of infancy is a clinical entity of relative frequency in the first years of life. While usually self-limited, it may lead to clinical complications that go beyond an increased head circumference, such as a higher incidence of subdural hematomas resulting from incidental, low-energy head trauma. The condition has been referred to by different names throughout the years, such as benign external hydrocephalus, idiopathic external hydrocephalus, and benign extra-axial collections of infancy. The requested term will be modified according to MedDRA capitalisation conventions and added without the accronym BMI as PT Benign macrocrania of infancy to primary HLT Musculoskeletal and connective tissue disorders of skull congenital and secondary HLT Hydrocephalic conditions.

Supplemental Update Report

CR Number: 2022210007 **Implementation Date:** 04-Aug-22 Related CR: 2022210007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cyst cerebellar*	Approved Not as Requested	Proposed PT *Cerebellar cyst*	10088238
			HLT primary *Nervous system cysts and polyps*	10068205
			SOC primary *Nervous system disorders*	10029205
			HLT secondary *Nervous system cysts and polyps*	10068205
			SOC secondary *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*	10029104

MSSO Comment: The proposal to add a new LLT Cyst cerebellar is approved but not as requested. Brain cysts, although they tend to be benign (non-cancerous), they are sometimes found in parts of the brain that control vital functions such as the cerebellum. The proposed term will be modified for natural word order and added as PT Cerebellar cyst and linked to HLT Nervous system cysts and polyps (bi-axial at HLGT level to primary SOC Nervous system disorders and to secondary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps)).

CR Number: 2022210009 **Implementation Date:** 04-Aug-22 Related CR: 2022210009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Immune related (medical Sign or symptom)*	Rejected		

MSSO Comment: The proposal to add a new term Immune related (medical Sign or symptom) is not approved. In relation with the comment on the lack of immune-related events in MedDRA, please take into account that MedDRA version 25.1 already contains 55 immune-mediated conditions specific for both organ system or type of disease. For the example given in the justification around a compound presenting with rheumatologic adverse events, existing terms like Immune-mediated arthritis, Immune-mediated synovitis, Immune-mediated myositis, or Immune-mediated necrotising myopathy could be considered. Furthermore, the broad PT Immune-mediated adverse reaction is also available for coding options of unspecific reports.

CR Number: 2022213001 **Implementation Date:** 04-Aug-22 Related CR: 2022213001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*WRIST FISTULA*	Rejected		

MSSO Comment: The proposal to add a new LLT WRIST FISTULA is not approved. Wrist fistula is ambiguous in meaning as most often used as indicating a cimino shunt - an arterio-venous fistula at the forearm or wrist as best choice for hemadialysis access and is probably not indicating a location of an percutaneous fistula.

Supplemental Update Report

CR Number: 2022213007 **Implementation Date:** 04-Aug-22 Related CR: 2022213007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Herbst appliance*	Approved Not as Requested	Proposed LLT		
			Orthodontic overbite appliance	10088240	Current
			To PT		
			Oral appliance	10085270	

MSSO Comment: The proposal to add a new term Herbst appliance is approved but not as requested. The proposed term is a trademark of one type of oral appliance. Oral appliances are form-fitting dental mouthpieces that help advance the position of your jaw, tongue and soft palate for various dental orthodontic purposes. The proposed concept will be modified and added as LLT Orthodontic overbite appliance under PT Oral appliance. In a related change, LLT Forsus springs appliance will as be added to PT Oral appliance.

CR Number: 2022216004 **Implementation Date:** 04-Aug-22 Related CR: 2022213007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Forsus springs appliance*	Approved as Requested	Proposed LLT		
To PT	*Oral appliance*		*Forsus springs appliance*	10088244	Current
			To PT		
			Oral appliance	10085270	

MSSO Comment:

Supplemental Update Report

CR Number: 2022213008 **Implementation Date:** 04-Aug-22 Related CR: 2022213008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Oligodontia*	Approved as Requested	Proposed PT	
			Oligodontia	10088239
			HLT primary	
			Dental disorders congenital	10044036
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Dental developmental disorders and anomalies	10012321
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Oligodontia is approved as requested. Oligodontia is a rare genetic disorder which represents the congenital absence of more than six teeth in primary, permanent or both dentitions. It is usually a part of a syndrome and seldom occurs as an isolated entity. Proposed term will be added as new PT Oligodontia under primary HLT Dental disorders congenital and secondary HLT Dental developmental disorders and anomalies. In a related change, the secondary HLT for PT Anodontia will be moved from HLT Tooth missing to HLT Dental developmental disorders and anomalies.

CR Number: 2022216005 **Implementation Date:** 04-Aug-22 Related CR: 2022213008

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anodontia*	Approved as Requested	Proposed PT	
			Anodontia	10002583
From HLT	*Tooth missing*		From HLT	
			Tooth missing	10044048
To HLT	*Dental developmental disorders and anomalies*		To HLT	
			Dental developmental disorders and anomalies	10012321

MSSO Comment:

Supplemental Update Report

CR Number: 2022213009 **Implementation Date:** 04-Aug-22 Related CR: 2022213009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Enamel pearl*	Approved as Requested	Proposed LLT *Enamel pearl*	10088245 Current
			To PT *Enameloma*	10088243

MSSO Comment: The proposal to add a new term Enamel pearl is approved as requested. Enamel pearls are one of a number of different enamel structures that can be found on the roots of deciduous and permanent teeth. Enamel pearls are a developmental anomaly of teeth, also known as enameloma, enamel droplets, enamel globules, enamel nodules, enamel knots and enamel exostoses. Enamel pearl will be added as an LLT to a new PT Enameloma, which will be added, in a related change, to a primary HLT Dental disorders congenital and to secondary HLT Dental developmental disorders and anomalies.

CR Number: 2022216006 **Implementation Date:** 04-Aug-22 Related CR: 2022213009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Enameloma*	Approved as Requested	Proposed PT *Enameloma*	10088243
HLT primary	*Dental disorders congenital*		HLT primary *Dental disorders congenital*	10044036
SOC primary	*Congenital, familial and genetic disorders*		SOC primary *Congenital, familial and genetic disorders*	10010331
			HLT secondary *Dental developmental disorders and anomalies*	10012321
			SOC secondary *Gastrointestinal disorders*	10017947

MSSO Comment:

Supplemental Update Report

CR Number: 2022213010 **Implementation Date:** 04-Aug-22 Related CR: 2022213010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Dens evaginatus*	Approved as Requested	Proposed LLT *Dens evaginatus* To PT *Tooth malformation hereditary*	10088242 Current 10044047

MSSO Comment: The proposal to add a new term Dens evaginatus is approved as requested. Dens evaginatus is a rare odontogenic developmental anomaly and is exhibited by protrusion of a tubercle from occlusal surfaces of posterior teeth, and lingual surfaces of anterior teeth. Dens evaginatus will be added as an LLT to PT Tooth malformation hereditary. In a related change, the recently added LLT Talon cusp will be moved from PT Tooth malformation to PT Tooth malformation hereditary for better alignment.

CR Number: 2022216007 **Implementation Date:** 04-Aug-22 Related CR: 2022213010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Talon cusp*	Approved as Requested	Proposed LLT *Talon cusp*	10088213 Current
From PT	*Tooth malformation*		From PT *Tooth malformation*	10044046
To PT	*Tooth malformation hereditary*		To PT *Tooth malformation hereditary*	10044047

MSSO Comment:

CR Number: 2022213011 **Implementation Date:** 04-Aug-22 Related CR: 2022213011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Dens invaginatus*	Approved as Requested	Proposed LLT *Dens invaginatus* To PT *Tooth malformation hereditary*	10088241 Current 10044047

MSSO Comment: The proposal to add a new term Dens invaginatus is approved as requested. Dens invaginatus is a developmental anomaly resulting from the invaginations of the enamel organ into the dental papilla during the soft tissue stage of development. These infolds represent stagnation sites for bacteria and can predispose to dental caries. Dens invaginatus will be added as an LLT to PT Tooth malformation hereditary.

Supplemental Update Report

CR Number: 2022213013 **Implementation Date:** 08-Aug-22 Related CR: 2022213013

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tooth gemination*	Approved as Requested	Proposed PT	
			Tooth gemination	10088263
			HLT primary	
			Dental developmental disorders and anomalies	10012321
			SOC primary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Tooth gemination is approved as requested. Gemination is an anomaly caused by a single tooth germ that attempted to divide during its development, resulting in a bifid crown. Proposed term will be added as new PT Tooth gemination under HLT Dental developmental disorders and anomalies.

CR Number: 2022213014 **Implementation Date:** 04-Aug-22 Related CR: 2022213014

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Temporal Puls Increased*	Approved Not as Requested	Proposed PT	
HLT primary	*Heart rate and pulse investigations*		*Temporal pulse increased*	10088249
SOC primary	*Investigations*		HLT primary	
			Heart rate and pulse investigations	10053103
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Temporal Puls Increased to primary HLT Heart rate and pulse investigations in SOC Investigations is approved but not as requested. Characteristics of the temporal artery pulse can signal disease process in the temporal artery. In fact, in temporal arteritis often the pulse through this artery cannot be felt at all or feeling a pulse through the temporal artery can signal a malformation in the blood vessel. Proposed term will be modified for MedDRA capitalization conventions and spelling and added as new PT Temporal pulse increased under HLT Heart rate and pulse investigations.

CR Number: 2022213015 **Implementation Date:** 04-Aug-22 Related CR: 2022213015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Shoulder Arthropathy*	Rejected		
To PT	*Arthropathy*			

MSSO Comment: The proposal to add a new LLT Shoulder Arthropathy to PT Arthropathy is not approved. Proposed concept term already exists as LLT Arthropathy, unspecified, involving shoulder region under PT Arthropathy.

Supplemental Update Report

CR Number: 2022213016 **Implementation Date:** 04-Aug-22 Related CR: 2022213016

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Postural drop*	Approved Not as Requested	Proposed LLT	
To PT	*Orthostatic hypotension*		*Postural blood pressure drop*	10088255 Current
			To PT	
			Orthostatic hypotension	10031127

MSSO Comment: The proposal to add a new LLT Postural drop to PT Orthostatic hypotension is approved but not as requested. Postural drop in blood pressure (postural hypotension) can occur because of loss of effective blood volume. Postural blood pressure drop modified for clarity will be added as an LLT to PT Orthostatic hypotension.

CR Number: 2022213017 **Implementation Date:** 04-Aug-22 Related CR: 2022213017

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Flare up irritable bowel syndrome*	Approved Not as Requested	Proposed LLT	
To PT	*Irritable bowel syndrome*		*Irritable bowel syndrome flare up*	10088259 Current
			To PT	
			Irritable bowel syndrome	10023003

MSSO Comment: The proposal to add a new LLT Flare up irritable bowel syndrome to PT Irritable bowel syndrome is approved but not as requested. In an irritable bowel syndrome flare-up you may experience more gut symptoms, such as stomach cramps, bloating, diarrhea, and constipation. The flare up may be caused by stress, anxiety, depression, and post-traumatic stress syndrome or eating “trigger” foods. Proposed term will be modified for better alignment and added as sub-concept LLT Irritable bowel syndrome flare up under PT Irritable bowel syndrome.

CR Number: 2022213018 **Implementation Date:** 04-Aug-22 Related CR: 2022213018

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Sensory Aura*	Approved Not as Requested	Proposed LLT	
To PT	*Aura*		*Sensory aura*	10088258 Current
			To PT	
			Aura	10003791

MSSO Comment: The proposal to add a new LLT Sensory Aura to PT Aura is approved but not as requested. The sensory aura is also common and typically follows the visual aura within minutes, although it may also occur without the visual aura. A sensory aura usually begins as a tingling in one limb or on one side of the face. Proposed term will be modified for MedDRA capitalization conventions and added as sub-concept LLT Sensory aura under PT Aura.

Supplemental Update Report

CR Number: 2022213019 **Implementation Date:** 04-Aug-22 Related CR: 2022213019

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Left Ventricular Mass Index*	Approved Not as Requested	Proposed PT	
HLT primary	*Cardiac function diagnostic procedures*		*Left ventricular mass index*	10088246
SOC primary	*Investigations*		HLT primary	
			Cardiac function diagnostic procedures	10007566
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Left Ventricular Mass Index to primary HLT Cardiac function diagnostic procedures in SOC Investigations is approved but not as requested. Left ventricular mass index is a parameter used in echocardiography and cardiac MRI, which is represented by the ratio left ventricular mass/body surface area and is an independent predictor of sudden cardiac death with an efficacy frequently beyond conventional cardiovascular risk factors. The proposed term will be modified according to MedDRA capitalization conventions and added as PT Left ventricular mass index to HLT Cardiac function diagnostic procedures.

CR Number: 2022213020 **Implementation Date:** 04-Aug-22 Related CR: 2022213020

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed PT	*Regenerative injection therapy*	Approved Not as Requested	Proposed LLT		
HLT primary	*Therapeutic procedures NEC*		*Regenerative injection therapy*	10088260	Current
SOC primary	*Surgical and medical procedures*		To PT		
			Orthobiologic treatment	10088250	

MSSO Comment: The proposal to add a new PT Regenerative injection therapy to primary HLT Therapeutic procedures NEC in SOC Surgical and medical procedures is approved but not as requested. Regenerative injection therapy involves the injection of a small volume of solution into multiple sites of painful ligament and tendon insertions and adjacent joint spaces, with the goal of reducing pain and ostensibly promoting tissue repair and growth. Regenerative injection therapy will be added as an LLT to a new PT Orthobiologic treatment which will be added, in a related change, and linked to HLT Therapeutic procedures NEC.

CR Number: 2022216009 **Implementation Date:** 04-Aug-22 Related CR: 2022213020

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Orthobiologic treatment*	Approved as Requested	Proposed PT	
HLT primary	*Therapeutic procedures NEC*		*Orthobiologic treatment*	10088250
SOC primary	*Surgical and medical procedures*		HLT primary	
			Therapeutic procedures NEC	10027700
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment:

Supplemental Update Report

CR Number: 2022213021 **Implementation Date:** 04-Aug-22 Related CR: 2022213021

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Electrocardiogram RR interval abnormal*	Approved as Requested	Proposed PT	
HLT primary	*ECG investigations*		*Electrocardiogram RR interval abnormal*	10088247
SOC primary	*Investigations*		HLT primary	
			ECG investigations	10053104
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Electrocardiogram RR interval abnormal to primary HLT ECG investigations in SOC Investigations is approved as requested. The RR interval, the time elapsed between two successive R waves of the QRS signal on the electrocardiogram and is a function of intrinsic properties of the sinus node as well as autonomic influences. The R-R interval is the same as the P-P interval in normal rhythms, and certain conduction abnormalities cause variations in the R-R interval.

CR Number: 2022213022 **Implementation Date:** 04-Aug-22 Related CR: 2022213022

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Electrocardiogram RR interval decreased*	Approved Not as Requested	Proposed PT	
HLT primary	*ECG investigations*		*Electrocardiogram RR interval shortened*	10088248
SOC primary	*Investigations*		HLT primary	
			ECG investigations	10053104
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Electrocardiogram RR interval decreased to primary HLT ECG investigations in SOC Investigations is approved but not as requested. The decreased variability of R-R intervals in patients with ischaemic heart disease has an important prognostic value. The predominance of the sympathetic over the depressed vagal activity signalizes an increased risk of sudden coronary death. The proposed term will be modified and added as PT Electrocardiogram RR interval shortened to HLT ECG investigations.

CR Number: 2022213023 **Implementation Date:** 04-Aug-22 Related CR: 2022213023

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*N-telopeptide serum abnormal*	Approved Not as Requested	Proposed LLT	
HLT primary	*Biochemical markers of bone metabolism*		*N-telopeptide serum abnormal*	10088262 Current
SOC primary	*Investigations*		To PT	
			N-telopeptide abnormal	10088251

MSSO Comment: The proposal to add a new PT N-telopeptide serum abnormal to primary HLT Biochemical markers of bone metabolism in SOC Investigations is approved but not as requested. N-telopeptide serum abnormal will be added as sub-concept LLT to a new PT N-telopeptide abnormal which will be added and linked to HLT Biochemical markers of bone metabolism. In related change, PT N-telopeptide urine abnormal will be demoted under the new PT N-telopeptide abnormal based on the MedDRA conventions that specimens are placed as LLTs to the specific test terms. N-telopeptides can be measured in blood and urine as bone turnover markers.

Supplemental Update Report

CR Number: 2022216010 **Implementation Date:** 04-Aug-22 Related CR: 2022213023

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*N-telopeptide abnormal*	Approved as Requested	Proposed PT	
HLT primary	*Biochemical markers of bone metabolism*		*N-telopeptide abnormal*	10088251
SOC primary	*Investigations*		HLT primary	
			Biochemical markers of bone metabolism	10067225
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022216011 **Implementation Date:** 04-Aug-22 Related CR: 2022213023

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*N-telopeptide urine abnormal*	Approved as Requested	PT to merge	
To PT	*N-telopeptide abnormal*		*N-telopeptide urine abnormal*	10053953 Current
			To PT	
			N-telopeptide abnormal	10088251

MSSO Comment:

CR Number: 2022213024 **Implementation Date:** 04-Aug-22 Related CR: 2022213024

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*N-telopeptide serum normal*	Approved Not as Requested	Proposed LLT	
HLT primary	*Biochemical markers of bone metabolism*		*N-telopeptide serum normal*	10088261 Current
SOC primary	*Investigations*		To PT	
			N-telopeptide normal	10088252

MSSO Comment: The proposal to add a new PT N-telopeptide serum normal to primary HLT Biochemical markers of bone metabolism in SOC Investigations is approved but not as requested. N-telopeptide serum normal will be added as sub-concept LLT to a new PT N-telopeptide normal which will added and linked to HLT Biochemical markers of bone metabolism. In related change, PT N-telopeptide urine normal will be demoted under the new PT N-telopeptide normal based on the MedDRA conventions that specimens are placed as LLTs to the specific test terms. N-telopeptides can be measured in blood and urine as bone turnover markers.

Supplemental Update Report

CR Number: 2022216012 **Implementation Date:** 04-Aug-22 Related CR: 2022213024

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*N-telopeptide normal*	Approved as Requested	Proposed PT	
HLT primary	*Biochemical markers of bone metabolism*		*N-telopeptide normal*	10088252
SOC primary	*Investigations*		HLT primary	
			Biochemical markers of bone metabolism	10067225
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022216013 **Implementation Date:** 04-Aug-22 Related CR: 2022213024

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*N-telopeptide urine normal*	Approved as Requested	PT to merge		
To PT	*N-telopeptide normal*		*N-telopeptide urine normal*	10053952	Current
			To PT		
			N-telopeptide normal	10088252	

MSSO Comment:

CR Number: 2022213025 **Implementation Date:** 04-Aug-22 Related CR: 2022213025

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed PT	*N-telopeptide serum increased*	Approved Not as Requested	Proposed LLT		
HLT primary	*Biochemical markers of bone metabolism*		*N-telopeptide serum increased*	10088256	Current
SOC primary	*Investigations*		To PT		
			N-telopeptide increased	10088254	

MSSO Comment: The proposal to add a new PT N-telopeptide serum increased to primary HLT Biochemical markers of bone metabolism in SOC Investigations is approved but not as requested. N-telopeptide serum increased will be added as sub-concept LLT to a new PT N-telopeptide increased which will be added and linked to HLT Biochemical markers of bone metabolism. In related change, PT N-telopeptide urine increased will be demoted under the new PT N-telopeptide increased based on the MedDRA conventions that specimens are placed as LLTs to the specific test terms. N-telopeptides can be measured in blood and urine as bone turnover markers. Furthermore, new PT N-telopeptide decreased will be added and linked to HLT Biochemical markers of bone metabolism and PT N-telopeptide urine decreased will be merged under new PT N-telopeptide decreased. In addition, PT N-telopeptide urine will be merged under PT N-telopeptide.

Supplemental Update Report

CR Number: 2022216014 **Implementation Date:** 04-Aug-22 Related CR: 2022213025

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*N-telopeptide increased*	Approved as Requested	Proposed PT	
HLT primary	*Biochemical markers of bone metabolism*		*N-telopeptide increased*	10088254
SOC primary	*Investigations*		HLT primary	
			Biochemical markers of bone metabolism	10067225
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022216015 **Implementation Date:** 04-Aug-22 Related CR: 2022213025

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*N-telopeptide urine increased*	Approved as Requested	PT to merge		
To PT	*N-telopeptide increased*		*N-telopeptide urine increased*	10053954	Current
			To PT		
			N-telopeptide increased	10088254	

MSSO Comment:

CR Number: 2022216016 **Implementation Date:** 04-Aug-22 Related CR: 2022213025

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*N-telopeptide decreased*	Approved as Requested	Proposed PT	
HLT primary	*Biochemical markers of bone metabolism*		*N-telopeptide decreased*	10088253
SOC primary	*Investigations*		HLT primary	
			Biochemical markers of bone metabolism	10067225
			SOC primary	
			Investigations	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2022216017 **Implementation Date:** 04-Aug-22 Related CR: 2022213025

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*N-telopeptide urine decreased*	Approved as Requested	PT to merge	
			N-telopeptide urine decreased	10053955 Current
To PT	*N-telopeptide decreased*		To PT	
			N-telopeptide decreased	10088253

MSSO Comment:

CR Number: 2022216018 **Implementation Date:** 04-Aug-22 Related CR: 2022213025

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*N-telopeptide urine*	Approved as Requested	PT to merge	
			N-telopeptide urine	10053951 Current
To PT	*N-telopeptide*		To PT	
			N-telopeptide	10066811

MSSO Comment:

CR Number: 2022213026 **Implementation Date:** 04-Aug-22 Related CR: 2022213026

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Abscess pilonidal*	Rejected		
From PT	*Pilonidal disease*			

MSSO Comment: The proposal to promote the LLT Abscess pilonidal from PT Pilonidal disease is not approved. Nearly all patients initially diagnosed with pilonidal disease have an acute abscess episode. The term pilonidal disease is defined as a chronic skin infection in the crease of the buttocks near the coccyx and may present in a multitude of ways. The existing LLT Abscess pilonidal is appropriately placed as a subconcept under the PT Pilonidal disease.

Supplemental Update Report

CR Number: 2022213027 **Implementation Date:** 04-Aug-22 Related CR: 2022213027

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Infra-Hisian Block*	Approved Not as Requested	Proposed LLT	
To PT	*Defect conduction intraventricular*		*Infra-Hisian block*	10088257 Current
			To PT	
			Atrioventricular block	10003671

MSSO Comment: The proposal to add a new LLT Infra-Hisian Block to PT Defect conduction intraventricular is approved but not as requested. Although Mobitz Type I AV blocks tend to be from supra-Hisian blocks with narrow QRS waves, whereas Type II AV blocks tend to be infra-Hisian with broader QRS, this is not a rigid rule and may be inverted. Infra-Hisian blocks are generally associated to a worse prognosis. The proposed term will be modified according to MedDRA capitalization conventions to Infra-Hisian block and added as an LLT to PT Atrioventricular block, where the related LLT Supra-Hisian AV block can be found.

CR Number: 2022214001 **Implementation Date:** 08-Aug-22 Related CR: 2022214001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Bile Acid Synthesis Disorders*	Approved Not as Requested	Proposed PT	
			Bile acid synthesis disorder	10088265
			HLT primary	
			Inborn errors of steroid synthesis	10021608
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Inborn errors of steroid synthesis	10021608
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to add a new term Bile Acid Synthesis Disorders is approved but not as requested. Bile acid synthesis disorders (BASDs) are a group of rare metabolic disorders characterized by defects in the creation (synthesis) of bile acids. Disorders of bile acid synthesis can be broadly classified as primary or secondary. The requested term will be modified according MedDRA capitalisation conventions and in singular form as PT Bile acid synthesis disorder to bi-axial HLT Inborn errors of steroid synthesis with primary SOC Congenital, familial and genetic disorders and secondary SOC Metabolism and nutrition disorders. PT Bile acid synthesis disorder will also be linked to HLT Cholestasis and jaundice. In a related change, PT Inborn error in primary bile acid synthesis will be merged as sub-concept LLT to new PT Bile acid synthesis disorder.

Supplemental Update Report

CR Number: 2022220003 **Implementation Date:** 08-Aug-22 Related CR: 2022214001

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Inborn error in primary bile acid synthesis*	Approved as Requested	PT to merge	
To PT	*Bile acid synthesis disorder*		*Inborn error in primary bile acid synthesis*	10070882 Current
			To PT	
			Bile acid synthesis disorder	10088265

MSSO Comment:

CR Number: 2022220004 **Implementation Date:** 08-Aug-22 Related CR: 2022214001

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Bile acid synthesis disorder*	Approved as Requested	Proposed PT	
To HLT	*Cholestasis and jaundice*		*Bile acid synthesis disorder*	10088265
			To HLT	
			Cholestasis and jaundice	10008636

MSSO Comment:

Supplemental Update Report

CR Number: 2022214002 **Implementation Date:** 08-Aug-22 Related CR: 2022214002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cerebrocostomandibular syndrome*	Approved as Requested	Proposed PT *Cerebrocostomandibular syndrome*	10088264
			HLT primary *Musculoskeletal disorders congenital NEC*	10029513
			SOC primary *Congenital, familial and genetic disorders*	10010331
			HLT secondary *Musculoskeletal disorders congenital NEC*	10029513
			SOC secondary *Musculoskeletal and connective tissue disorders*	10028395

MSSO Comment: The proposal to add a new term Cerebrocostomandibular syndrome is approved as requested. Cerebrocostomandibular syndrome (CCMS) is a disorder that involves a small chin (micrognathia), an opening in the roof of the mouth (cleft palate), a narrow chest, missing ribs, gaps between ribs, and breathing and feeding difficulties. Other common features include scoliosis, developmental delay or intellectual disability, and hearing loss. Cerebrocostomandibular syndrome will be added as PT to bi-axial HLT Musculoskeletal disorders congenital NEC with primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders. PT Cerebrocostomandibular syndrome will also be linked to secondary HLT Intellectual disabilities.

CR Number: 2022220002 **Implementation Date:** 08-Aug-22 Related CR: 2022214002

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cerebrocostomandibular syndrome*	Approved as Requested	Proposed PT *Cerebrocostomandibular syndrome*	10088264
To HLT	*Intellectual disabilities*		To HLT *Intellectual disabilities*	10077548

MSSO Comment:

Supplemental Update Report

CR Number: 2022214003 **Implementation Date:** 08-Aug-22 Related CR: 2022214003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Centronuclear myopathy*	Approved as Requested	Proposed LLT *Centronuclear myopathy* To PT *Congenital myopathy*	10088268 Current 10062547

MSSO Comment: The proposal to add a new term Centronuclear myopathy is approved as requested. Centronuclear myopathy is an inherited neuromuscular disorder characterised by clinical features of a congenital myopathy and centrally placed nuclei on muscle biopsy. The incidence of X-linked myotubular myopathy is estimated at 2/100000 male births but epidemiological data for other forms are not currently available. Centronuclear myopathy will be added as an LLT to PT Congenital myopathy.

CR Number: 2022214004 **Implementation Date:** 08-Aug-22 Related CR: 2022214004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Chronic Intestinal Pseudo-Obstruction*	Approved Not as Requested	Proposed LLT *Chronic intestinal pseudo-obstruction* To PT *Intestinal pseudo-obstruction*	10088266 Current 10022698

MSSO Comment: The proposal to add a new term Chronic Intestinal Pseudo-Obstruction is approved but not as requested. Intestinal pseudo-obstruction is a condition characterized by impairment of the muscle contractions that move food through the digestive tract. It can occur at any time of life, and its symptoms range from mild to severe. The condition may arise from abnormalities of the gastrointestinal muscles themselves (myogenic) or from problems with the nerves that control the muscle contractions (neurogenic). The condition can be episodic (acute) or persistent (chronic).The requested term will be modified according to MedDRA capitalisation conventions and added as LLT Chronic intestinal pseudo-obstruction to PT Intestinal pseudo-obstruction aligned with the acute sub-type LLT Ogilvie's syndrome.

CR Number: 2022214005 **Implementation Date:** 08-Aug-22 Related CR: 2022214005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Systemic primary carnitine deficiency*	Approved as Requested	Proposed LLT *Systemic primary carnitine deficiency* To PT *Congenital carnitine deficiency*	10088267 Current 10062698

MSSO Comment: The proposal to add a new term Systemic primary carnitine deficiency is approved as requested. Systemic primary carnitine deficiency is a rare metabolic disorder in which the body cannot properly process fats into energy. Carnitine functions to carry fatty acids obtained through diet to the energy centers in muscle cells (mitochondria). A deficiency of carnitine results in accumulation of fats in the liver, muscle, and heart. Systemic primary carnitine deficiency is a disorder of the carnitine cycle that results in defective fatty acid oxidation. Systemic primary carnitine deficiency will be added as sub-concept LLT to PT Congenital carnitine deficiency.

Supplemental Update Report

CR Number: 2022214006 **Implementation Date:** 08-Aug-22 Related CR: 2022214006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Vertebral hyperplasia*	Approved as Requested	Proposed LLT *Vertebral hyperplasia*	10088269 Current
			To PT *Bone hypertrophy*	10005973

MSSO Comment: The proposal to add a new term Vertebral hyperplasia is approved as requested. Bone hyperplasia is a disease caused by the pathological hyperplasia of bones, which will result in the moving obstacles of local joint, muscle and ligament, usually pain is its main symptom. This pathological hyperplasia can happen e.g. on cervical vertebra, or lumbar vertebra; Vertebral hyperplasia will be added as anatomical sub-concept LLT to PT Bone hypertrophy aligned with LLT Bone hyperplasia.

CR Number: 2022214007 **Implementation Date:** 08-Aug-22 Related CR: 2022214007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Folliculitis barbae*	Approved Not as Requested	Proposed LLT *Folliculitis barbae*	10088270
To PT	*Folliculitis*		To PT *Sycosis barbae*	10042731 Current

MSSO Comment: The proposal to add a new LLT Folliculitis barbae to PT Folliculitis is approved but not as requested. Folliculitis barbae is an itchy and sometimes tender papulopustular eruption of hair follicles in skin areas prone to shaving, such as the beard-line in men and is most often due to Staphylococcus aureus colonization of more superficial portions of the hair follicle. Folliculitis barbae will be added as an LLT to PT Sycosis barbae. In a related change, existing PT Sycosis barbae will be swapped with LLT Folliculitis barbae to have the broader concept at PT level. Sycosis barbae is deep-seated folliculitis barbae leading to scarring and areas of permanent hair loss.

CR Number: 2022220005 **Implementation Date:** 08-Aug-22 Related CR: 2022214007

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Sycosis barbae*	Approved as Requested	Proposed PT *Sycosis barbae*	10042731 Current
With LLT	*Folliculitis barbae*		With LLT *Folliculitis barbae*	10088270

MSSO Comment:

Supplemental Update Report

CR Number: 2022214008 **Implementation Date:** 08-Aug-22 Related CR: 2022214008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Prostatic artery embolization*	Approved as Requested	Proposed LLT *Prostatic artery embolization*	10088272 Current
			To PT *Prostatic artery embolisation*	10088271

MSSO Comment: The proposal to add a new LLT Prostatic artery embolization is approved as requested. Prostatic artery embolization is a minimally invasive treatment that helps improve lower urinary tract symptoms caused by a Benign Prostatic Hyperplasia. Prostatic artery embolization will be added as LLT to new PT Prostatic artery embolisation which will be added, in a related change, under HLT Prostatic therapeutic procedures.

CR Number: 2022220006 **Implementation Date:** 08-Aug-22 Related CR: 2022214008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Prostatic artery embolisation*	Approved as Requested	Proposed PT *Prostatic artery embolisation*	10088271
HLT primary	*Prostatic therapeutic procedures*		HLT primary *Prostatic therapeutic procedures*	10036967
SOC primary	*Surgical and medical procedures*		SOC primary *Surgical and medical procedures*	10042613

MSSO Comment:

CR Number: 2022214009 **Implementation Date:** 08-Aug-22 Related CR: 2022214009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Hemimandibulectomy*	Approved as Requested	Proposed LLT *Hemimandibulectomy*	10088273 Current
			To PT *Jaw operation*	10059242

MSSO Comment: The proposal to add a new term Hemimandibulectomy is approved as requested. Hemimandibulectomy is surgical removal of one lateral half of the mandible. Hemimandibulectomy will be added as a sub-concept LLT to PT Jaw operation consistent with placement of LLT Mandibulectomy.

Supplemental Update Report

CR Number: 2022214010 **Implementation Date:** 08-Aug-22 Related CR: 2022214010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tooth concrescence*	Approved as Requested	Proposed PT	
			Tooth concrescence	10088274
			HLT primary	
			Dental developmental disorders and anomalies	10012321
			SOC primary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Tooth concrescence is approved as requested. Concrescence is a condition of teeth where the cementum overlying the roots of at least two teeth join together due to developmental anomaly of dental hard tissues. Tooth concrescence will be added as a PT to HLT Dental developmental disorders and anomalies.

CR Number: 2022215001 **Implementation Date:** 08-Aug-22 Related CR: 2022215001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Nanoknife ablation*	Rejected		

MSSO Comment: The proposal to add a new term Nanoknife ablation is not approved. MedDRA refrains from adding trade names, as NanoKnife. The requested ablation technique can be specifically represented by current PT/LLT Irreversible electroporation

---

CR Number: 2022215002 **Implementation Date:** 08-Aug-22 Related CR: 2022215002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Combined large cell neuroendocrine carcinoma*	Approved as Requested	Proposed LLT	
			Combined large cell neuroendocrine carcinoma	10088277 Current
			To PT	
			Neuroendocrine tumour of the lung	10078174

MSSO Comment: The proposal to add a new term Combined large cell neuroendocrine carcinoma is approved as requested. Combined large cell neuroendocrine carcinoma (combined LCNEC) is a rare histological type of primary lung carcinoma that has components of adenocarcinoma, squamous cell carcinoma, giant cell carcinoma, and/or spindle cell carcinoma. Combined large cell neuroendocrine carcinoma will be added as an LLT to PT Neuroendocrine tumour of the lung.

Supplemental Update Report

CR Number: 2022215003 **Implementation Date:** 08-Aug-22 Related CR: 2022215003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Neuroischemic diabetic foot*	Approved as Requested	Proposed LLT *Neuroischemic diabetic foot* To PT *Diabetic foot*	10088279 Current 10060734

MSSO Comment: The proposal to add a new term Neuroischemic diabetic foot is approved as requested. The neuroischaemic foot is a cool, pulseless foot; the skin is thin, shiny, and without hair. There is also atrophy of the subcutaneous tissue, and intermittent claudication and rest pain may be absent because of neuropathy. Neuroischemic diabetic foot will be added as an LLT to PT Diabetic foot. In a related change, its counterpart British spelling Neuroischaemic diabetic foot will also be added to PT Diabetic foot.

CR Number: 2022220007 **Implementation Date:** 08-Aug-22 Related CR: 2022215003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Neuroischaemic diabetic foot*	Approved as Requested	Proposed LLT *Neuroischaemic diabetic foot* To PT *Diabetic foot*	10088280 Current 10060734
To PT	*Diabetic foot*			

MSSO Comment:

CR Number: 2022215004 **Implementation Date:** 08-Aug-22 Related CR: 2022215004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Enterobiotic sbo*	Approved Not as Requested	Proposed LLT *Enterobiotic soil based organism therapy* To PT *Probiotic therapy*	10088276 Current 10068048

MSSO Comment: The proposal to add a new term Enterobiotic sbo is approved but not as requested. The term soil-based organism (SBO) encompasses over 100 highly diverse species of bacteria (and other life forms) naturally found in soil. Before the introduction of industrialization and modern farming, we had regular, daily contact with these bacteria. In recent years, some soil-based organisms have been isolated and adapted for use as probiotics. The proposed term will be modified for clarification to Enterobiotic soil based organism therapy and added as LLT to PT Probiotic therapy.

Supplemental Update Report

CR Number: 2022215005 **Implementation Date:** 08-Aug-22 Related CR: 2022215005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Camurati-Engelmann disease*	Approved as Requested	Proposed LLT		
			Camurati-Engelmann disease	10088278	Current
			To PT		
			Progressive diaphyseal dysplasia	10087147	

MSSO Comment: The proposal to add a new term Camurati-Engelmann disease is approved as requested. Camurati-Engelmann disease is a rare entity due to mutations in the gene encoding the TGF-β. It is characterised by hyperostosis of long bones and skull, accompanied by severe bone pain, and occasionally muscular weakness and a waddling gait. Camurati-Engelmann disease will be added as a synonym LLT to PT Progressive diaphyseal dysplasia.

CR Number: 2022215006 **Implementation Date:** 08-Aug-22 Related CR: 2022215006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Inspire Implant*	Approved Not as Requested	Proposed PT	
			Sleep apnoea device implant	10088275
			HLT primary	
			Respiratory tract therapeutic procedures NEC	10052727
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Inspire Implant is approved but not as requested. MedDRA refrains from adding trade names, as Inspire implant. However, the descriptive concept Sleep apnoea device implant will be added as PT to HLT Respiratory tract therapeutic procedures NEC. In a related change, PT Hypoglossal nerve stimulation will be merged under the new PT Sleep apnoea device implant. Furthermore, the American English spelled counterpart Sleep apnea device implant will also be added as an LLT to PT Sleep apnoea device implant.

CR Number: 2022220008 **Implementation Date:** 08-Aug-22 Related CR: 2022215006

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*Hypoglossal nerve stimulation*	Approved as Requested	PT to merge		
To PT	*Sleep apnoea device implant*		*Hypoglossal nerve stimulation*	10087032	Current
			To PT		
			Sleep apnoea device implant	10088275	

MSSO Comment:

Supplemental Update Report

CR Number: 2022220009 **Implementation Date:** 08-Aug-22 Related CR: 2022215006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Sleep apnea device implant*	Approved as Requested	Proposed LLT	
To PT	*Sleep apnoea device implant*		*Sleep apnea device implant*	10088281 Current
			To PT	
			Sleep apnoea device implant	10088275

MSSO Comment:

CR Number: 2022215007 **Implementation Date:** 09-Aug-22 Related CR: 2022215007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Eye bayoneting*	Approved Not as Requested	Proposed LLT	
			Retinal vessel bayoneting	10088298 Current
			To PT	
			Retinal vascular disorder	10038901

MSSO Comment: The proposal to add a new term Eye bayoneting is approved but not as requested. In severe glaucoma, retinal vessels may disappear as they make a sharp turn into the optic cup, a finding termed as "bayoneting" of the vessels. Eye bayoneting will modified for clarity and added as LLT Retinal vessel bayoneting to PT Retinal vascular disorder. In a related change, the following LLTs will be moved from PT Retinopathy to PT Retinal vascular disorder for better alignment: LLT Retinal arteriovenous nicking, LLT Retinal arterial nipping, LLT Retinal AV nipping and LLT Varying retinal vessel calibre.

CR Number: 2022221004 **Implementation Date:** 09-Aug-22 Related CR: 2022215007

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Retinal arteriovenous nicking*	Approved as Requested	Proposed LLT	
From PT	*Retinopathy*		*Retinal arteriovenous nicking*	10058007 Current
To PT	*Retinal vascular disorder*		From PT	
			Retinopathy	10038923
			To PT	
			Retinal vascular disorder	10038901

MSSO Comment:

Supplemental Update Report

CR Number: 2022221005 **Implementation Date:** 09-Aug-22 Related CR: 2022215007

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Retinal arterial nipping*	Approved as Requested	Proposed LLT		
From PT	*Retinopathy*		*Retinal arterial nipping*	10038823	Current
To PT	*Retinal vascular disorder*		From PT		
			Retinopathy	10038923	
			To PT		
			Retinal vascular disorder	10038901	

MSSO Comment:

CR Number: 2022221006 **Implementation Date:** 09-Aug-22 Related CR: 2022215007

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Retinal AV nipping*	Approved as Requested	Proposed LLT		
From PT	*Retinopathy*		*Retinal AV nipping*	10038833	Current
To PT	*Retinal vascular disorder*		From PT		
			Retinopathy	10038923	
			To PT		
			Retinal vascular disorder	10038901	

MSSO Comment:

CR Number: 2022221007 **Implementation Date:** 09-Aug-22 Related CR: 2022215007

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Varying retinal vessel calibre*	Approved as Requested	Proposed LLT		
From PT	*Retinopathy*		*Varying retinal vessel calibre*	10047035	Current
To PT	*Retinal vascular disorder*		From PT		
			Retinopathy	10038923	
			To PT		
			Retinal vascular disorder	10038901	

MSSO Comment:

Supplemental Update Report

CR Number: 2022215008 **Implementation Date:** 09-Aug-22 Related CR: 2022215008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Bayonet deformity wrist*	Approved as Requested	Proposed LLT *Bayonet deformity wrist* To PT *Wrist deformity*	10088301 Current 10061415

MSSO Comment: The proposal to add a new term Bayonet deformity wrist is approved as requested. A bayonet deformity of the wrist occurs as the result of a malunited distal radial fracture, usually a Colles fracture. Bayonet deformity wrist will be added as an LLT to PT Wrist deformity.

CR Number: 2022215009 **Implementation Date:** 09-Aug-22 Related CR: 2022215009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Bayonet sign*	Approved Not as Requested	Proposed LLT *Oesophageal bayonet sign* To PT *Oesophageal compression*	10088302 Current 10074074

MSSO Comment: The proposal to add a new term Bayonet sign is approved but not as requested. The "Bayonet sign" on esophagography describes the deformity of the barium-filled thoracic esophagus produced by an aberrant right subclavian artery. The requested term will be modified for clarity and added as LLT Oesophageal bayonet sign to PT Oesophageal compression. In a related change, the American spelled counterpart Esophageal bayonet sign will be added as an LLT to PT Oesophageal compression.

CR Number: 2022221008 **Implementation Date:** 09-Aug-22 Related CR: 2022215009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT To PT	*Esophageal bayonet* *Oesophageal compression*	Approved as Requested	Proposed LLT *Esophageal bayonet* To PT *Oesophageal compression*	 10088306 10074074

MSSO Comment:

Supplemental Update Report

CR Number: 2022215010 **Implementation Date:** 09-Aug-22 Related CR: 2022215010

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Lipogram*	Approved as Requested	Proposed LLT	
		Lipogram	10088303 Current
		To PT	
		Lipids	10024587

MSSO Comment: The proposal to add a new term Lipogram is approved as requested. A lipogram measures the total cholesterol, lipid carrying proteins and triglycerides in the blood. Lipogram will be added as an LLT to PT Lipids.

CR Number: 2022215011 **Implementation Date:** 09-Aug-22 Related CR: 2022215011

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Myopic tilted disc*	Approved Not as Requested	Proposed LLT	
		Myopic tilted optic disc	10088299 Current
		To PT	
		Myopic disc	10069088

MSSO Comment: The proposal to add a new term Myopic tilted disc is approved but not as requested. Tilted optic discs often arise due to acquired changes related to the progression of myopia. The proposed term will be rephrased to provide greater clarity and will be added as LLT Myopic tilted optic disc under PT Myopic disc.

CR Number: 2022215012 **Implementation Date:** 09-Aug-22 Related CR: 2022215012

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Tibial eminence fracture*	Approved as Requested	Proposed LLT	
		Tibial eminence fracture	10088297 Current
		To PT	
		Tibia fracture	10043827

MSSO Comment: The proposal to add a new term Tibial eminence fracture is approved as requested. Tibial eminence fractures (sometimes referred to as tibial spine fractures) occur most commonly in the pediatric population and are considered to be an anterior cruciate ligament (ACL) equivalent injury in children. In regards to the anatomy, the tibial eminence is non-articular and is located between condylar surfaces of tibial plateaus. Tibial eminence fracture will be added as an LLT under PT Tibia fracture.

Supplemental Update Report

CR Number: 2022215013 **Implementation Date:** 09-Aug-22 Related CR: 2022215013

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Tibial spine fracture*	Approved as Requested	Proposed LLT *Tibial spine fracture*	10088304 Current
		To PT *Tibia fracture*	10043827

MSSO Comment: The proposal to add a new term Tibial spine fracture is approved as requested. Tibial spine fractures (also referred to as tibial eminence fractures) occur most commonly in the pediatric population and are considered to be an anterior cruciate ligament (ACL) equivalent injury in children. In regards to the anatomy, the tibial spine is non-articular and is located between condylar surfaces of tibial plateaus. Tibial spine fracture will be added as an LLT under PT Tibia fracture.

CR Number: 2022215014 **Implementation Date:** 09-Aug-22 Related CR: 2022215014

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Viscogonioplasty*	Approved as Requested	Proposed LLT *Viscogonioplasty*	10088300 Current
		To PT *Viscocanalostomy*	10077985 Current

MSSO Comment: The proposal to add a new term Viscogonioplasty is approved as requested. Viscogonioplasty uses an injection of viscoelastics instead of a surgical instrument to break the peripheral anterior synechiae and open the angle in glaucoma. Viscogonioplasty will be added as LLT under the existing PT Viscocanalostomy.

CR Number: 2022215015 **Implementation Date:** 09-Aug-22 Related CR: 2022215015

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Collarettes*	Rejected		

MSSO Comment: The proposal to add a new term Collarettes is not approved. Collarettes is an ambiguous term as it is a descriptor which may refer to different pathologies such as skin, iris.

Supplemental Update Report

CR Number: 2022215016 **Implementation Date:** 09-Aug-22 Related CR: 2022215016

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Nasalization of vessels*	Approved Not as Requested	Proposed LLT *Retinal vessel trunk nasalization* To PT *Retinal vascular disorder*	10088296 Current 10038901

MSSO Comment: The proposal to add a new term Nasalization of vessels is approved but not as requested. In progressive glaucoma, retinal blood vessels can shift nasally; this is attributed to deterioration of adjacent nerve fiber tissue. The requested term will be renamed for clarity and added as LLT Retinal vessel trunk nasalization to PT Retinal vascular disorder. In a related change, the British English spelled counterpart Retinal vessel trunk nasalisation will also be added as LLT to PT Retinal vascular disorder.

CR Number: 2022221009 **Implementation Date:** 09-Aug-22 Related CR: 2022215016

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Retinal vessel trunk nasalisation*	Approved as Requested	Proposed LLT *Retinal vessel trunk nasalisation* To PT *Retinal vascular disorder*	10088305 Current 10038901
To PT	*Retinal vascular disorder*			

MSSO Comment:

CR Number: 2022215017 **Implementation Date:** 08-Aug-22 Related CR: 2022215017

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Thoracic mass*	Rejected		

MSSO Comment: The proposal to add a new LLT Thoracic mass is not approved. “Mass” is an imprecise word, and terms containing this word will generally not be added into MedDRA when a more precise “disorder” terms exist. If the nature of the mass is not known, then the corresponding “disorder” or “disease” term can be used for coding. A “mass” term will only be added into MedDRA, if it represents an internationally recognized distinct and robust medical concept.

Supplemental Update Report

CR Number: 2022215018 **Implementation Date:** 08-Aug-22 Related CR: 2022215018

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Solitary Lung nodule*	Rejected		

MSSO Comment: The proposal to add a new LLT Solitary Lung nodule is not approved. As per the Introductory Guide MedDRA Version 25.0, in general, new terms containing “nodule” are not added to MedDRA, except when a nodule represents a full diagnostic expression, such as PT Milker's nodules.

CR Number: 2022215019 **Implementation Date:** 08-Aug-22 Related CR: 2022215019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Multiple lung nodules*	Rejected		

MSSO Comment: The proposal to add a new LLT Multiple lung nodules is not approved. As per the Introductory Guide MedDRA Version 25.0, in general, new terms containing “nodule” are not added to MedDRA, except when a nodule represents a full diagnostic expression, such as PT Milker's nodules.

CR Number: 2022215020 **Implementation Date:** 08-Aug-22 Related CR: 2022215020

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Exercise stress echocardiogram*	Approved as Requested	Proposed LLT *Exercise stress echocardiogram* To PT *Stress echocardiogram*	 10088282 Current 10050241

MSSO Comment: The proposal to add a new LLT Exercise stress echocardiogram is approved as requested. An exercise stress echocardiogram assesses heart function when beating fast. Stress on the heart is created by exercising on a treadmill or bicycle. This test is also commonly called stress echocardiogram or echocardiogram stress test. Proposed term will be added as sub-concept LLT Exercise stress echocardiogram under PT Stress echocardiogram.

Supplemental Update Report

CR Number: 2022215021 **Implementation Date:** 08-Aug-22 Related CR: 2022215021

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Pharmacological stress echocardiogram*	Approved as Requested	Proposed LLT *Pharmacological stress echocardiogram* To PT *Stress echocardiogram*	10088283 10050241	Current

MSSO Comment: The proposal to add a new LLT Pharmacological stress echocardiogram is approved as requested. In a pharmacological stress echocardiogram medications, including dobutamine and vasodilators, are used instead of exercise to produce stress. Dobutamine increases the heart rate and vasodilators expand the blood vessels, which increases blood flow through the heart. Proposed term will be added as LLT Pharmacological stress echocardiogram under PT Stress echocardiogram.

CR Number: 2022215022 **Implementation Date:** 08-Aug-22 Related CR: 2022215022

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Exercise stress echocardiogram normal*	Approved as Requested	Proposed LLT *Exercise stress echocardiogram normal* To PT *Stress echocardiogram normal*	10088284 10070745	Current

MSSO Comment: The proposal to add a new LLT Exercise stress echocardiogram normal is approved as requested. An exercise stress echocardiogram assesses heart function when beating fast. Stress on the heart is created by exercising on a treadmill or bicycle. This test is also commonly called stress echocardiogram or echocardiogram stress test. Proposed term will be added as the normal finding of this test as LLT Exercise stress echocardiogram normal under PT Stress echocardiogram normal.

CR Number: 2022215023 **Implementation Date:** 08-Aug-22 Related CR: 2022215023

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Exercise stress echocardiogram abnormal*	Approved as Requested	Proposed LLT *Exercise stress echocardiogram abnormal* To PT *Stress echocardiogram abnormal*	10088286 10070746	Current

MSSO Comment: The proposal to add a new LLT Exercise stress echocardiogram abnormal is approved as requested. An exercise stress echocardiogram assesses heart function when beating fast. Stress on the heart is created by exercising on a treadmill or bicycle. This test is also commonly called stress echocardiogram or echocardiogram stress test. Proposed term will be added as the abnormal finding of this test as LLT Exercise stress echocardiogram abnormal under PT Stress echocardiogram abnormal.

Supplemental Update Report

CR Number: 2022215024 **Implementation Date:** 08-Aug-22 Related CR: 2022215024

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pharmacological stress echocardiogram normal*	Approved as Requested	Proposed LLT	
			Pharmacological stress echocardiogram normal	10088287 Current
			To PT	
			Stress echocardiogram normal	10070745

MSSO Comment: The proposal to add a new LLT Pharmacological stress echocardiogram normal is approved as requested. In a pharmacological stress echocardiogram the test uses medications, including dobutamine and vasodilators, instead of exercise to produce stress. Dobutamine increases the heart rate and vasodilators expand the blood vessels, which increases blood flow through the heart. Proposed term will be added as LLT Pharmacological stress echocardiogram normal under PT Stress echocardiogram normal.

CR Number: 2022215025 **Implementation Date:** 08-Aug-22 Related CR: 2022215025

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pharmacological stress echocardiogram abnormal*	Approved as Requested	Proposed LLT	
			Pharmacological stress echocardiogram abnormal	10088285 Current
			To PT	
			Stress echocardiogram abnormal	10070746

MSSO Comment: The proposal to add a new LLT Pharmacological stress echocardiogram abnormal is approved as requested. In a pharmacological stress echocardiogram the test uses medications, including dobutamine and vasodilators, instead of exercise to produce stress. Dobutamine increases the heart rate. Vasodilators expand the blood vessels, which increases blood flow through the heart. Proposed term will be added as the abnormal finding of this test as LLT Pharmacological stress echocardiogram abnormal under PT Stress echocardiogram abnormal.

CR Number: 2022215026 **Implementation Date:** 08-Aug-22 Related CR: 2022215026

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Six minutes walk test*	Approved Not as Requested	Proposed LLT	
			Six minute walk test	10088288 Current
			To PT	
			Cardiopulmonary exercise test	10074357

MSSO Comment: The proposal to add a new LLT Six minutes walk test is approved but not as requested. The 6 Minute Walk Test is a sub-maximal exercise test used to assess aerobic capacity and endurance. The distance covered over a time of 6 minutes is used as the outcome by which to compare changes in performance capacity. The test was initially designed to help in the assessment of patients with cardiopulmonary issues. Six minutes walk test will be rephrased to Six minute walk test and added as sub-concept LLT to PT Cardiopulmonary exercise test.

Supplemental Update Report

CR Number: 2022215027 **Implementation Date:** 08-Aug-22 Related CR: 2022215027

Change Requested		Final Disposition	Final Placement	MedDRA Code #	
Add a New LLT					
Proposed LLT	*Six minutes walk test normal*	Approved Not as Requested	Proposed LLT		
			Six minute walk test normal	10088289	Current
			To PT		
			Cardiopulmonary exercise test normal	10074358	

MSSO Comment: The proposal to add a new LLT Six minutes walk test normal is approved but not as requested. The 6 Minute Walk Test is a sub-maximal exercise test used to assess aerobic capacity and endurance. The distance covered over a time of 6 minutes is used as the outcome by which to compare changes in performance capacity. The test was initially designed to help in the assessment of patient with cardiopulmonary issues. Six minutes walk test normal will be rephrased to Six minute walk test normal and added as sub-concept LLT to PT Cardiopulmonary exercise test normal.

CR Number: 2022215028 **Implementation Date:** 08-Aug-22 Related CR: 2022215028

Change Requested		Final Disposition	Final Placement	MedDRA Code #	
Add a New LLT					
Proposed LLT	*Six minutes walk test abnormal*	Approved Not as Requested	Proposed LLT		
			Six minute walk test abnormal	10088290	Current
			To PT		
			Cardiopulmonary exercise test abnormal	10074359	

MSSO Comment: The proposal to add a new LLT Six minutes walk test abnormal is approved but not as requested. The 6 Minute Walk Test is a sub-maximal exercise test used to assess aerobic capacity and endurance. The distance covered over a time of 6 minutes is used as the outcome by which to compare changes in performance capacity. The test was initially designed to help in the assessment of patient with cardiopulmonary issues. Six minutes walk test abnormal will be rephrased to Six minute walk test abnormal and added as sub-concept LLT to PT Cardiopulmonary exercise test abnormal.

CR Number: 2022215029 **Implementation Date:** 09-Aug-22 Related CR: 2022215029

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*More than prescribed dose consumed*	Rejected After Suspension		

MSSO Comment: The proposal to add a new LLT More than prescribed dose consumed is not approved after suspension. Proposed concept may be represented by existing LLT Intentional dose increase under PT Intentional product use issue.

Supplemental Update Report

CR Number: 2022215030 **Implementation Date:** 08-Aug-22 Related CR: 2022215030

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Cardiac device implantation*	Approved Not as Requested	Proposed PT	
			Cardiac device implantation	10088292
			HLT primary	
			Cardiac device therapeutic procedures	10007600
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Cardiac device implantation is approved but not as requested. Cardiac device implantation will be added as PT to HLT Cardiac device therapeutic procedures to provide a broad term for cardiac devices if no specific type is reported.

CR Number: 2022215031 **Implementation Date:** 08-Aug-22 Related CR: 2022215031

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Cardiac device replacement*	Approved Not as Requested	Proposed PT	
			Cardiac device replacement	10088293
			HLT primary	
			Cardiac device therapeutic procedures	10007600
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Cardiac device replacement is approved but not as requested. Cardiac device replacement will be added as PT to HLT Cardiac device therapeutic procedures to provide a broad term for cardiac devices if no specific type is reported.

CR Number: 2022215032 **Implementation Date:** 08-Aug-22 Related CR: 2022215032

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Watchman device placement*	Rejected		

MSSO Comment: The proposal to add a new LLT Watchman device placement is not approved. Watchman device is a trade name and therefore out of MedDRA scope. However the concept may be represented by existing PT Left atrial appendage closure implant.

Supplemental Update Report

CR Number: 2022215033 **Implementation Date:** 08-Aug-22 Related CR: 2022215033

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Head swelling NOS*	Rejected		

MSSO Comment: The proposal to add a new LLT Head swelling NOS is not approved. At the direction of the MedDRA Management Committee, as of MedDRA Version 6.1, no additional “NOS” terms will be accepted into the terminology. Furthermore, head swelling without specific anatomical detail is ambiguous as it may refer to brain edema or external swelling of the head.

CR Number: 2022215034 **Implementation Date:** 08-Aug-22 Related CR: 2022215034

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Nucleic acid amplification test positive*	Approved as Requested	Proposed LLT	
			Nucleic acid amplification test positive	10088294 Current
			To PT	
			Nucleic acid test positive	10088291

MSSO Comment: The proposal to add a new LLT Nucleic acid amplification test positive is approved as requested. Since the amount of a certain genetic material is usually very small, many Nucleic acid tests (NATs), include a step that amplifies the genetic material—that is, makes many copies of it. Such NATs are called nucleic acid amplification tests (NAATs). There are several ways of amplification, including polymerase chain reaction (PCR), strand displacement assay (SDA), or transcription mediated assay (TMA). Nucleic acid amplification test positive will be added as LLT to a new PT Nucleic acid test positive, which will be linked, in a related change, to HLT Microbiology and serology tests NEC.

CR Number: 2022220010 **Implementation Date:** 08-Aug-22 Related CR: 2022215034

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nucleic acid test positive*	Approved as Requested	Proposed PT	
HLT primary	*Microbiology and serology tests NEC*		*Nucleic acid test positive*	10088291
SOC primary	*Investigations*		HLT primary	
			Microbiology and serology tests NEC	10027530
			SOC primary	
			Investigations	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2022215035 **Implementation Date:** 08-Aug-22 Related CR: 2022215035

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vital signs unstable*	Rejected		

MSSO Comment: The proposal to add a new LLT Vital signs unstable is not approved. The proposed term has a very broad and imprecise connotation and thus is best represented by specific terms as related to case scenario.

CR Number: 2022215043 **Implementation Date:** 09-Aug-22 Related CR: 2022215043

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Calcifying odontogenic cyst*	Approved as Requested	Proposed LLT	
			Calcifying odontogenic cyst	10088307 Current
			To PT	
			Odontogenic cyst	10063413

MSSO Comment: The proposal to add a new term Calcifying odontogenic cyst is approved as requested. The calcifying odontogenic cyst is a rare developmental odontogenic cyst with notable presence of histopathological features which include a cystic lining demonstrating characteristic “Ghost” epithelial cells with a propensity to calcify. Proposed term will be added as subconcept LLT Calcifying odontogenic cyst under PT Odontogenic cyst.

CR Number: 2022215044 **Implementation Date:** 10-Aug-22 Related CR: 2022215044

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tooth fusion*	Approved as Requested	Proposed PT	
			Tooth fusion	10088308
			HLT primary	
			Dental developmental disorders and anomalies	10012321
			SOC primary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Tooth fusion is approved as requested. Tooth fusion is what happens when two separate tooth buds grow together and form into one tooth that is literally fused together. On some occasions, two independent pulp chambers and root canals can be seen. Proposed term will be added as new PT Tooth fusion under HLT Dental developmental disorders and anomalies.

Supplemental Update Report

CR Number: 2022215045 **Implementation Date:** 10-Aug-22 Related CR: 2022215045

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ameloblastic fibrosarcoma*	Approved as Requested	Proposed PT	
			Ameloblastic fibrosarcoma	10088309
			HLT primary	
			Fibrosarcomas malignant	10016634
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Malignant oral cavity neoplasms	10026660
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Ameloblastic fibrosarcoma is approved as requested. Ameloblastic fibrosarcoma is a rare, aggressive malignant odontogenic tumor. It is defined by the World Health Organization as a neoplasm with similar structure to ameloblastic fibroma, but in which the ectomesenchyme has the characteristics of a sarcoma. In >50% reported cases of ameloblastic fibroma, malignant transformation is observed. Ameloblastic fibrosarcoma will be added as a PT with a primary link to HLT Fibrosarcomas malignant and a secondary link to HLT Malignant oral cavity neoplasms.

CR Number: 2022215046 **Implementation Date:** 10-Aug-22 Related CR: 2022215046

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Myofunctional therapy*	Approved as Requested	Proposed PT	
			Myofunctional therapy	10088310
			HLT primary	
			Muscle therapeutic procedures	10028321
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Myofunctional therapy is approved as requested. Myofunctional therapy is an exercise training program for the muscles around face, mouth, and tongue, which are designed to improve issues with talking, eating, or breathing. Myofunctional therapy will be added as PT to HLT Muscle therapeutic procedures.

Supplemental Update Report

CR Number: 2022216008 **Implementation Date:** 10-Aug-22 Related CR: 2022216008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Faltering growth*	Approved as Requested	Proposed LLT	
To PT	*Failure to thrive*		*Faltering growth*	10088311 Current
			To PT	
			Failure to thrive	10016165

MSSO Comment: The proposal to add a new LLT Faltering growth to PT Failure to thrive is approved as requested. The term faltering growth is synonymously used with failure to thrive and refers to a slower rate of weight gain in childhood than expected for age and sex.

CR Number: 2022216019 **Implementation Date:** 10-Aug-22 Related CR: 2022216019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Phlyctenae*	Approved Not as Requested	Proposed LLT	
			Phlyctena	10088312 Current
			To PT	
			Blister	10005191

MSSO Comment: The proposal to add a new LLT Phlyctenae is approved but not as requested. The requested term will be added in singular form as LLT Phlyctena; a small blister, vesicle, or pustule to PT Blister.

CR Number: 2022216020 **Implementation Date:** 10-Aug-22 Related CR: 2022216020

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*EOSINOPHILIC ESOPHAGITIS FLARE*	Approved Not as Requested	Proposed LLT	
			Eosinophilic oesophagitis flare	10088313 Current
			To PT	
			Eosinophilic oesophagitis	10064212

MSSO Comment: The proposal to add a new PT EOSINOPHILIC ESOPHAGITIS FLARE is approved but not as requested. Eosinophilic esophagitis (EoE) is an allergic inflammatory condition of the esophagus that involves eosinophils. The long-term prognosis for patients with EoE is unknown. Some patients may follow a “waxing and waning” course characterized by symptomatic episodes followed by periods of remission. The requested term will be modified according to MedDRA capitalisation conventions and added as LLT Eosinophilic oesophagitis flare to PT Eosinophilic oesophagitis. In a related change the American English LLT Eosinophilic esophagitis flare will also be added to PT Eosinophilic oesophagitis.

Supplemental Update Report

CR Number: 2022222005 **Implementation Date:** 10-Aug-22 Related CR: 2022216020

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Eosinophilic esophagitis flare*	Approved as Requested	Proposed LLT	
To PT	*Eosinophilic oesophagitis*		*Eosinophilic esophagitis flare*	10088314 Current
			To PT	
			Eosinophilic oesophagitis	10064212

MSSO Comment:

CR Number: 2022216021 **Implementation Date:** 10-Aug-22 Related CR: 2022216021

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Periapical disease*	Approved as Requested	Proposed PT	
			Periapical disease	10088315
			HLT primary	
			Dental disorders NEC	10044037
			SOC primary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Periapical disease is approved as requested. Periapical disease refers to pathology around the apex of a tooth root. Periapical disease will be added as PT to HLT Dental disorders NEC.

CR Number: 2022217001 **Implementation Date:** 10-Aug-22 Related CR: 2022217001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cache Valley virus infection*	Approved as Requested	Proposed PT	
HLT primary	*Arboviral infections NEC*		*Cache Valley virus infection*	10088316
SOC primary	*Infections and infestations*		HLT primary	
			Arboviral infections NEC	10057198
			SOC primary	
			Infections and infestations	10021881

MSSO Comment: The proposal to add a new PT Cache Valley virus infection to primary HLT Arboviral infections NEC in SOC Infections and infestations is approved as requested. Cache Valley virus is spread to people by infected mosquitoes and can cause an illness with fever or more severe disease, including encephalitis, meningitis and myelitis.

Supplemental Update Report

CR Number: 2022217002 **Implementation Date:** 10-Aug-22 Related CR: 2022217002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Abdominal Epilepsy*	Approved Not as Requested	Proposed LLT	
			Abdominal epilepsy	10088319 Current
			To PT	
			Autonomic seizure	10049612

MSSO Comment: The proposal to add a new term Abdominal Epilepsy is approved but not as requested. Abdominal epilepsy is a rare condition, most frequently found in children but reported in adults as well, consisting of gastrointestinal disturbances caused by epileptiform seizure activity. It often presents with chronic and recurrent gastrointestinal symptoms with one or more neuropsychiatric manifestations. Proposed term will be modified for MedDRA capitalization conventions and added as LLT Abdominal epilepsy to PT Autonomic seizure.

CR Number: 2022217003 **Implementation Date:** 10-Aug-22 Related CR: 2022217003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Familial atrial fibrillation*	Approved as Requested	Proposed PT	
			Familial atrial fibrillation	10088317
			HLT primary	
			Cardiac disorders congenital NEC	10007542
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Supraventricular arrhythmias	10042600
			SOC secondary	
			Cardiac disorders	10007541

MSSO Comment: The proposal to add a new term Familial atrial fibrillation is approved as requested. Familial atrial fibrillation is an inherited abnormality of the heart's normal rhythm. Atrial fibrillation is characterized by episodes of uncoordinated electrical activity (fibrillation). Proposed term will be added as new PT Familial atrial fibrillation under primary HLT Cardiac disorders congenital NEC and secondary HLT Supraventricular arrhythmias.

CR Number: 2022217004 **Implementation Date:** 10-Aug-22 Related CR: 2022217004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Postvaccinal encephalitis*	Rejected		

MSSO Comment: The proposal to add a new term Postvaccinal encephalitis is not approved. Proposed concept is represented by existing LLT Encephalitis post immunisation.

Supplemental Update Report

CR Number: 2022217005 **Implementation Date:** 10-Aug-22 Related CR: 2022217005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Neurotrophic keratitis*	Approved as Requested	Proposed LLT		
To PT	*Neurotrophic keratopathy*		*Neurotrophic keratitis*	10088320	Current
			To PT		
			Neurotrophic keratopathy	10069732	

MSSO Comment: The proposal to add a new LLT Neurotrophic keratitis to PT Neurotrophic keratopathy is approved as requested. Neurotrophic keratitis and neurotrophic keratopathy are synonymously used.

CR Number: 2022217006 **Implementation Date:** 10-Aug-22 Related CR: 2022217006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Paramyotonia congenita*	Approved as Requested	Proposed PT	
			Paramyotonia congenita	10088318
			HLT primary	
			Non-site specific muscle disorders congenital	10029512
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Hereditary muscle disorders	10019888
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Paramyotonia congenita is approved as requested. Paramyotonia congenita is a rare congenital autosomal dominant neuromuscular disorder characterized by "paradoxical" myotonia because it becomes worse with exercise (unlike myotonia congenita, which is alleviated by exercise). Proposed term will be added as new PT Paramyotonia congenita linked to primary HLT Non-site specific muscle disorders congenital and to secondary HLT Hereditary muscle disorders.

Supplemental Update Report

CR Number: 2022217007 **Implementation Date:** 10-Aug-22 Related CR: 2022217007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Isthmic Spondylolisthesis*	Approved Not as Requested	Proposed LLT	
			Isthmic spondylolisthesis	10088321 Current
			To PT	
			Spondylolisthesis	10063550

MSSO Comment: The proposal to add a new term Isthmic Spondylolisthesis is approved but not as requested. The spine condition called isthmic spondylolisthesis occurs when one vertebral body slips forward on the one below it because of a small fracture in a piece of bone that connects the two joints on the back side of the spinal segment. The requested term will be modified for MedDRA capitalisaiton conventions and added as sub-concept LLT Isthmic spondylolisthesis to PT Spondylolisthesis. In a related change, the PT Spondylolisthesis will be linked secondarily to HLT Spinal fractures and dislocations to reflect cases with traumatic etiology.

CR Number: 2022222001 **Implementation Date:** 10-Aug-22 Related CR: 2022217007

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spondylolisthesis*	Approved as Requested	Proposed PT	
To HLT	*Spinal fractures and dislocations*		*Spondylolisthesis*	10063550
			To HLT	
			Spinal fractures and dislocations	10041574

MSSO Comment:

CR Number: 2022217008 **Implementation Date:** 10-Aug-22 Related CR: 2022217008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pars Defect*	Rejected		
To PT	*Spondylolysis*			

MSSO Comment: The proposal to add a new LLT Pars Defect to PT Spondylolysis is not approved. The proposed term can be represented by LLT Pars interarticularis defect. In a related change, PT Spondylolysis will be linked to secondary HLT Spinal fractures and dislocations. Then PT Spondylolysis will have the primary SOC moved from SOC Musculoskeletal and connective tissue disorders to SOC Injury, poisoning and procedural complications. Then secondary HLT for PT Spondylolysis will be changed from HLT Spine and neck deformities to HLT Spinal column fractures.

Supplemental Update Report

CR Number: 2022222002 **Implementation Date:** 10-Aug-22 Related CR: 2022217008

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spondylolysis*	Approved as Requested	Proposed PT	
			Spondylolysis	10052013
To HLT	*Spinal fractures and dislocations*		To HLT	
			Spinal fractures and dislocations	10041574

MSSO Comment:

CR Number: 2022222003 **Implementation Date:** 10-Aug-22 Related CR: 2022217008

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spondylolysis*	Approved as Requested	Proposed PT	
			Spondylolysis	10052013
Old Primary SOC	*Musculoskeletal and connective tissue disorders*		Old Primary SOC	
			Musculoskeletal and connective tissue disorders	10028395
New Primary SOC	*Injury, poisoning and procedural complications*		New Primary SOC	
			Injury, poisoning and procedural complications	10022117

MSSO Comment:

CR Number: 2022222004 **Implementation Date:** 10-Aug-22 Related CR: 2022217008

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spondylolysis*	Approved as Requested	Proposed PT	
			Spondylolysis	10052013
From HLT	*Spine and neck deformities*		From HLT	
			Spine and neck deformities	10012140
To HLT	*Spinal column fractures*		To HLT	
			Spinal column fractures	10072985

MSSO Comment:

Supplemental Update Report

CR Number: 2022217009 **Implementation Date:** 10-Aug-22 Related CR: 2022217009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Intrinsic eczema*	Approved as Requested	Proposed LLT		
			Intrinsic eczema	10088322	Current
			To PT		
			Dermatitis atopic	10012438	

MSSO Comment: The proposal to add a new term Intrinsic eczema is approved as requested. Atopic dermatitis (AD) caused by an allergen is known as extrinsic AD, while intrinsic AD does not arise from an allergen. Roughly 20% of people with AD have the intrinsic type, while the remaining 80% have extrinsic AD. Intrinsic eczema is a synonym for intrinsic AD. Extrinsic or allergic AD shows high total serum IgE levels and the presence of specific IgE for environmental and food allergens, whereas intrinsic or non-allergic AD exhibits normal total IgE values and the absence of specific IgE. Intrinsic eczema will be added as sub-concept LLT to PT Dermatitis atopic.

CR Number: 2022217010 **Implementation Date:** 10-Aug-22 Related CR: 2022217010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Dropped shoulder syndrome*	Approved as Requested	Proposed PT	
			Dropped shoulder syndrome	10088323
			HLT primary	
			Musculoskeletal and connective tissue pain and discomfort	10068757
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395
			HLT secondary	
			Cervical spinal cord and nerve root disorders	10052771
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Dropped shoulder syndrome is approved as requested. A dropped shoulder results from shoulder separation, an injury to the soft tissue between the clavicle and scapula at the acromioclavicular joint. It presents as pain in one or both shoulders radiating to the ipsilateral upper limb and other adjacent regions, and often symptoms of lower cervical radiculopathy. The severity of the injury can range from a mild strain to a full tear, and rehabilitation is performed by strengthening the muscles of the shoulder, back and chest through the various ranges of motion. Dropped shoulder syndrome will be added as a PT with a primary link to HLT Musculoskeletal and connective tissue pain and discomfort and a secondary link to HLT Cervical spinal cord and nerve root disorders.

Supplemental Update Report

CR Number: **2022220001** **Implementation Date:** 10-Aug-22 Related CR: 2022220001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Exposure during breatfeeding*	Rejected		

MSSO Comment: The proposal to add a new PT Exposure during breatfeeding is not approved. The concept may be represented in LLT Exposure during breast feeding.

CR Number: **2022220011** **Implementation Date:** 16-Aug-22 Related CR: 2022220011

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cerebellar density decreased*	Rejected		
From PT	*Brain scan abnormal*			
To PT	*Cerebral disorder*			

MSSO Comment: The proposal to move the LLT Cerebellar density decreased from PT Brain scan abnormal to PT Cerebral disorder is not approved. Cerebellar density decreased can only be the result of an imaging observation, and would not be used as a diagnostic entity. It may indicate cerebellar white matter degeneration/atrophy but the term as such is appropriately placed in the SOC Investigations based on MedDRA conventions.

CR Number: **2022221001** **Implementation Date:** 16-Aug-22 Related CR: 2022221001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Angiodystonia*	Approved as Requested	Proposed LLT	
			Angiodystonia	10088324 Current
			To PT	
			Autonomic nervous system imbalance	10003840

MSSO Comment: The proposal to add a new term Angiodystonia is approved as requested. Angiodystonia is a change in the tone of blood vessels of various organs and tissues that occurs due to a malfunction of the autonomic nervous system. The main signs of an angiodystonia are headaches of various character and an etiology, differences of arterial pressure, dizziness, sleeplessness, numbness of extremities. Proposed term will be added as LLT Angiodystonia under PT Autonomic nervous system imbalance as synonym to existing LLT Vegetovascular dystonia.

Supplemental Update Report

CR Number: 2022221002 **Implementation Date:** 16-Aug-22 Related CR: 2022221002

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Burning sensation in face*	Approved as Requested	Proposed LLT		
From PT	*Burning sensation*		*Burning sensation in face*	10006787	Current
To PT	*Skin burning sensation*		From PT		
			Burning sensation	10006784	
			To PT		
			Skin burning sensation	10054786	

MSSO Comment: The proposal to move the LLT Burning sensation in face from PT Burning sensation to PT Skin burning sensation is approved as requested. LLT Burning sensation in face will be moved from existing PT Burning sensation to PT Skin burning sensation in order to also be represented in SOC Skin and subcutaneous tissue disorders.

CR Number: 2022221003 **Implementation Date:** 16-Aug-22 Related CR: 2022221003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Keyhole knee surgery*	Approved as Requested	Proposed LLT		
From PT	*Arthroscopy*		*Keyhole knee surgery*	10087825	Current
To PT	*Knee operation*		From PT		
			Arthroscopy	10003411	
			To PT		
			Knee operation	10049548	

MSSO Comment: The proposal to move the LLT Keyhole knee surgery from PT Arthroscopy to PT Knee operation is approved as requested for better alignment as a surgical intervention.

CR Number: 2022221010 **Implementation Date:** 16-Aug-22 Related CR: 2022221010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Asthmatoid bronchitis*	Approved Not as Requested	Proposed LLT		
From PT	*Asthma*		*Asthmatoid bronchitis*	10003568	Current
To PT	*Bronchitis*		From PT		
			Asthma	10003553	
			To PT		
			Bronchitis chronic	10006458	

MSSO Comment: The proposal to move the LLT Asthmatoid bronchitis from PT Asthma to PT Bronchitis is approved but not as requested. Asthmatic or asthmatoid bronchitis, is the worst case scenario of chronic bronchitis as seen e.g. in smokers. LLT Asthmatoid bronchitis will be moved from PT Asthma to PT Bronchitis chronic.

Supplemental Update Report

CR Number: 2022221011 **Implementation Date:** 16-Aug-22 Related CR: 2022221011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Xpert MTB RIF assay g4*	Approved Not as Requested	Proposed LLT	
			Rapid molecular test MTB/RIF	10088325 Current
			To PT	
			Mycobacterium test	10070407

MSSO Comment: The proposal to add a new term Xpert MTB RIF assay g4 is approved but not as requested. The Xpert® MTB/RIF (Xpert) assay is a rapid PCR-based assay for the detection of Mycobacterium tuberculosis complex DNA (MTBc) and mutations associated with rifampin resistance (RIF). Since MedDRA avoids adding trade mark names, the proposed term will be modified to both reflect the nature of the test and make it a little broader in meaning. The resulting modified term, Rapid molecular test MTB/RIF, will be added as an LLT under PT Mycobacterium test.

CR Number: 2022222006 **Implementation Date:** 16-Aug-22 Related CR: 2022222006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Positional talipes equinovarus*	Approved Not as Requested	Proposed LLT	
To PT	*Talipes*		*Positional talipes equinovarus*	10088326 Current
			To PT	
			Foot deformity	10061159

MSSO Comment: The proposal to add a new LLT Positional talipes equinovarus to PT Talipes is approved but not as requested. Positional talipes equinovarus is a common condition of the foot in new-born babies where a baby's foot turns inwards and downwards, which is thought to be caused by the baby's position during pregnancy. It is not the same as congenital talipes equinovarus because the foot is not 'stuck' in this position and will have a full range of movement. Positional talipes equinovarus will be added as an LLT to PT Foot deformity.

Supplemental Update Report

CR Number: 2022223001 **Implementation Date:** 16-Aug-22 Related CR: 2022223001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pupillary capture*	Approved Not as Requested	Proposed PT	
			Pupillary capture	10088327
			HLT primary	
			Eye and ear procedural complications	10015908
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Pupil disorders	10037514
			SOC secondary	
			Eye disorders	10015919

MSSO Comment: The proposal to add a new LLT Pupillary capture is approved but not as requested. Pupillary capture occurs when part of the IOL is displaced anteriorly in front of the pupil and it is typically noted as an early postoperative event, although a late form is also recognized. Pupillary capture will be added as a PT with a primary link to HLT Eye and ear procedural complications, to secondary HLT Pupil disorders and to secondary HLT Eye complications associated with device.

CR Number: 2022228107 **Implementation Date:** 16-Aug-22 Related CR: 2022223001

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pupillary capture*	Approved as Requested	Proposed PT	
To HLT	*Eye complications associated with device*		*Pupillary capture*	10088327
			To HLT	
			Eye complications associated with device	10069786

MSSO Comment:

Supplemental Update Report

CR Number: 2022223070 **Implementation Date:** 16-Aug-22 Related CR: 2022223070

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Brain radiation necrosis*	Approved Not as Requested	Proposed PT	
			Brain radiation necrosis	10088328
			HLT primary	
			Radiation injuries	10037759
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Structural brain disorders NEC	10042259
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new LLT Brain radiation necrosis is approved but not as requested. Radiation necrosis is a rare but devastating side effect of high-dose radiation that results in permanent death of brain tissue. Proposed term will be added as new PT Brain radiation necrosis under primary HLT Radiation injuries and secondary HLT Structural brain disorders NEC.

CR Number: 2022224001 **Implementation Date:** 16-Aug-22 Related CR: 2022224001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Submandibular Swelling*	Rejected		

MSSO Comment: The proposal to add a new term Submandibular Swelling is not approved. Submandibular swelling is an ambiguous term because it may be caused by different pathologies such as mumps, sialadenitis, Sjögren syndrome, cysts, infections and certain neoplastic growth.

CR Number: 2022224002 **Implementation Date:** 16-Aug-22 Related CR: 2022224002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Microlaryngoscopy*	Approved as Requested	Proposed LLT	
To PT	*Laryngoscopy*		*Microlaryngoscopy*	10088331 Current
			To PT	
			Laryngoscopy	10023888

MSSO Comment: The proposal to add a new LLT Microlaryngoscopy to PT Laryngoscopy is approved as requested. Microlaryngoscopy is a procedure performed through a laryngoscope which exposes the vocal folds to then be visualized in detail with the use of a microscope. Using this technique, vocal fold lesions (such as cysts, polyps, papilloma, nodules or cancer) are removed without making any external incisions.

Supplemental Update Report

CR Number: 2022224003 **Implementation Date:** 16-Aug-22 Related CR: 2022224003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Rigid Bronchoscopy*	Approved Not as Requested	Proposed LLT	
To PT	*Bronchoscopy*		*Rigid bronchoscopy*	10088329 Current
			To PT	
			Bronchoscopy	10006479

MSSO Comment: The proposal to add a new LLT Rigid Bronchoscopy to PT Bronchoscopy is approved but not as requested. Rigid bronchoscopy is a procedure used to gain access to the patient's airway and allows the passage of larger airway instruments and cameras to diagnose and treat airway disease. Rigid bronchoscopy will be modified to comply with MedDRA capitalization conventions, and added as an LLT to the PT Bronchoscopy.

CR Number: 2022224004 **Implementation Date:** 16-Aug-22 Related CR: 2022224004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Benign vocal cord lesion*	Rejected		

MSSO Comment: The proposal to add a new term Benign vocal cord lesion is not approved. The requested concept can be represented with PT/LLT Vocal cord disorder. As stated in section 5, PT AND LLT NAMING CONVENTIONS of the MedDRA Introductory Guide, “lesion terms may be considered for inclusion in MedDRA when the word “lesion” is part of a medical concept, e.g., PT Glomerulonephritis minimal lesion or a well-documented medical concept, e.g., LLT Brain lesion. However, the term will not be added when adding a broad “lesion” term only adds an additional imprecise term to existing “disorder” concepts.

CR Number: 2022224005 **Implementation Date:** 16-Aug-22 Related CR: 2022224005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Vocal fold leukoplakia*	Rejected		

MSSO Comment: The proposal to add a new term Vocal fold leukoplakia is not approved. The requested condition can be coded with existing PT/LLT Vocal cord leukoplakia.

Supplemental Update Report

CR Number: 2022224006 **Implementation Date:** 16-Aug-22 Related CR: 2022224006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Nondiabetic hyperglycemia*	Approved as Requested	Proposed LLT *Nondiabetic hyperglycemia* To PT *Hyperglycaemia*	10088330 Current 10020635

MSSO Comment: The proposal to add a new term Nondiabetic hyperglycemia is approved as requested. Nondiabetic hyperglycemia is a form of hyperglycemia seen secondary to stress or trauma of any kind which causes a bodily response characterized by enhanced metabolism and hyperglycemia. Nondiabetic hyperglycemia and its British English spelled counterpart Nondiabetic hyperglycaemia will both be added as LLTs to PT Hyperglycaemia.

CR Number: 2022228108 **Implementation Date:** 16-Aug-22 Related CR: 2022224006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Nondiabetic hyperglycaemia*	Approved as Requested	Proposed LLT *Nondiabetic hyperglycaemia* To PT *Hyperglycaemia*	10088332 Current 10020635
To PT	*Hyperglycaemia*			

MSSO Comment:

CR Number: 2022224148 **Implementation Date:** 16-Aug-22 Related CR: 2022224148

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Dermatitis eyelid*	Approved Not as Requested	Proposed LLT *Dermatitis eyelid* From PT *Blepharitis* To PT *Eczema eyelids*	10012460 Current 10005148 10014194
From PT	*Blepharitis*			
To PT	*Dermatitis*			

MSSO Comment: The proposal to move the LLT Dermatitis eyelid from PT Blepharitis to PT Dermatitis is approved but not as requested. Eyelid dermatitis is also called eyelid eczema. LLT Dermatitis eyelid will be moved from PT Blepharitis to the more specific PT Eczema eyelids.

Supplemental Update Report

CR Number: 2022224149 **Implementation Date:** 16-Aug-22 Related CR: 2022224149

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Complement analysis*	Approved as Requested	Proposed LLT *Complement analysis*	10088333	
			To PT *Total complement activity test*	10077882	Current

MSSO Comment: The proposal to add a new LLT Complement analysis is approved as requested. Total complement activity test, also known as CH50 and CH100, assesses overall activity of the complement system. Proposed term will be added as synonym LLT Complement analysis under PT Total complement activity test. In a related change, PT Total complement activity test will be swapped with LLT Complement analysis to have the broader concept at the PT level.

CR Number: 2022228109 **Implementation Date:** 16-Aug-22 Related CR: 2022224149

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed PT	*Total complement activity test*	Approved as Requested	Proposed PT *Total complement activity test*	10077882	Current
With LLT	*Complement analysis*		With LLT *Complement analysis*	10088333	

MSSO Comment:

CR Number: 2022224150 **Implementation Date:** 16-Aug-22 Related CR: 2022224150

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Limbitis*	Approved as Requested	Proposed LLT *Limbitis*	10088334	Current
			To PT *Keratitis*	10023332	

MSSO Comment: The proposal to add a new term Limbitis is approved as requested. Limbitis is inflammation of the corneal limbus. Proposed term will be added as subconcept LLT Limbitis under PT Keratitis aligned with existing LLT Corneal inflammation.

Supplemental Update Report

CR Number: 2022226001 **Implementation Date:** 23-Aug-22 Related CR: 2022226001

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Eye Canaloplasty*	Approved as Requested	Term to modify	
Replacement term	*Eye canaloplasty*		*Eye Canaloplasty*	10088174
			Replacement term	
			Eye canaloplasty	10088174

MSSO Comment: The proposal to rename PT/LLT Eye Canaloplasty to Eye canaloplasty is approved as requested to comply with MedDRA capitalisation conventions.

CR Number: 2022227001 **Implementation Date:** 23-Aug-22 Related CR: 2022227001

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Obstructive pneumonitis*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Obstructive pneumonitis to non-current is not approved. Obstructive pneumonitis, the opacity that develops distal to an obstructing endobronchial lesion or external compression, refers to to inflammation of lung tissue. The term is appropriately placed as it is the condition that develops distal to the causality of an obstructing endobronchial lesion or external compression.

CR Number: 2022227002 **Implementation Date:** 12-Sep-22 Related CR: 2022227002

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Status asthmaticus*	Approved After Suspension	PT to merge	
To PT	*Asthmatic crisis*		*Status asthmaticus*	10041961 Current
			To PT	
			Asthmatic crisis	10064823

MSSO Comment: The proposal to demote the PT Status asthmaticus under PT Asthmatic crisis is approved as requested after suspension. Status asthmaticus is an older term for what's now more commonly known as acute severe asthma or asthmatic crisis.

Supplemental Update Report

CR Number: 2022227003 **Implementation Date:** 23-Aug-22 Related CR: 2022227003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*INGROWN TOENAIL*	Rejected		

MSSO Comment: The proposal to add a new term INGROWN TOENAIL is not approved. Proposed term already exists as LLT Ingrown toe nail under PT Ingrowing nail.

CR Number: 2022228001 **Implementation Date:** 23-Aug-22 Related CR: 2022228001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*CHEST WALL EDEMA*	Approved Not as Requested	Proposed LLT	
			Chest wall edema	10088335 Current
			To PT	
			Localised oedema	10048961

MSSO Comment: The proposal to add a new term CHEST WALL EDEMA is approved but not as requested. Chest wall edema may not always arise from constituents of the chest wall but may represent an extension of the mass or pathology inside. Proposed term will be modified for MedDRA capitalization conventions and added as subconcept LLT Chest wall edema under PT Localised oedema. In addition, the British English spelled counterpart LLT Chest wall oedema will also be added under PT Localised oedema.

CR Number: 2022235005 **Implementation Date:** 23-Aug-22 Related CR: 2022228001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Chest wall oedema*	Approved as Requested	Proposed LLT	
To PT	*Localised oedema*		*Chest wall oedema*	10088336 Current
			To PT	
			Localised oedema	10048961

MSSO Comment:

Supplemental Update Report

CR Number: 2022229001 **Implementation Date:** 23-Aug-22 Related CR: 2022229001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*VIBRIO CHOLERA INFECTION*	Approved Not as Requested	Proposed LLT *Vibrio cholera infection* To PT *Cholera*	 10088337 Current 10008631

MSSO Comment: The proposal to add a new LLT VIBRIO CHOLERA INFECTION is approved but not as requested. Cholera is an acute diarrheal illness caused by infection of the intestine with Vibrio cholerae bacteria. People can get sick when they swallow food or water contaminated with cholera bacteria. The infection is often mild or without symptoms, but can sometimes be severe and life-threatening. The requested term will be modified according to MedDRA capitalisation conventions and added as synonym LLT Vibrio cholera infection to PT Cholera. In a related change, PT Cholera will be moved from secondary HLT Gastrointestinal infections, site unspecified to the more specific HLT Intestinal infections.

CR Number: 2022235002 **Implementation Date:** 23-Aug-22 Related CR: 2022229001

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cholera*	Approved as Requested	Proposed PT *Cholera*	 10008631
From HLT	*Gastrointestinal infections, site unspecified*		From HLT *Gastrointestinal infections, site unspecified*	 10017968
To HLT	*Intestinal infections*		To HLT *Intestinal infections*	 10022678

MSSO Comment:

CR Number: 2022229002 **Implementation Date:** 23-Aug-22 Related CR: 2022229002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*PERIANAL RASH*	Approved Not as Requested	Proposed LLT *Perianal rash* To PT *Anal rash*	 10088338 Current 10084123

MSSO Comment: The proposal to add a new LLT PERIANAL RASH is approved but not as requested. Perianal rash commonly occurs with psoriasis, or inflammatory dermatosis which predominantly involves the anogenital area. Proposed term will be modified for MedDRA capitalization conventions and added as LLT Perianal rash under PT Anal rash.

Supplemental Update Report

CR Number: 2022229003 **Implementation Date:** 23-Aug-22 Related CR: 2022229003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Drug-induced aseptic meningitis*	Rejected		
SOC primary	*Nervous System Disorders*			

MSSO Comment: The proposal to add a new PT Drug-induced aseptic meningitis in SOC Nervous System Disorders is not approved. The proposed term implies a causal relationship between an event and a drug, and therefore represents a combination term. The MSSO refrains from adding further "drug-induced" terms.

CR Number: 2022229004 **Implementation Date:** 23-Aug-22 Related CR: 2022229004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Rhizobium radiobacter bacteraemia*	Approved as Requested	Proposed PT	
			Rhizobium radiobacter bacteraemia	10088344
			HLT primary	
			Bacterial infections NEC	10004047
			SOC primary	
			Infections and infestations	10021881

MSSO Comment: The proposal to add a new PT Rhizobium radiobacter bacteraemia is approved as requested. Rhizobium infections, although rare, have been seen in immunocompromised patients; generally those with cancer or HIV infection. Intravenous catheters have commonly been cited as the source of infection. Proposed term will be added as new PT Rhizobium radiobacter bacteraemia under HLT Bacterial infections NEC. In a related change, US English spelled counterpart LLT Rhizobium radiobacter bacteremia, will also be added to PT Rhizobium radiobacter bacteraemia.

CR Number: 2022235010 **Implementation Date:** 23-Aug-22 Related CR: 2022229004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Rhizobium radiobacter bacteremia*	Approved as Requested	Proposed LLT	
To PT	*Rhizobium radiobacter bacteraemia*		*Rhizobium radiobacter bacteremia*	10088345 Current
			To PT	
			Rhizobium radiobacter bacteraemia	10088344

MSSO Comment:

Supplemental Update Report

CR Number: 2022230002 **Implementation Date:** 23-Aug-22 Related CR: 2022230002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Abnormal esophageal CT scan*	Approved Not as Requested	Proposed LLT		
			Esophageal CT scan abnormal	10088343	Current
			To PT		
			Computerised tomogram oesophagus abnormal	10088340	

MSSO Comment: The proposal to add a new LLT Abnormal esophageal CT scan is approved but not as requested. CT esophagography is a CT study designed to primarily evaluate the esophagus, particularly in the situation of esophageal trauma and potential perforation. The requested term will be modified for consistency with other similar investigation CT terms and added as LLT Esophageal CT scan abnormal to a new PT Computerised tomogram oesophagus abnormal. In a related change, new PT Computerised tomogram oesophagus abnormal will be added to HLT Gastrointestinal and abdominal imaging procedures. Furthermore, LLT Oesophageal CT scan abnormal and LLT Computerized tomogram esophagus abnormal will also be added to PT Computerised tomogram oesophagus abnormal.

CR Number: 2022235006 **Implementation Date:** 23-Aug-22 Related CR: 2022230002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Oesophageal CT scan abnormal*	Approved as Requested	Proposed LLT		
To PT	*Computerised tomogram oesophagus abnormal*		*Oesophageal CT scan abnormal*	10088341	Current
			To PT		
			Computerised tomogram oesophagus abnormal	10088340	

MSSO Comment:

CR Number: 2022235007 **Implementation Date:** 23-Aug-22 Related CR: 2022230002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Computerized tomogram esophagus abnormal*	Approved as Requested	Proposed LLT		
To PT	*Computerised tomogram oesophagus abnormal*		*Computerized tomogram esophagus abnormal*	10088342	Current
			To PT		
			Computerised tomogram oesophagus abnormal	10088340	

MSSO Comment:

Supplemental Update Report

CR Number: 2022235008 **Implementation Date:** 23-Aug-22 Related CR: 2022230002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Computerised tomogram oesophagus abnormal*	Approved as Requested	Proposed PT	
HLT primary	*Gastrointestinal and abdominal imaging procedures*		*Computerised tomogram oesophagus abnormal*	10088340
SOC primary	*Investigations*		HLT primary	
			Gastrointestinal and abdominal imaging procedures	10017963
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022230003 **Implementation Date:** 23-Aug-22 Related CR: 2022230003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*ECTOPIC ATRIAL RHYTHM*	Approved Not as Requested	Proposed PT	
			Ectopic atrial rhythm	10088339
			HLT primary	
			Supraventricular arrhythmias	10042600
			SOC primary	
			Cardiac disorders	10007541

MSSO Comment: The proposal to add a new term ECTOPIC ATRIAL RHYTHM is approved but not as requested. An atrial ectopic rhythm occurs when the dominant pacepoint is an ectopic pace point in the atrium rather than a sinoatrial node. It may be atrial escape rhythm due to sinus node failure, usually at 30 to 60 bpm, or it may be an accelerated atrial ectopic pace point that exceeds the sinus node. The requested term will be modified according to MedDRA capitalisation conventions and added as PT Ectopic atrial rhythm to HLT Supraventricular arrhythmias. In a related change, LLT Ectopic pacemaker will be moved from PT Supraventricular extrasystoles to the new PT Ectopic atrial rhythm for better alignment.

Supplemental Update Report

CR Number: 2022235009 **Implementation Date:** 23-Aug-22 Related CR: 2022230003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ectopic pacemaker*	Approved as Requested	Proposed LLT	
From PT	*Supraventricular extrasystoles*		*Ectopic pacemaker*	10070462 Current
To PT	*Ectopic atrial rhythm*		From PT	
			Supraventricular extrasystoles	10042602
			To PT	
			Ectopic atrial rhythm	10088339

MSSO Comment:

CR Number: 2022230004 **Implementation Date:** 23-Aug-22 Related CR: 2022230004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Visual processing disorder*	Approved as Requested	Proposed PT	
HLT primary	*Cortical dysfunction NEC*		*Visual processing disorder*	10088346
SOC primary	*Nervous system disorders*		HLT primary	
			Cortical dysfunction NEC	10011168
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Specific cognitive ability disturbances	10041427
			SOC secondary	
			Psychiatric disorders	10037175

MSSO Comment: The proposal to add a new PT Visual processing disorder to primary HLT Cortical dysfunction NEC in SOC Nervous system disorders is approved as requested. Visual processing disorders or visual processing issues arise when the visual centers in the brain responsible for processing and making meaning of what the eye sees, including symbols, distances and pictures are not functioning properly. Proposed term will be added as new PT Visual processing disorder under primary HLT Cortical dysfunction NEC and secondary HLT Specific cognitive ability disturbances.

Supplemental Update Report

CR Number: 2022230005 **Implementation Date:** 23-Aug-22 Related CR: 2022230005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Burning Diarrhea*	Rejected		

MSSO Comment: The proposal to add a new term Burning Diarrhea is not approved. The proposed term is a combination of diarrhea and an associated symptom of burning sensation.

CR Number: 2022230006 **Implementation Date:** 23-Aug-22 Related CR: 2022230006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Gastrooesophageal haemorrhage*	Approved as Requested	Proposed LLT *Gastrooesophageal haemorrhage* To PT *Oesophageal haemorrhage*	 10088347 Current 10030172

MSSO Comment: The proposal to add a new term Gastrooesophageal haemorrhage is approved as requested. Causes of gastrooesophageal haemorrhage may be suggested by the patient's symptoms and may be due to: peptic ulcer,esophageal ulcer, gastroesophageal reflux, Mallory-Weiss tear, variceal hemorrhage, portal hypertensive gastropathy or malignancy. Proposed term will be added as subconcept LLT Gastrooesophageal haemorrhage under PT Oesophageal haemorrhage. In a related change, the American English counterpart LLT Gastroesophageal hemorrhage will also be added under PT Oesophageal haemorrhage.

CR Number: 2022235011 **Implementation Date:** 23-Aug-22 Related CR: 2022230006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Gastroesophageal hemorrhage*	Approved as Requested	Proposed LLT *Gastroesophageal hemorrhage* To PT *Oesophageal haemorrhage*	 10088348 Current 10030172
To PT	*Oesophageal haemorrhage*			

MSSO Comment:

Supplemental Update Report

CR Number: 2022230007 **Implementation Date:** 23-Aug-22 Related CR: 2022230007

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Retrograde nephroureteral stent*	Approved Not as Requested	LLT to change	
Replacement term	*Retrograde nephroureteral stent insertion*		*Retrograde nephroureteral stent*	10088065 Non-Current
			Status	
			Non-current	

MSSO Comment: The proposal to rename PT/LLT Retrograde nephroureteral stent to Retrograde nephroureteral stent insertion is approved but not as requested. Retrograde nephroureteral stent will be made non-current as it does not clarify term as a procedural concept. In a related change, new LLT Retrograde nephroureteral stent placement will be added under PT Ureteral stent insertion.

CR Number: 2022235012 **Implementation Date:** 23-Aug-22 Related CR: 2022230007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Retrograde nephroureteral stent placement*	Approved as Requested	Proposed LLT	
To PT	*Ureteral stent insertion*		*Retrograde nephroureteral stent placement*	10088349 Current
			To PT	
			Ureteral stent insertion	10050307

MSSO Comment:

CR Number: 2022231001 **Implementation Date:** 14-Sep-22 Related CR: 2022231001

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vaccination complication*	Rejected After Suspension		
Old Primary SOC	*Injury, poisoning and procedural complications*			
New Primary SOC	*Immune system disorders*			

MSSO Comment: The proposal to reassign the primary SOC of PT Vaccination complication from current SOC Injury, poisoning and procedural complications to SOC Immune system disorders is not approved after suspension. Vaccination complications are not limited to immune reaction. Therefore, vaccination complication is better to have a primary link to HLT Vaccination related complications in the SOC Injury, poisoning and procedural complications which is the same placement as similar concept terms for primary presentation. In a related change, the primary SOC for PT Immunisation reaction will be re-assigned from SOC Immune system disorders to SOC Injury, poisoning and procedural complications for consistency reasons of related terms. Furthermore, PT Post vaccination syndrome will be secondarily linked to HLT Immune and associated conditions NEC.

Supplemental Update Report

CR Number: 2022257019 **Implementation Date:** 14-Sep-22 Related CR: 2022231001

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Immunisation reaction*	Approved as Requested	Proposed PT	
			Immunisation reaction	10021432
Old Primary SOC	*Immune system disorders*		Old Primary SOC	
			Immune system disorders	10021428
New Primary SOC	*Injury, poisoning and procedural complications*		New Primary SOC	
			Injury, poisoning and procedural complications	10022117

MSSO Comment:

CR Number: 2022257020 **Implementation Date:** 14-Sep-22 Related CR: 2022231001

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Post vaccination syndrome*	Approved as Requested	Proposed PT	
			Post vaccination syndrome	10036242
To HLT	*Immune and associated conditions NEC*		To HLT	
			Immune and associated conditions NEC	10027682

MSSO Comment:

CR Number: 2022231003 **Implementation Date:** 23-Aug-22 Related CR: 2022231003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*VENTRICULAR OUTFLOW TRACT DREDGING*	Approved Not as Requested	Proposed PT	
			Ventricular outflow tract dredging	10088350
			HLT primary	
			Cardiac therapeutic procedures NEC	10027660
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT VENTRICULAR OUTFLOW TRACT DREDGING is approved but not as requested. Ventricular outflow tract dredging is often used for left ventricular outflow tract obstruction and outflow tract stenosis cases. Proposed term will be modified for MedDRA capitalization conventions and added as new PT Ventricular outflow tract dredging under HLT Cardiac therapeutic procedures NEC.

Supplemental Update Report

CR Number: 2022231004 **Implementation Date:** 23-Aug-22 Related CR: 2022231004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*ECTOPIC ATRIAL RHYTHM*	Rejected		

MSSO Comment: The proposal to add a new LLT ECTOPIC ATRIAL RHYTHM is not approved. Technical rejection. This term has already been submitted in change request 2022230003 and will be processed.

CR Number: 2022231005 **Implementation Date:** 14-Sep-22 Related CR: 2022231005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Drug taken by mother to treat fetus*	Approved Not as Requested After Suspension	Proposed PT	
HLT primary	*Medication errors, product use errors and issues NEC*		*Maternal-foetal therapy*	10088442
SOC primary	*Injury, poisoning and procedural complications*		HLT primary	
			Foetal therapeutic procedures	10057186
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Drug taken by mother to treat fetus to primary HLT Medication errors, product use errors and issues NEC in SOC Injury, poisoning and procedural complications is approved but not as requested after suspension. It's not appropriate to place this term in HLT Medication errors, product use errors and issues NEC since it's an intentional use of a product. Maternal-foetal therapy is a broad term that could apply to situations like using beta-blockers to treat fetal arrhythmias and antenatal steroids to treat lung prematurity. In order to capture the intentional nature of the event, consider using LLTs under PT Intentional product use issue or, if off label use is specifically stated in the verbatim, select an appropriate off label use term. The proposed term will be modified for clarification and added as PT Maternal-foetal therapy to HLT Foetal therapeutic procedures. In a related change, the American English counterpart LLT Maternal-fetal therapy will be added to new PT Maternal-foetal therapy. Furthermore, PT Maternal therapy to enhance foetal lung maturity will be moved from HLT Obstetric therapeutic procedures to HLT Foetal therapeutic procedures for better alignment.

CR Number: 2022255018 **Implementation Date:** 14-Sep-22 Related CR: 2022231005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Maternal-fetal therapy*	Approved as Requested	Proposed LLT	
To PT	*Maternal-foetal therapy*		*Maternal-fetal therapy*	10088443 Current
			To PT	
			Maternal-foetal therapy	10088442

MSSO Comment:

Supplemental Update Report

CR Number: 2022255019 **Implementation Date:** 14-Sep-22 Related CR: 2022231005

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Maternal therapy to enhance foetal lung maturity*	Approved as Requested	Proposed PT	
From HLT	*Obstetric therapeutic procedures*		*Maternal therapy to enhance foetal lung maturity*	10058340
To HLT	*Foetal therapeutic procedures*		From HLT	
			Obstetric therapeutic procedures	10029906
			To HLT	
			Foetal therapeutic procedures	10057186

MSSO Comment:

CR Number: 2022231051 **Implementation Date:** 14-Sep-22 Related CR: 2022231051

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neurodevelopmental delay*	Approved After Suspension	Proposed PT	
			Neurodevelopmental delay	10088444
			HLT primary	
			Nervous system disorders NEC	10057185
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Pervasive developmental disorders NEC	10034740
			SOC secondary	
			Psychiatric disorders	10037175

MSSO Comment: The proposal to add a new PT Neurodevelopmental delay is approved as requested after suspension. Neurodevelopmental delay is a term used to describe delays in skill development of infants and young children. Neurodevelopmental delay will be added as a PT to primary HLT Nervous system disorders NEC, and to secondary HLT Pervasive developmental disorders NEC. In a related change, the primary SOC for PT Neurodevelopmental disorder will be re-assigned from SOC Psychiatric disorders to SOC Nervous system disorders. Furthermore, HLT for PT Neurodevelopmental disorder will be changed from HLT Developmental disorders cognitive to HLT Nervous system disorders NEC for consistent alignment.

Supplemental Update Report

CR Number: 2022257021 **Implementation Date:** 14-Sep-22 Related CR: 2022231051

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neurodevelopmental disorder*	Approved as Requested	Proposed PT	
			Neurodevelopmental disorder	10064062
Old Primary SOC	*Psychiatric disorders*		Old Primary SOC	
			Psychiatric disorders	10037175
New Primary SOC	*Nervous system disorders*		New Primary SOC	
			Nervous system disorders	10029205

MSSO Comment:

CR Number: 2022257022 **Implementation Date:** 14-Sep-22 Related CR: 2022231051

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neurodevelopmental disorder*	Approved as Requested	Proposed PT	
			Neurodevelopmental disorder	10064062
From HLT	*Developmental disorders cognitive*		From HLT	
			Developmental disorders cognitive	10012561
To HLT	*Nervous system disorders NEC*		To HLT	
			Nervous system disorders NEC	10057185

MSSO Comment:

CR Number: 2022231052 **Implementation Date:** 23-Aug-22 Related CR: 2022231052

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cognitive communication therapy*	Approved as Requested	Proposed LLT	
			Cognitive communication therapy	10088351 Current
			To PT	
			Cognitive rehabilitation	10067056

MSSO Comment: The proposal to add a new LLT Cognitive communication therapy is approved as requested. Cognitive speech therapy, also referred to as cognitive-communication therapy, is designed to help improve communication skills and restore cognitive function. Proposed term will be added as subconcept LLT Cognitive communication therapy under PT Cognitive rehabilitation.

Supplemental Update Report

CR Number: 2022233001 **Implementation Date:** 23-Aug-22 Related CR: 2022233001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Deep tissue injury*	Approved Not as Requested	Proposed PT	
To PT	*Decubitus ulcer*		*Deep tissue injury*	10088352
			HLT primary	
			Musculoskeletal and connective tissue conditions NEC	10080711
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395
			HLT secondary	
			Musculoskeletal necrosis and vascular insufficiency	10065876
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new LLT Deep tissue injury to PT Decubitus ulcer is approved but not as requested. A deep tissue injury is a serious type of pressure injury that begins in the muscle closest to the bone and may not be visible in its early stages. Deep tissue injury will be added as PT to primary HLT Musculoskeletal and connective tissue conditions NEC and secondary HLT Musculoskeletal necrosis and vascular insufficiency.

CR Number: 2022234001 **Implementation Date:** 26-Aug-22 Related CR: 2022234001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cracked tooth syndrome*	Approved as Requested	Proposed LLT	
			Cracked tooth syndrome	10088353 Current
			To PT	
			Tooth fracture	10062544

MSSO Comment: The proposal to add a new term Cracked tooth syndrome is approved as requested. Cracked tooth syndrome results from a fracture plane of unknown depth and direction passing through tooth structure that, if not already involving, may progress to communicate with the pulp and/or periodontal ligament. Cracked tooth syndrome will be added as an LLT to PT Tooth fracture.

Supplemental Update Report

CR Number: 2022234002 **Implementation Date:** 26-Aug-22 Related CR: 2022234002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ganser syndrome*	Approved as Requested	Proposed PT	
			Ganser syndrome	10088354
			HLT primary	
			Dissociative states	10013470
			SOC primary	
			Psychiatric disorders	10037175

MSSO Comment: The proposal to add a new term Ganser syndrome is approved as requested. Ganser syndrome is a rare dissociative disorder characterized by nonsensical or wrong answers to questions and other dissociative symptoms such as fugue, amnesia or conversion disorder, often with visual pseudohallucinations and a decreased state of consciousness. Ganser syndrome will be added as a PT to HLT Dissociative states.

CR Number: 2022234003 **Implementation Date:** 26-Aug-22 Related CR: 2022234003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Galloway mowat syndrome*	Approved Not as Requested	Proposed PT	
			Galloway Mowat syndrome	10088355
			HLT primary	
			Neurological disorders congenital NEC	10029300
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Structural brain disorders NEC	10042259
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Galloway mowat syndrome is approved but not as requested. Galloway Mowat syndrome is a rare, genetic multi-system disorder characterized by a neurodegenerative disorder associating global developmental delay, progressive microcephaly, and progressive cerebral and cerebellar atrophy with extrapyramidal involvement, progressive optic atrophy, and in many patients early-onset steroid-resistant nephrotic syndrome. The proposed term will be modified to capitalize the proper name “Mowat”, in accordance with MedDRA capitalization conventions, and added as PT Galloway Mowat syndrome with a primary link to HLT Neurological disorders congenital NEC and secondary links to HLT Structural brain disorders NEC and HLT Glomerulonephritis and nephrotic syndrome.

Supplemental Update Report

CR Number: 2022238012 **Implementation Date:** 26-Aug-22 Related CR: 2022234003

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Galloway Mowat syndrome*	Approved as Requested	Proposed PT	
To HLT	*Glomerulonephritis and nephrotic syndrome*		*Galloway Mowat syndrome*	10088355
			To HLT	
			Glomerulonephritis and nephrotic syndrome	10018365

MSSO Comment:

CR Number: 2022234024 **Implementation Date:** 26-Aug-22 Related CR: 2022234024

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Accommodative asthenopia*	Approved as Requested	Proposed LLT	
			Accommodative asthenopia	10088356 Current
			To PT	
			Asthenopia	10003552

MSSO Comment: The proposal to add a new LLT Accommodative asthenopia is approved as requested. Accommodative asthenopia is a sense of eye-tiredness and discomfort and occasional headache from sustained narrowing of the eyes resulting from a refractive error that imposes the need to make unusually strong accommodative effort. Accommodative asthenopia will be added as sub-concept LLT under PT Asthenopia.

CR Number: 2022234025 **Implementation Date:** 26-Aug-22 Related CR: 2022234025

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site induration*	Approved as Requested	Proposed PT	
HLT primary	*Cardiac and vascular procedural complications*		*Vascular access site induration*	10088357
SOC primary	*Injury, poisoning and procedural complications*		HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Vascular access site induration to primary HLT Cardiac and vascular procedural complications in SOC Injury, poisoning and procedural complications is approved as requested. Common complications which are associated with vascular access sites include swelling, redness, heat, induration, purulence, a palpable venous cord (hard vein) and pain.

Supplemental Update Report

CR Number: 2022234026 **Implementation Date:** 26-Aug-22 Related CR: 2022234026

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site hyperpigmentation*	Approved Not as Requested	Proposed LLT	
HLT primary	*Cardiac and vascular procedural complications*		*Vascular access site hyperpigmentation*	10088360 Current
SOC primary	*Injury, poisoning and procedural complications*		To PT	
			Vascular access site discolouration	10085945

MSSO Comment: The proposal to add a new PT Vascular access site hyperpigmentation to primary HLT Cardiac and vascular procedural complications in SOC Injury, poisoning and procedural complications is approved but not as requested. Common complications which are associated with vascular access sites include swelling, redness, heat, induration, hyperpigmentation, purulence, a palpable venous cord (hard vein) and pain. Vascular access site hyperpigmentation will be added as an LLT to PT Vascular access site discolouration.

CR Number: 2022234027 **Implementation Date:** 26-Aug-22 Related CR: 2022234027

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site numbness*	Approved Not as Requested	Proposed LLT	
HLT primary	*Cardiac and vascular procedural complications*		*Vascular access site numbness*	10088359 Current
SOC primary	*Injury, poisoning and procedural complications*		To PT	
			Vascular access site hypoaesthesia	10082931

MSSO Comment: The proposal to add a new PT Vascular access site numbness to primary HLT Cardiac and vascular procedural complications in SOC Injury, poisoning and procedural complications is approved but not as requested. Common complications which are associated with vascular access sites include swelling, numbness, redness, heat, induration, hyperpigmentation, purulence, a palpable venous cord (hard vein) and pain. Vascular access site numbness will be added as an LLT to PT Vascular access site hypoaesthesia.

CR Number: 2022234028 **Implementation Date:** 26-Aug-22 Related CR: 2022234028

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site reaction*	Approved as Requested	Proposed PT	
HLT primary	*Cardiac and vascular procedural complications*		*Vascular access site reaction*	10088358
SOC primary	*Injury, poisoning and procedural complications*		HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Vascular access site reaction to primary HLT Cardiac and vascular procedural complications in SOC Injury, poisoning and procedural complications is approved as requested. Common complications which are associated with vascular access sites include a reaction which may include swelling, numbness, redness, heat, induration, hyperpigmentation, purulence, a palpable venous cord (hard vein) and pain.

Supplemental Update Report

CR Number: 2022234029 **Implementation Date:** 26-Aug-22 Related CR: 2022234029

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Effusive-constrictive pericarditis*	Approved Not as Requested	Proposed LLT *Effusive-constrictive pericarditis* To PT *Pericarditis constrictive*	 10088361 Current 10034487

MSSO Comment: The proposal to add a new PT Effusive-constrictive pericarditis is approved but not as requested. Effusive constrictive pericarditis is pericarditis characterized by pericardial effusion in the presence of visceral pericardial constriction, manifest as continued elevation of right atrial pressure after pericardiocentesis. Effusive-constrictive pericarditis will be added as an LLT to PT Pericarditis constrictive.

CR Number: 2022234030 **Implementation Date:** 12-Sep-22 Related CR: 2022234030

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hemorrhagic detachment of retinal pigment epithelium*	Approved Not as Requested After Suspension	Proposed LLT *Hemorrhagic detachment of retinal pigment epithelium*	 10019599 Current
From PT	*Retinal haemorrhage*		From PT *Retinal haemorrhage*	 10038867
			To PT *Detachment of retinal pigment epithelium*	 10052501

MSSO Comment: The proposal to promote the LLT Hemorrhagic detachment of retinal pigment epithelium from PT Retinal haemorrhage is approved but not as requested after suspension. Retinal pigment epithelial (RPE) detachments are characterized by separation between the RPE and the inner most aspect of Bruch's membrane. The space created by this separation is occupied by blood, serous exudate, drusenoid material, fibrovascular tissue or a combination of the above. Proposed term, LLT Hemorrhagic detachment of retinal pigment epithelium will be moved from PT Retinal haemorrhage as subtype LLT to PT Detachment of retinal pigment epithelium for better alignment. In a related change the British English spelled counterpart, LLT Haemorrhagic detachment of retinal pigment epithelium, will also be moved from PT Retinal haemorrhage to PT Detachment of retinal pigment epithelium.

Supplemental Update Report

CR Number: 2022255020 **Implementation Date:** 12-Sep-22 Related CR: 2022234030

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Haemorrhagic detachment of retinal pigment epithelium*	Approved as Requested	Proposed LLT *Haemorrhagic detachment of retinal pigment epithelium*	10055854 Current
From PT	*Retinal haemorrhage*		From PT *Retinal haemorrhage*	10038867
To PT	*Detachment of retinal pigment epithelium*		To PT *Detachment of retinal pigment epithelium*	10052501

MSSO Comment:

CR Number: 2022234031 **Implementation Date:** 26-Aug-22 Related CR: 2022234031

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Immune-mediated optic neuritis*	Approved Not as Requested	Proposed PT *Immune-mediated optic neuritis*	10088362
			HLT primary *Optic nerve disorders NEC*	10030933
			SOC primary *Nervous system disorders*	10029205
			HLT secondary *Optic nerve infections and inflammations*	10030937
			SOC secondary *Eye disorders*	10015919

MSSO Comment: The proposal to add a new LLT Immune-mediated optic neuritis is approved but not as requested. "Immune mediated" is defined as an inflammatory process caused by an unspecified immune reaction leading to dysregulation of the normal immune response. Immune mediated diseases are often based on, but not limited to, an autoimmune mechanism. Immune-mediated optic neuritis will be added as a new PT with a primary link to HLT Optic nerve disorders NEC, and secondary links to HLT Optic nerve infections and inflammations and HLT Immune and associated conditions NEC.

Supplemental Update Report

CR Number: 2022238002 **Implementation Date:** 26-Aug-22 Related CR: 2022234031

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Immune-mediated optic neuritis*	Approved as Requested	Proposed PT	
To HLT	*Immune and associated conditions NEC*		*Immune-mediated optic neuritis*	10088362
			To HLT	
			Immune and associated conditions NEC	10027682

MSSO Comment:

CR Number: 2022235001 **Implementation Date:** 26-Aug-22 Related CR: 2022235001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Electrocardiogram Depolarization abnormality*	Approved Not as Requested	Proposed LLT		
			Electrocardiogram depolarization abnormality	10088368	Current
			To PT		
			Electrocardiogram abnormal	10014363	

MSSO Comment: The proposal to add a new LLT Electrocardiogram Depolarization abnormality is approved but not as requested. The proposed term, modified for MedDRA capitalization standards, will be added as sub-concept LLT Electrocardiogram depolarization abnormality to PT Electrocardiogram abnormal.

CR Number: 2022235003 **Implementation Date:** 14-Sep-22 Related CR: 2022235003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Red man syndrome*	Rejected After Suspension		
From PT	*Vancomycin infusion reaction*			
To PT	*Red man syndrome*			

MSSO Comment: The proposal to move the LLT Red man syndrome from PT Vancomycin infusion reaction to PT Red man syndrome is not approved after suspension. In v25.0 PT Red man syndrome was demoted under new PT Vancomycin infusion reaction with the following rationale: The proposal to demote the PT Red man syndrome under PT Vancomycin infusion reaction is approved as requested. Vancomycin infusion reaction is now the currently accepted nomenclature for this specific drug reaction and is intended to provide an alternative for a PT level term for the concept of “Red Man Syndrome” which carries racist connotations and implies a white male reference. In a related change, LLT Red man will be flagged non-current as it is inappropriate. Because of this change in the accepted nomenclature, red man syndrome will not be again promoted to a PT. The decision was made in consultation with regulators and professional associations. We recognize that red man syndrome reported and coded as an exact verbatim with other antibiotics will result in it appearing as PT Vancomycin infusion reaction. In these circumstances, company conventions could be established to code the reaction to another appropriate antibiotic reaction term instead of the exact match verbatim. Another alternative would be to note on the output if any of the PTs Vancomycin infusion reaction were actually the result of other antibiotics and not vancomycin.

Supplemental Update Report

CR Number: 2022235004 **Implementation Date:** 26-Aug-22 Related CR: 2022235004

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cerebellar density decreased*	Approved as Requested	Proposed LLT	
From PT	*Brain scan abnormal*		*Cerebellar density decreased*	10085586
HLT primary	*Structural brain disorders NEC*		From PT	
			Brain scan abnormal	10061943
			HLT primary	
			Structural brain disorders NEC	10042259
			SOC primary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to promote the LLT Cerebellar density decreased from PT Brain scan abnormal to primary HLT Structural brain disorders NEC in SOC Nervous system disorders is approved as requested. The term Cerebellar density decreased is a specific finding in a specific anatomical location (even though it might not be pathological) and is more appropriately placed under SOC Nervous system disorders. The newly promoted PT Cerebellar density decreased is similarly placed like PT Cerebellar atrophy and PT Hyperintensity in brain deep nuclei under HLT Structural brain disorders NEC. In a related change, LLT Cerebellar hemisphere density decreased will be moved from PT Brain scan abnormal to new PT Cerebellar density decreased for better alignment.

CR Number: 2022238006 **Implementation Date:** 26-Aug-22 Related CR: 2022235004

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Cerebellar hemisphere density decreased*	Approved as Requested	Proposed LLT		
From PT	*Brain scan abnormal*		*Cerebellar hemisphere density decreased*	10085590	Current
To PT	*Cerebellar density decreased*		From PT		
			Brain scan abnormal	10061943	
			To PT		
			Cerebellar density decreased	10085586	

MSSO Comment:

Supplemental Update Report

CR Number: 2022235013 **Implementation Date:** 26-Aug-22 Related CR: 2022235013

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Electronic Chromoendoscopy*	Approved Not as Requested	Proposed LLT *Electronic chromoendoscopy* To PT *Endoscopy gastrointestinal*	 10088365 Current 10014809

MSSO Comment: The proposal to add a new term Electronic Chromoendoscopy is approved but not as requested. Electronic chromo-endoscopy or digital chromoendoscopy refers to advanced endoscopic imaging technologies that provide detailed contrast enhancement of the mucosal surface and blood vessels based on the principle of observing light transmittance at selected wavelength given interaction of particular tissue structures with light is wavelength dependent. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as LLT Electronic chromoendoscopy to PT Endoscopy gastrointestinal. In a related change, the related term LLT Digital chromoendoscopy proactively will be added to PT Endoscopy gastrointestinal.

CR Number: 2022238003 **Implementation Date:** 26-Aug-22 Related CR: 2022235013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT To PT	*Digital chromoendoscopy proactively* *Endoscopy gastrointestinal*	Approved as Requested	Proposed LLT *Digital chromoendoscopy proactively* To PT *Endoscopy gastrointestinal*	 10088367 10014809

MSSO Comment:

CR Number: 2022235014 **Implementation Date:** 26-Aug-22 Related CR: 2022235014

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Aponeurosis resection*	Approved Not as Requested	Proposed LLT *Levator aponeurosis resection* To PT *Ptosis repair*	 10088366 Current 10037275

MSSO Comment: The proposal to add a new term Aponeurosis resection is approved but not as requested. Levator aponeurosis resection is an easy and effective technique in elevating the eyelid in patients with very poor levator function due to eyelid ptosis. The proposed term will be renamed to Levator aponeurosis resection for greater clarity and added as LLT under PT Ptosis repair.

Supplemental Update Report

CR Number: 2022235015 **Implementation Date:** 26-Aug-22 Related CR: 2022235015

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cluster differentiated antigen*	Approved as Requested	Proposed PT	
			Cluster differentiated antigen	10088363
			HLT primary	
			Cell marker analyses	10072981
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Cluster differentiated antigen is approved as requested. The cluster of differentiation is a protocol used for the identification and investigation of cell surface molecules providing targets for immunophenotyping of cells. In this process, a cluster differentiated antigen is a cell surface antigen with an important role for immune reactions having a relevant role in diagnosis and treatment targeting. Cluster differentiated antigen will be added as a PT to HLT Cell marker analyses.

CR Number: 2022235016 **Implementation Date:** 26-Aug-22 Related CR: 2022235016

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Post Vaccination fever*	Approved Not as Requested	Proposed PT	
			Post vaccination fever	10088364
			HLT primary	
			Vaccination related complications	10068755
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Febrile disorders	10016286
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new term Post Vaccination fever is approved but not as requested. Postvaccination fever is a mild adverse event that is usually self-limiting over a few days without any specific complications. However, it is highly prevalent and, in some cases, accompanied with febrile convulsions, which can cause excessive anxiety in parents and caregivers. The proposed term will be modified according to MedDRA capitalization conventions and added as PT Post vaccination fever with a primary link to HLT Vaccination related complications, to secondary HLT Febrile disorders and to secondary HLT Immune and associated conditions NEC.

Supplemental Update Report

CR Number: 2022238004 **Implementation Date:** 26-Aug-22 Related CR: 2022235016

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Post vaccination fever*	Approved as Requested	Proposed PT	
To HLT	*Immune and associated conditions NEC*		*Post vaccination fever*	10088364
			To HLT	
			Immune and associated conditions NEC	10027682

MSSO Comment:

CR Number: 2022236001 **Implementation Date:** 26-Aug-22 Related CR: 2022236001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*IDIOPATHIC SMALL INTESTINAL PERFORATION*	Approved Not as Requested	Proposed LLT	
			Idiopathic small intestinal perforation	10088373 Current
			To PT	
			Small intestinal perforation	10041103

MSSO Comment: The proposal to add a new term IDIOPATHIC SMALL INTESTINAL PERFORATION is approved but not as requested. Idiopathic perforation of the small intestine is extremely rare. The definition depends on the absence of any detectable pathology that could be responsible for the perforation. The proposed term will be modified for MedDRA capitalization conventions and added as LLT Idiopathic small intestinal perforation under PT Small intestinal perforation.

CR Number: 2022236002 **Implementation Date:** 26-Aug-22 Related CR: 2022236002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cervical Esophagostomy*	Approved Not as Requested	Proposed LLT	
			Cervical esophagostomy	10088370 Current
			To PT	
			Oesophagostomy	10053056

MSSO Comment: The proposal to add a new term Cervical Esophagostomy is approved but not as requested. Cervical esophagostomy is a surgical procedure by providing long-term tubal alimentation for the chronically ill and debilitated patient. Elimination of an unsightly feeding tube and unpleasant irritation to the nose and upper-airway passages contributes to the patient's comfort and well-being. The proposed term will be modified for MedDRA capitalization conventions and added as LLT Cervical esophagostomy under PT Oesophagostomy. In a related change, the British English counterpart LLT Cervical oesophagostomy will also be added under PT Oesophagostomy.

Supplemental Update Report

CR Number: 2022238005 **Implementation Date:** 26-Aug-22 Related CR: 2022236002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Cervical oesophagostomy*	Approved as Requested	Proposed LLT		
To PT	*Oesophagostomy*		*Cervical oesophagostomy*	10088374	Current
			To PT		
			Oesophagostomy	10053056	

MSSO Comment:

CR Number: 2022236003 **Implementation Date:** 26-Aug-22 Related CR: 2022236003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Cranial CT scan*	Approved as Requested	Proposed LLT		
To PT	*Computerised tomogram head*		*Cranial CT scan*	10088372	Current
			To PT		
			Computerised tomogram head	10054003	

MSSO Comment: The proposal to add a new LLT Cranial CT scan to PT Computerised tomogram head is approved as requested. A cranial CT scan is a diagnostic tool used to create detailed pictures of features inside the head, such as the skull, brain, paranasal sinuses, ventricles, and eye sockets.

CR Number: 2022236004 **Implementation Date:** 26-Aug-22 Related CR: 2022236004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pharyngography*	Approved as Requested	Proposed PT	
			Pharyngography	10088369
			HLT primary	
			Respiratory tract and thoracic imaging procedures	10006476
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Pharyngography is approved as requested. Pharyngography remains an important diagnostic tool in the evaluation of patients with dysphagia and helps identify a wide spectrum of structural and detect functional abnormalities in children and adults. The proposed term will be added as new PT Pharyngography under HLT Respiratory tract and thoracic imaging procedures.

Supplemental Update Report

CR Number: 2022236005 **Implementation Date:** 26-Aug-22 Related CR: 2022236005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Geriatric consultation*	Approved as Requested	Proposed LLT	
To PT	*Specialist consultation*		*Geriatric consultation*	10088371 Current
			To PT	
			Specialist consultation	10076498

MSSO Comment: The proposal to add a new LLT Geriatric consultation to PT Specialist consultation is approved as requested. A geriatric consultation is a specialized evaluation by a geriatrics physician, in order to address aging-related challenges for patients aged 65 and above.

CR Number: 2022237001 **Implementation Date:** 13-Oct-22 Related CR: 2022237001

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Haemodilution*	Approved as Requested	Proposed PT	
To SMQ	*Haemodynamic oedema, effusions and fluid overload (SMQ)*		*Haemodilution*	10059484
Term scope	*Narrow*		To SMQ	
			Haemodynamic oedema, effusions and fluid overload (SMQ)	20000145
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Haemodilution to Haemodynamic oedema, effusions and fluid overload (SMQ) as a narrow term is approved as requested. Haemodilution fits the inclusion criteria for terms for fluid or volume overload conditions. PT Hypervolaemia is already included. All terms are narrow scope.

Supplemental Update Report

CR Number: **2022238001** **Implementation Date:** 02-Sep-22 Related CR: 2022238001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Jackson-pratt (jp) surgical drain*	Approved Not as Requested	Proposed LLT	
			Jackson-Pratt surgical drain placement	10088377 Current
			To PT	
			Post procedural drainage	10053175

MSSO Comment: The proposal to add a new term Jackson-pratt (jp) surgical drain is approved but not as requested. A Jackson-Pratt drain (also called a JP drain) is a closed-suction medical device that is commonly used as a post-operative drain for collecting bodily fluids from surgical sites. Proposed term will be modified for MedDRA capitalization conventions and for greater clarity and added as sub-concept LLT Jackson-Pratt surgical drain placement under PT Post procedural drainage. In a related change, the synonym LLT Closed-suction drain placement will also be added under PT Post procedural drainage.

CR Number: **2022245001** **Implementation Date:** 02-Sep-22 Related CR: 2022238001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Closed-suction drain placement*	Approved as Requested	Proposed LLT	
To PT	*Post procedural drainage*		*Closed-suction drain placement*	10088378 Current
			To PT	
			Post procedural drainage	10053175

MSSO Comment:

CR Number: **2022238007** **Implementation Date:** 11-Oct-22 Related CR: 2022238007

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dopamine agonist withdrawal syndrome*	Rejected		
To SMQ	*Drug withdrawal (SMQ)*			
Term scope	*Narrow*			

MSSO Comment: The proposal to add PT Dopamine agonist withdrawal syndrome to Drug withdrawal (SMQ) as a narrow term is not approved. This is a technical rejection. PT Dopamine agonist withdrawal syndrome was added to Drug withdrawal (SMQ) as a broad scope term as part of the MSSO's SMQ maintenance process. See batch # 29116363; change request # 2022266084.

Supplemental Update Report

CR Number: 2022238008 **Implementation Date:** 02-Sep-22 Related CR: 2022238008

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Dopamine agonist withdrawal syndrome*	Rejected		

MSSO Comment: The proposal to add a new LLT Dopamine agonist withdrawal syndrome is not approved. Technical rejection. The requested concept has been added at the PT level in change request 2022238011 in this batch. Every new MedDRA PT concept is mirrored at the LLT level with an LLT of its very same name.

CR Number: 2022238009 **Implementation Date:** 02-Sep-22 Related CR: 2022238009

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Dopamine agonist withdrawal symptoms*	Rejected		

MSSO Comment: The proposal to add a new LLT Dopamine agonist withdrawal symptoms is not approved. This concept is already represented by PT Dopamine agonist withdrawal syndrome added in change request 2022238011. Every syndrome is essentially composed by signs and symptoms, which makes it unnecessary to a term referring specifically to them.

CR Number: 2022238010 **Implementation Date:** 02-Sep-22 Related CR: 2022238010

Change Requested		Final Disposition	Final Placement	MedDRA Code #	
Add a New LLT					
Proposed LLT	*Chronic dopamine agonist withdrawal syndrome*	Approved as Requested	Proposed LLT		
			Chronic dopamine agonist withdrawal syndrome	10088380	Current
			To PT		
			Dopamine agonist withdrawal syndrome	10088379	

MSSO Comment: The proposal to add a new LLT Chronic dopamine agonist withdrawal syndrome is approved as requested. Impulse control disorders appear to be a major risk factor for dopamine agonist withdrawal syndrome, and are present in virtually all affected patients. Some patients who are unable to discontinue dopamine agonist therapy may experience chronic impulse control disorders. Chronic dopamine agonist withdrawal syndrome will be added as LLT to the new PT Dopamine agonist withdrawal syndrome added in change request 2022238011.

Supplemental Update Report

CR Number: 2022238011 **Implementation Date:** 02-Sep-22 Related CR: 2022238011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dopamine agonist withdrawal syndrome*	Approved Not as Requested	Proposed PT	
HLT primary	*Withdrawal and rebound effects*		*Dopamine agonist withdrawal syndrome*	10088379
SOC primary	*General disorders and administration site conditions*		HLT primary	
			Withdrawal and rebound effects	10068756
			SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Parkinson's disease and parkinsonism	10034005
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new PT Dopamine agonist withdrawal syndrome to primary HLT Withdrawal and rebound effects in SOC General disorders and administration site conditions and secondary HLT Anxiety symptoms in SOC Psychiatric disorders is approved but not as requested. The dopamine agonist withdrawal syndrome develops occasionally in patients in whom a dopamine agonist is tapered and it consists of a combination of distressing physical and psychological symptoms that are refractory to levodopa and other dopaminergic medications and may persist for months or longer. There is no effective treatment other than reintroducing than the dopamine agonist to be tapered more gradually if possible. Dopamine agonist withdrawal syndrome will be added as PT with a primary link to HLT Withdrawal and rebound effects and secondary links to HLT Parkinson's disease and parkinsonism and HLT Substance related and addictive disorders.

CR Number: 2022245002 **Implementation Date:** 02-Sep-22 Related CR: 2022238011

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dopamine agonist withdrawal syndrome*	Approved as Requested	Proposed PT	
To HLT	*Substance related and addictive disorders*		*Dopamine agonist withdrawal syndrome*	10088379
			To HLT	
			Substance related and addictive disorders	10079102

MSSO Comment:

Supplemental Update Report

CR Number: 2022240001 **Implementation Date:** 02-Sep-22 Related CR: 2022240001

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Focal dystonia*	Approved as Requested	Proposed LLT	
		Focal dystonia	10088381 Current
		To PT	
		Dystonia	10013983

MSSO Comment: The proposal to add a new term Focal dystonia is approved as requested. Classification of dystonias according to their body distribution has relevant clinical and treatment implications. Focal dystonias are those affecting a single body part. They typically start during adulthood, after age 20 to 30 years. Focal dystonia will be added as LLT to PT Dystonia.

CR Number: 2022241003 **Implementation Date:** 02-Sep-22 Related CR: 2022241003

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Radiation induced encephalopathy*	Approved as Requested	Proposed PT	
		Radiation induced encephalopathy	10088375
		HLT primary	
		Radiation injuries	10037759
		SOC primary	
		Injury, poisoning and procedural complications	10022117
		HLT secondary	
		Encephalopathies toxic and metabolic	10014624
		SOC secondary	
		Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Radiation induced encephalopathy is approved as requested. Radiation encephalopathy is a late complication of cranial irradiation which involves significant cognitive and emotional dysfunction following radiation therapy to the brain. Radiation induced encephalopathy will be added as a PT with a primary link to HLT Radiation injuries and a secondary link to HLT Encephalopathies toxic and metabolic.

Supplemental Update Report

CR Number: 2022241004 **Implementation Date:** 02-Sep-22 Related CR: 2022241004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Superoxide dismutase increased*	Approved Not as Requested	Proposed PT	
			Superoxide dismutase activity increased	10088376
			HLT primary	
			Tissue enzyme analyses NEC	10043891
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Superoxide dismutase increased is approved but not as requested. Superoxide dismutase, which catalyzes the dismutation of the superoxide anion into hydrogen peroxide and molecular oxygen, is one of the most important antioxidant enzymes. The superoxide dismutase activity test is a colorimetric activity assay designed for the detection and quantification of superoxide dismutase activity in serum. The proposed term will be modified to Superoxide dismutase activity increased, which is its more frequently used representation in literature, and added as PT to HLT Tissue enzyme analyses NEC.

CR Number: 2022241005 **Implementation Date:** 02-Sep-22 Related CR: 2022241005

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Digital chromoendoscopy proactively*	Approved as Requested	Term to modify	
Replacement term	*Digital chromoendoscopy*		*Digital chromoendoscopy proactively*	10088367
			Replacement term	
			Digital chromoendoscopy	10088367 Current

MSSO Comment: The proposal to rename PT/LLT Digital chromoendoscopy proactively to Digital chromoendoscopy is approved as requested. Digital chromoendoscopy proactively will be renamed to Digital chromoendoscopy to correct a typographical error occurred during the process of addition of the term to MedDRA.

CR Number: 2022242001 **Implementation Date:** 02-Sep-22 Related CR: 2022242001

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Explorative thoracotomy*	Rejected		
From PT	*Thoracotomy*			
HLT primary	*Chest wall and mediastinal therapeutic procedures*			

MSSO Comment: The proposal to promote the LLT Explorative thoracotomy from PT Thoracotomy to primary HLT Chest wall and mediastinal therapeutic procedures in SOC Surgical and medical procedures is not approved. Explorative thoracotomy is a qualified term indicating the aim of the surgical intervention, and therefore is correctly subordinated to the PT Thoracotomy referring to the surgery in general terms. As an associated change, and to warrant consistency with other similar terms, the PT Explorative laparotomy will be demoted under the general PT Laparotomy, in line with current placement of the requested term.

Supplemental Update Report

CR Number: 2022245003 **Implementation Date:** 02-Sep-22 Related CR: 2022242001

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Explorative laparotomy*	Approved as Requested	PT to merge	
To PT	*Laparotomy*		*Explorative laparotomy*	10053361 Current
			To PT	
			Laparotomy	10023696

MSSO Comment:

CR Number: 2022242002 **Implementation Date:** 02-Sep-22 Related CR: 2022242002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Dementia due to Hyponatremia*	Rejected		
To PT	*Dementia*			

MSSO Comment: The proposal to add a new LLT Dementia due to Hyponatremia to PT Dementia is not approved. The MSSO considers this proposed term to be of a “due to” nature. Terms that state or imply a “due to” concept are generally not added to MedDRA. Please note that the MedDRA Term Selection: Points to Consider document Section 3.5.4 provides the option for splitting and coding.

CR Number: 2022242003 **Implementation Date:** 02-Sep-22 Related CR: 2022242003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Itchy Mole*	Approved Not as Requested	Proposed LLT	
			Itchy mole	10088382 Current
			To PT	
			Melanocytic naevus	10027145

MSSO Comment: The proposal to add a new term Itchy Mole is approved but not as requested. Most moles are normal and usually harmless, but sometimes they can turn cancerous. An itchy mole, along with other changes like crusting and bleeding, could be a sign of melanoma. Proposed term will be modified per MedDRA capitalization conventions and added as subconcept LLT Itchy mole under PT Melanocytic naevus.

Supplemental Update Report

CR Number: 2022242004 **Implementation Date:** 02-Sep-22 Related CR: 2022242004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Perietal pleura lipoma*	Approved Not as Requested	Proposed LLT *Parietal pleura lipoma* To PT *Benign pleural neoplasm*	10088383 Current 10004443

MSSO Comment: The proposal to add a new term Perietal pleura lipoma is approved but not as requested. Pleural lipomas are the most common benign soft tissue tumor of the pleura and are thought to originate from the submesothelial layers of the parietal pleura or mediastinal pleura, extending into the subpleural, pleural, or extrapleural space. Proposed term will be modified for spelling and added as sub-concept LLT Parietal pleura lipoma to PT Benign pleural neoplasm.

CR Number: 2022242005 **Implementation Date:** 02-Sep-22 Related CR: 2022242005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Left ventricle outflow tract STENOSIS*	Rejected		

MSSO Comment: The proposal to add a new term Left ventricle outflow tract STENOSIS is not approved. The proposed term can be misleading, since it may be understood was a synonym of the "functional" or "dynamic" concept that ventricle outflow tract obstruction represents, or as an encompassing term for the stenotic conditions involving the left ventricle outflow tract, such as a Cardiac septal hypertrophy, Hypertrophic cardiomyopathy, Aortic valve stenosis, Subvalvular aortic stenosis, Supravalvular aortic stenosis. All these concepts (functional or morphologic) have a corresponding term in MedDRA that might be used depending upon the context.

CR Number: 2022242006 **Implementation Date:** 02-Sep-22 Related CR: 2022242006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Exertional rhabdomyolysis*	Approved as Requested	Proposed PT *Exertional rhabdomyolysis*	10088386
HLT primary	*Myopathies*		HLT primary *Myopathies*	10028640
SOC primary	*Musculoskeletal and connective tissue disorders*		SOC primary *Musculoskeletal and connective tissue disorders*	10028395

MSSO Comment: The proposal to add a new PT Exertional rhabdomyolysis to primary HLT Myopathies in SOC Musculoskeletal and connective tissue disorders is approved as requested. Exertional rhabdomyolysis is a relatively uncommon condition associated to intense physical exercise, which presents with pain, weakness, and swelling in the muscles affected as well as significantly elevated levels of creatine kinase in serum and potential presence of myoglobinuria. Hydration is the mainstay of treatment, which may include dialysis in cases complicated with acute renal failure.

Supplemental Update Report

CR Number: 2022242007 **Implementation Date:** 02-Sep-22 Related CR: 2022242007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Exertional rhabdomyolysis*	Rejected		
To PT	*Exertional rhabdomyolysis*			

MSSO Comment: The proposal to add a new LLT Exertional rhabdomyolysis to PT Exertional rhabdomyolysis is not approved. Every new MedDRA PT added automatically has an exact match-mirror image LLT added as well.

CR Number: 2022242008 **Implementation Date:** 12-Sep-22 Related CR: 2022242008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Exertional induced muscle injury*	Approved Not as Requested After Suspension	Proposed LLT	
To PT	*Exertional rhabdomyolysis*		*Exercise induced muscle damage*	10088423 Current
			To PT	
			Exertional rhabdomyolysis	10088386

MSSO Comment: The proposal to add a new LLT Exertional induced muscle injury to PT Exertional rhabdomyolysis is approved but not as requested after suspension. The proposed term will be modified to the more prevalent term used in literature and added as LLT Exercise induced muscle damage to PT Exertional rhabdomyolysis.

CR Number: 2022242009 **Implementation Date:** 02-Sep-22 Related CR: 2022242009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Benign exertional rhabdomyolysis*	Rejected		
To PT	*Exertional rhabdomyolysis*			

MSSO Comment: The proposal to add a new LLT Benign exertional rhabdomyolysis to PT Exertional rhabdomyolysis is not approved. To avoid overpopulation of the terminology, MedDRA refrains from adding severity descriptors.

Supplemental Update Report

CR Number: 2022242010 **Implementation Date:** 11-Oct-22 Related CR: 2022242010

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*exertional rhabdomyolysis*	Rejected		
To SMQ	*Rhabdomyolysis/myopathy (SMQ)*			
Term scope	*Narrow*			

MSSO Comment: The proposal to add PT exertional rhabdomyolysis to Rhabdomyolysis/myopathy (SMQ) as a narrow term is not approved. This is a technical rejection. PT Exertional rhabdomyolysis was added to Rhabdomyolysis/myopathy (SMQ) as a scope term narrow term as part of the MSSO's SMQ maintenance process. See batch # 29116363; change request # 2022266048.

CR Number: 2022242011 **Implementation Date:** 02-Sep-22 Related CR: 2022242011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Post-viral cough*	Rejected		
To PT	*Cough*			

MSSO Comment: The proposal to add a new LLT Post-viral cough to PT Cough is not approved. Proposed term is a dual concept and can be represented by existing terms in MedDRA.

CR Number: 2022242012 **Implementation Date:** 07-Sep-22 Related CR: 2022242012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hymenal tag*	Approved Not as Requested	Proposed PT	
HLT primary	*Female reproductive tract disorders congenital*		*Hymenal tag*	10088387
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Vulvovaginal disorders NEC	10047790
			SOC primary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new PT Hymenal tag to primary HLT Female reproductive tract disorders congenital in SOC Congenital, familial and genetic disorders and secondary HLT Vulvovaginal disorders NEC in SOC Reproductive system and breast disorders is approved but not as requested. Hymenal tags, remnants of the hymen consisting on extra tissue that protrudes from the edge of the hymen, are most often seen after child birth or sexual abuse. PT Hymenal tag will be added to HLT Vulvovaginal disorders NEC.

Supplemental Update Report

CR Number: 2022243001 **Implementation Date:** 02-Sep-22 Related CR: 2022243001

Change Requested		Final Disposition	Final Placement	MedDRA Code #	
Add a New Term					
Proposed Term	*Vitamin b deficiency*	Approved Not as Requested	Proposed LLT		
			Vitamin B deficiency	10088384	Current
			To PT		
			Vitamin B complex deficiency	10061580	

MSSO Comment: The proposal to add a new term Vitamin b deficiency is approved but not as requested. Vitamin B deficiency will be modified to comply with MedDRA capitalization conventions and added as synonym LLT to PT Vitamin B complex deficiency.

CR Number: 2022243002 **Implementation Date:** 02-Sep-22 Related CR: 2022243002

Change Requested		Final Disposition	Final Placement	MedDRA Code #	
Add a New Term					
Proposed Term	*Prostatic adenocarcinoma in situ*	Approved as Requested	Proposed LLT		
			Prostatic adenocarcinoma in situ	10088385	Current
			To PT		
			Prostate cancer stage 0	10036912	

MSSO Comment: The proposal to add a new term Prostatic adenocarcinoma in situ is approved as requested. Prostatic adenocarcinoma in situ represents a stage of a prostatic adenocarcinoma in which abnormal cells have not spread beyond where they first formed and have not yet broken the basal membrane. Prostatic adenocarcinoma in situ will be added as sub-concept LLT to PT Prostate cancer stage 0.

CR Number: 2022243003 **Implementation Date:** 02-Sep-22 Related CR: 2022243003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Impetiginized dyshidrotic eczema*	Rejected		

MSSO Comment: The proposal to add a new term Impetiginized dyshidrotic eczema is not approved. The proposed term results from the coexistence of a dyshidrotic eczema with a superimposed significant infection with Staphylococcus aureus, and therefore is a combination term which can be represented with existing terms in MedDRA.

Supplemental Update Report

CR Number: 2022243004 **Implementation Date:** 02-Sep-22 Related CR: 2022243004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Borreliosis*	Rejected		

MSSO Comment: The proposal to add a new term Borreliosis is not approved. Although Borreliosis is often used synonymously with Lyme disease, it may be also used in the context of Relapsing fever, thus leading to confusion, especially when translated to other languages. Please consider the more specific LLT Lyme borreliosis for your coding needs.

CR Number: 2022243006 **Implementation Date:** 07-Sep-22 Related CR: 2022243006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Antibody-dependent enhancement*	Approved as Requested	Proposed PT	
HLT primary	*Immune and associated conditions NEC*		*Antibody-dependent enhancement*	10088388
SOC primary	*Immune system disorders*		HLT primary	
			Immune and associated conditions NEC	10027682
			SOC primary	
			Immune system disorders	10021428
			HLT secondary	
			Vaccination related complications	10068755
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Antibody-dependent enhancement to primary HLT Immune and associated conditions NEC in SOC Immune system disorders is approved as requested. Antibody-dependent enhancement can be mediated by antibody Fc receptor-associated internalization of a virus, thus resulting in more extensive viral replication and cytokine release in the presence of virus-specific antibodies. PT Antibody-dependent enhancement will also be linked to secondary HLT Vaccination related complications. In a related change, PT Vaccine associated enhanced disease will be merged under PT Antibody-dependent enhancement. In context with vaccines, LLT Vaccine associated enhanced disease can be considered a sub-concept.

Supplemental Update Report

CR Number: 2022250014 **Implementation Date:** 07-Sep-22 Related CR: 2022243006

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Vaccine associated enhanced disease*	Approved as Requested	PT to merge	
To PT	*Antibody-dependent enhancement*		*Vaccine associated enhanced disease*	10085491 Current
			To PT	
			Antibody-dependent enhancement	10088388

MSSO Comment:

CR Number: 2022243007 **Implementation Date:** 07-Sep-22 Related CR: 2022243007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Enhanced respiratory disease*	Approved as Requested	Proposed PT	
HLT primary	*Immune and associated conditions NEC*		*Enhanced respiratory disease*	10088389
SOC primary	*Immune system disorders*		HLT primary	
			Immune and associated conditions NEC	10027682
			SOC primary	
			Immune system disorders	10021428
			HLT secondary	
			Lower respiratory tract inflammatory and immunologic conditions	10024972
			SOC secondary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new PT Enhanced respiratory disease to primary HLT Immune and associated conditions NEC in SOC Immune system disorders is approved as requested. Enhanced respiratory disease (ERD) describes severer clinical symptoms after respiratory virus infection, such as with respiratory syncytial virus and influenza virus, due to previous immune responses. Enhanced respiratory disease can happen during homotypic or heterotypic serotype virus infection after vaccination, natural infection or transfer of maternal passive immunity. PT Enhanced respiratory disease will also be linked to secondary HLT Lower respiratory tract inflammatory and immunologic conditions and to secondary HLT Vaccination related complications. In a related change, PT Vaccine associated enhanced respiratory disease will be demoted under PT Enhanced respiratory disease as a sub-concept LLT.

Supplemental Update Report

CR Number: 2022250015 **Implementation Date:** 07-Sep-22 Related CR: 2022243007

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Vaccine associated enhanced respiratory disease*	Approved as Requested	PT to merge	
To PT	*Enhanced respiratory disease*		*Vaccine associated enhanced respiratory disease*	10085001 Current
			To PT	
			Enhanced respiratory disease	10088389

MSSO Comment:

CR Number: 2022250016 **Implementation Date:** 07-Sep-22 Related CR: 2022243007

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Enhanced respiratory disease*	Approved as Requested	Proposed PT	
To HLT	*Vaccination related complications*		*Enhanced respiratory disease*	10088389
			To HLT	
			Vaccination related complications	10068755

MSSO Comment:

CR Number: 2022243008 **Implementation Date:** 07-Sep-22 Related CR: 2022243008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Punctoplasty*	Approved Not as Requested	Proposed PT	
			Punctoplasty	10088390
			HLT primary	
			Lacrimal apparatus therapeutic procedures	10023617
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Punctoplasty is approved but not as requested. Punctoplasty is a surgical procedure to restore proper drainage of tears when the lacrimal punctum becomes narrowed or blocked in one or both eyes. Punctoplasty will be added as a PT under HLT Lacrimal apparatus therapeutic procedures.

Supplemental Update Report

CR Number: 2022243009 **Implementation Date:** 07-Sep-22 Related CR: 2022243009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*TOOTH DEVITALIZATION*	Approved Not as Requested	Proposed LLT	
			Tooth devitalization	10088392 Current
			To PT	
			Endodontic procedure	10051085

MSSO Comment: The proposal to add a new LLT TOOTH DEVITALIZATION is approved but not as requested. A tooth devitalization is the procedure for the removal of necrotic or infected pulp material and the scrupulous cleansing of the channels contained in the roots of the tooth, within which the branches of the nerve flow. Tooth devitalization will be modified according to MedDRA capitalization conventions and will be added as a synonym LLT to PT Endodontic procedure. In a related change, the counterpart British English spelling Tooth devitalisation will also be added as an LLT to PT Endodontic procedure.

CR Number: 2022250017 **Implementation Date:** 07-Sep-22 Related CR: 2022243009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tooth devitalisation*	Approved as Requested	Proposed LLT	
To PT	*Endodontic procedure*		*Tooth devitalisation*	10088393 Current
			To PT	
			Endodontic procedure	10051085

MSSO Comment:

CR Number: 2022243010 **Implementation Date:** 07-Sep-22 Related CR: 2022243010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Balloon dilation bronchoscopy*	Approved as Requested	Proposed LLT	
			Balloon dilation bronchoscopy	10088391 Current
			To PT	
			Bronchoplasty	10063653

MSSO Comment: The proposal to add a new LLT Balloon dilation bronchoscopy is approved as requested. Balloon dilation bronchoscopy will be added as a synonym LLT to PT Bronchoplasty.

Supplemental Update Report

CR Number: 2022244001 **Implementation Date:** 07-Sep-22 Related CR: 2022244001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Fever due to infection*	Rejected		
To PT	*Infection*			

MSSO Comment: The proposal to add a new LLT Fever due to infection to PT Infection is not approved. The proposed concept is a combined term related to the causal relationship of two conditions, fever and infection, which are already represented in MedDRA.

CR Number: 2022244002 **Implementation Date:** 07-Sep-22 Related CR: 2022244002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Axial arthropathy*	Approved Not as Requested	Proposed LLT	
To PT	*Spondyloarthropathy*		*Axial spondyloarthropathy*	10088394 Current
			To PT	
			Spondyloarthropathy	10051265

MSSO Comment: The proposal to add a new LLT Axial arthropathy to PT Spondyloarthropathy is approved but not as requested. The proposed term will be modified to Axial spondyloarthropathy and added as an LLT to PT Spondyloarthropathy. Using 'Axial' always refers to spondyloarthropathy, spine and sacroiliac joints.

CR Number: 2022245004 **Implementation Date:** 12-Sep-22 Related CR: 2022245004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Drug shortage outside of pandemic*	Approved Not as Requested	Proposed LLT	
			Drug shortage	10088401 Current
			To PT	
			Product availability issue	10077800

MSSO Comment: The proposal to add a new LLT Drug shortage outside of pandemic is approved but not as requested. Drug shortages can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. Proposed term will be modified without descriptor and added as sub-concept LLT Drug shortage under PT Product availability issue.

Supplemental Update Report

CR Number: 2022247001 **Implementation Date:** 07-Sep-22 Related CR: 2022247001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*COLON ANGIODYSPLASIA*	Approved Not as Requested	Proposed LLT	
To PT	*Gastrointestinal angiodysplasia*		*Colon angiodysplasia*	10088396 Current
			To PT	
			Gastrointestinal angiodysplasia	10017928

MSSO Comment: The proposal to add a new LLT COLON ANGIODYSPLASIA to PT Gastrointestinal angiodysplasia is approved but not as requested. Colonic angiodysplasias are arteriovenous malformations formed by dilated, tortuous vessels that typically develop in the cecum and ascending colon and may cause recurrent bleeding, which is rarely massive. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as LLT Colon angiodysplasia to PT Gastrointestinal angiodysplasia.

CR Number: 2022247002 **Implementation Date:** 07-Sep-22 Related CR: 2022247002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*EMPHYSEMATOUS COPD*	Approved Not as Requested	Proposed LLT	
To PT	*COPD*		*Emphysematous COPD*	10088395 Current
			To PT	
			Chronic obstructive pulmonary disease	10009033

MSSO Comment: The proposal to add a new LLT EMPHYSEMATOUS COPD to PT COPD is approved but not as requested. Chronic obstructive pulmonary disease is airflow limitation caused by an inflammatory response to inhaled toxins, often cigarette smoke, which is very often associated with emphysema, a destruction of lung parenchyma leading to loss of elastic recoil and loss of alveolar septa and radial airway traction. The proposed term represents this frequent association and - once modified in accord with MedDRA capitalization naming conventions - will be added as LLT Emphysematous COPD to PT Chronic obstructive pulmonary disease.

CR Number: 2022248001 **Implementation Date:** 07-Sep-22 Related CR: 2022248001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*FRONTAL SINUS APLASIA*	Approved Not as Requested	Proposed LLT	
			Frontal sinus aplasia	10088397 Current
			To PT	
			Paranasal sinus aplasia	10074401

MSSO Comment: The proposal to add a new term FRONTAL SINUS APLASIA is approved but not as requested. Frontal sinus aplasia is the absence or incomplete development of the frontal sinus due to lack or deficient pneumatization of the frontal recess into the frontal bone. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as LLT Frontal sinus aplasia to PT Paranasal sinus aplasia.

Supplemental Update Report

CR Number: 2022248002 **Implementation Date:** 07-Sep-22 Related CR: 2022248002

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Anxiety(nos)*	Rejected		

MSSO Comment: The proposal to add a new term Anxiety(nos) is not approved. From MedDRA Version 6.1, no additional “NOS” (not otherwise specified) terms will be accepted into the terminology.

CR Number: 2022248003 **Implementation Date:** 07-Sep-22 Related CR: 2022248003

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Class 1 dental malocclusion*	Approved as Requested	Proposed LLT *Class 1 dental malocclusion*	10088398 Current
		To PT *Malocclusion*	10061274

MSSO Comment: The proposal to add a new term Class 1 dental malocclusion is approved as requested. Dental malocclusions are classified based on the positioning of the upper and lower molars. A class 1 malocclusion occurs when the molar position, or bite, is normal, but there is some kind of misalignment of other teeth. Class 1 dental malocclusion will be added as an LLT to PT Malocclusion.

CR Number: 2022248004 **Implementation Date:** 07-Sep-22 Related CR: 2022248004

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Class 2 dental malocclusion*	Approved as Requested	Proposed LLT *Class 2 dental malocclusion*	10088399 Current
		To PT *Malocclusion*	10061274

MSSO Comment: The proposal to add a new term Class 2 dental malocclusion is approved as requested. Class 2 (or class II) malocclusions are characterized by upper molars that are too far forward compared to the lower molars. This overbite can be caused by an overly prominent upper jaw or an underdeveloped lower jaw. Class 2 dental malocclusion will be added as LLT to PT Malocclusion. In a related change, LLT Class 3 dental malocclusion will also be added proactively to PT Malocclusion in order to represent the third element of this classification, which is characterized by lower molars that are too far forward compared to the upper molars, causing an underbite.

Supplemental Update Report

CR Number: 2022250019 **Implementation Date:** 07-Sep-22 Related CR: 2022248004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Class 3 dental malocclusion*	Approved as Requested	Proposed LLT	
To PT	*Malocclusion*		*Class 3 dental malocclusion*	10088400 Current
			To PT	
			Malocclusion	10061274

MSSO Comment:

CR Number: 2022249001 **Implementation Date:** 12-Sep-22 Related CR: 2022249001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*VENTRICULAR OUTFLOW TRACT STENOSIS*	Rejected		

MSSO Comment: The proposal to add a new term VENTRICULAR OUTFLOW TRACT STENOSIS is not approved. In reference to change requests 2022242005 (Left ventricle outflow tract STENOSIS) and 2022249001, we would request that you resubmit the change request and provide detailed justification on clinical scenarios that would cause ventricular outflow tract stenosis and the possible difference with existing left and right acquired outflow tract obstructions.

CR Number: 2022249002 **Implementation Date:** 12-Sep-22 Related CR: 2022249002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Localized hypertrophic neuropathy*	Approved as Requested	Proposed LLT	
			Localized hypertrophic neuropathy	10088406 Current
			To PT	
			Hypertrophic neuropathy	10088404

MSSO Comment: The proposal to add a new LLT Localized hypertrophic neuropathy is approved as requested. Localized hypertrophic neuropathy is a rare condition resulting in onion bulb-like Schwann cell hypertrophy from repeated demyelination and remyelination. The fusiform enlargement of the nerve is focal and separable from the hypertrophic neuropathies (Charcot-Marie-Tooth disease, Dejerine-Sottas disease, hereditary neuropathy with liability to pressure palsy, and chronic inflammatory demyelinating polyneuropathy) only by the lack of a diffuse polyneuropathy. Proposed term will be added as sub-concept LLT Localized hypertrophic neuropathy under new PT Hypertrophic neuropathy. In a related change, new PT Hypertrophic neuropathy will be added under primary HLT Nervous system neoplasms benign NEC. In addition, the British English spelled counterpart LLT Localised hypertrophic neuropathy will also be added under the new PT Hypertrophic neuropathy.

Supplemental Update Report

CR Number: 2022255012 **Implementation Date:** 12-Sep-22 Related CR: 2022249002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypertrophic neuropathy*	Approved as Requested	Proposed PT *Hypertrophic neuropathy*	10088404
HLT primary	*Nervous system neoplasms benign NEC*		HLT primary *Nervous system neoplasms benign NEC*	10029210
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		SOC primary *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*	10029104

MSSO Comment:

CR Number: 2022255013 **Implementation Date:** 12-Sep-22 Related CR: 2022249002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Localised hypertrophic neuropathy*	Approved as Requested	Proposed LLT *Localised hypertrophic neuropathy*	10088407 Current
To PT	*Hypertrophic neuropathy*		To PT *Hypertrophic neuropathy*	10088404

MSSO Comment:

Supplemental Update Report

CR Number: 2022249003 **Implementation Date:** 12-Sep-22 Related CR: 2022249003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Laryngeal angioma*	Approved Not as Requested	Proposed PT	
			Laryngeal angioma	10088403
			HLT primary	
			Pharyngeal and laryngeal neoplasms benign	10034807
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Vascular neoplasms	10057189
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new LLT Laryngeal angioma is approved but not as requested. Laryngeal angiomas, are divided into hemangiomas and lymphangiomas, are slowly progressing vascular tumors, which are commonly diagnosed in children, but are rarer in adults. They may occur in the vocal chamber, arytenoid cartilage or aryepiglottic fold. Laryngeal angioma will be added as a PT to primary HLT Pharyngeal and laryngeal neoplasms benign, to secondary HLT Vascular neoplasms and to secondary HLT Upper respiratory tract neoplasms.

CR Number: 2022255014 **Implementation Date:** 12-Sep-22 Related CR: 2022249003

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Laryngeal angioma*	Approved as Requested	Proposed PT	
To HLT	*Upper respiratory tract neoplasms*		*Laryngeal angioma*	10088403
			To HLT	
			Upper respiratory tract neoplasms	10046311

MSSO Comment:

Supplemental Update Report

CR Number: 2022249004 **Implementation Date:** 12-Sep-22 Related CR: 2022249004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Genu flexum*	Approved as Requested	Proposed LLT *Genu flexum*	10088405 Current
			To PT *Knee deformity*	10062061

MSSO Comment: The proposal to add a new LLT Genu flexum is approved as requested. Genu flexum, or constant flexed knee, corresponds to an attitude of the joint which cannot extend fully. Proposed term will be added as new LLT Genu flexum under PT Knee deformity. In a related change, LLT Hyperextension of knee and LLT Genu recurvatum will both be moved from PT Joint hyperextension to PT Knee deformity for better alignment.

CR Number: 2022255015 **Implementation Date:** 12-Sep-22 Related CR: 2022249004

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hyperextension of knee*	Approved as Requested	Proposed LLT *Hyperextension of knee*	10020628 Current
From PT	*Joint hyperextension*		From PT *Joint hyperextension*	10062310
To PT	*Knee deformity*		To PT *Knee deformity*	10062061

MSSO Comment:

CR Number: 2022255016 **Implementation Date:** 12-Sep-22 Related CR: 2022249004

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Genu recurvatum*	Approved as Requested	Proposed LLT *Genu recurvatum*	10018194 Current
From PT	*Joint hyperextension*		From PT *Joint hyperextension*	10062310
To PT	*Knee deformity*		To PT *Knee deformity*	10062061

MSSO Comment:

Supplemental Update Report

CR Number: 2022249005 **Implementation Date:** 12-Sep-22 Related CR: 2022249005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Nail dysplasia*	Approved Not as Requested	Proposed PT	
			Nail dysplasia	10088402
			HLT primary	
			Hair and nail disorders congenital	10072983
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Nail and nail bed conditions (excl infections and infestations)	10028685
			SOC secondary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new LLT Nail dysplasia is approved but not as requested. Nail dysplasia is often present at birth and may present as nail hypoplasia, anonychia, longitudinal ridging, splitting, and spooning of the nail. Nail dysplasia will be added as a PT to primary HLT Hair and nail disorders congenital and to secondary HLT Nail and nail bed conditions (excl infections and infestations).

CR Number: 2022249006 **Implementation Date:** 12-Sep-22 Related CR: 2022249006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Posterior pituitary injection*	Approved Not as Requested	Proposed PT	
			Posterior pituitary injection	10088409
			HLT primary	
			Haematological therapeutic procedures NEC	10052724
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Posterior pituitary injection is approved but not as requested. Posterior pituitary injection is an extract prepared from the dried posterior lobe of the pituitary gland from domestic animals containing two octapeptide hormones, oxytocin and vasopressin. Posterior pituitary injection carries an approved therapeutic indication as an adjunct measure for achieving surgical hemostasis. Proposed term will be added as new PT Posterior pituitary injection under primary HLT Haematological therapeutic procedures NEC.

Supplemental Update Report

CR Number: 2022249007 **Implementation Date:** 12-Sep-22 Related CR: 2022249007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Dental sepsis*	Approved Not as Requested	Proposed PT	
			Dental sepsis	10088408
			HLT primary	
			Sepsis, bacteraemia, viraemia and fungaemia NEC	10040054
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Dental and periodontal infections and inflammations	10012325
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new LLT Dental sepsis is approved but not as requested. When an infection occurs, bacteria can move out of the tooth to the bone or tissue below, forming a dental abscess. A dental infection can lead to sepsis. Dental sepsis will be added as a PT to primary HLT Sepsis, bacteraemia, viraemia and fungaemia NEC and to secondary HLT Dental and periodontal infections and inflammations.

CR Number: 2022249008 **Implementation Date:** 12-Sep-22 Related CR: 2022249008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*CARDIAC INFLAMMATION*	Approved Not as Requested	Proposed LLT	
			Cardiac inflammation	10088410 Current
			To PT	
			Carditis	10062746

MSSO Comment: The proposal to add a new term CARDIAC INFLAMMATION is approved but not as requested. The proposed term will be modified for MedDRA capitalization standards to Cardiac inflammation and will be added as a synonym LLT under PT Carditis.

Supplemental Update Report

CR Number: 2022250001 **Implementation Date:** 12-Sep-22 Related CR: 2022250001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Wheat allergy*	Approved as Requested	Proposed LLT *Wheat allergy* To PT *Food allergy*	10088411 Current 10016946

MSSO Comment: The proposal to add a new term Wheat allergy is approved as requested. Wheat allergy is an allergy to wheat which typically presents itself as a food allergy, but can also be a contact allergy resulting from occupational exposure. Wheat allergy will be added as LLT to PT Food allergy.

CR Number: 2022250003 **Implementation Date:** 12-Sep-22 Related CR: 2022250003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Iliac artery stent insertion*	Approved as Requested	Proposed LLT *Iliac artery stent insertion* To PT *Peripheral artery stent insertion*	10088416 Current 10072562

MSSO Comment: The proposal to add a new term Iliac artery stent insertion is approved as requested. Endovascular iliac stent placement has been widely used for the treatment of aortoiliac occlusive disease, specially in lesions that respond poorly to percutaneous transluminal angioplasty, such as complex calcified or eccentric stenoses, plaques with ulceration or aneurysm formation or long segmental stenoses. Iliac artery stent insertion will be added as LLT to PT Peripheral artery stent insertion, along with the related existing LLT Femoropopliteal artery prosthesis insertion.

CR Number: 2022250004 **Implementation Date:** 12-Sep-22 Related CR: 2022250004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Uretero-fallopian fistula*	Approved as Requested	Proposed LLT *Uretero-fallopian fistula* To PT *Female genital tract fistula*	10088414 Current 10061149

MSSO Comment: The proposal to add a new term Uretero-fallopian fistula is approved as requested. Uretero-fallopian fistula is a very rare surgery complication which usually happens after surgeries of fallopian tube or ureter that could lead to severe complications like hydronephrosis and infection, posing a great challenge for surgical repair. Uretero-fallopian fistula will be added as LLT to PT Female genital tract fistula. In a related change, PT Female genital tract fistula will be given a secondary link to HLT Reproductive tract and breast procedural complications, in relation to its frequent procedural etiology.

Supplemental Update Report

CR Number: 2022255017 **Implementation Date:** 12-Sep-22 Related CR: 2022250004

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Female genital tract fistula*	Approved as Requested	Proposed PT	
			Female genital tract fistula	10061149
To HLT	*Reproductive tract and breast procedural complications*		To HLT	
			Reproductive tract and breast procedural complications	10038609

MSSO Comment:

CR Number: 2022250005 **Implementation Date:** 12-Sep-22 Related CR: 2022250005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Salpingoclasia*	Approved as Requested	Proposed LLT	
			Salpingoclasia	10088412 Current
			To PT	
			Female sterilisation	10056199

MSSO Comment: The proposal to add a new term Salpingoclasia is approved as requested. LLT Salpingoclasia, a rarely used synonym of LLT Tubal ligation, will be added to PT Female sterilisation.

CR Number: 2022250006 **Implementation Date:** 12-Sep-22 Related CR: 2022250006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Endoprosthesis*	Approved Not as Requested	Proposed LLT	
			Endoprosthesis implantation	10088417 Current
			To PT	
			Prosthesis implantation	10054825

MSSO Comment: The proposal to add a new term Endoprosthesis is approved but not as requested. Endoprosthesis is a prosthesis placed entirely within the body, such as in arthroplasty or as in the placement of a hollow stent in an artery. The proposed term will be renamed to Endoprosthesis implantation for greater clarity, and added as LLT to PT Prosthesis implantation.

Supplemental Update Report

CR Number: 2022250007 **Implementation Date:** 12-Sep-22 Related CR: 2022250007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Stoma reversal*	Approved as Requested	Proposed LLT	
			Stoma reversal	10088418 Current
			To PT	
			Stoma closure	10074172

MSSO Comment: The proposal to add a new term Stoma reversal is approved as requested. A stoma reversal is surgery to attach your bowel together after a colostomy or ileostomy (also called ostomies). Stoma reversal will be added as synonym LLT under PT Stoma closure.

CR Number: 2022250008 **Implementation Date:** 12-Sep-22 Related CR: 2022250008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Endoscopic vein harvesting (EVH)*	Approved Not as Requested	Proposed LLT	
			Endoscopic vein harvesting	10088415 Current
			To PT	
			Vessel harvesting	10081419

MSSO Comment: The proposal to add a new term Endoscopic vein harvesting (EVH) is approved but not as requested. The endoscopic vein harvesting procedure uses a smaller incision to obtain a bypass conduit for CABG than traditional vessel harvesting procedures. LLT Endoscopic vein harvesting, will be modified by removing parenthesed acronym and added as a synonym of existing LLT Endoscopic vessel harvesting, under PT Vessel harvesting.

CR Number: 2022250009 **Implementation Date:** 12-Sep-22 Related CR: 2022250009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Retropubic suspension*	Approved as Requested	Proposed LLT	
			Retropubic suspension	10088413 Current
			To PT	
			Urinary bladder suspension	10079992

MSSO Comment: The proposal to add a new term Retropubic suspension is approved as requested. Retropubic suspension surgery is used to treat urinary incontinence, which lifts the sagging bladder neck and urethra that have dropped abnormally low in the pelvic area. LLT Retropubic suspension will be added under PT Urinary bladder suspension, aligned with existing synonym LLT Burch procedure.

Supplemental Update Report

CR Number: 2022250018 **Implementation Date:** 12-Sep-22 Related CR: 2022250018

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Sternectomy*	Approved as Requested	Proposed PT	
HLT primary	*Chest wall and mediastinal therapeutic procedures*		*Sternectomy*	10088419
SOC primary	*Surgical and medical procedures*		HLT primary	
			Chest wall and mediastinal therapeutic procedures	10008494
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Sternectomy to primary HLT Chest wall and mediastinal therapeutic procedures in SOC Surgical and medical procedures is approved as requested. A sternectomy involves partial or total debridement of the sternum to remove infected bone. Sternectomy is also the treatment of choice for primary sternal tumours because these tumours are often chemo- and radio-insensitive like chondrosarcomas, while in case of secondary sternal tumours the Sternectomy is indicated with palliative intent.

CR Number: 2022251001 **Implementation Date:** 12-Sep-22 Related CR: 2022251001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Rectal tumour excision*	Approved Not as Requested	Proposed PT	
HLT primary	*Anorectal therapeutic procedures*		*Rectal neoplasm excision*	10088420
SOC primary	*Surgical and medical procedures*		HLT primary	
			Anorectal therapeutic procedures	10002580
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Rectal tumour excision to primary HLT Anorectal therapeutic procedures in SOC Surgical and medical procedures is approved but not as requested. Early stage rectal tumors without involvement of mesorectal nodes can potentially be cured with a local excision of the portion of the rectal wall containing the tumor. The proposed term will be modified for consistency at PT level for neoplasms and added as PT Rectal neoplasm excision to HLT Anorectal therapeutic procedures.

CR Number: 2022251002 **Implementation Date:** 12-Sep-22 Related CR: 2022251002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Preauricular appendage*	Approved as Requested	Proposed LLT	
			Preauricular appendage	10088421 Current
			To PT	
			Accessory auricle	10000361

MSSO Comment: The proposal to add a new LLT Preauricular appendage is approved as requested. Preauricular appendage, a small congenital skin tag usually located anterior to the tragus of the ear, will be added as LLT to PT Accessory auricle aligned with the synonym LLT Preauricular skin tag.

Supplemental Update Report

CR Number: 2022251003 **Implementation Date:** 14-Sep-22 Related CR: 2022251003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Poirier-Bienvenu neurodevelopmental syndrome*	Approved as Requested	Proposed PT	
			Poirier-Bienvenu neurodevelopmental syndrome	10088424
			HLT primary	
			Neurological disorders congenital NEC	10029300
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Seizures and seizure disorders NEC	10039912
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Poirier-Bienvenu neurodevelopmental syndrome is approved as requested. Poirier-Bienvenu neurodevelopmental syndrome (POBINDS) is a neurologic disorder characterized in most cases by early-onset seizures and variably impaired intellectual development (ID). The severity of neurologic impairment is highly variable: some patients may have refractory seizures and be bedridden with no meaningful speech, whereas others may have treatment-responsive seizures and achieve normal psychomotor development. Poirier-Bienvenu neurodevelopmental syndrome will be added as PT to primary HLT Neurological disorders congenital NEC, to secondary HLT Seizures and seizure disorders NEC and to secondary HLT Pervasive developmental disorders NEC.

CR Number: 2022257011 **Implementation Date:** 14-Sep-22 Related CR: 2022251003

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Poirier-Bienvenu neurodevelopmental syndrome*	Approved as Requested	Proposed PT	
To HLT	*Pervasive developmental disorders NEC*		*Poirier-Bienvenu neurodevelopmental syndrome*	10088424
			To HLT	
			Pervasive developmental disorders NEC	10034740

MSSO Comment:

Supplemental Update Report

CR Number: 2022251004 **Implementation Date:** 14-Sep-22 Related CR: 2022251004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*POBINDS*	Approved as Requested	Proposed LLT	
			POBINDS	10088426 Current
			To PT	
			Poirier-Bienvenu neurodevelopmental syndrome	10088424

MSSO Comment: The proposal to add a new term POBINDS is approved as requested. POBINDS, the accronym of Poirier-Bienvenu neurodevelopmental syndrome, will be added as LLT to the new PT Poirier-Bienvenu neurodevelopmental syndrome, added in change request 2022251003.

CR Number: 2022251005 **Implementation Date:** 14-Sep-22 Related CR: 2022251005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Moisture-Associated skin damage (MASD)*	Approved Not as Requested	Proposed PT	
			Moisture-associated skin damage	10088425
			HLT primary	
			Dermatitis and eczema	10012435
			SOC primary	
			Skin and subcutaneous tissue disorders	10040785
			HLT secondary	
			Skin injuries NEC	10027699
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new term Moisture-Associated skin damage (MASD) is approved but not as requested. Moisture-associated skin damage (MASD) can result when the skin has prolonged or continuous exposure to excessive moisture. If the skin experiences too much moisture, it becomes overhydrated and is prone to maceration. MASD is a collective definition and it has four main causes: incontinence-associated dermatitis, periwound skin damage, intertriginous dermatitis and peristomal moisture-associated dermatitis. Moisture-associated skin damage, with modified spelling according to MedDRA capitalisation conventions and without the acronym, will be added as PT to primary HLT Dermatitis and eczema and secondary HLT Skin injuries NEC.

Supplemental Update Report

CR Number: 2022251006 **Implementation Date:** 12-Sep-22 Related CR: 2022251006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Hyperthyreosis*	Approved as Requested	Proposed LLT		
To PT	*Hyperthyroidism*		*Hyperthyreosis*	10088422	Current
			To PT		
			Hyperthyroidism	10020850	

MSSO Comment: The proposal to add a new LLT Hyperthyreosis to PT Hyperthyroidism is approved as requested. Hyperthyreosis is synonymously used to hyperthyroidism.

CR Number: 2022251007 **Implementation Date:** 14-Sep-22 Related CR: 2022251007

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #	
Term to modify	*Mole excision*	Approved Not as Requested	Proposed LLT		
Replacement term	*Melanocytic naevus excision*		*Melanocytic naevus excision*	10088428	Current
			To PT		
			Mole excision	10027805	

MSSO Comment: The proposal to rename PT/LLT Mole excision to Melanocytic naevus excision is approved but not as requested. Proposed term wil be added as synonym LLT Melanocytic naevus excision under PT Mole excision. In a related change, the American English spelled term LLT Melanocytic nevus excision will also be added under PT Mole excision.

CR Number: 2022257012 **Implementation Date:** 14-Sep-22 Related CR: 2022251007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Melanocytic nevus excision*	Approved as Requested	Proposed LLT		
To PT	*Mole excision*		*Melanocytic nevus excision*	10088429	Current
			To PT		
			Mole excision	10027805	

MSSO Comment:

Supplemental Update Report

CR Number: 2022251008 **Implementation Date:** 14-Sep-22 Related CR: 2022251008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Penile cyst*	Approved as Requested	Proposed PT	
HLT primary	*Penile disorders NEC (excl erection and ejaculation)*		*Penile cyst*	10088427
SOC primary	*Reproductive system and breast disorders*		HLT primary	
			Penile disorders NEC (excl erection and ejaculation)	10034304
			SOC primary	
			Reproductive system and breast disorders	10038604
			HLT secondary	
			Skin cysts and polyps	10068207
			SOC secondary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new PT Penile cyst to primary HLT Penile disorders NEC (excl erection and ejaculation) in SOC Reproductive system and breast disorders and secondary HLT Skin cysts and polyps in SOC Skin and subcutaneous tissue disorders is approved as requested. Penile cysts are fluid-filled bumps that may develop from multiple causes, such as epidermoid cysts or sebaceous cysts

CR Number: 2022251009 **Implementation Date:** 14-Sep-22 Related CR: 2022251009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anorectal chlamydial infection*	Rejected		
HLT primary	*Bacterial infections NEC*			
SOC primary	*Infections and infestations*			

MSSO Comment: The proposal to add a new PT Anorectal chlamydial infection to primary HLT Bacterial infections NEC in SOC Infections and infestations and secondary HLT Anal, rectal, perianal and perirectal infections in SOC Gastrointestinal disorders is not approved. It is not possible to represent every permutation of closely related anatomical structures' infection at PT level. The proposed concept may be represented by LLT Chlamydia trachomatis infection of anus and rectum under the PT Anal chlamydia infection.

CR Number: 2022251010 **Implementation Date:** 14-Sep-22 Related CR: 2022251010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*IGRT*	Approved as Requested	Proposed LLT	
To PT	*Radiotherapy*		*IGRT*	10088430 Current
			To PT	
			Radiotherapy	10037794

MSSO Comment: The proposal to add a new LLT IGRT to PT Radiotherapy is approved as requested. IGRT is the commonly used acronym for recently added LLT Image guided radiation therapy.

Supplemental Update Report

CR Number: 2022251011 **Implementation Date:** 14-Sep-22 Related CR: 2022251011

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *SPILT TOOTH*	Approved Not as Requested	Proposed LLT *Split tooth*	10088431 Current
		To PT *Tooth fracture*	10062544

MSSO Comment: The proposal to add a new term SPILT TOOTH is approved but not as requested. Split tooth is the progression of a cracked tooth to the extent that the tooth segments are now entirely separate. Split tooth, modified according to MedDRA capitalisation and spelling conventions, will be added as sub-concept LLT to PT Tooth fracture.

CR Number: 2022252001 **Implementation Date:** 14-Sep-22 Related CR: 2022252001

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Pediatric Non-Small Cell Lung Cancer*	Rejected		

MSSO Comment: The proposal to add a new term Pediatric Non-Small Cell Lung Cancer is not approved. MedDRA does not add demographic terms unless they represent a specific concept such as PT Paediatric acute-onset neuropsychiatric syndrome. Non-small cell lung cancer in pediatric age group is histologically indistinguishable from those seen in adults.

Supplemental Update Report

CR Number: 2022252002 **Implementation Date:** 14-Sep-22 Related CR: 2022252002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Oculocerebrocutaneous syndrome*	Approved as Requested	Proposed PT	
			Oculocerebrocutaneous syndrome	10088432
			HLT primary	
			Central nervous system disorders congenital NEC	10009713
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Congenital eye disorders NEC	10010464
			SOC secondary	
			Eye disorders	10015919

MSSO Comment: The proposal to add a new term Oculocerebrocutaneous syndrome is approved as requested. Oculocerebrocutaneous syndrome is a rare genetic disorder characterized primarily by eye, skin, and brain malformations. It has been described mostly in males. Findings in affected individuals may include orbital cysts, areas of underdeveloped or absent skin, and hypoplasia or agenesis of the corpus callosum. Oculocerebrocutaneous syndrome will be added as a PT with a primary link to HLT Central nervous system disorders congenital NEC and secondary links to HLT Congenital eye disorders NEC, HLT Congenital and hereditary central nervous system disorders NEC and HLT Skin hypoplasias and atrophies.

CR Number: 2022257013 **Implementation Date:** 14-Sep-22 Related CR: 2022252002

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Oculocerebrocutaneous syndrome*	Approved as Requested	Proposed PT	
			Oculocerebrocutaneous syndrome	10088432
To HLT	*Congenital and hereditary central nervous system disorders NEC*		To HLT	
			Congenital and hereditary central nervous system disorders NEC	10010332

MSSO Comment:

Supplemental Update Report

CR Number: 2022257014 **Implementation Date:** 14-Sep-22 Related CR: 2022252002

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Oculocerebrocutaneous syndrome*	Approved as Requested	Proposed PT	
			Oculocerebrocutaneous syndrome	10088432
To HLT	*Skin hypoplasias and atrophies*		To HLT	
			Skin hypoplasias and atrophies	10040870

MSSO Comment:

CR Number: 2022252003 **Implementation Date:** 14-Sep-22 Related CR: 2022252003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ulcerative pancolitis*	Approved Not as Requested	Proposed LLT	
			Ulcerative pancolitis	10088434 Current
To PT	*Ulcerative colitis*		To PT	
			Colitis ulcerative	10009900

MSSO Comment: The proposal to add a new LLT Ulcerative pancolitis to PT Ulcerative colitis is approved but not as requested. Ulcerative pancolitis is the most extensive form of ulcerative colitis (beyond the less extended ulcerative proctitis and left-sided ulcerative colitis) representing a subset of particular importance for its clinical severity and association with specific serological and genetic markers. Ulcerative pancolitis will be added as an LLT to PT Colitis ulcerative.

CR Number: 2022252004 **Implementation Date:** 14-Sep-22 Related CR: 2022252004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Urine output fluctuation*	Approved Not as Requested	Proposed PT	
			Urine output fluctuation	10088433
			HLT primary	
			Urinary tract function analyses NEC	10049179
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new LLT Urine output fluctuation is approved but not as requested. Urine output fluctuation represents an irregular rising and falling urine output, which can be seen in cases of compromised residual kidney function even with a very low glomerular filtration rate. Urine output fluctuation will be added as PT to HLT Urinary tract function analyses NEC.

Supplemental Update Report

CR Number: 2022252005 **Implementation Date:** 14-Sep-22 Related CR: 2022252005

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Menoschesis*	Rejected		

MSSO Comment: The proposal to add a new term Menoschesis is not approved. The proposed term is an outdated term and rarely found in international literature.

CR Number: 2022252006 **Implementation Date:** 14-Sep-22 Related CR: 2022252006

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Cyclospasm*	Approved as Requested	Proposed LLT *Cyclospasm*	10088435 Current
		To PT *Ciliary muscle spasm*	10009185

MSSO Comment: The proposal to add a new term Cyclospasm is approved as requested. Cyclospasm is the contraction of the ciliary muscle in the eye, in the accommodation of focus for near vision. Proposed term will be added as synonym LLT Cyclospasm under PT Ciliary muscle spasm.

CR Number: 2022255001 **Implementation Date:** 19-Sep-22 Related CR: 2022255001

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Prawn allergy*	Rejected		

MSSO Comment: The proposal to add a new term Prawn allergy is not approved. The proposed type of allergy can be represented by existing LLT Seafood allergy. Adding terms specific to every sort of seafood would imply a level of specificity that - if applied in other fields - would lead to an overpopulation of the terminology.

Supplemental Update Report

CR Number: 2022255002 **Implementation Date:** 19-Sep-22 Related CR: 2022255002

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Crab allergy*	Rejected		

MSSO Comment: The proposal to add a new term Crab allergy is not approved. The proposed type of allergy can be represented by existing LLT Seafood allergy. Adding terms specific to every sort of seafood would imply a level of specificity that - if applied in other fields - would lead to an overpopulation of the terminology.

CR Number: 2022255003 **Implementation Date:** 19-Sep-22 Related CR: 2022255003

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Class 1 dental caries*	Approved Not as Requested	Proposed LLT	
		Dental caries Black's class 1	10088445 Current
		To PT	
		Dental caries	10012318

MSSO Comment: The proposal to add a new term Class 1 dental caries is approved but not as requested. According to Black's classification of dental caries, class 1 dental caries are those affecting pits and fisures on occlusal third of molars and premolars, occlusal two-thirds of molars and premolars, and lingual part of anterior teeth. As there are several classifications for dental caries, the requested term will be modified based upon literature provided by subscriber and added as LLT Dental caries Black's class 1 to PT Dental caries.

CR Number: 2022255004 **Implementation Date:** 19-Sep-22 Related CR: 2022255004

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Rice allergy*	Approved as Requested	Proposed LLT	
		Rice allergy	10088446 Current
		To PT	
		Food allergy	10016946

MSSO Comment: The proposal to add a new term Rice allergy is approved as requested. Rice is known to be a relatively low allergenic food and there are few reports of rice allergies in the West. Allergy to rice is caused by reaction to some rice proteins after eating rice or breathe in rice steam. Rice allergy will be added as LLT to PT Food allergy.

Supplemental Update Report

CR Number: 2022255005 **Implementation Date:** 14-Sep-22 Related CR: 2022255005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Esophageal wall thickening*	Approved as Requested	Proposed LLT	
			Esophageal wall thickening	10088439 Current
			To PT	
			Oesophageal wall hypertrophy	10088436

MSSO Comment: The proposal to add a new LLT Esophageal wall thickening is approved as requested. After reconsideration of change request 2022115003 and provided that wall hypertrophy may also involve esophageal layers other than muscular, the proposed term will be added as LLT Esophageal wall thickening a new PT Oesophageal wall hypertrophy which will be added to HLT Oesophageal disorders NEC. In a related change, the British English spelled counterpart LLT Oesophageal wall thickening and LLT Esophageal wall hypertrophy will also be added under PT Oesophageal wall hypertrophy. Furthermore, PT Oesophageal muscular hypertrophy will be merged the new PT Oesophageal wall hypertrophy.

CR Number: 2022257015 **Implementation Date:** 14-Sep-22 Related CR: 2022255005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Oesophageal wall thickening*	Approved as Requested	Proposed LLT	
To PT	*Oesophageal wall hypertrophy*		*Oesophageal wall thickening*	10088438 Current
			To PT	
			Oesophageal wall hypertrophy	10088436

MSSO Comment:

CR Number: 2022257016 **Implementation Date:** 14-Sep-22 Related CR: 2022255005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Esophageal wall hypertrophy*	Approved as Requested	Proposed LLT	
To PT	*Oesophageal wall hypertrophy*		*Esophageal wall hypertrophy*	10088437 Current
			To PT	
			Oesophageal wall hypertrophy	10088436

MSSO Comment:

Supplemental Update Report

CR Number: 2022257017 **Implementation Date:** 14-Sep-22 Related CR: 2022255005

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Oesophageal muscular hypertrophy*	Approved as Requested	PT to merge	
To PT	*Oesophageal wall hypertrophy*		*Oesophageal muscular hypertrophy*	10087744 Current
			To PT	
			Oesophageal wall hypertrophy	10088436

MSSO Comment:

CR Number: 2022257018 **Implementation Date:** 14-Sep-22 Related CR: 2022255005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Oesophageal wall hypertrophy*	Approved as Requested	Proposed PT	
HLT primary	*Oesophageal disorders NEC*		*Oesophageal wall hypertrophy*	10088436
SOC primary	*Gastrointestinal disorders*		HLT primary	
			Oesophageal disorders NEC	10030168
			SOC primary	
			Gastrointestinal disorders	10017947

MSSO Comment:

CR Number: 2022255006 **Implementation Date:** 14-Sep-22 Related CR: 2022255006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Perfume allergy*	Approved as Requested	Proposed LLT	
			Perfume allergy	10088440 Current
			To PT	
			Perfume sensitivity	10034434

MSSO Comment: The proposal to add a new term Perfume allergy is approved as requested. Even if sensitivity is an irritative reaction not always triggered an immune system response, it is in some cases, and therefore Perfume allergy can be added as a sub-element LLT to PT Perfume sensitivity.

Supplemental Update Report

CR Number: 2022255007 **Implementation Date:** 14-Sep-22 Related CR: 2022255007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Paraben allergy*	Approved as Requested	Proposed LLT	
			Paraben allergy	10088441 Current
			To PT	
			Reaction to preservatives	10064788

MSSO Comment: The proposal to add a new term Paraben allergy is approved as requested. Parabens are a class of widely used preservatives in cosmetic and pharmaceutical products. Proposed term will be added as sub-concept LLT Paraben allergy under PT Reaction to preservatives.

CR Number: 2022255008 **Implementation Date:** 19-Sep-22 Related CR: 2022255008

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Honey allergy*	Approved as Requested	Proposed LLT	
			Honey allergy	10088448 Current
			To PT	
			Food allergy	10016946

MSSO Comment: The proposal to add a new term Honey allergy is approved as requested. Honey allergy is rare, with an estimated incidence of less than 0.001% in the general population. The main allergens in the honey that trigger an allergic reaction are pollen and glandular proteins that the bees produce. Honey allergy will be added as LLT to PT Food allergy.

CR Number: 2022255009 **Implementation Date:** 19-Sep-22 Related CR: 2022255009

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Mint allergy*	Approved as Requested	Proposed LLT	
			Mint allergy	10088447 Current
			To PT	
			Food allergy	10016946

MSSO Comment: The proposal to add a new term Mint allergy is approved as requested. Mint may uncommonly induce symptoms of food allergy or cutaneous allergy in sensitised individuals. Reactions to menthol and peppermint oil, both compounds extracted from mint, have been frequently reported, in particular in skin sensitisation. Mint allergy will be added as LLT to PT Food allergy.

Supplemental Update Report

CR Number: 2022255010 **Implementation Date:** 19-Sep-22 Related CR: 2022255010

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Urinary tract spasm*	Approved as Requested	Proposed PT	
		Urinary tract spasm	10088449
		HLT primary	
		Urinary tract signs and symptoms NEC	10046591
		SOC primary	
		Renal and urinary disorders	10038359

MSSO Comment: The proposal to add a new term Urinary tract spasm is approved as requested. Urinary tract spasm will be added as PT to HLT Urinary tract signs and symptoms NEC to facilitate coding for reports for such broad concepts without further specific anatomical location such as bladder, ureter, urethra.

CR Number: 2022255011 **Implementation Date:** 19-Sep-22 Related CR: 2022255011

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Genitourinary spasm*	Rejected		

MSSO Comment: The proposal to add a new term Genitourinary spasm is not approved. The proposed term is a very broad and non-specific.

CR Number: 2022255021 **Implementation Date:** 19-Sep-22 Related CR: 2022255021

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Dilutional anemia*	Approved as Requested	Proposed LLT	
		Dilutional anemia	10088451 Current
		To PT	
		Dilutional anaemia	10088450

MSSO Comment: The proposal to add a new term Dilutional anemia is approved as requested. Dilutional anemia arises from an increased plasma volume while true anemia is from a decreased red cell volume. Dilutional anemia is common in patients with CHF. Haemodilution due to fluid overload has also been shown to contribute to diutional anaemia. Dilutional anemia will be added as an LLT to the British English spelled new PT Dilutional anaemia. Dilutional anaemia will be added to primary HLT Anaemias NEC, and to secondary HLT Non-site specific procedural complications.

Supplemental Update Report

CR Number: 2022262009 **Implementation Date:** 19-Sep-22 Related CR: 2022255021

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dilutional anaemia*	Approved as Requested	Proposed PT	
HLT primary	*Anaemias NEC*		*Dilutional anaemia*	10088450
SOC primary	*Blood and lymphatic system disorders*		HLT primary	
			Anaemias NEC	10002067
			SOC primary	
			Blood and lymphatic system disorders	10005329
			HLT secondary	
			Non-site specific procedural complications	10029559
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment:

CR Number: 2022255022 **Implementation Date:** 19-Sep-22 Related CR: 2022255022

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Immunisation reaction*	Rejected		
To PT	*Adverse event following immunisation*			

MSSO Comment: The proposal to demote the PT Immunisation reaction under PT Adverse event following immunisation is not approved. PT Adverse event following immunisation represents any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. On the contrary, PT Immunisation reaction, like adverse drug reaction, means that there is a causal relationship, and is a general term to be typically used when a specific reaction is not reported.

Supplemental Update Report

CR Number: 2022255023 **Implementation Date:** 19-Sep-22 Related CR: 2022255023

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Acute on chronic renal failure*	Rejected		
From PT	*Acute kidney injury*			

MSSO Comment: The proposal to promote the LLT Acute on chronic renal failure from PT Acute kidney injury is not approved. Acute on chronic kidney disease is primarily considered to be an acute form of kidney disease, recognizing that an acute decline in kidney function is often secondary to an injury that causes functional or structural changes in the kidneys. Acute kidney injury/acute renal failure is more commonly reversible than chronic kidney disease. In MedDRA, acute on chronic organ disease is usually represented as a subconcept LLT of the respective PT term concept for the acute form of the condition, with the sole exception of PT Acute on chronic liver failure which represents a disorder that is recognized internationally as a specific pathological classification of liver disease.

CR Number: 2022255024 **Implementation Date:** 19-Sep-22 Related CR: 2022255024

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Para stent regurgitation*	Rejected		

MSSO Comment: The proposal to add a new term Para stent regurgitation is not approved. Please review the existing PT Stent-graft endoleak and all specific sub-type LLTs, for the most appropriate LLT representing the requested term (eg Stent-graft endoleak type IB) or re-submit change request with further clarification of context.

CR Number: 2022255025 **Implementation Date:** 19-Sep-22 Related CR: 2022255025

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Para stent leakage*	Rejected		
To PT	*Para stent regurgitation*			

MSSO Comment: The proposal to add a new LLT Para stent leakage to PT Para stent regurgitation is not approved. Please review the existing PT Stent-graft endoleak and all specific sub-type LLTs, for the most appropriate LLT representing the requested term (eg Stent-graft endoleak type IB) or re-submit change request with further clarification of context.

Supplemental Update Report

CR Number: 2022255026 **Implementation Date:** 19-Sep-22 Related CR: 2022255026

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Difficluty speaking*	Rejected		

MSSO Comment: The proposal to add a new term Difficluty speaking is not approved. This is an imprecise lay expression that may be represented by LLT Speech disorder for instances where no further information is available about the specific context.

CR Number: 2022255027 **Implementation Date:** 19-Sep-22 Related CR: 2022255027

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Burning sensation in pelvic area*	Rejected		

MSSO Comment: The proposal to add a new term Burning sensation in pelvic area is not approved. MedDRA cannot provide "burning sensation" terms for all possible anatomical locations. Most often "burning" represents a type of pain especially for the pelvic region.

CR Number: 2022255028 **Implementation Date:** 19-Sep-22 Related CR: 2022255028

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Excoriation of foreskin*	Approved as Requested	Proposed LLT	
		Excoriation of foreskin	10088452 Current
		To PT	
		Penile erosion	10064061

MSSO Comment: The proposal to add a new term Excoriation of foreskin is approved as requested. Excoriation of foreskin, a raw irritated lesion, will be added as sub-concept LLT to PT Penile erosion.

Supplemental Update Report

CR Number: 2022255029 **Implementation Date:** 19-Sep-22 Related CR: 2022255029

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Atrial fibrillation- intermittent*	Approved Not as Requested	Proposed LLT *Intermittent atrial fibrillation* To PT *Atrial fibrillation*	10088453 Current 10003658

MSSO Comment: The proposal to add a new term Atrial fibrillation- intermittent is approved but not as requested. Proxysmal atrial fibrillation occurs when a rapid, erratic heart rate begins suddenly and then stops on its own within 7 days. It is also known as intermittent Atrial fibrillation and often lasts for less than 24 hours. Atrial fibrillation- intermittent will be re-phrased to natural word order and added as LLT Intermittent atrial fibrillation to PT Atrial fibrillation, aligned with LLT Paroxysmal atrial fibrillation.

CR Number: 2022256001 **Implementation Date:** 19-Sep-22 Related CR: 2022256001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Noninfectious aseptic meningitis*	Rejected		
SOC primary	*Nervous System Disorders*			

MSSO Comment: The proposal to add a new PT Noninfectious aseptic meningitis in SOC Nervous System Disorders is not approved. Proposed concept may be represented by existing LLT/PT Meningitis noninfective.

CR Number: 2022256002 **Implementation Date:** 19-Sep-22 Related CR: 2022256002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Perianal numbness*	Approved as Requested	Proposed LLT *Perianal numbness* To PT *Anal hypoaesthesia*	10088454 Current 10075521

MSSO Comment: The proposal to add a new term Perianal numbness is approved as requested. Perianal numbness is hypoaesthesia near or around the anus. Proposed term will be added as LLT Perianal numbness under PT Anal hypoaesthesia.

Supplemental Update Report

CR Number: **2022256003** **Implementation Date:** 19-Sep-22 Related CR: 2022256003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Tongue white*	Approved as Requested	Proposed LLT		
From PT	*Tongue discolouration*		*Tongue white*	10043993	Current
To PT	*Tongue coated*		From PT		
			Tongue discolouration	10043949	
			To PT		
			Tongue coated	10043945	

MSSO Comment: The proposal to move the LLT Tongue white from PT Tongue discolouration to PT Tongue coated is approved as requested. White tongue, also referrred often as coated tongue, is the result of an overgrowth and swelling of the fingerlike projections (papillae) on the surface of your tongue. The appearance of a white coating is caused by debris, bacteria and dead cells getting lodged between the enlarged and sometimes inflamed papillae.

CR Number: **2022256004** **Implementation Date:** 19-Sep-22 Related CR: 2022256004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Coated white tongue*	Rejected		

MSSO Comment: The proposal to add a new term Coated white tongue is not approved. It is not possible to have a descriptive permutation of every tongue signs/symptoms.

CR Number: **2022256005** **Implementation Date:** 19-Sep-22 Related CR: 2022256005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Airway suction*	Approved as Requested	Proposed LLT		
To PT	*Airway secretion clearance therapy*		*Airway suction*	10088455	Current
			To PT		
			Airway secretion clearance therapy	10074363	

MSSO Comment: The proposal to add a new LLT Airway suction to PT Airway secretion clearance therapy is approved as requested. Airway suction is a vital part of airway management.

Supplemental Update Report

CR Number: 2022257001 **Implementation Date:** 19-Sep-22 Related CR: 2022257001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*TONGUE RIDGING*	Approved Not as Requested	Proposed LLT	
			Tongue ridging	10088456 Current
			To PT	
			Plicated tongue	10035630

MSSO Comment: The proposal to add a new term TONGUE RIDGING is approved but not as requested. Tongue ridging will be modified in accordance with MedDRA capitalization conventions and added as sub-concept LLT to PT Plicated tongue.

CR Number: 2022257002 **Implementation Date:** 19-Sep-22 Related CR: 2022257002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*POST-DISCECTOMY SYNDROME*	Approved Not as Requested	Proposed LLT	
			Post discectomy syndrome	10088457 Current
			To PT	
			Failed back surgery syndrome	10067487

MSSO Comment: The proposal to add a new term POST-DISCECTOMY SYNDROME is approved but not as requested. Post discectomy syndromes is a type of failed back surgery syndrome (a generalized way of referring to an unsuccessful back surgery) where patients still experience pain, discomfort and troublesome symptoms and notice returning disc-related symptoms following a microdiscectomy for a herniated disc. Post discectomy syndrome, de-hyphenated and modified in accordance with MedDRA capitalization conventions, will be added as an LLT to the PT Failed back surgery syndrome. In a related change, the LLT Failed back surgery syndrome will be swapped with PT Post laminectomy syndrome to have the broader concept at the PT level.

CR Number: 2022262010 **Implementation Date:** 19-Sep-22 Related CR: 2022257002

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Post laminectomy syndrome*	Approved as Requested	Proposed PT	
With LLT	*Failed back surgery syndrome*		*Post laminectomy syndrome*	10057239 Current
			With LLT	
			Failed back surgery syndrome	10067487

MSSO Comment:

Supplemental Update Report

CR Number: 2022257003 **Implementation Date:** 19-Sep-22 Related CR: 2022257003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Megalencephaly*	Approved Not as Requested	Proposed PT	
			Megalencephaly	10088459
			HLT primary	
			Cerebral disorders congenital	10052634
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Congenital and peripartum cerebral disorders	10010334
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new LLT Megalencephaly is approved but not as requested. Megalencephaly, also called macrencephaly, is a condition in which an infant or child has an abnormally large, heavy, and usually malfunctioning brain. Often, the child has neurological and developmental problems as well. Megalencephaly can affect both parts of the brain or just one part, called hemimegalencephaly. Megalencephaly will be added as PT to primary HLT Cerebral disorders congenital and secondary HLT Congenital and peripartum cerebral disorders. In related changes synonym LLT Macrencephaly and LLT Macroencephaly will also be added to new PT Megalencephaly, and PT Hemimegalencephaly will be merged under the new PT Megalencephaly as sub-concept LLT.

CR Number: 2022262011 **Implementation Date:** 19-Sep-22 Related CR: 2022257003

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Hemimegalencephaly*	Approved as Requested	PT to merge	
			Hemimegalencephaly	10078100 Current
To PT	*Megalencephaly*		To PT	
			Megalencephaly	10088459

MSSO Comment:

Supplemental Update Report

CR Number: 2022262012 **Implementation Date:** 19-Sep-22 Related CR: 2022257003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Macrencephaly*	Approved as Requested	Proposed LLT	
To PT	*Megalencephaly*		*Macrencephaly*	10088461 Current
			To PT	
			Megalencephaly	10088459

MSSO Comment:

CR Number: 2022262013 **Implementation Date:** 19-Sep-22 Related CR: 2022257003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Macroencephaly*	Approved as Requested	Proposed LLT	
To PT	*Megalencephaly*		*Macroencephaly*	10088460 Current
			To PT	
			Megalencephaly	10088459

MSSO Comment:

CR Number: 2022257004 **Implementation Date:** 19-Sep-22 Related CR: 2022257004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Piezogenic papules*	Approved Not as Requested	Proposed PT	
			Piezogenic papules	10088458
			HLT primary	
			Connective tissue disorders	10010760
			SOC primary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new LLT Piezogenic papules is approved but not as requested. Piezogenic papules are painful small fatty herniations through fascial defects of the heels, the wrists and ulnar margins of the hands. Piezogenic papules will be added as PT to HLT Connective tissue disorders.

Supplemental Update Report

CR Number: 2022257005 **Implementation Date:** 26-Sep-22 Related CR: 2022257005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Osteoclastoma*	Approved as Requested	Proposed LLT	
To PT	*Bone giant cell tumour benign*		*Osteoclastoma*	10088487 Current
			To PT	
			Bone giant cell tumour benign	10005970

MSSO Comment: The proposal to add a new LLT Osteoclastoma to PT Bone giant cell tumour benign is approved as requested. The giant cell tumor of bone, also known as an osteoclastoma or a myeloid sarcoma, is a benign local aggressive osteolytic neoplasm that primarily affects skeletally mature young adults.

CR Number: 2022257006 **Implementation Date:** 26-Sep-22 Related CR: 2022257006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Diamine oxidase deficiency*	Approved as Requested	Proposed PT	
HLT primary	*Inborn errors of metabolism NEC*		*Diamine oxidase deficiency*	10088485
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Inborn errors of metabolism NEC	10021606
			SOC primary	
			Congenital, familial and genetic disorders	10010331

MSSO Comment: The proposal to add a new PT Diamine oxidase deficiency to primary HLT Inborn errors of metabolism NEC in SOC Congenital, familial and genetic disorders is approved as requested. Diamine oxidase is an enzyme that your body makes to break down histamine from foods. Diamine oxidase deficiency is an alteration in the metabolism of dietary histamine that occurs when the activity of the Diamine Oxidase (DAO) enzyme is reduced, that is, when for certain causes (genetic alterations, diseases or consumption of certain drugs) a considerable deficiency in the functional activity of the main enzyme in the metabolization of histamine is created.

CR Number: 2022257007 **Implementation Date:** 26-Sep-22 Related CR: 2022257007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ponytail syndrome*	Approved as Requested	Proposed LLT	
To PT	*Cauda equina syndrome*		*Ponytail syndrome*	10088488 Current
			To PT	
			Cauda equina syndrome	10007821

MSSO Comment: The proposal to add a new LLT Ponytail syndrome to PT Cauda equina syndrome is approved as requested. Proposed term will be added as synonym LLT Ponytail syndrome under PT Cauda equina syndrome.

Supplemental Update Report

CR Number: 2022257008 **Implementation Date:** 26-Sep-22 Related CR: 2022257008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Wound cellulitis*	Approved as Requested	Proposed PT	
			Wound cellulitis	10088486
			HLT primary	
			Bacterial infections NEC	10004047
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Skin and subcutaneous tissue bacterial infections	10040788
			SOC secondary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new PT Wound cellulitis is approved as requested. Wound cellulitis is an infection of a wound with an acute, diffuse, spreading, edematous, suppurative inflammation of the deep subcutaneous tissues and sometimes muscle, sometimes with abscess formation. It is usually caused by bacteria. Proposed term will be added as new PT Wound cellulitis with primary HLT Bacterial infections NEC and secondary HLT Skin and subcutaneous tissue bacterial infections and secondary HLT Non-site specific injuries NEC.

CR Number: 2022269004 **Implementation Date:** 26-Sep-22 Related CR: 2022257008

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Wound cellulitis*	Approved as Requested	Proposed PT	
To HLT	*Non-site specific injuries NEC*		*Wound cellulitis*	10088486
			To HLT	
			Non-site specific injuries NEC	10029511

MSSO Comment:

CR Number: 2022257024 **Implementation Date:** 19-Sep-22 Related CR: 2022257024

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Abdominal cavity effusion*	Rejected		
To PT	*Intra-abdominal fluid collection*			

MSSO Comment: The proposal to add a new LLT Abdominal cavity effusion to PT Intra-abdominal fluid collection is not approved. Although the requested term is requested as a synonym of PT Intra-abdominal fluid collection (therefore an encompassing term of existing LLTs Peritoneal effusion, Retroperitoneal effusion and/or Pelvic effusion) it is most often used in literature as a synonym of ascites.

Supplemental Update Report

CR Number: 2022258001 **Implementation Date:** 22-Sep-22 Related CR: 2022258001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Fecal lactoferrin*	Approved as Requested	Proposed LLT *Fecal lactoferrin*	10088465 Current
			To PT *Faecal lactoferrin*	10088462

MSSO Comment: The proposal to add a new LLT Fecal lactoferrin is approved as requested. Fecal lactoferrin is a neutrophil-derived surrogate marker of intestinal inflammation that is elevated in patients with inflammatory bowel disease. Fecal lactoferrin will be added as LLT to the new British spelled PT Faecal lactoferrin which will be linked to HLT Faecal analyses NEC.

CR Number: 2022265002 **Implementation Date:** 22-Sep-22 Related CR: 2022258001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Faecal lactoferrin*	Approved as Requested	Proposed PT *Faecal lactoferrin*	10088462
HLT primary	*Faecal analyses NEC*		HLT primary *Faecal analyses NEC*	10065878
SOC primary	*Investigations*		SOC primary *Investigations*	10022891

MSSO Comment:

CR Number: 2022258002 **Implementation Date:** 22-Sep-22 Related CR: 2022258002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Fecal lactoferrin increased*	Approved as Requested	Proposed LLT *Fecal lactoferrin increased*	10088464 Current
			To PT *Faecal lactoferrin increased*	10088463

MSSO Comment: The proposal to add a new LLT Fecal lactoferrin increased is approved as requested. Fecal lactoferrin is a neutrophil-derived surrogate marker of intestinal inflammation that is elevated in patients with inflammatory bowel disease. Fecal lactoferrin increased will be added as LLT to the new British spelled PT Faecal lactoferrin increased which will be linked to HLT Faecal analyses NEC.

Supplemental Update Report

CR Number: 2022265003 **Implementation Date:** 22-Sep-22 Related CR: 2022258002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Faecal lactoferrin increased*	Approved as Requested	Proposed PT	
HLT primary	*Faecal analyses NEC*		*Faecal lactoferrin increased*	10088463
SOC primary	*Investigations*		HLT primary	
			Faecal analyses NEC	10065878
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022258003 **Implementation Date:** 22-Sep-22 Related CR: 2022258003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*B-cell acute lymphoblastic leukemia*	Approved Not as Requested	Proposed LLT	
			B-cell acute lymphoblastic leukemia	10088466 Current
			To PT	
			B-cell type acute leukaemia	10003917

MSSO Comment: The proposal to add a new PT B-cell acute lymphoblastic leukemia is approved but not as requested. Acute lymphoblastic leukemia (ALL), also called acute lymphocytic leukemia, is the most common form of cancer found in children. ALL is a blood cancer that develops from lymphocytes — white blood cells that are part of the body's immune system. Lymphocytes include B cells, T cells, and natural killer cells. When ALL develops from B cells, it is called B-cell acute lymphoblastic leukemia. B-cell acute lymphoblastic leukemia and the British spelled counterpart B-cell acute lymphoblastic leukaemia will both be added as LLTs to PT B-cell type acute leukaemia.

CR Number: 2022265004 **Implementation Date:** 22-Sep-22 Related CR: 2022258003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*B-cell acute lymphoblastic leukaemia*	Approved as Requested	Proposed LLT	
To PT	*B-cell type acute leukaemia*		*B-cell acute lymphoblastic leukaemia*	10088467 Current
			To PT	
			B-cell type acute leukaemia	10003917

MSSO Comment:

Supplemental Update Report

CR Number: 2022259001 **Implementation Date:** 22-Sep-22 Related CR: 2022259001

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Tongue hyperpigmentation*	Approved as Requested	Proposed LLT	
		Tongue hyperpigmentation	10088470 Current
		To PT	
		Tongue pigmentation	10069164

MSSO Comment: The proposal to add a new term Tongue hyperpigmentation is approved as requested. Tongue hyperpigmentation can be caused by several oral or systemic diseases as well as to poor hygiene or due to racial features. Tongue hyperpigmentation will be added as a synonym LLT to PT Tongue pigmentation.

CR Number: 2022259002 **Implementation Date:** 22-Sep-22 Related CR: 2022259002

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Fazekas scale*	Approved as Requested	Proposed PT	
		Fazekas scale	10088471
		HLT primary	
		Neurologic diagnostic procedures	10029285
		SOC primary	
		Investigations	10022891

MSSO Comment: The proposal to add a new term Fazekas scale is approved as requested. The Fazekas scale is used to simply quantify the amount of white matter T2 hyperintense lesions usually attributed to chronic small vessel ischaemia, although clearly not all such lesions are due to this. Fazekas scale will be added as PT to HLT Neurologic diagnostic procedures.

CR Number: 2022259003 **Implementation Date:** 22-Sep-22 Related CR: 2022259003

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Nickel allergy*	Approved as Requested	Proposed LLT	
		Nickel allergy	10088472 Current
		To PT	
		Allergy to metals	10066414

MSSO Comment: The proposal to add a new term Nickel allergy is approved as requested. Nickel allergy is a form of allergic contact dermatitis caused by exposure to the chemical element nickel. Nickel allergy will be added as LLT to PT Allergy to metals.

Supplemental Update Report

CR Number: 2022259004 **Implementation Date:** 22-Sep-22 Related CR: 2022259004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Dental overjet*	Approved as Requested	Proposed LLT *Dental overjet* To PT *Malocclusion*	10088473 Current 10061274

MSSO Comment: The proposal to add a new term Dental overjet is approved as requested. An overjet occurs when the upper front teeth protrude outward. Whereas an overbite is marked by an excessive vertical distance between the front upper and lower teeth, an overjet has a greater horizontal difference between the two sets. Dental overjet will be added as an LLT to PT Malocclusion.

CR Number: 2022259005 **Implementation Date:** 22-Sep-22 Related CR: 2022259005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Dental overbite*	Rejected		

MSSO Comment: The proposal to add a new term Dental overbite is not approved. Concept exists in LLT Overbite.

CR Number: 2022259006 **Implementation Date:** 22-Sep-22 Related CR: 2022259006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Allergy to dental impression materials*	Approved as Requested	Proposed LLT *Allergy to dental impression materials* To PT *Allergy to dental material*	10088476 Current 10088474

MSSO Comment: The proposal to add a new term Allergy to dental impression materials is approved as requested. Contact allergies to impression materials are towards polyether, very few are towards alginate, polysulfide, or impression compound. On rare occasions anaphylactic reactions are reported ranging from mild rashes to life threatening situations have been reported. Allergy to dental impression materials will be added as LLT to a broader new PT Allergy to dental material which will be added, in a related change, to HLT Allergies to foods, food additives, drugs and other chemicals.

Supplemental Update Report

CR Number: 2022265009 **Implementation Date:** 22-Sep-22 Related CR: 2022259006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Allergy to dental material*	Approved as Requested	Proposed PT	
HLT primary	*Allergies to foods, food additives, drugs and other chemicals*		*Allergy to dental material*	10088474
SOC primary	*Immune system disorders*		HLT primary	
			Allergies to foods, food additives, drugs and other chemicals	10001737
			SOC primary	
			Immune system disorders	10021428

MSSO Comment:

CR Number: 2022259007 **Implementation Date:** 22-Sep-22 Related CR: 2022259007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Allergy to resin materials composites*	Approved as Requested	Proposed LLT	
			Allergy to resin materials composites	10088475 Current
			To PT	
			Allergy to dental material	10088474

MSSO Comment: The proposal to add a new term Allergy to resin materials composites is approved as requested. Composite resins are a class of dental restorative materials that are a mixture of organic and inorganic components. The three primary organic components are the resin, the coupling agent, and the initiator, with the primary inorganic component being the filler. Allergy to resin materials composites will be added as sub-concept LLT to the newly added PT Allergy to dental material in change request 2022259006.

CR Number: 2022261001 **Implementation Date:** 23-Nov-22 Related CR: 2022261001

Change Requested	Add a New SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed SOC	*Public health*	Rejected After Suspension		

MSSO Comment: The proposal to add a new SOC Public health is not approved after suspension. Per the MedDRA Introductory Guide, the MedDRA terminology applies to all phases of development of medical products for human use, excluding animal toxicology. The scope of MedDRA encompasses medical, health-related, and regulatory concepts pertaining to such products. Although social circumstances are not usually regarded as medical terms, they fall within the “medical” scope if they are relevant to the evaluation of regulatory data (e.g., in the assessment of clinical outcome of treatment in the light of exposure to risk factors). The proposed scope of this SOC encompassing factors such as environmental quality (clean air, water, and food), sanitation, climate change, health equity, health reform, access to healthcare) falls outside the scope of MedDRA.

Supplemental Update Report

CR Number: 2022262001 **Implementation Date:** 22-Sep-22 Related CR: 2022262001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Granulomatous inflammation*	Approved as Requested	Proposed LLT *Granulomatous inflammation* To PT *Granuloma*	10088477 Current 10018691

MSSO Comment: The proposal to add a new LLT Granulomatous inflammation is approved as requested. Granulomatous inflammation is inflammation, usually chronic, characterized by formation of granulomas. Proposed term will be added as sub-concept LLT Granulomatous inflammation under PT Granuloma.

CR Number: 2022262002 **Implementation Date:** 22-Sep-22 Related CR: 2022262002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Microperforate hymen*	Approved Not as Requested	Proposed LLT *Microperforate hymen* To PT *Imperforate hymen*	10088469 Current 10021529

MSSO Comment: The proposal to add a new PT Microperforate hymen is approved but not as requested. A microperforate hymen is essentially an imperforate hymen with a very small hole within the hymen. Proposed term will be added as subconcept LLT Microperforate hymen under PT Imperforate hymen.

Supplemental Update Report

CR Number: 2022262003 **Implementation Date:** 22-Sep-22 Related CR: 2022262003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Mainzer-saldino syndrome*	Approved Not as Requested	Proposed PT	
			Mainzer-Saldino syndrome	10088468
			HLT primary	
			Renal disorders congenital	10038431
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Retinal structural change, deposit and degeneration	10038896
			SOC secondary	
			Eye disorders	10015919

MSSO Comment: The proposal to add a new PT Mainzer-saldino syndrome is approved but not as requested. Mainzer-Saldino syndrome is a disorder characterized by kidney disease, eye problems, and skeletal abnormalities. Proposed term will be modified for MedDRA capitalization conventions and added as PT Mainzer-Saldino syndrome under primary HLT Renal disorders congenital and secondary HLT Retinal structural change, deposit and degeneration and secondary HLT Musculoskeletal and connective tissue conditions NEC.

CR Number: 2022265005 **Implementation Date:** 22-Sep-22 Related CR: 2022262003

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Mainzer-Saldino syndrome*	Approved as Requested	Proposed PT	
			Mainzer-Saldino syndrome	10088468
To HLT	*Musculoskeletal and connective tissue conditions NEC*		To HLT	
			Musculoskeletal and connective tissue conditions NEC	10080711

MSSO Comment:

Supplemental Update Report

CR Number: 2022262004 **Implementation Date:** 22-Sep-22 Related CR: 2022262004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cognitive slowing*	Approved as Requested	Proposed LLT *Cognitive slowing*	10088478 Current
			To PT *Cognitive disorder*	10057668

MSSO Comment: The proposal to add a new LLT Cognitive slowing is approved as requested. Cognitive decline is associated with loss of other cognitive abilities, for example, loss of visual perception and language. It slows down the process of thinking, learning, and practicing skills. It is a normal aging phenomenon, but sometimes, it occurs earlier due to brain damage, neurodegenerative disorders, weakness, and trauma. LLT Cognitive slowing will be added as quasi-synonym of LLT Cognitive impairment under PT Cognitive disorder.

CR Number: 2022262005 **Implementation Date:** 22-Sep-22 Related CR: 2022262005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Maxillary expansion*	Approved as Requested	Proposed PT *Maxillary expansion*	10088479
			HLT primary *Dental and gingival therapeutic procedures*	10012317
			SOC primary *Surgical and medical procedures*	10042613

MSSO Comment: The proposal to add a new term Maxillary expansion is approved as requested. Maxillary expansion treatments have been used to correct maxillary transverse deficiency. Correction of the transverse discrepancy usually requires expansion of the palate by a combination of orthopedic and orthodontic tooth movements. Proposed term will be added as new PT Maxillary expansion under primary HLT Dental and gingival therapeutic procedures. In a related change, PT Oral appliance will be moved from HLT Head, neck and oral cavity therapeutic procedures NEC to HLT Dental and gingival therapeutic procedures.

CR Number: 2022265006 **Implementation Date:** 22-Sep-22 Related CR: 2022262005

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Oral appliance*	Approved as Requested	Proposed PT *Oral appliance*	10085270
From HLT	*Head, neck and oral cavity therapeutic procedures NEC*		From HLT *Head, neck and oral cavity therapeutic procedures NEC*	10052723
To HLT	*Dental and gingival therapeutic procedures*		To HLT *Dental and gingival therapeutic procedures*	10012317

MSSO Comment:

Supplemental Update Report

CR Number: 2022262006 **Implementation Date:** 22-Sep-22 Related CR: 2022262006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Hyrax expander*	Approved as Requested	Proposed LLT *Hyrax expander*	10088481 Current
			To PT *Oral appliance*	10085270

MSSO Comment: The proposal to add a new term Hyrax expander is approved as requested. A tooth borne appliance makes use of a nonspring loaded jackscrew with an all wire frame. The screws have heavy gauge wire extensions that are adapted to follow the palatal contours and soldered to bands on premolar and molar. Hyrax expander and the synonym Hygenic rapid expander both will be added as LLTs under PT Oral appliance.

CR Number: 2022265007 **Implementation Date:** 22-Sep-22 Related CR: 2022262006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hygenic rapid expander*	Approved as Requested	Proposed LLT *Hygenic rapid expander*	10088484 Current
To PT	*Oral appliance*		To PT *Oral appliance*	10085270

MSSO Comment:

CR Number: 2022262007 **Implementation Date:** 22-Sep-22 Related CR: 2022262007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Issacson expander*	Approved as Requested	Proposed LLT *Issacson expander*	10088480 Current
			To PT *Oral appliance*	10085270

MSSO Comment: The proposal to add a new term Issacson expander is approved as requested. Issacson expander is a tooth borne appliance with calibrated coil spring. LLT Issacson expander will be added under PT Oral appliance.

Supplemental Update Report

CR Number: 2022262008 **Implementation Date:** 22-Sep-22 Related CR: 2022262008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*W arch appliance*	Approved as Requested	Proposed LLT *W arch appliance*	10088482 Current
			To PT *Oral appliance*	10085270

MSSO Comment: The proposal to add a new term W arch appliance is approved as requested. The W Arch, or Porter expander, is used to expand the posterior segments of the arch, correct bilataral or unilataral cross bites, and help align crowded teeth. It is activated simply by opening the steel wire apices of W-arch. W arch appliance and Porter expander will both be added as an LLTs to PT Oral appliance.

CR Number: 2022265008 **Implementation Date:** 22-Sep-22 Related CR: 2022262008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Porter expander*	Approved as Requested	Proposed LLT	
To PT	*Oral appliance*		*Porter expander*	10088483 Current
			To PT *Oral appliance*	10085270

MSSO Comment:

CR Number: 2022262014 **Implementation Date:** 26-Sep-22 Related CR: 2022262014

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Donovanosis*	Approved as Requested	Proposed LLT	
To PT	*Granuloma inguinale*		*Donovanosis*	10088493 Current
			To PT *Granuloma inguinale*	10018693

MSSO Comment: The proposal to add a new LLT Donovanosis to PT Granuloma inguinale is approved as requested. Donovanosis is a progressive infection of genital and perineal skin caused by Klebsiella granulomatis, characterized by slowly progressive skin lesions that are beefy red, raised, painless, and often ulcerated. In a related changes, PT Granuloma inguinale will be added to HLT Genitourinary tract infections and inflammations NEC and HLT Skin and subcutaneous tissue bacterial infections.

Supplemental Update Report

CR Number: 2022269005 **Implementation Date:** 26-Sep-22 Related CR: 2022262014

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Granuloma inguinale*	Approved as Requested	Proposed PT	
To HLT	*Genitourinary tract infections and inflammations NEC*		*Granuloma inguinale*	10018693
			To HLT	
			Genitourinary tract infections and inflammations NEC	10018191

MSSO Comment:

CR Number: 2022269006 **Implementation Date:** 26-Sep-22 Related CR: 2022262014

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Granuloma inguinale*	Approved as Requested	Proposed PT	
To HLT	*Skin and subcutaneous tissue bacterial infections*		*Granuloma inguinale*	10018693
			To HLT	
			Skin and subcutaneous tissue bacterial infections	10040788

MSSO Comment:

CR Number: 2022262015 **Implementation Date:** 26-Sep-22 Related CR: 2022262015

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Focal Segmental Glomerular Sclerosis*	Rejected		

MSSO Comment: The proposal to add a new term Focal Segmental Glomerular Sclerosis is not approved. Concept exists in PT/LLT Focal segmental glomerulosclerosis.

Supplemental Update Report

CR Number: 2022262016 **Implementation Date:** 26-Sep-22 Related CR: 2022262016

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Refractory Gout*	Approved Not as Requested	Proposed LLT	
			Refractory gout	10088490 Current
			To PT	
			Gout	10018627

MSSO Comment: The proposal to add a new term Refractory Gout is approved but not as requested. Refractory gout presents when treatment fails to maintain a target serum urate level of less than 6 mg/dl, a circumstance which often results in more or larger tophi, functional impairment and joint destruction. After modification to the MedDRA capitalization conventions, Refractory gout will be added as LLT under PT Gout.

CR Number: 2022262017 **Implementation Date:** 26-Sep-22 Related CR: 2022262017

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*INTRAHEPATIC CHOLESTASIS OF PREGNANCY*	Approved Not as Requested	Proposed LLT	
			Intrahepatic cholestasis of pregnancy	10088491 Current
			To PT	
			Cholestasis of pregnancy	10049055

MSSO Comment: The proposal to add a new term INTRAHEPATIC CHOLESTASIS OF PREGNANCY is approved but not as requested. Intrahepatic cholestasis of pregnancy, also known as obstetric cholestasis, cholestasis of pregnancy, jaundice of pregnancy, and prurigo gravidarum results from idiosyncratic exaggeration of normal pregnancy bile stasis due to hormonal changes. Intense pruritus, the earliest symptom, develops during the 2nd or 3rd trimester; dark urine and jaundice sometimes follow. Once modified according to MedDRA capitalization conventions, Intrahepatic cholestasis of pregnancy will be added as a sub-element LLT to PT Cholestasis of pregnancy.

CR Number: 2022262018 **Implementation Date:** 26-Sep-22 Related CR: 2022262018

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Spleen Cancer*	Approved Not as Requested	Proposed LLT	
			Spleen cancer	10088492 Current
			To PT	
			Malignant splenic neoplasm	10026702

MSSO Comment: The proposal to add a new term Spleen Cancer is approved but not as requested. Spleen cancer is typically secondary, the most common causes being lymphomas and leukemias and, on occasion, other cancers, such as breast, lung, stomach, pancreatic, liver, or colon. Once modified in accordance with MedDRA capitalization conventions, Spleen cancer will be added as synonym LLT to PT Malignant splenic neoplasm.

Supplemental Update Report

CR Number: 2022262019 **Implementation Date:** 26-Sep-22 Related CR: 2022262019

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Distal Renal Tubular Acidosis*	Approved Not as Requested	Proposed LLT *Distal renal tubular acidosis* To PT *Renal tubular acidosis*	10088489 Current 10038535

MSSO Comment: The proposal to add a new term Distal Renal Tubular Acidosis is approved but not as requested. Distal renal tubular acidosis is characterized by a failure of H+ secretion into lumen of nephron by the alpha intercalated cells of the medullary collecting duct of the distal nephron. Once modified in accordance with MedDRA capitalization conventions, Distal renal tubular acidosis will be added as an LLT to PT Renal tubular acidosis, as a synonym of current LLT Type 1 (distal) RTA.

CR Number: 2022263001 **Implementation Date:** 26-Sep-22 Related CR: 2022263001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Postmastectomy pain syndrome*	Approved as Requested	Proposed LLT *Postmastectomy pain syndrome* To PT *Post breast therapy pain syndrome*	10088494 Current 10079061
To PT	*Post breast therapy pain syndrome*			

MSSO Comment: The proposal to add a new LLT Postmastectomy pain syndrome to PT Post breast therapy pain syndrome is approved as requested. Postmastectomy pain syndrome (PMPS) is a chronic neuropathic pain condition, affecting many women who have undergone breast cancer surgery. The development of PMPS is complex and the treatment options are limited.

CR Number: 2022263005 **Implementation Date:** 26-Sep-22 Related CR: 2022263005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Menstrual clots*	Approved as Requested	Proposed PT *Menstrual clots* HLT primary *Menstruation and uterine bleeding NEC* SOC primary *Reproductive system and breast disorders*	10088498 10027335 10038604
HLT primary	*Menstruation and uterine bleeding NEC*			
SOC primary	*Reproductive system and breast disorders*			

MSSO Comment: The proposal to add a new PT Menstrual clots to primary HLT Menstruation and uterine bleeding NEC in SOC Reproductive system and breast disorders is approved as requested. There is value in having a term for menstrual clots which can then be reviewed to determine if this represents an abnormality or not. This request is based on a review of change request 2022056003.

Supplemental Update Report

CR Number: 2022263006 **Implementation Date:** 26-Sep-22 Related CR: 2022263006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Target mutations leading to drug resistance*	Approved as Requested	Proposed LLT		
To PT	*Drug resistance mutation*		*Target mutations leading to drug resistance*	10088499	Current
			To PT		
			Drug resistance mutation	10087795	

MSSO Comment: The proposal to add a new LLT Target mutations leading to drug resistance to PT Drug resistance mutation is approved as requested to clarify the meaning of PT Drug resistance mutation. Mutation in drug targets is a critical mechanism that results in drug resistance.

CR Number: 2022263007 **Implementation Date:** 26-Sep-22 Related CR: 2022263007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Target mutation induced drug resistance*	Approved as Requested	Proposed LLT		
To PT	*Drug resistance mutation*		*Target mutation induced drug resistance*	10088500	Current
			To PT		
			Drug resistance mutation	10087795	

MSSO Comment: The proposal to add a new LLT Target mutation induced drug resistance to PT Drug resistance mutation is approved as requested. Mutation in drug targets is a critical mechanism that results in drug resistance. This synonym LLT Target mutation induced drug resistance is being added to further clarify the meaning of PT Drug resistance mutation.

CR Number: 2022263008 **Implementation Date:** 21-Oct-22 Related CR: 2022263008

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Hereditary angioedema type II*	Approved After Suspension	Proposed LLT		
From PT	*Hereditary angioedema with normal C1 esterase inhibitor*		*Hereditary angioedema type II*	10080960	Current
To PT	*Hereditary angioedema with C1 esterase inhibitor deficiency*		From PT		
			Hereditary angioedema with normal C1 esterase inhibitor	10080953	
			To PT		
			Hereditary angioedema with C1 esterase inhibitor deficiency	10080955	

MSSO Comment: The proposal to move the LLT Hereditary angioedema type II from PT Hereditary angioedema with normal C1 esterase inhibitor to PT Hereditary angioedema with C1 esterase inhibitor deficiency is approved as requested after suspension for better alignment of Type I and Type II for hereditary angioedema.

Supplemental Update Report

CR Number: 2022264001 **Implementation Date:** 28-Sep-22 Related CR: 2022264001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Radiofrequency microneedling*	Approved as Requested	Proposed LLT	
			Radiofrequency microneedling	10088502 Current
			To PT	
			Microneedling	10088501

MSSO Comment: The proposal to add a new LLT Radiofrequency microneedling is approved as requested. Microneedling is a cosmetic procedure and involves pricking the skin with tiny, sterilized needles to induce collagen and elastin production. When the procedure uses radiofrequency waves, it is called radiofrequency microneedling, also called as radiofrequency percutaneous collagen induction. The proposed term will be added as sub-concept LLT Radiofrequency microneedling under new PT Microneedling which will be linked, in a related change, to primary HLT Skin and subcutaneous tissue therapeutic procedures NEC.

CR Number: 2022271003 **Implementation Date:** 28-Sep-22 Related CR: 2022264001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Microneedling*	Approved as Requested	Proposed PT	
HLT primary	*Skin and subcutaneous tissue therapeutic procedures NEC*		*Microneedling*	10088501
			HLT primary	
SOC primary	*Surgical and medical procedures*		*Skin and subcutaneous tissue therapeutic procedures NEC*	10040794
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment:

CR Number: 2022264002 **Implementation Date:** 26-Sep-22 Related CR: 2022264002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Mandibular arch expansion*	Approved as Requested	Proposed PT	
			Mandibular arch expansion	10088495
			HLT primary	
			Dental and gingival therapeutic procedures	10012317
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Mandibular arch expansion is approved as requested. Mandibular arch expansion using mandibular expansion appliance is an effective techniques for enhancing the effective space of the mandibular arch as part of orthodontic treatments. Mandibular arch expansion will be added as PT to HLT Dental and gingival therapeutic procedures.

Supplemental Update Report

CR Number: 2022264003 **Implementation Date:** 26-Sep-22 Related CR: 2022264003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Canine retraction*	Approved as Requested	Proposed PT	
			Canine retraction	10088496
			HLT primary	
			Dental and gingival therapeutic procedures	10012317
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Canine retraction is approved as requested. Canine retraction, a very important step in orthodontic treatment of patients with crowding using several technics/methods, will be added as PT to HLT Dental and gingival therapeutic procedures.

CR Number: 2022264004 **Implementation Date:** 26-Sep-22 Related CR: 2022264004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Nance palatal arch space maintainer*	Approved as Requested	Proposed LLT	
			Nance palatal arch space maintainer	10088497 Current
			To PT	
			Oral appliance	10085270

MSSO Comment: The proposal to add a new term Nance palatal arch space maintainer is approved as requested. The Nance palatal arch is considered a useful means of maintaining arch length and reinforcing anchorage control in the orthodontic patient. Nance palatal arch space maintainer will be added as an LLT to PT Oral appliance.

CR Number: 2022264005 **Implementation Date:** 26-Sep-22 Related CR: 2022264005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Steroid induced intraocular pressure increase*	Rejected		
To PT	*Intraocular pressure increased*			

MSSO Comment: The proposal to add a new LLT Steroid induced intraocular pressure increase to PT Intraocular pressure increased is not approved. The proposed term implies a causal relationship between two concepts and, therefore, represents a combination term, in this case between a drug as cause and and a medical condition as effect. The MSSO refrains from adding "due to" or "drug induced" terms (PT Glaucoma steroid-induced, is in MedDRA since v2.1)

Supplemental Update Report

CR Number: 2022264006 **Implementation Date:** 28-Sep-22 Related CR: 2022264006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Metastatic rectal adenocarcinoma*	Approved as Requested	Proposed LLT *Metastatic rectal adenocarcinoma* To PT *Rectal adenocarcinoma*	10088503 Current 10038019

MSSO Comment: The proposal to add a new LLT Metastatic rectal adenocarcinoma is approved as requested. Metastatic rectal adenocarcinoma will be added as LLT to PT Rectal adenocarcinoma, aligned with the synonym LLT Rectal adenocarcinoma stage IV,

CR Number: 2022264007 **Implementation Date:** 28-Sep-22 Related CR: 2022264007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Incisional Biopsy*	Approved Not as Requested	Proposed LLT *Incisional biopsy* To PT *Biopsy*	10088504 Current 10004720

MSSO Comment: The proposal to add a new term Incisional Biopsy is approved but not as requested. Incisional biopsy is a medical test to remove a piece of tissue from a lesion or mass, most often used technique for lesions involving the skin, breast, muscles, and lymph nodes. The proposed term will be modified as Incisional biopsy, according to MedDRA capitalisation conventions and will be added as LLT to PT Biopsy, aligned with LLT Excision biopsy.

Supplemental Update Report

CR Number: 2022265001 **Implementation Date:** 28-Sep-22 Related CR: 2022265001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Benign neuroendocrine Tumor of appendix*	Approved Not as Requested	Proposed PT	
			Benign neuroendocrine tumour of appendix	10088509
			HLT primary	
			Upper gastrointestinal neoplasms benign	10046275
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Benign neoplasms gastrointestinal (excl oral cavity)	10017988
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new PT Benign neuroendocrine Tumor of appendix is approved but not as requested.The biological behavior of appendiceal neuroendocrine tumors ranges from totally benign tumors less than 1cm to goblet cell carcinomas which behave similarly to colorectal adenocarcinoma. Benign appendiceal neuroendocrine tumors represent the second commonest neuroendocrine neoplasms of the gastrointestinal tract. Proposed term will be modified as per MedDRA capitalization and spelling conventions and added as new PT Benign neuroendocrine tumour of appendix under primary HLT Upper gastrointestinal neoplasms benign and secondary HLT Benign neoplasms gastrointestinal (excl oral cavity) and secondary HLT Endocrine neoplasms NEC. In a related change, the American English spelled counterpart LLT Benign neuroendocrine tumor of appendix will also be added under new PT Benign neuroendocrine tumour of appendix.

CR Number: 2022271008 **Implementation Date:** 28-Sep-22 Related CR: 2022265001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Benign neuroendocrine tumor of appendix*	Approved as Requested	Proposed LLT		
To PT	*Benign neuroendocrine tumour of appendix*		*Benign neuroendocrine tumor of appendix*	10088510	Current
			To PT		
			Benign neuroendocrine tumour of appendix	10088509	

MSSO Comment:

Supplemental Update Report

CR Number: 2022271009 **Implementation Date:** 28-Sep-22 Related CR: 2022265001

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Benign neuroendocrine tumour of appendix*	Approved as Requested	Proposed PT	
To HLT	*Endocrine neoplasms NEC*		*Benign neuroendocrine tumour of appendix*	10088509
			To HLT	
			Endocrine neoplasms NEC	10014714

MSSO Comment:

CR Number: 2022265010 **Implementation Date:** 28-Sep-22 Related CR: 2022265010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Radical Retropubic Prostatectomy*	Approved Not as Requested	Proposed LLT	
			Radical retropubic prostatectomy	10088505 Current
			To PT	
			Radical prostatectomy	10050756

MSSO Comment: The proposal to add a new term Radical Retropubic Prostatectomy is approved but not as requested. Radical retropubic prostatectomy is standard procedure in early stages of prostate cancer. The requested term will be modified according to MedDRA capitalisation conventions and added as sub-concept LLT Radical retropubic prostatectomy to PT Radical prostatectomy.

CR Number: 2022265011 **Implementation Date:** 28-Sep-22 Related CR: 2022265011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Simple Prostatectomy*	Approved Not as Requested	Proposed LLT	
			Simple prostatectomy	10088507 Current
			To PT	
			Prostatectomy	10061916

MSSO Comment: The proposal to add a new term Simple Prostatectomy is approved but not as requested. Simple prostatectomy is usually performed as treatment for benign prostatic hyperplasia by removing the inner part of the prostate via several techniques such as transuretral, laser, or open surgery. The requested term will be modified according to MedDRA capitalisation conventions and added as LLT Simple prostatectomy under PT Prostatectomy. In a related change, PT Retro-pubic prostatectomy will be merged under PT Prostatectomy. Open (simple) prostatectomy has three different approaches: retropubic, suprapubic, and perineal.

Supplemental Update Report

CR Number: 2022271007 **Implementation Date:** 28-Sep-22 Related CR: 2022265011

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Retro-pubic prostatectomy*	Approved as Requested	PT to merge	
To PT	*Prostatectomy*		*Retro-pubic prostatectomy*	10038961 Current
			To PT	
			Prostatectomy	10061916

MSSO Comment:

CR Number: 2022265012 **Implementation Date:** 28-Sep-22 Related CR: 2022265012

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Percutaneous cholecystostomy*	Approved as Requested	Proposed LLT	
			Percutaneous cholecystostomy	10088508 Current
			To PT	
			Cholecystostomy	10008624

MSSO Comment: The proposal to add a new term Percutaneous cholecystostomy is approved as requested. Percutaneous cholecystostomy, a technique that consists of percutaneous catheter placement in the gallbladder lumen under imaging guidance, has become an alternative to surgical cholecystostomy in recent years. The proposed term Percutaneous cholecystostomy will be added as sub-concept LLT to PT Cholecystostomy.

CR Number: 2022265013 **Implementation Date:** 28-Sep-22 Related CR: 2022265013

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Acute compartment syndrome*	Approved as Requested	Proposed LLT	
			Acute compartment syndrome	10088506 Current
			To PT	
			Compartment syndrome	10010121

MSSO Comment: The proposal to add a new term Acute compartment syndrome is approved as requested. Acute compartment syndrome occurs when pressure increases within a confined closed fascial space causing subsequently reduced blood flow and tissue perfusion that may lead to ischemic pain, possible soft-tissue damage, and limb-threatening. The proposed term Acute compartment syndrome will be added as sub-concept LLT to PT Compartment syndrome.

Supplemental Update Report

CR Number: 2022266001 **Implementation Date:** 28-Sep-22 Related CR: 2022266001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Sarcomatoid carcinoma of the prostate*	Approved Not as Requested	Proposed LLT	
HLT primary	*Prostatic neoplasms malignant*		*Sarcomatoid carcinoma of the prostate*	10088513 Current
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		To PT	
			Prostate sarcoma	10088511

MSSO Comment: The proposal to add a new PT Sarcomatoid carcinoma of the prostate to primary HLT Prostatic neoplasms malignant in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved but not as requested. Sarcomatoid carcinoma of the prostate is a rare variant of prostatic cancer, with less than 100 cases reported in the literature up to date. Tumors are most commonly composed of an admixture of both malignant glandular and spindle cell elements. Sarcomatoid carcinoma of the prostate will be added as an LLT to PT Prostate sarcoma added in change request 2022266002.

CR Number: 2022266002 **Implementation Date:** 28-Sep-22 Related CR: 2022266002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Prostate sarcoma*	Approved as Requested	Proposed PT	
HLT primary	*Prostatic neoplasms malignant*		*Prostate sarcoma*	10088511
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		HLT primary	
			Prostatic neoplasms malignant	10036908
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Prostatic neoplasms and hypertrophy	10036966
			SOC secondary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new PT Prostate sarcoma to primary HLT Prostatic neoplasms malignant in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved as requested. Prostate sarcomas are an uncommon and heterogeneous group of tumors arising from mesenchymal cells in and around the prostate (as opposed to the more common prostate adenocarcinoma which derives from the glandular tissue). Prostate sarcoma is a recognized concept and will be added as a PT to primary HLT Prostatic neoplasms malignant and secondary HLT Prostatic neoplasms and hypertrophy.

Supplemental Update Report

CR Number: 2022266003 **Implementation Date:** 28-Sep-22 Related CR: 2022266003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Prostatic stromal sarcoma*	Approved as Requested	Proposed LLT	
			Prostatic stromal sarcoma	10088512 Current
			To PT	
			Prostate sarcoma	10088511

MSSO Comment: The proposal to add a new LLT Prostatic stromal sarcoma is approved as requested. Prostate sarcomas are an uncommon and heterogeneous group of tumors arising from mesenchymal cells in and around the prostate. The proposed term Prostatic stromal sarcoma will be added as sub-type LLT to PT Prostate sarcoma, added in change request 2022266002.

CR Number: 2022266004 **Implementation Date:** 30-Sep-22 Related CR: 2022266004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Epileptic Encephalopathy with spike-wave activation in sleep*	Approved Not as Requested	Proposed LLT	
HLT primary	*Seizures and seizure disorders NEC*		*Epileptic encephalopathy with continuous spike and wave during sleep*	10088516 Current
SOC primary	*Nervous system disorders*		To PT	
			CSWS syndrome	10078827

MSSO Comment: The proposal to add a new PT Epileptic Encephalopathy with spike-wave activation in sleep to primary HLT Seizures and seizure disorders NEC in SOC Nervous system disorders is approved but not as requested. Epileptic encephalopathy with continuous spike and wave during sleep is also known as Continuous spike and wave during slow wave sleep (CSWS) or epilepsy with continuous spike-wave during slow wave sleep. Proposed term will be modified as Epileptic encephalopathy with continuous spike and wave during sleep according to MedDRA capitalisation conventions and added as synonym LLT under PT CSWS syndrome.

CR Number: 2022266005 **Implementation Date:** 30-Sep-22 Related CR: 2022266005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Drug related pseudo richter's syndrome*	Approved Not as Requested	Proposed PT	
HLT primary	*Diffuse large B-cell lymphomas*		*Pseudo Richter's syndrome*	10088517
SOC primary	*Blood and lymphatic system disorders*		HLT primary	
			Diffuse large B-cell lymphomas	10012819
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104

MSSO Comment: The proposal to add a new PT Drug related pseudo richter's syndrome to primary HLT Diffuse large B-cell lymphomas in SOC Blood and lymphatic system disorders is approved but not as requested. Pseudo Richter's syndrome occurs when chronic lymphocytic leukaemia/small lymphocytic lymphoma cases develop Richter's syndrome with morphological and clinical features, after dose interruption of ibrutinib. Resumption of ibrutinib led to resolution of clinical manifestations in all cases, and confirmed pathologic regression to chronic lymphocytic leukaemia/small lymphocytic lymphoma. Proposed term will be modified for MedDRA spelling conventions and in form found most prevalent in literature and added as PT Pseudo Richter's syndrome under HLT Diffuse large B-cell lymphomas.

Supplemental Update Report

CR Number: 2022266006 **Implementation Date:** 30-Sep-22 Related CR: 2022266006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Retrobulbar edema*	Approved Not as Requested	Proposed LLT	
HLT primary	*Ocular disorders NEC*		*Retrobulbar edema*	10088519 Current
SOC primary	*Eye disorders*		To PT	
			Retrobulbar oedema	10088518

MSSO Comment: The proposal to add a new PT Retrobulbar edema to primary HLT Ocular disorders NEC in SOC Eye disorders is approved but not as requested. Retrobulbar edema is a collection of fluid behind the globe of the eye. Retrobulbar edema will be added as an LLT to new PT Retrobulbar oedema. In a related change, the British English counterpart new PT Retrobulbar oedema will be added to HLT Ocular disorders NEC.

CR Number: 2022273270 **Implementation Date:** 30-Sep-22 Related CR: 2022266006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Retrobulbar oedema*	Approved as Requested	Proposed PT	
HLT primary	*Ocular disorders NEC*		*Retrobulbar oedema*	10088518
SOC primary	*Eye disorders*		HLT primary	
			Ocular disorders NEC	10030032
			SOC primary	
			Eye disorders	10015919

MSSO Comment:

CR Number: 2022266007 **Implementation Date:** 30-Sep-22 Related CR: 2022266007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ocular dystonia*	Approved as Requested	Proposed LLT	
To PT	*Oculogyric crisis*		*Ocular dystonia*	10088520 Current
			To PT	
			Oculogyric crisis	10030071

MSSO Comment: The proposal to add a new LLT Ocular dystonia to PT Oculogyric crisis is approved as requested. Oculogyric crisis is the name of a dystonic reaction to certain drugs or medical conditions characterized by a prolonged involuntary upward deviation of the eyes. Ocular dystonia is one of the many possible responses associated with the crisis.

Supplemental Update Report

CR Number: 2022266008 **Implementation Date:** 30-Sep-22 Related CR: 2022266008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Treatment resistant depression*	Approved Not as Requested	Proposed LLT	
HLT primary	*Depressive disorders*		*Treatment resistant depression*	10088521 Current
SOC primary	*Psychiatric disorders*		To PT	
			Depression	10012378

MSSO Comment: The proposal to add a new PT Treatment resistant depression to primary HLT Depressive disorders in SOC Psychiatric disorders is approved but not as requested. Agreement on the definition of treatment resistant depression has remained elusive but generally most classifications tend to describe it as failure to attain significant level of improvement from an accurately defined depressive episode following treatment with an antidepressant medication given at an adequate (minimum effective) dose for a minimum of six weeks. Proposed term will be added as sub-concept LLT Treatment resistant depression under PT Depression.

CR Number: 2022266009 **Implementation Date:** 30-Sep-22 Related CR: 2022266009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Proctitis viral*	Approved Not as Requested	Proposed PT	
HLT primary	*Anal, rectal, perianal and perirectal infections*		*Proctitis viral*	10088522
SOC primary	*Gastrointestinal disorders*		HLT primary	
			Viral infections NEC	10047465
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Anal, rectal, perianal and perirectal infections	10002114
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new PT Proctitis viral to primary HLT Anal, rectal, perianal and perirectal infections in SOC Gastrointestinal disorders and secondary HLT Viral infectious disorders is approved but not as requested. Proctitis is a condition in which the lining tissue of the inner rectum becomes inflamed and may be caused by bacteria, viruses, and fungi. Proposed term Proctitis viral will be added as a PT but with primary HLT Viral infections NEC and secondary HLT Anal, rectal, perianal and perirectal infections.

Supplemental Update Report

CR Number: 2022266010 **Implementation Date:** 30-Sep-22 Related CR: 2022266010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ictal bradycardia asystole*	Approved Not as Requested	Proposed PT	
HLT primary	*Seizures and seizure disorders NEC*		*Ictal bradycardia*	10088523
SOC primary	*Nervous system disorders*		HLT primary	
			Seizures and seizure disorders NEC	10039912
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Rate and rhythm disorders NEC	10037908
			SOC secondary	
			Cardiac disorders	10007541

MSSO Comment: The proposal to add a new PT Ictal bradycardia asystole to primary HLT Seizures and seizure disorders NEC in SOC Nervous system disorders and secondary HLT Ventricular arrhythmias and cardiac arrest in SOC Cardiac disorders is approved but not as requested. Ictal bradycardia, defined as an R–R interval is greater than 2 seconds, is the more common expression and will be added as PT to primary HLT Seizures and seizure disorders NEC to secondary HLT Rate and rhythm disorders NEC. In a related change, Ictal asystole, which is defined as the absence of ventricular complexes for > 4 s accompanied by electrographic seizure onset, will be added as an LLT to PT Ictal bradycardia.

CR Number: 2022273007 **Implementation Date:** 30-Sep-22 Related CR: 2022266010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ictal asystole*	Approved as Requested	Proposed LLT	
To PT	*Ictal bradycardia*		*Ictal asystole*	10088524 Current
			To PT	
			Ictal bradycardia	10088523

MSSO Comment:

Supplemental Update Report

CR Number: 2022266011 **Implementation Date:** 28-Sep-22 Related CR: 2022266011

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Sliding hernia*	Approved as Requested	Proposed LLT *Sliding hernia*	10088514 Current
		To PT *Hernia*	10019909

MSSO Comment: The proposal to add a new term Sliding hernia is approved as requested. Even though sliding hernias refer either to hiatal or inguinal hernias, to facilitate coding for reports without specifying the anatomical site, Sliding hernia will be added as LLT to the broad PT Hernia.

CR Number: 2022266012 **Implementation Date:** 28-Sep-22 Related CR: 2022266012

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Squamous cell carcinoma hand*	Rejected		

MSSO Comment: The proposal to add a new term Squamous cell carcinoma hand is not approved. MedDRA cannot provide for all possible anatomical location term for squamous cell carcinoma as this may lead to overpopulation.

CR Number: 2022266013 **Implementation Date:** 28-Sep-22 Related CR: 2022266013

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *HIV 1 test*	Approved Not as Requested	Proposed LLT *HIV-1 test*	10088515 Current
		To PT *HIV test*	10020185

MSSO Comment: The proposal to add a new term HIV 1 test is approved but not as requested. Human immunodeficiency virus (HIV) is a virus that infects cells in the immune system. There are actually two types of HIV: HIV-1 and HIV-2. Of the two, HIV-1 is the most common. There are several test methods to identify type 1/2. The proposed term will be added with a hyphen for consistency as LLT HIV-1 test to PT HIV test.

Supplemental Update Report

CR Number: 2022266014 **Implementation Date:** 28-Sep-22 Related CR: 2022266014

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Neck fracture*	Rejected		

MSSO Comment: The proposal to add a new term Neck fracture is not approved. The proposed term is ambiguous as it may refer to different anatomical regions (cervical neck vs. femur neck).

CR Number: 2022266015 **Implementation Date:** 30-Sep-22 Related CR: 2022266015

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Stuck contact lens*	Approved Not as Requested	Proposed LLT *Contact lens dislocation*	10088525 Current
			To PT *Device dislocation*	10064684

MSSO Comment: The proposal to add a new PT Stuck contact lens is approved but not as requested. The proposed term is too colloquial but will be added and represented by the more medically appropriate LLT Contact lens dislocation to PT Device dislocation.

CR Number: 2022266017 **Implementation Date:** 13-Oct-22 Related CR: 2022266017

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cardiac device implantation*	Approved as Requested	Proposed PT *Cardiac device implantation*	10088292
To SMQ	*Cardiac failure (SMQ)*		To SMQ *Cardiac failure (SMQ)*	20000004
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Cardiac device implantation to Cardiac failure (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ for relevant procedure related terms. Similar procedure and device terms are included as broad scope.

Supplemental Update Report

CR Number: 2022266018 **Implementation Date:** 13-Oct-22 Related CR: 2022266018

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cardiac device implantation*	Approved as Requested	Proposed PT *Cardiac device implantation*	10088292
To SMQ	*Cardiomyopathy (SMQ)*		To SMQ *Cardiomyopathy (SMQ)*	20000150
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Cardiac device implantation to Cardiomyopathy (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ for relevant procedure related terms. Similar procedure and device terms are included as broad scope.

CR Number: 2022266019 **Implementation Date:** 13-Oct-22 Related CR: 2022266019

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Orthobiologic treatment*	Approved as Requested	Proposed PT *Orthobiologic treatment*	10088250
To SMQ	*Tendinopathies and ligament disorders (SMQ)*		To SMQ *Tendinopathies and ligament disorders (SMQ)*	20000223
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Orthobiologic treatment to Tendinopathies and ligament disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ for relevant procedure related terms. Regenerative injection therapy - a form of orthobiologic treatment - involves the injection of a small volume of solution into multiple sites of painful ligament and tendon insertions and adjacent joint spaces, with the goal of reducing pain and ostensibly promoting tissue repair and growth.

Supplemental Update Report

CR Number: 2022266020 **Implementation Date:** 13-Oct-22 Related CR: 2022266020

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Sleep apnoea device implant*	Approved as Requested	Proposed PT *Sleep apnoea device implant*	10088275
To SMQ	*Acute central respiratory depression (SMQ)*		To SMQ *Acute central respiratory depression (SMQ)*	20000116
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Sleep apnoea device implant to Acute central respiratory depression (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ for relevant procedure related terms. Similar procedure terms are included as broad scope.

CR Number: 2022266021 **Implementation Date:** 13-Oct-22 Related CR: 2022266021

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ventricular outflow tract dredging*	Approved as Requested	Proposed PT *Ventricular outflow tract dredging*	10088350
To SMQ	*Cardiomyopathy (SMQ)*		To SMQ *Cardiomyopathy (SMQ)*	20000150
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Ventricular outflow tract dredging to Cardiomyopathy (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ for relevant procedure related terms. Ventricular outflow tract dredging is often used for left ventricular outflow tract obstruction and outflow tract stenosis cases. Similar procedure terms are included as broad scope.

Supplemental Update Report

CR Number: 2022266022 **Implementation Date:** 13-Oct-22 Related CR: 2022266022

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ventricular outflow tract dredging*	Approved as Requested	Proposed PT *Ventricular outflow tract dredging*	10088350
To SMQ	*Cardiac failure (SMQ)*		To SMQ *Cardiac failure (SMQ)*	20000004
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Ventricular outflow tract dredging to Cardiac failure (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ for relevant procedure related terms. Ventricular outflow tract dredging is often used for left ventricular outflow tract obstruction and outflow tract stenosis cases. Similar procedure terms are included as broad scope.

CR Number: 2022266023 **Implementation Date:** 13-Oct-22 Related CR: 2022266023

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Benign macrocrania of infancy*	Approved as Requested	Proposed PT *Benign macrocrania of infancy*	10088237
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Benign macrocrania of infancy to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2022266024 **Implementation Date:** 13-Oct-22 Related CR: 2022266024

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Bile acid synthesis disorder*	Approved as Requested	Proposed PT *Bile acid synthesis disorder*	10088265
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Bile acid synthesis disorder to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2022266025 **Implementation Date:** 13-Oct-22 Related CR: 2022266025

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cerebral folate deficiency*	Approved as Requested	Proposed PT *Cerebral folate deficiency*	10088217
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Cerebral folate deficiency to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2022266026 **Implementation Date:** 13-Oct-22 Related CR: 2022266026

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cerebrocostomandibular syndrome*	Approved as Requested	Proposed PT *Cerebrocostomandibular syndrome*	10088264
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Cerebrocostomandibular syndrome to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2022266027 **Implementation Date:** 13-Oct-22 Related CR: 2022266027

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Enameloma*	Approved as Requested	Proposed PT *Enameloma*	10088243
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Enameloma to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2022266028 **Implementation Date:** 13-Oct-22 Related CR: 2022266028

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Familial atrial fibrillation*	Approved as Requested	Proposed PT	
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		*Familial atrial fibrillation*	10088317
Term scope	*Narrow*		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Familial atrial fibrillation to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2022266029 **Implementation Date:** 13-Oct-22 Related CR: 2022266029

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Familial dilated cardiomyopathy*	Approved as Requested	Proposed PT	
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		*Familial dilated cardiomyopathy*	10088172
Term scope	*Narrow*		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Familial dilated cardiomyopathy to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2022266030 **Implementation Date:** 13-Oct-22 Related CR: 2022266030

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Fumarase deficiency*	Approved as Requested	Proposed PT *Fumarase deficiency*	10088204
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Fumarase deficiency to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2022266031 **Implementation Date:** 13-Oct-22 Related CR: 2022266031

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Galloway Mowat syndrome*	Approved as Requested	Proposed PT *Galloway Mowat syndrome*	10088355
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Galloway Mowat syndrome to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2022266032 **Implementation Date:** 13-Oct-22 Related CR: 2022266032

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gestational alloimmune liver disease*	Approved as Requested	Proposed PT *Gestational alloimmune liver disease*	10088236
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Gestational alloimmune liver disease to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2022266033 **Implementation Date:** 13-Oct-22 Related CR: 2022266033

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Glutaric acidaemia type I*	Approved as Requested	Proposed PT *Glutaric acidaemia type I*	10088192
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Glutaric acidaemia type I to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2022266034 **Implementation Date:** 13-Oct-22 Related CR: 2022266034

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hereditary gingival fibromatosis*	Approved as Requested	Proposed PT	
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		*Hereditary gingival fibromatosis*	10088210
Term scope	*Narrow*		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Hereditary gingival fibromatosis to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2022266035 **Implementation Date:** 13-Oct-22 Related CR: 2022266035

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Infantile neuroaxonal dystrophy*	Approved as Requested	Proposed PT	
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		*Infantile neuroaxonal dystrophy*	10088200
Term scope	*Narrow*		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Infantile neuroaxonal dystrophy to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2022266036 **Implementation Date:** 13-Oct-22 Related CR: 2022266036

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Macular hypoplasia*	Approved as Requested	Proposed PT *Macular hypoplasia*	10088203
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Macular hypoplasia to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2022266037 **Implementation Date:** 13-Oct-22 Related CR: 2022266037

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nail dysplasia*	Approved as Requested	Proposed PT *Nail dysplasia*	10088402
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Nail dysplasia to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2022266038 **Implementation Date:** 13-Oct-22 Related CR: 2022266038

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Oligodontia*	Approved as Requested	Proposed PT *Oligodontia*	10088239
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Oligodontia to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2022266039 **Implementation Date:** 13-Oct-22 Related CR: 2022266039

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Paramyotonia congenita*	Approved as Requested	Proposed PT *Paramyotonia congenita*	10088318
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Paramyotonia congenita to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2022266040 **Implementation Date:** 13-Oct-22 Related CR: 2022266040

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular rings and slings*	Approved as Requested	Proposed PT *Vascular rings and slings*	10088205
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Vascular rings and slings to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2022266041 **Implementation Date:** 13-Oct-22 Related CR: 2022266041

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ectopic atrial rhythm*	Approved as Requested	Proposed PT *Ectopic atrial rhythm*	10088339
To SMQ	*Disorders of sinus node function (SMQ)*		To SMQ *Disorders of sinus node function (SMQ)*	20000055
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Ectopic atrial rhythm to Disorders of sinus node function (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion criteria - all PTs as narrow in scope. An atrial ectopic rhythm occurs when the dominant pacepoint is an ectopic pace point in the atrium rather than a sinoatrial node. It may be atrial escape rhythm due to sinus node failure, usually at 30 to 60 bpm, or it may be an accelerated atrial ectopic pace point that exceeds the sinus node. LLT Ectopic pacemaker was originally under included PT Supraventricular extrasystoles and is now moved under this new PT.

Supplemental Update Report

CR Number: 2022266042 **Implementation Date:** 13-Oct-22 Related CR: 2022266042

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ectopic atrial rhythm*	Approved as Requested	Proposed PT *Ectopic atrial rhythm*	10088339
To SMQ	*Conduction defects (SMQ)*		To SMQ *Conduction defects (SMQ)*	20000056
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Ectopic atrial rhythm to Conduction defects (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion criteria - all PTs as narrow in scope. An atrial ectopic rhythm occurs when the dominant pace point is an ectopic pace point in the atrium rather than a sinoatrial node. It may be atrial escape rhythm due to sinus node failure, usually at 30 to 60 bpm, or it may be an accelerated atrial ectopic pace point that exceeds the sinus node.

CR Number: 2022266043 **Implementation Date:** 13-Oct-22 Related CR: 2022266043

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Familial atrial fibrillation*	Approved as Requested	Proposed PT *Familial atrial fibrillation*	10088317
To SMQ	*Supraventricular tachyarrhythmias (SMQ)*		To SMQ *Supraventricular tachyarrhythmias (SMQ)*	20000057
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Familial atrial fibrillation to Supraventricular tachyarrhythmias (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion criteria as a narrow term, aligned with PT Atrial fibrillation and PT Congenital supraventricular tachycardia. Familial atrial fibrillation is an inherited abnormality of the heart's normal rhythm.

Supplemental Update Report

CR Number: 2022266044 **Implementation Date:** 13-Oct-22 Related CR: 2022266044

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Familial atrial fibrillation*	Approved as Requested	Proposed PT *Familial atrial fibrillation*	10088317
To SMQ	*Congenital and neonatal arrhythmias (SMQ)*		To SMQ *Congenital and neonatal arrhythmias (SMQ)*	20000052
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Familial atrial fibrillation to Congenital and neonatal arrhythmias (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion as narrow in scope. Familial atrial fibrillation is an inherited abnormality of the heart's normal rhythm.

CR Number: 2022266045 **Implementation Date:** 13-Oct-22 Related CR: 2022266045

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Congenital supraventricular tachycardia*	Approved as Requested	Proposed PT *Congenital supraventricular tachycardia*	10082343
To SMQ	*Congenital and neonatal arrhythmias (SMQ)*		To SMQ *Congenital and neonatal arrhythmias (SMQ)*	20000052
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Congenital supraventricular tachycardia to Congenital and neonatal arrhythmias (SMQ) as a Narrow term is approved as requested. PT Congenital supraventricular tachycardia was added to MedDRA in v22.0 and may have been an oversight. The term fits inclusion criteria as narrow in scope.

Supplemental Update Report

CR Number: 2022266046 **Implementation Date:** 13-Oct-22 Related CR: 2022266046

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Electrocardiogram RR interval abnormal*	Approved as Requested	Proposed PT *Electrocardiogram RR interval abnormal*	10088247
To SMQ	*Arrhythmia related investigations, signs and symptoms (SMQ)*		To SMQ *Arrhythmia related investigations, signs and symptoms (SMQ)*	20000051
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Electrocardiogram RR interval abnormal to Arrhythmia related investigations, signs and symptoms (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion as narrow in scope, aligned with PT Electrocardiogram RR interval prolonged. PT Electrocardiogram RR interval abnormal may be indicative of tachy- or bradyarrhythmic deviations.

CR Number: 2022266047 **Implementation Date:** 13-Oct-22 Related CR: 2022266047

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Electrocardiogram RR interval shortened*	Approved as Requested	Proposed PT *Electrocardiogram RR interval shortened*	10088248
To SMQ	*Arrhythmia related investigations, signs and symptoms (SMQ)*		To SMQ *Arrhythmia related investigations, signs and symptoms (SMQ)*	20000051
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Electrocardiogram RR interval shortened to Arrhythmia related investigations, signs and symptoms (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion as narrow in scope, aligned with PT Electrocardiogram RR interval prolonged. Shortened RR-intervalls are indicative for tachyarrhythmias.

Supplemental Update Report

CR Number: 2022266048 **Implementation Date:** 13-Oct-22 Related CR: 2022266048

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Exertional rhabdomyolysis*	Approved as Requested	Proposed PT *Exertional rhabdomyolysis*	10088386
To SMQ	*Rhabdomyolysis/myopathy (SMQ)*		To SMQ *Rhabdomyolysis/myopathy (SMQ)*	20000002
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Exertional rhabdomyolysis to Rhabdomyolysis/myopathy (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion as narrow in scope "diagnoses and laboratory test results that are unique or directly lead to rhabdomyolysis/myopathy. Exertional rhabdomyolysis is a relatively uncommon but potentially fatal condition affecting athletes that requires prompt recognition and appropriate management.

CR Number: 2022266049 **Implementation Date:** 13-Oct-22 Related CR: 2022266049

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Enhanced respiratory disease*	Approved as Requested	Proposed PT *Enhanced respiratory disease*	10088389
To SMQ	*Anaphylactic reaction (SMQ)*		To SMQ *Anaphylactic reaction (SMQ)*	20000021
Term scope	*Broad*		Term scope *Broad*	
			Term_category *B*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Enhanced respiratory disease to Anaphylactic reaction (SMQ) as a Broad term is approved as requested. New term for v26.0. Former PT Vaccine associated enhanced respiratory disease is now demoted under this new PT. In severe cases, enhanced respiratory disease may cause a severe anaphylactic reaction.

Supplemental Update Report

CR Number: 2022266050 **Implementation Date:** 13-Oct-22 Related CR: 2022266050

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Enhanced respiratory disease*	Approved as Requested	Proposed PT *Enhanced respiratory disease*	10088389
To SMQ	*Hypersensitivity (SMQ)*		To SMQ *Hypersensitivity (SMQ)*	20000214
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Enhanced respiratory disease to Hypersensitivity (SMQ) as a Broad term is approved as requested. New term for v26.0. Former as broad included PT Vaccine associated enhanced respiratory disease is now LLT to this new PT.

CR Number: 2022266051 **Implementation Date:** 13-Oct-22 Related CR: 2022266051

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pupillary capture*	Approved as Requested	Proposed PT *Pupillary capture*	10088327
To SMQ	*Lens disorders (SMQ)*		To SMQ *Lens disorders (SMQ)*	20000155
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Pupillary capture to Lens disorders (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion criterion; Therapeutic procedural terms and related complications and assigned as a narrow term similar to PT Cataract operation complication. Pupillary capture is an unusual complication of posterior chamber intraocular lens implantation and may occur in the early or late postoperative period.

Supplemental Update Report

CR Number: 2022266052 **Implementation Date:** 13-Oct-22 Related CR: 2022266052

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ameloblastic fibrosarcoma*	Approved as Requested	Proposed PT	
To SMQ	*Non-haematological malignant tumours (SMQ)*		*Ameloblastic fibrosarcoma*	10088309
Term scope	*Narrow*		To SMQ	
			Non-haematological malignant tumours (SMQ)	20000228
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Ameloblastic fibrosarcoma to Non-haematological malignant tumours (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion criterion of this SMQ. Ameloblastic fibrosarcoma is a rare, aggressive malignant odontogenic tumor.

CR Number: 2022266053 **Implementation Date:** 13-Oct-22 Related CR: 2022266053

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Uterine cervix lymphoma*	Approved as Requested	Proposed PT	
To SMQ	*Malignant lymphomas (SMQ)*		*Uterine cervix lymphoma*	10088190
Term scope	*Narrow*		To SMQ	
			Malignant lymphomas (SMQ)	20000215
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Uterine cervix lymphoma to Malignant lymphomas (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion criterion of the SMQ. Primary lymphomas of the cervix and uterus are rare.

Supplemental Update Report

CR Number: 2022266054 **Implementation Date:** 13-Oct-22 Related CR: 2022266054

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Uterine cervix lymphoma*	Approved as Requested	Proposed PT *Uterine cervix lymphoma*	10088190
To SMQ	*Uterine and fallopian tube malignant tumours (SMQ)*		To SMQ *Uterine and fallopian tube malignant tumours (SMQ)*	20000206
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Uterine cervix lymphoma to Uterine and fallopian tube malignant tumours (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion criterion of the SMQ. Primary lymphomas of the cervix and uterus are rare.

CR Number: 2022266055 **Implementation Date:** 13-Oct-22 Related CR: 2022266055

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Immune-mediated optic neuritis*	Approved as Requested	Proposed PT *Immune-mediated optic neuritis*	10088362
To SMQ	*Optic nerve disorders (SMQ)*		To SMQ *Optic nerve disorders (SMQ)*	20000148
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Immune-mediated optic neuritis to Optic nerve disorders (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion as a narrow term, similar to the narrow PT Optic neuritis which is already included. Optic neuritis may result from a diverse number of inflammatory, immune meditated, autoimmune or infectious conditions.

Supplemental Update Report

CR Number: 2022266056 **Implementation Date:** 13-Oct-22 Related CR: 2022266056

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anterior chamber reformation*	Approved as Requested	Proposed PT *Anterior chamber reformation*	10088168
To SMQ	*Corneal disorders (SMQ)*		To SMQ *Corneal disorders (SMQ)*	20000156
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Anterior chamber reformation to Corneal disorders (SMQ) as a Broad term is approved as requested. New term for v26.0 which fits inclusion as a broad term, aligned with PT Corneal suture. Anterior chamber reformation refers to management of a flat anterior chamber - see included PT Flat anterior chamber of eye - because of over filtration in the early postoperative period after trabeculectomy.

CR Number: 2022266057 **Implementation Date:** 13-Oct-22 Related CR: 2022266057

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anterior chamber reformation*	Approved as Requested	Proposed PT *Anterior chamber reformation*	10088168
To SMQ	*Glaucoma (SMQ)*		To SMQ *Glaucoma (SMQ)*	20000146
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Anterior chamber reformation to Glaucoma (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion as a narrow term - procedural terms that are specific or clearly related to glaucoma. Anterior chamber reformation refers to management of a flat anterior chamber because of over filtration in the early postoperative period after trabeculectomy.

Supplemental Update Report

CR Number: 2022266058 **Implementation Date:** 13-Oct-22 Related CR: 2022266058

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Eye canaloplasty*	Approved as Requested	Proposed PT *Eye canaloplasty*	10088174
To SMQ	*Glaucoma (SMQ)*		To SMQ *Glaucoma (SMQ)*	20000146
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Eye canaloplasty to Glaucoma (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion criterion as narrow in scope - procedural terms that are specific or clearly related to glaucoma. Canaloplasty is a relatively new non-penetrating surgery for the reduction of intraocular pressure in patients affected by glaucoma.

CR Number: 2022266059 **Implementation Date:** 13-Oct-22 Related CR: 2022266059

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Macular pneumatic displacement*	Approved as Requested	Proposed PT *Macular pneumatic displacement*	10088232
To SMQ	*Retinal disorders (SMQ)*		To SMQ *Retinal disorders (SMQ)*	20000158
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Macular pneumatic displacement to Retinal disorders (SMQ) as a Broad term is approved as requested. New term for v26.0 which fits as inclusion as broad in scope. Macular pneumatic displacement is a treatment after retinal bleeding that aims to shift blood from under the macula to other parts of the retina that are less vital for vision.

Supplemental Update Report

CR Number: 2022266060 **Implementation Date:** 13-Oct-22 Related CR: 2022266060

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Punctoplasty*	Approved as Requested	Proposed PT *Punctoplasty*	10088390
To SMQ	*Lacrimal disorders (SMQ)*		To SMQ *Lacrimal disorders (SMQ)*	20000176
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Punctoplasty to Lacrimal disorders (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion criterion for this SMQ - Terms for lacrimal apparatus procedures (see closely related included PT Lacrimal duct procedure). Punctoplasty is a surgical procedure to restore proper drainage of tears when the lacrimal punctum becomes narrowed or blocked.

CR Number: 2022266061 **Implementation Date:** 13-Oct-22 Related CR: 2022266061

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Rectal neoplasm excision*	Approved as Requested	Proposed PT *Rectal neoplasm excision*	10088420
To SMQ	*Malignancy related therapeutic and diagnostic procedures (SMQ)*		To SMQ *Malignancy related therapeutic and diagnostic procedures (SMQ)*	20000093
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Rectal neoplasm excision to Malignancy related therapeutic and diagnostic procedures (SMQ) as a Narrow term is approved as requested. New term for v26.0 which fits inclusion criterion. Even though a broad term and not qualified as removal of a malignant tumor, it may be relevant to find cases of underlying malignancies. Similar terms such as PT Bladder neoplasm surgery, PT Breast tumour excision and many others are in this SMQ.

Supplemental Update Report

CR Number: 2022266062 **Implementation Date:** 13-Oct-22 Related CR: 2022266062

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pseudophakia*	Approved as Requested	Proposed PT *Pseudophakia*	10048867
To SMQ	*Lens disorders (SMQ)*		To SMQ *Lens disorders (SMQ)*	20000155
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Pseudophakia to Lens disorders (SMQ) as a Narrow term is approved as requested. Existing term which was promoted from under the non-included procedural PT Intraocular lens implant. Pseudophakia is used to explain the state that results after cataract surgery, when an intraocular lens is implanted.

CR Number: 2022266063 **Implementation Date:** 13-Oct-22 Related CR: 2022266063

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Intraocular lens implant*	Approved as Requested	Proposed PT *Intraocular lens implant*	10067434
To SMQ	*Lens disorders (SMQ)*		To SMQ *Lens disorders (SMQ)*	20000155
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Intraocular lens implant to Lens disorders (SMQ) as a Broad term is approved as requested. Term was added to MedDRA already in v.10.1 but may have been an oversight to be added to this SMQ during the implementation of this SMQ in v11.1. Intraocular lens implant is a procedure closely related to cataract. Similar PT Lens extraction is included as well as a broad term.

Supplemental Update Report

CR Number: 2022266064 **Implementation Date:** 13-Oct-22 Related CR: 2022266064

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Antibody-dependent enhancement*	Approved as Requested	Proposed PT *Antibody-dependent enhancement*	10088388
To SMQ	*Hypersensitivity (SMQ)*		To SMQ *Hypersensitivity (SMQ)*	20000214
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Antibody-dependent enhancement to Hypersensitivity (SMQ) as a Broad term is approved as requested. New term for v26.0. Former included PT Vaccine associated enhanced disease is now demoted as sub-concept LLT.

CR Number: 2022266065 **Implementation Date:** 13-Oct-22 Related CR: 2022266065

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypertriglycaeridemic waist phenotype*	Approved as Requested	Proposed PT *Hypertriglycaeridemic waist phenotype*	10088156
To SMQ	*Dyslipidaemia (SMQ)*		To SMQ *Dyslipidaemia (SMQ)*	20000026
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Hypertriglycaeridemic waist phenotype to Dyslipidaemia (SMQ) as a Narrow term is approved as requested. PT Hypertriglycaeridemic waist phenotype was added in V26.0 and is defined as an elevated waist circumference along with an elevated plasma triglyceride concentrations. Addition of this PT is in line with the SMQ inclusion criteria: Terms with roots of “lipid,” “cholesterol,” “triglyceride,” and “lipoprotein” and Medical terms closely related to lipids, lipoproteins, cholesterol and triglycerides in blood. All PTs of this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2022266066 **Implementation Date:** 13-Oct-22 Related CR: 2022266066

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site induration*	Approved as Requested	Proposed PT	
To SMQ	*Extravasation events (injections, infusions and implants) (SMQ)*		*Vascular access site induration*	10088357
Term scope	*Broad*		To SMQ	
			Extravasation events (injections, infusions and implants) (SMQ)	20000136
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Vascular access site induration to Extravasation events (injections, infusions and implants) (SMQ) as a Broad term is approved as requested. PT Vascular access site induration was added in V26.0 and matches the inclusion criterion "Terms with “injection”, “infusion”, “implant”, “catheter,” “vascular access,” and “device” when combined with “induration”, “edema”, “effusion”, “swelling”, “irritation”, “necrosis”, and “ulcer”".

CR Number: 2022266067 **Implementation Date:** 13-Oct-22 Related CR: 2022266067

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gestational alloimmune liver disease*	Approved as Requested	Proposed PT	
To SMQ	*Congenital, familial, neonatal and genetic disorders of the liver (SMQ)*		*Gestational alloimmune liver disease*	10088236
Term scope	*Narrow*		To SMQ	
			Congenital, familial, neonatal and genetic disorders of the liver (SMQ)	20000014
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Gestational alloimmune liver disease to Congenital, familial, neonatal and genetic disorders of the liver (SMQ) as a Narrow term is approved as requested. Gestational alloimmune liver disease is initiated by maternal antibodies that attack fetal hepatocytes. The fetal immune response to the antibodies causes liver damage. The closely related PT Hereditary haemochromatosis is in the narrow scope of this SMQ.

Supplemental Update Report

CR Number: 2022266068 **Implementation Date:** 13-Oct-22 Related CR: 2022266068

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Bile acids increased*	Approved as Requested	Proposed PT	
To SMQ	*Liver related investigations, signs and symptoms (SMQ)*		*Bile acids increased*	10088182
Term scope	*Narrow*		To SMQ	
			Liver related investigations, signs and symptoms (SMQ)	20000008
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Bile acids increased to Liver related investigations, signs and symptoms (SMQ) as a Narrow term is approved as requested. Bile acids are increased in patients with acute hepatitis, chronic hepatitis, liver sclerosis, liver cancer and obstetric cholestatis. Bile Acids can also be estimated in gastric juice as a valuable marker for duodenogastric bile reflux and also in faeces for intestinal disorders. This new PT overrides the demoted PT Total bile acids increased in the narrow scope.

CR Number: 2022266069 **Implementation Date:** 13-Oct-22 Related CR: 2022266069

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Laparotomy*	Approved as Requested	Proposed PT	
To SMQ	*Gastrointestinal perforation, ulcer, haemorrhage, obstruction non-specific findings/procedures (SMQ)*		*Laparotomy*	10023696
Term scope	*Broad*		To SMQ	
			Gastrointestinal perforation, ulcer, haemorrhage, obstruction non-specific findings/procedures (SMQ)	20000104
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Laparotomy to Gastrointestinal perforation, ulcer, haemorrhage, obstruction non-specific findings/procedures (SMQ) as a Broad term is approved as requested. Terms for medical and surgical procedures and for diagnostic investigations related to perforation, ulceration, or hemorrhage are included. Demoted PT Explorative laparotomy was in the broad scope of this SMQ.

Supplemental Update Report

CR Number: 2022266070 **Implementation Date:** 13-Oct-22 Related CR: 2022266070

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cache Valley virus infection*	Approved as Requested	Proposed PT *Cache Valley virus infection*	10088316
To SMQ	*Opportunistic infections (SMQ)*		To SMQ *Opportunistic infections (SMQ)*	20000235
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Cache Valley virus infection to Opportunistic infections (SMQ) as a Broad term is approved as requested. Severe forms of Cache Valley virus infection, such as encephalitis has rarely been reported in immunocompetent patients, and it is mostly a manifestation of the immunosuppressed patient, with clinical presentations such as fatal meningoencephalitis or multiorgan failure. Since the term refers to the infection in general and not to the complicated cases, the term will be added in the broad scope, similarly to the existing arbovirosis Encephalitis california and Jamestown Canyon encephalitis.

CR Number: 2022266071 **Implementation Date:** 13-Oct-22 Related CR: 2022266071

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dental sepsis*	Approved as Requested	Proposed PT *Dental sepsis*	10088408
To SMQ	*Opportunistic infections (SMQ)*		To SMQ *Opportunistic infections (SMQ)*	20000235
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Dental sepsis to Opportunistic infections (SMQ) as a Broad term is approved as requested. Sepsis or septic terms imply extension of pathogens and are more frequent in the immunocompromised host. Like other sepsis terms based on anatomical origin (such as Pelvic sepsis, Pulmonary sepsis, Urosepsis, etc) this term will be added to the broad scope of this SMQ.

Supplemental Update Report

CR Number: 2022266072 **Implementation Date:** 13-Oct-22 Related CR: 2022266072

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Rhizobium radiobacter bacteraemia*	Approved as Requested	Proposed PT *Rhizobium radiobacter bacteraemia*	10088344
To SMQ	*Opportunistic infections (SMQ)*		To SMQ *Opportunistic infections (SMQ)*	20000235
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Rhizobium radiobacter bacteraemia to Opportunistic infections (SMQ) as a Narrow term is approved as requested. Catheter related bacteremia, continuous ambulatory peritoneal dialysis peritonitis, urinary tract infections and rarely endophthalmitis, endocarditis, brain abscess and pneumonia are the most common clinical conditions caused by these bacteria, which is recognized as an emerging opportunistic pathogen affecting mostly immunocompromised and chronically debilitated host with under lying conditions such as malignancies, chronic renal failure, human immunodeficiency virus, as well as bone marrow transplant recipients. This PT will be added the narrow scope of this SMQ.

CR Number: 2022266073 **Implementation Date:** 13-Oct-22 Related CR: 2022266073

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Antibody-dependent enhancement*	Approved as Requested	Proposed PT *Antibody-dependent enhancement*	10088388
To SMQ	*Immune-mediated/autoimmune disorders (SMQ)*		To SMQ *Immune-mediated/autoimmune disorders (SMQ)*	20000236
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Antibody-dependent enhancement to Immune-mediated/autoimmune disorders (SMQ) as a Narrow term is approved as requested. Antibody-dependent enhancement can be mediated by antibody Fc receptor-associated internalization of a virus, thus resulting in more extensive viral replication and cytokine release in the presence of virus-specific antibodies. This term overrides former PT Vaccine associated enhanced disease, now demoted. "Terms referring to immune-mediated and autoimmune disorders which may potentially be associated with immunotherapeutic agents or vaccines" is the first inclusion criterium of this SMQ, and therefore the term will be added to the narrow scope.

Supplemental Update Report

CR Number: 2022266074 **Implementation Date:** 13-Oct-22 Related CR: 2022266074

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Enhanced respiratory disease*	Approved as Requested	Proposed PT *Enhanced respiratory disease*	10088389
To SMQ	*Immune-mediated/autoimmune disorders (SMQ)*		To SMQ *Immune-mediated/autoimmune disorders (SMQ)*	20000236
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Enhanced respiratory disease to Immune-mediated/autoimmune disorders (SMQ) as a Narrow term is approved as requested. Enhanced respiratory disease can happen during homotypic or heterotypic serotype virus infection after vaccination, natural infection or transfer of maternal passive immunity. This term overrides former PT Vaccine associated enhanced respiratory disease, now demoted. "Terms referring to immune-mediated and autoimmune disorders which may potentially be associated with immunotherapeutic agents or vaccines" is the first inclusion criterium of this SMQ, and therefore the term will be added to the narrow scope.

CR Number: 2022266075 **Implementation Date:** 13-Oct-22 Related CR: 2022266075

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dropped shoulder syndrome*	Approved as Requested	Proposed PT *Dropped shoulder syndrome*	10088323
To SMQ	*Accidents and injuries (SMQ)*		To SMQ *Accidents and injuries (SMQ)*	20000135
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Dropped shoulder syndrome to Accidents and injuries (SMQ) as a Narrow term is approved as requested. A dropped shoulder results from shoulder separation, an injury to the soft tissue between the clavicle and scapula at the acromioclavicular joint. It presents as pain in one or both shoulders radiating to the ipsilateral upper limb and other adjacent regions, and often symptoms of lower cervical radiculopathy. The severity of the injury can range from a mild strain to a full tear, and rehabilitation is performed by strengthening the muscles of the shoulder, back and chest through the various ranges of motion. Since this term describes a specific type of injury, it will be added to the narrow search terms of this SMQ.

Supplemental Update Report

CR Number: 2022266076 **Implementation Date:** 13-Oct-22 Related CR: 2022266076

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Deep tissue injury*	Approved as Requested	Proposed PT *Deep tissue injury*	10088352
To SMQ	*Accidents and injuries (SMQ)*		To SMQ *Accidents and injuries (SMQ)*	20000135
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Deep tissue injury to Accidents and injuries (SMQ) as a Narrow term is approved as requested. A deep tissue injury is a serious type of pressure injury that begins in the muscle closest to the bone and may not be visible in its early stages. Since this term describes a specific type of injury, it will be added to the narrow search terms of this SMQ.

CR Number: 2022266077 **Implementation Date:** 13-Oct-22 Related CR: 2022266077

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Bile acid synthesis disorder*	Approved as Requested	Proposed PT *Bile acid synthesis disorder*	10088265
To SMQ	*Congenital biliary disorders (SMQ)*		To SMQ *Congenital biliary disorders (SMQ)*	20000122
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Bile acid synthesis disorder to Congenital biliary disorders (SMQ) as a Narrow term is approved as requested. Bile acid synthesis disorders (BASDs) are a group of rare metabolic disorders characterized by defects in the creation (synthesis) of bile acids.

Supplemental Update Report

CR Number: 2022266078 **Implementation Date:** 13-Oct-22 Related CR: 2022266078

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Bile acids increased*	Approved as Requested	Proposed PT	
To SMQ	*Biliary system related investigations, signs and symptoms (SMQ)*		*Bile acids increased*	10088182
Term scope	*Broad*		To SMQ	
			Biliary system related investigations, signs and symptoms (SMQ)	20000123
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Bile acids increased to Biliary system related investigations, signs and symptoms (SMQ) as a Broad term is approved as requested. Bile acids are increased in patients with internal and external cholestasis.

CR Number: 2022266079 **Implementation Date:** 13-Oct-22 Related CR: 2022266079

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pulmonary tractotomy*	Approved as Requested	Proposed PT	
To SMQ	*Accidents and injuries (SMQ)*		*Pulmonary tractotomy*	10088225
Term scope	*Broad*		To SMQ	
			Accidents and injuries (SMQ)	20000135
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Pulmonary tractotomy to Accidents and injuries (SMQ) as a Broad term is approved as requested. A pulmonary tractotomy is a surgical technique to treat a penetrating lung injury. It is for emergency surgery for a penetrating lung injury (e.g., an accident or a gunshot). This term describes a procedure used for the treatment of a traumatic injury and will be added to the broad search terms of this SMQ.

Supplemental Update Report

CR Number: 2022266080 **Implementation Date:** 13-Oct-22 Related CR: 2022266080

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Immune-mediated optic neuritis*	Approved as Requested	Proposed PT *Immune-mediated optic neuritis*	10088362
To SMQ	*Demyelination (SMQ)*		To SMQ *Demyelination (SMQ)*	20000154
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Immune-mediated optic neuritis to Demyelination (SMQ) as a Narrow term is approved as requested. "Immune-mediated" is defined as an inflammatory process caused by an unspecified immune reaction leading to dysregulation of the normal immune response. Immune mediated diseases are often based on, but not limited to, an autoimmune mechanism. Immune-mediated demyelination of the optic nerve, so called optic neuritis, is a common clinical presentation of multiple sclerosis. This new PT will be added as a narrow search term in this SMQ.

CR Number: 2022266081 **Implementation Date:** 13-Oct-22 Related CR: 2022266081

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Bile acids increased*	Approved as Requested	Proposed PT *Bile acids increased*	10088182
To SMQ	*Acute pancreatitis (SMQ)*		To SMQ *Acute pancreatitis (SMQ)*	20000022
Term scope	*Broad*		Term scope *Broad*	
			Term_category *B*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Bile acids increased to Acute pancreatitis (SMQ) as a Broad term is approved as requested. This fits the inclusion criteria of this SMQ for relevant investigation terms. These terms are in broad scope, category B. Biliary pancreatitis is the leading cause of acute pancreatitis in both children and adults. A proposed mechanism is the reflux of bile into the pancreatic duct. Bile acid exposure causes pancreatic acinar cell injury through a sustained rise in cytosolic Ca(2+).

Supplemental Update Report

CR Number: 2022266082 **Implementation Date:** 13-Oct-22 Related CR: 2022266082

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypertriglycaeridemic waist phenotype*	Approved as Requested	Proposed PT *Hypertriglycaeridemic waist phenotype*	10088156
To SMQ	*Lipodystrophy (SMQ)*		To SMQ *Lipodystrophy (SMQ)*	20000177
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Hypertriglycaeridemic waist phenotype to Lipodystrophy (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ for increasing abdominal girth (increasing belt or waist size). Related terms for elevated triglycerides and fat tissue increased are included as broad scope terms.

CR Number: 2022266083 **Implementation Date:** 13-Oct-22 Related CR: 2022266083

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Rhizobium radiobacter bacteraemia*	Approved as Requested	Proposed PT *Rhizobium radiobacter bacteraemia*	10088344
To SMQ	*Sepsis (SMQ)*		To SMQ *Sepsis (SMQ)*	20000234
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Rhizobium radiobacter bacteraemia to Sepsis (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Bacillus bacteraemia and PT Citrobacter bacteraemia are already included as broad scope terms.

Supplemental Update Report

CR Number: 2022266084 **Implementation Date:** 13-Oct-22 Related CR: 2022266084

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dopamine agonist withdrawal syndrome*	Approved as Requested	Proposed PT *Dopamine agonist withdrawal syndrome*	10088379
To SMQ	*Drug withdrawal (SMQ)*		To SMQ *Drug withdrawal (SMQ)*	20000102
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Dopamine agonist withdrawal syndrome to Drug withdrawal (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Steroid withdrawal syndrome and PT Topical steroid withdrawal reaction are already included as broad scope terms.

CR Number: 2022266085 **Implementation Date:** 13-Oct-22 Related CR: 2022266085

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dental sepsis*	Approved as Requested	Proposed PT *Dental sepsis*	10088408
To SMQ	*Sepsis (SMQ)*		To SMQ *Sepsis (SMQ)*	20000234
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Dental sepsis to Sepsis (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Biliary sepsis and PT Pelvic sepsis are already included as narrow scope terms.

Supplemental Update Report

CR Number: 2022266086 **Implementation Date:** 13-Oct-22 Related CR: 2022266086

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*N-telopeptide increased*	Approved as Requested	Proposed PT *N-telopeptide increased*	10088254
To SMQ	*Osteoporosis/osteopenia (SMQ)*		To SMQ *Osteoporosis/osteopenia (SMQ)*	20000178
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT N-telopeptide increased to Osteoporosis/osteopenia (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ which includes terms for investigations used in assessment of patients. Similar terms such as PT N-telopeptide urine increased and PT C-telopeptide increased are already included as broad scope terms.

CR Number: 2022266087 **Implementation Date:** 13-Oct-22 Related CR: 2022266087

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*N-telopeptide abnormal*	Approved as Requested	Proposed PT *N-telopeptide abnormal*	10088251
To SMQ	*Osteoporosis/osteopenia (SMQ)*		To SMQ *Osteoporosis/osteopenia (SMQ)*	20000178
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT N-telopeptide abnormal to Osteoporosis/osteopenia (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Bone resorption test abnormal and PT Bone formation test abnormal are already included as broad scope terms.

Supplemental Update Report

CR Number: 2022266088 **Implementation Date:** 13-Oct-22 Related CR: 2022266088

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gestational alloimmune liver disease*	Approved as Requested	Proposed PT *Gestational alloimmune liver disease*	10088236
To SMQ	*Foetal disorders (SMQ)*		To SMQ *Foetal disorders (SMQ)*	20000190
Term scope	*Narrow*		Term scope *Narrow* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Gestational alloimmune liver disease to Foetal disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Diabetic foetopathy and PT Maternal hypertension affecting foetus are already included as narrow scope terms.

CR Number: 2022266089 **Implementation Date:** 13-Oct-22 Related CR: 2022266089

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Radiation induced encephalopathy*	Approved as Requested	Proposed PT *Radiation induced encephalopathy*	10088375
To SMQ	*Noninfectious encephalopathy/delirium (SMQ)*		To SMQ *Noninfectious encephalopathy/delirium (SMQ)*	20000133
Term scope	*Narrow*		Term scope *Narrow* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Radiation induced encephalopathy to Noninfectious encephalopathy/delirium (SMQ) as a Narrow term is approved as requested. Radiation encephalopathy is a late complication of cranial irradiation which involves significant cognitive and emotional dysfunction following radiation therapy to the brain.Since this term describes a specific type of noninfectious encephalopathy, it will be added to the narrow search terms of this SMQ.

Supplemental Update Report

CR Number: 2022269001 **Implementation Date:** 28-Sep-22 Related CR: 2022269001

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term	Rejected		

Proposed Term *Eye Drusen*

MSSO Comment: The proposal to add a new term Eye Drusen is not approved. Drusen are yellow-colored spots that form under the retina. They are caused by the accumulation of proteins, lipids, and other unwanted material in the retina. The requested term can be represented by PT Retinal drusen or sub-ordinated LLTs.

CR Number: 2022269002 **Implementation Date:** 28-Sep-22 Related CR: 2022269002

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New LLT	Rejected		

Proposed LLT *PHARYNGEAL FRACTURE*

MSSO Comment: The proposal to add a new LLT PHARYNGEAL FRACTURE is not approved. The pharynx mainly exists out of muscular and soft tissue. "Fracture" for this part does not seem to be a valid concept or report.

CR Number: 2022269003 **Implementation Date:** 03-Oct-22 Related CR: 2022269003

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New LLT	Rejected		

Proposed LLT *Cardiovascular magnetic resonance*

MSSO Comment: The proposal to add a new LLT Cardiovascular magnetic resonance is not approved. Proposed concept is available in existing terms such as LLT/PT Magnetic resonance imaging heart.

Supplemental Update Report

CR Number: 2022269007 **Implementation Date:** 03-Oct-22 Related CR: 2022269007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Hepatic Langerhans cell histiocytosis*	Approved as Requested	Proposed LLT		
To PT	*Langerhans' cell histiocytosis*		*Hepatic Langerhans cell histiocytosis*	10088526	Current
			To PT		
			Langerhans' cell histiocytosis	10069698	

MSSO Comment: The proposal to add a new LLT Hepatic Langerhans cell histiocytosis to PT Langerhans' cell histiocytosis is approved as requested. Hepatic Langerhans cell histiocytosis (LCH) is characterized by proliferation and accumulation of Langerhans cells in the liver, causing liver dysfunction or forming a mass lesion. The liver can be involved in isolation, or be affected along with other organs. A common clinical hepatic presentation is cholestasis with pruritis, fatigue and direct hyperbilirubinemia. In a related change, PT Langerhans' cell histiocytosis will linked to secondary HLT Hepatic and hepatobiliary disorders NEC.

CR Number: 2022276005 **Implementation Date:** 03-Oct-22 Related CR: 2022269007

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Langerhans' cell histiocytosis*	Approved as Requested	Proposed PT	
To HLT	*Hepatic and hepatobiliary disorders NEC*		*Langerhans' cell histiocytosis*	10069698
			To HLT	
			Hepatic and hepatobiliary disorders NEC	10027681

MSSO Comment:

CR Number: 2022269008 **Implementation Date:** 30-Sep-22 Related CR: 2022269008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Burning sensation of chest wall*	Rejected		

MSSO Comment: The proposal to add a new term Burning sensation of chest wall is not approved. MedDRA cannot provide "burning sensation" terms for all possible anatomical locations. Most often "burning" represents a type of pain especially for the region of chest/thorax.

Supplemental Update Report

CR Number: 2022270001 **Implementation Date:** 11-Oct-22 Related CR: 2022270001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*"Hy's law" PT, "Potential DILI" PT*	Approved Not as Requested After Suspension	Proposed PT	
			Suspected drug-induced liver injury	10088572
			HLT primary	
			Hepatocellular damage and hepatitis NEC	10019833
			SOC primary	
			Hepatobiliary disorders	10019805
			HLT secondary	
			Poisoning and toxicity	10035777
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new term "Hy's law" PT, "Potential DILI" PT is approved but not as requested after suspension. The MSSO will add new PT Suspected drug-induced liver injury to primary HLT Hepatocellular damage and hepatitis NEC; secondary HLT Poisoning and toxicity. In a related change, the MSSO will add LLT Suspected Hy's Law case to new PT Suspected drug-induced liver injury. Suspected cases of drug-induced liver injury are typically required to be reported in an expedited fashion before fully working up the patient to rule out other etiologies.

CR Number: 2022284089 **Implementation Date:** 11-Oct-22 Related CR: 2022270001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Suspected Hy's law case*	Approved as Requested	Proposed LLT		
To PT	*Suspected drug-induced liver injury*		*Suspected Hy's law case*	10088573	Current
			To PT		
			Suspected drug-induced liver injury	10088572	

MSSO Comment:

Supplemental Update Report

CR Number: 2022270002 **Implementation Date:** 03-Oct-22 Related CR: 2022270002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Femoro-crural bypass*	Approved as Requested	Proposed LLT	
			Femoro-crural bypass	10088527 Current
			To PT	
			Peripheral artery bypass	10072561

MSSO Comment: The proposal to add a new LLT Femoro-crural bypass is approved as requested. Femoro-distal or femoro-crural bypass are grafts that originate from the femoral artery at the groin and take blood to one of the 3 calf blood vessels (anterior and posterior tibial arteries and peroneal artery). Proposed term will be added as subconcept LLT Femoro-crural bypass under PT Peripheral artery bypass.

CR Number: 2022270003 **Implementation Date:** 03-Oct-22 Related CR: 2022270003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Speech latency*	Approved Not as Requested	Proposed PT	
			Speech latency	10088528
			HLT primary	
			Speech and language abnormalities	10041460
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Specific cognitive ability disturbances	10041427
			SOC secondary	
			Psychiatric disorders	10037175

MSSO Comment: The proposal to add a new LLT Speech latency is approved but not as requested. Speech latency entails the lag time between when someone asks a question and the other person responds. Speech latency will be added as a PT to primary HLT Speech and language abnormalities and to secondary HLT Specific cognitive ability disturbances.

CR Number: 2022270004 **Implementation Date:** 03-Oct-22 Related CR: 2022270004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*CT cardiac angiography*	Approved as Requested	Proposed LLT	
			CT cardiac angiography	10088529 Current
			To PT	
			Computerised tomogram coronary artery	10060804 Current

MSSO Comment: The proposal to add a new LLT CT cardiac angiography is approved as requested. CT cardiac angiography, also known as coronary CT angiography, or CT angiogram, is an imaging exam to view the heart and blood vessels. CT cardiac angiography will be added as LLT to PT Computerised tomogram coronary artery aligned with LLT CT coronary angiogram.

Supplemental Update Report

CR Number: 2022270005 **Implementation Date:** 03-Oct-22 Related CR: 2022270005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Intestinal laceration*	Approved as Requested	Proposed LLT *Intestinal laceration*	10088530 Current
			To PT *Gastrointestinal injury*	10061172

MSSO Comment: The proposal to add a new LLT Intestinal laceration is approved as requested. Intestinal laceration, a cut or rupture of any part of the intestine, will be added as LLT to PT Gastrointestinal injury.

CR Number: 2022270006 **Implementation Date:** 03-Oct-22 Related CR: 2022270006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cerebral Creatine deficiency*	Approved Not as Requested	Proposed LLT *Cerebral creatine deficiency*	10088531 Current
			To PT *Creatine deficiency syndrome*	10084104

MSSO Comment: The proposal to add a new term Cerebral Creatine deficiency is approved but not as requested. Cerebral creatine deficiency syndromes (CCDS) are inborn errors of creatine metabolism which interrupt the formation or transportation of creatine. Creatine is essential to sustain the high energy levels needed for muscle and brain development. Cerebral creatine deficiency, modified according to MedDRA capitalisation conventions, will be added as synonym LLT to PT Creatine deficiency syndrome.

CR Number: 2022271001 **Implementation Date:** 03-Oct-22 Related CR: 2022271001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Drug-induced interstitial lung disease*	Rejected		

MSSO Comment: The proposal to add a new term Drug-induced interstitial lung disease is not approved. The MSSO refrains from adding "drug-induced" terms as causal relationship with a given drug is part of the case assessment.

Supplemental Update Report

CR Number: 2022271002 **Implementation Date:** 03-Oct-22 Related CR: 2022271002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vascular access site tenderness*	Approved as Requested	Proposed LLT	
To PT	*Vascular access site pain*		*Vascular access site tenderness*	10088532 Current
			To PT	
			Vascular access site pain	10077762

MSSO Comment: The proposal to add a new LLT Vascular access site tenderness to PT Vascular access site pain is approved as requested. As per Dorland's Medical Dictionary, Tenderness is an abnormal sensitiveness to touch or pressure. Proposed term will be added as subconcept LLT Vascular access site tenderness under PT Vascular access site pain.

CR Number: 2022271004 **Implementation Date:** 03-Oct-22 Related CR: 2022271004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vascular access site itching*	Approved as Requested	Proposed LLT	
To PT	*Vascular access site pruritus*		*Vascular access site itching*	10088533 Current
			To PT	
			Vascular access site pruritus	10083112

MSSO Comment: The proposal to add a new LLT Vascular access site itching to PT Vascular access site pruritus is approved as requested. Proposed term will be added as synonym LLT Vascular access site itching under PT Vascular access site pruritus.

CR Number: 2022271005 **Implementation Date:** 03-Oct-22 Related CR: 2022271005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vascular access site redness*	Approved as Requested	Proposed LLT	
To PT	*Vascular access site erythema*		*Vascular access site redness*	10088535 Current
			To PT	
			Vascular access site erythema	10083109

MSSO Comment: The proposal to add a new LLT Vascular access site redness to PT Vascular access site erythema is approved as requested. Proposed term will be added as synonym LLT Vascular access site redness under PT Vascular access site erythema.

Supplemental Update Report

CR Number: 2022271006 **Implementation Date:** 03-Oct-22 Related CR: 2022271006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Acquired optociliary shunt vessels*	Approved Not as Requested	Proposed LLT *Optociliary shunt vessels*	10088534 Current
			To PT *Retinal collateral vessels*	10077911

MSSO Comment: The proposal to add a new PT Acquired optociliary shunt vessels is approved but not as requested. Optociliary shunt vessels are collateral vessels on the optic nerve that connect the choroidal and retinal circulations and are associated with ophthalmic conditions that produce impaired retinal venous outflow. Proposed term will be modified without qualifier and added as an LLT Optociliary shunt vessels to PT Retinal collateral vessels.

CR Number: 2022272002 **Implementation Date:** 06-Oct-22 Related CR: 2022272002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Lumpy Skin Disease Virus*	Approved Not as Requested	Proposed LLT *Lumpy skin disease virus test*	10088538 Current
			To PT *Capripoxvirus test*	10088537

MSSO Comment: The proposal to add a new LLT Lumpy Skin Disease Virus is approved but not as requested. PCR is the best lab test in detecting lumpy skin disease virus from blood and skin samples. However, virus isolation may still be required when the infectivity of the LSD virus is to be determined. The proposed term will be modified to Lumpy skin disease virus test both for greater clarity and to comply with MedDRA capitalization conventions, and added as an LLT to PT Capripoxvirus test which represents the genus for the species. In a related change, Capripoxvirus test will be added as a PT to HLT Virus identification and serology.

CR Number: 2022279006 **Implementation Date:** 06-Oct-22 Related CR: 2022272002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Capripoxvirus test*	Approved as Requested	Proposed PT *Capripoxvirus test*	10088537
HLT primary	*Virus identification and serology*		HLT primary *Virus identification and serology*	10047490
SOC primary	*Investigations*		SOC primary *Investigations*	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2022272003 **Implementation Date:** 06-Oct-22 Related CR: 2022272003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Lumpy Skin Disease*	Approved Not as Requested	Proposed LLT *Lumpy skin disease*	10088540 Current
			To PT *Capripox viral infection*	10088536

MSSO Comment: The proposal to add a new LLT Lumpy Skin Disease is approved but not as requested. Lumpy skin disease virus is capable of infecting humans with direct transmission without the need for insects vector; that most probably by inhalation and certainly by the direct contacts with infected materials, infected persons [man to man], and as laboratory acquired infection. Human lumpy skin disease causes skin nodules and may lead to death in cases of generalized infections and if involving the internal organs. Lumpy skin disease will be modified according to MedDRA capitalisation conventions and added as LLT to a new PT Capripox viral infection which will be added in a related change, to primary HLT Viral infections NEC and to secondary HLT Skin and subcutaneous tissue viral infections.

CR Number: 2022279007 **Implementation Date:** 06-Oct-22 Related CR: 2022272003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Capripox viral infection*	Approved as Requested	Proposed PT *Capripox viral infection*	10088536
HLT primary	*Viral infections NEC*		HLT primary *Viral infections NEC*	10047465
SOC primary	*Infections and infestations*		SOC primary *Infections and infestations*	10021881
			HLT secondary *Skin and subcutaneous tissue viral infections*	10040797
			SOC secondary *Skin and subcutaneous tissue disorders*	10040785

MSSO Comment:

Supplemental Update Report

CR Number: 2022272004 **Implementation Date:** 06-Oct-22 Related CR: 2022272004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Sheeppox Virus*	Approved Not as Requested	Proposed LLT	
			Sheeppox virus test	10088543 Current
			To PT	
			Capripoxvirus test	10088537

MSSO Comment: The proposal to add a new LLT Sheeppox Virus is approved but not as requested. The proposed term will be modified according to MedDRA capitalisation standards and for clarification added as LLT Sheeppox virus test to PT Capripoxvirus test which represents the genus for the species added in change request 2022272002.

CR Number: 2022272005 **Implementation Date:** 06-Oct-22 Related CR: 2022272005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Sheeppox Virus Disease*	Approved Not as Requested	Proposed LLT	
			Sheeppox virus disease	10088541 Current
			To PT	
			Capripox viral infection	10088536

MSSO Comment: The proposal to add a new LLT Sheeppox Virus Disease is approved but not as requested. Sheeppox mainly affects sheep but sporadic transmissions to humans maybe reported. The proposed term will be modified according to MedDRA capitalisation standards and added as an LLT Sheeppox virus disease to PT Capripox viral infection added in change request 2022272003.

CR Number: 2022272006 **Implementation Date:** 06-Oct-22 Related CR: 2022272006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Goatpox Virus*	Approved Not as Requested	Proposed LLT	
			Goatpox virus test	10088542 Current
			To PT	
			Capripoxvirus test	10088537

MSSO Comment: The proposal to add a new LLT Goatpox Virus is approved but not as requested. The proposed term will be modified according to MedDRA capitalisation standards and for clarification added as LLT Goatpox virus test to PT Capripoxvirus test which represents the genus for the species added in change request 2022272002.

Supplemental Update Report

CR Number: 2022272007 **Implementation Date:** 06-Oct-22 Related CR: 2022272007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Goatpox Virus Disease*	Approved Not as Requested	Proposed LLT	
			Goatpox virus disease	10088539 Current
			To PT	
			Capripox viral infection	10088536

MSSO Comment: The proposal to add a new LLT Goatpox Virus Disease is approved but not as requested. Goatpox mainly affects goats but sporadic transmissions to humans maybe reported. The proposed term will be modified according to MedDRA capitalisation standards and added as an LLT Goatpox virus disease to PT Capripox viral infection added in change request 2022272003.

CR Number: 2022272008 **Implementation Date:** 06-Oct-22 Related CR: 2022272008

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Immune-mediated polyserositis*	Approved Not as Requested	Proposed PT	
			Immune-mediated polyserositis	10088550
			HLT primary	
			Inflammations	10021950
			SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Immune and associated conditions NEC	10027682
			SOC secondary	
			Immune system disorders	10021428

MSSO Comment: The proposal to add a new LLT Immune-mediated polyserositis is approved but not as requested. Treatments based on immunosuppression or the use of monoclonal antibodies in immune-oncology treatments may cause an uncontrolled raise of immune mediators which can lead to inflammation of serous membranes, such as pleura, peritoneum or pericardium. Immune-mediated polyserositis will be added as PT with primary link to HLT Inflammations and secondary link to HLT Immune and associated conditions NEC.

Supplemental Update Report

CR Number: 2022272009 **Implementation Date:** 06-Oct-22 Related CR: 2022272009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*TRANSURETHRAL CYSTOLITHOTRIPSY*	Approved Not as Requested	Proposed LLT	
			Transurethral cystolithotripsy	10088545 Current
			To PT	
			Bladder calculus removal	10005002

MSSO Comment: The proposal to add a new term TRANSURETHRAL CYSTOLITHOTRIPSY is approved but not as requested. Transurethral cystolithotripsy is an effective and safe procedure for large bladder stones. The requested term will be modified according to MedDRA capitalisation conventions and added as sub-concept LLT Transurethral cystolithotripsy to PT Bladder calculus removal.

CR Number: 2022272010 **Implementation Date:** 06-Oct-22 Related CR: 2022272010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Gastroesophageal Junction Adenocarcinoma*	Rejected		

MSSO Comment: The proposal to add a new term Gastroesophageal Junction Adenocarcinoma is not approved. The requested term is represented by existing LLT Adenocarcinoma of the gastroesophageal junction.

CR Number: 2022272011 **Implementation Date:** 06-Oct-22 Related CR: 2022272011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Early postoperative small bowel obstruction*	Rejected		
To PT	*Gastrointestinal procedural complication*			

MSSO Comment: The proposal to add a new LLT Early postoperative small bowel obstruction to PT Gastrointestinal procedural complication is not approved. The requested term represents a combination with a temporal and/or causal relationship with a procedure. The MSSO refrains from adding postoperative/postprocedural terms.

Supplemental Update Report

CR Number: 2022272012 **Implementation Date:** 06-Oct-22 Related CR: 2022272012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Esophagography*	Approved as Requested	Proposed LLT	
To PT	*Oesophagram*		*Esophagography*	10088547 Current
			To PT	
			Oesophagram	10053059

MSSO Comment: The proposal to add a new LLT Esophagography to PT Oesophagram is approved as requested. The imaging terms "-gram" and "-graphy" in MedDRA are used interchangeably. In a related change, the British spelled LLT Oesophagography will also be added to PT Oesophagram.

CR Number: 2022279009 **Implementation Date:** 06-Oct-22 Related CR: 2022272012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Oesophagography*	Approved as Requested	Proposed LLT	
To PT	*Oesophagram*		*Oesophagography*	10088549 Current
			To PT	
			Oesophagram	10053059

MSSO Comment:

CR Number: 2022272013 **Implementation Date:** 06-Oct-22 Related CR: 2022272013

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Jackson-Pratt drain*	Rejected		

MSSO Comment: The proposal to add a new term Jackson-Pratt drain is not approved. The requested concept was already added in change request 2022238001 as sub-concept LLT Jackson-Pratt surgical drain placement under PT Post procedural drainage.

Supplemental Update Report

CR Number: 2022272014 **Implementation Date:** 06-Oct-22 Related CR: 2022272014

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Percutaneous endoscopic jejunostomy*	Approved as Requested	Proposed LLT *Percutaneous endoscopic jejunostomy* To PT *Jejunostomy*	 10088544 Current 10023180

MSSO Comment: The proposal to add a new term Percutaneous endoscopic jejunostomy is approved as requested. Percutaneous endoscopic nutrition can be achieved by either a transgastric approach through percutaneous endoscopic gastrostomy (PEG) or a transjejunal approach, namely percutaneous endoscopic jejunostomy (PEJ). Percutaneous endoscopic jejunostomy will be added as LLT to PT Jejunostomy.

CR Number: 2022272015 **Implementation Date:** 06-Oct-22 Related CR: 2022272015

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pigtail Insertion*	Approved Not as Requested	Proposed LLT *Pigtail catheter insertion* To PT *Catheter placement*	 10088548 Current 10052915

MSSO Comment: The proposal to add a new term Pigtail Insertion is approved but not as requested. Pigtail catheter is a catheter ending in a tightly curled tip that resembles the tail of a pig, It is made of a polymer which is able to recover the curled shape after being stretched, used to drain fluid from cavities. The proposed term will be modified for MedDRA capitalization conventions and for clarity added as LLT Pigtail catheter insertion to PT Catheter placement.

CR Number: 2022272016 **Implementation Date:** 06-Oct-22 Related CR: 2022272016

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pneumococcal Urinary Antigen Testing*	Approved Not as Requested	Proposed LLT *Pneumococcal urinary antigen testing* To PT *Streptococcus test*	 10088546 Current 10070414

MSSO Comment: The proposal to add a new term Pneumococcal Urinary Antigen Testing is approved but not as requested. The pneumococcal urinary antigen test is commonly used in clinical practise for the diagnosis of community-acquired pneumonia and can be useful for targeting pathogen-directed therapy. The requested term will be modified according to MedDRA capitalisation conventions and added as LLT Pneumococcal urinary antigen testing to PT Streptococcus test.

Supplemental Update Report

CR Number: 2022272017 **Implementation Date:** 06-Oct-22 Related CR: 2022272017

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pulmonary artery stent insertion*	Approved as Requested	Proposed PT	
			Pulmonary artery stent insertion	10088551
			HLT primary	
			Arterial therapeutic procedures (excl aortic)	10003167
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Pulmonary artery stent insertion is approved as requested. Primary intravascular stent implantation is recommended in significant branch pulmonary artery stenosis when the vessel or patient is large enough to accommodate a stent that can be dilated to an adult diameter. Pulmonary artery stent insertion will be added as PT to HLT Arterial therapeutic procedures (excl aortic).

CR Number: 2022273001 **Implementation Date:** 06-Oct-22 Related CR: 2022273001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Unstable tear film*	Approved Not as Requested	Proposed PT	
			Tear film instability	10088552
			HLT primary	
			Lacrimation disorders	10072989
			SOC primary	
			Eye disorders	10015919

MSSO Comment: The proposal to add a new LLT Unstable tear film is approved but not as requested. In healthy eyes, the tear film remains intact for 10 seconds or longer after each blink. Variation in tear film thickness and tear film break-up may give rise to visual disturbances, including blurred and fluctuating vision, decreased contrast sensitivity, and increased forward scatter and glare. The requested term will be modified and added as PT Tear film instability to HLT Lacrimation disorders.

CR Number: 2022273002 **Implementation Date:** 06-Oct-22 Related CR: 2022273002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Corpus Gastritis*	Approved Not as Requested	Proposed LLT	
			Corpus gastritis	10088553 Current
			To PT	
			Gastritis	10017853

MSSO Comment: The proposal to add a new LLT Corpus Gastritis is approved but not as requested. The gastric corpus is the middle and largest portion of the stomach. The requested term will be modified according to MedDRA capitalisation conventions and added as anatomical sub-concept LLT Corpus gastritis to PT Gastritis.

Supplemental Update Report

CR Number: 2022273003 **Implementation Date:** 06-Oct-22 Related CR: 2022273003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Liver Hernia*	Approved Not as Requested	Proposed PT	
			Liver hernia	10088554
			HLT primary	
			Hepatic and hepatobiliary disorders NEC	10027681
			SOC primary	
			Hepatobiliary disorders	10019805
			HLT secondary	
			Abdominal and gastrointestinal injuries NEC	10083613
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new term Liver Hernia is approved but not as requested. Herniation of the liver is rare and commonly due to blunt trauma resulting in diaphragmatic rupture, or less often presenting as a postoperative complication. Risk factors include obesity, old age, poor nutrition, increased intra-abdominal pressure, smoking, weak abdominal wall, and postsurgical site infection. Proposed term will be modified for MedDRA capitalisation conventions and added as new PT Liver hernia under primary HLT Hepatic and hepatobiliary disorders NEC and secondary HLT Abdominal and gastrointestinal injuries NEC.

CR Number: 2022273004 **Implementation Date:** 06-Oct-22 Related CR: 2022273004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Transoral robotic surgery*	Approved as Requested	Proposed LLT	
			Transoral robotic surgery	10088555 Current
			To PT	
			Oropharyngeal surgery	10069824

MSSO Comment: The proposal to add a new term Transoral robotic surgery is approved as requested. Transoral robotic surgery is a type of operation that uses a computer system to help guide the surgical tools. Often used for treating mouth cancer and throat cancer. Proposed term will be added as sub-concept LLT Transoral robotic surgery under PT Oropharyngeal surgery.

Supplemental Update Report

CR Number: 2022273005 **Implementation Date:** 06-Oct-22 Related CR: 2022273005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Autofluorescence imaging videobronchoscopy*	Approved as Requested	Proposed LLT	
			Autofluorescence imaging videobronchoscopy	10088556 Current
			To PT	
			Bronchoscopy	10006479

MSSO Comment: The proposal to add a new term Autofluorescence imaging videobronchoscopy is approved as requested. Autofluorescence imaging videobronchoscopy is a new endoscopic tool that improves visualization of neoplastic changes in the bronchial mucosa. It significantly improves the assessment of central lung cancer extension and influences therapeutic strategy. Proposed term will be added as sub-concept LLT Autofluorescence imaging videobronchoscopy under PT Bronchoscopy.

CR Number: 2022273006 **Implementation Date:** 06-Oct-22 Related CR: 2022273006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Autofluorescence bronchoscopy*	Approved as Requested	Proposed LLT	
			Autofluorescence bronchoscopy	10088557 Current
			To PT	
			Bronchoscopy	10006479

MSSO Comment: The proposal to add a new term Autofluorescence bronchoscopy is approved as requested. Autofluorescence bronchoscopy is a diagnostic technique in interventional pulmonology usually used for detection of premalignant lesions and carcinoma in situ. Proposed term will be added as sub-concept LLT Autofluorescence bronchoscopy under PT Bronchoscopy.

CR Number: 2022273215 **Implementation Date:** 06-Oct-22 Related CR: 2022273215

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*MRSA Sinusitis*	Approved Not as Requested	Proposed LLT	
			MRSA sinusitis	10088559 Current
			To PT	
			Sinusitis bacterial	10060841

MSSO Comment: The proposal to add a new term MRSA Sinusitis is approved but not as requested. Methicillin resistant Staphylococcus aureus (MRSA) is increasingly being described as a cause of acute sinusitis. The proposed term, modified for MedDRA capitalization conventions, will be added as LLT MRSA sinusitis to PT Sinusitis bacterial.

Supplemental Update Report

CR Number: 2022273216 **Implementation Date:** 06-Oct-22 Related CR: 2022273216

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Citrobacter koseri infection*	Approved as Requested	Proposed LLT *Citrobacter koseri infection* To PT *Citrobacter infection*	10088558 Current 10051904

MSSO Comment: The proposal to add a new term Citrobacter koseri infection is approved as requested. Citrobacter freundii and Citrobacter koseri can cause urinary tract infections, and are found in wound, respiratory, meningitis, and sepsis. They can cause healthcare-associated infections, especially in pediatric and immunocompromised patients. Proposed term will be added as sub-concept LLT Citrobacter koseri infection under PT Citrobacter infection.

CR Number: 2022273217 **Implementation Date:** 06-Oct-22 Related CR: 2022273217

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Pericarditis post COVID infection*	Rejected		

MSSO Comment: The proposal to add a new LLT Pericarditis post COVID infection is not approved. The proposed term implies a temporal relationship between two concepts, and therefore represents a combination concept or a ‘due to’ relationship. Please note that the MedDRA Term Selection: Points to Consider document provides the option for splitting and coding verbatim terms.

CR Number: 2022273271 **Implementation Date:** 06-Oct-22 Related CR: 2022273271

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New PT				
Proposed PT	*DRUG MISUSE FOR ILLEGAL PURPOSES*	Rejected		

MSSO Comment: The proposal to add a new PT DRUG MISUSE FOR ILLEGAL PURPOSES is not approved. The definition of “misuse for illegal purpose” in the glossary of the document of the “Agence nationale de sécurité du médicament” (ANSM) is a broad concept overarching aspects of abuse, addiction, and drug diversion, all of which have specific terms in MedDRA and a clear definition and use guidance in the item "3.16 Misuse, Abuse and Addiction" of the MedDRA Term Selection: Points to Consider. The ANSM document refers also to circumstances around prescription, or the more general concept of “intentional misuse”, aspects which have already an ample span of options in MedDRA to describe a given scenario in relation to the requested concept through the use of more than one code.

Supplemental Update Report

CR Number: **2022276001** **Implementation Date:** 07-Oct-22 Related CR: 2022276001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Intermittent hypertension*	Rejected		

MSSO Comment: The proposal to add a new LLT Intermittent hypertension is not approved. Intermittent hypertension is an ambiguous term which may refer to either labile hypertension (an existing MedDRA PT) often due to excessive reactivity to environmental stressors or to an uncontrolled hypertension as a consequence of blood concentration fluctuations of some rapid onset anti-hypertensive drugs leading to lack of treatment compliance.

CR Number: **2022276002** **Implementation Date:** 07-Oct-22 Related CR: 2022276002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Intermittent cough*	Rejected		

MSSO Comment: The proposal to add a new term Intermittent cough is not approved. In the proposed term, the modifier "intermittent" is indicative of a fluctuating course of coughing, resulting in a qualified expression, which cannot be sustained as a recognized diagnostic entity or relevant clinical form of coughing. To avoid overpopulation of the terminology, MedDRA cannot add a new term to describe the possible fluctuating evolution of every condition.

CR Number: **2022276003** **Implementation Date:** 06-Oct-22 Related CR: 2022276003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Piezogenic papule*	Rejected		
To PT	*Papule*			

MSSO Comment: The proposal to add a new LLT Piezogenic papule to PT Papule is not approved. Piezogenic papules has been added to MedDRA in a recent change request (2022257004) and will be available in v26.0.

Supplemental Update Report

CR Number: 2022276004 **Implementation Date:** 07-Oct-22 Related CR: 2022276004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Juvenile osteoporosis*	Approved Not as Requested	Proposed PT	
			Idiopathic juvenile osteoporosis	10088561
			HLT primary	
			Metabolic bone disorders	10027425
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395
			HLT secondary	
			Bone metabolism disorders	10005992
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to add a new term Juvenile osteoporosis is approved but not as requested. Idiopathic juvenile osteoporosis is a primary condition of no known cause and is diagnosed after other causes of juvenile osteoporosis have been excluded , including primary diseases or medical therapies known to cause bone loss. The proposed term will be modified and added as PT Idiopathic juvenile osteoporosis to primary HLT Metabolic bone disorders and to secondary HLT Bone metabolism disorders.

CR Number: 2022276006 **Implementation Date:** 07-Oct-22 Related CR: 2022276006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Diffusion tensor Imaging*	Approved Not as Requested	Proposed LLT		
			Diffusion tensor imaging	10088565	Current
			To PT		
			Magnetic resonance imaging head	10085255	

MSSO Comment: The proposal to add a new term Diffusion tensor Imaging is approved but not as requested. Diffusion tensor imaging is a novel imaging technique that can reveal non-invasively unique information of white matter microstructures within the central nervous system. Proposed concept will be modified for MedDRA capitalization conventions and added as LLT Diffusion tensor imaging to PT Magnetic resonance imaging head.

Supplemental Update Report

CR Number: 2022276007 **Implementation Date:** 07-Oct-22 Related CR: 2022276007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ventricular tachycardia ablation*	Approved as Requested	Proposed LLT	
			Ventricular tachycardia ablation	10088566 Current
			To PT	
			Cardiac ablation	10059864

MSSO Comment: The proposal to add a new term Ventricular tachycardia ablation is approved as requested. Ventricular tachycardia ablation uses cold or heat energy to create tiny scars in the heart to block faulty signals targeting the areas of heart causing the arrhythmia. Proposed term will be added as sub-concept LLT Ventricular tachycardia ablation under PT Cardiac ablation.

CR Number: 2022276008 **Implementation Date:** 07-Oct-22 Related CR: 2022276008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Perennial Allergic Conjunctivitis*	Approved Not as Requested	Proposed LLT	
			Perennial allergic conjunctivitis	10088564 Current
			To PT	
			Conjunctivitis allergic	10010744

MSSO Comment: The proposal to add a new term Perennial Allergic Conjunctivitis is approved but not as requested. Perennial allergic conjunctivitis causes symptoms throughout the year, generally worse in the autumn when exposure to house dust mites, animal dander and fungal allergens is greatest. It is less common and tends to be milder than the seasonal form. Proposed term will be modified for MedDRA capitalization conventions and added as sub-concept LLT Perennial allergic conjunctivitis under PT Conjunctivitis allergic. In a related change, PT Rhinitis perennial well be demoted under PT Rhinitis allergic to reduce overgranularity at PT level.

CR Number: 2022280009 **Implementation Date:** 07-Oct-22 Related CR: 2022276008

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Rhinitis perennial*	Approved as Requested	PT to merge	
To PT	*Rhinitis allergic*		*Rhinitis perennial*	10039094 Current
			To PT	
			Rhinitis allergic	10039085

MSSO Comment:

Supplemental Update Report

CR Number: 2022276009 **Implementation Date:** 07-Oct-22 Related CR: 2022276009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Nicotine allergy*	Approved as Requested	Proposed PT	
			Nicotine allergy	10088563
			HLT primary	
			Allergies to foods, food additives, drugs and other chemicals	10001737
			SOC primary	
			Immune system disorders	10021428

MSSO Comment: The proposal to add a new term Nicotine allergy is approved as requested. Nicotine can cause allergic reactions and signs may include breathing difficulties, swelling of tongue or throat, and hives. Proposed term will be added as new PT Nicotine allergy under HLT Allergies to foods, food additives, drugs and other chemicals.

CR Number: 2022276010 **Implementation Date:** 07-Oct-22 Related CR: 2022276010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ampullary renal pelvis*	Approved as Requested	Proposed PT	
			Ampullary renal pelvis	10088562
			HLT primary	
			Renal disorders congenital	10038431
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Renal structural abnormalities and trauma	10038529
			SOC secondary	
			Renal and urinary disorders	10038359

MSSO Comment: The proposal to add a new term Ampullary renal pelvis is approved as requested. The morphology of the renal pelvis does not have uniform standards in anatomy and imaging. The shape of the renal pelvis can be divided into horn, branching, ampullary and transitional types. Proposed term will be added as new PT Ampullary renal pelvis under primary HLT Renal disorders congenital and secondary HLT Renal structural abnormalities and trauma.

Supplemental Update Report

CR Number: 2022276011 **Implementation Date:** 07-Oct-22 Related CR: 2022276011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Gastroduodenal artery aneurysm*	Approved Not as Requested	Proposed PT	
			Gastroduodenal artery aneurysm	10088567
			HLT primary	
			Gastrointestinal vascular malformations	10018032
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Aneurysms and dissections site specific NEC	10002365
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new LLT Gastroduodenal artery aneurysm is approved but not as requested. Gastroduodenal artery aneurysms are rare but a potentially fatal condition if rupture occurs. Chronic pancreatitis being reported as the commonest aetiological factor for rupture. Proposed term will be added as PT Gastroduodenal artery aneurysm under primary HLT Gastrointestinal vascular malformations and secondary HLT Aneurysms and dissections site specific NEC.

CR Number: 2022276012 **Implementation Date:** 07-Oct-22 Related CR: 2022276012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*ApoB gene mutation*	Approved as Requested	Proposed PT	
HLT primary	*Gene mutations and other alterations NEC*		*ApoB gene mutation*	10088569
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Gene mutations and other alterations NEC	10083625
			SOC primary	
			Congenital, familial and genetic disorders	10010331

MSSO Comment: The proposal to add a new PT ApoB gene mutation to primary HLT Gene mutations and other alterations NEC in SOC Congenital, familial and genetic disorders is approved as requested. Pathogenic variants of the apolipoprotein (ApoB) gene, resulting in decreased binding of LDL to the LDL-R are responsible for 5% to 15% of familial hypercholesterolemia cases.

Supplemental Update Report

CR Number: 2022276013 **Implementation Date:** 07-Oct-22 Related CR: 2022276013

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*PCSK9 gene mutation*	Approved as Requested	Proposed PT	
HLT primary	*Gene mutations and other alterations NEC*		*PCSK9 gene mutation*	10088568
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Gene mutations and other alterations NEC	10083625
			SOC primary	
			Congenital, familial and genetic disorders	10010331

MSSO Comment: The proposal to add a new PT PCSK9 gene mutation to primary HLT Gene mutations and other alterations NEC in SOC Congenital, familial and genetic disorders is approved as requested. Gain-of-function mutations in the gene for proprotein convertase subtilisin/kexin 9 (PCSK9), results in increased destruction of LDL-R, and are responsible for 1% of cases of familial hypercholesterolemia.

CR Number: 2022277001 **Implementation Date:** 07-Oct-22 Related CR: 2022277001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Sacral promontory dystocia*	Approved as Requested	Proposed LLT		
			Sacral promontory dystocia	10088560	Current
			To PT		
			Shoulder dystocia	10040613	

MSSO Comment: The proposal to add a new LLT Sacral promontory dystocia is approved as requested. The mother's prominent sacrum is shown adding difficulty to the delivery process and injuring the unborn child’s shoulder. Sacral promontory dystocia, difficult childbirth due to prominent sacrum, will be added as an LLT to PT Shoulder dystocia.

CR Number: 2022277002 **Implementation Date:** 07-Oct-22 Related CR: 2022277002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Blister of fingers*	Rejected		
To PT	*Blister*			

MSSO Comment: The proposal to add a new LLT Blister of fingers to PT Blister is not approved. The requested term can be represented by LLT Blister of fingers, without mention of infection. Furthermore, the non-current flagged LLTs of similar type do have more than one anatomical site addressed and therefore are non-current.

Supplemental Update Report

CR Number: 2022277003 **Implementation Date:** 07-Oct-22 Related CR: 2022277003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Product leakage*	Rejected		
From PT	*Product leakage*			
To PT	*Product container issue*			

MSSO Comment: The proposal to move the LLT Product leakage from PT Product leakage to PT Product container issue is not approved. LLT/PT Product leakage is appropriately placed to HLT Product physical issues. Not all medical products do have a container. Product issues include medical device issues as well. Testing for leak integrity is critical in the device industry because product failure presents significant hazards to patients and healthcare professionals and liabilities for manufacturers.

CR Number: 2022277093 **Implementation Date:** 07-Oct-22 Related CR: 2022277093

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*IgG4 related cholangiopathy*	Approved Not as Requested	Proposed LLT	
			IgG4 related cholangiopathy	10088570 Current
			To PT	
			Cholangitis sclerosing	10008609

MSSO Comment: The proposal to add a new PT IgG4 related cholangiopathy is approved but not as requested. IgG4-related sclerosing cholangitis can occur usually in patients who also have autoimmune pancreatitis. This combination is highly suggestive of IgG4-related disease. Proposed term will be added as sub-concept LLT IgG4 related cholangiopathy under PT Cholangitis sclerosing.

CR Number: 2022277094 **Implementation Date:** 07-Oct-22 Related CR: 2022277094

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hepatic embolisation*	Approved as Requested	Proposed PT	
From HLT	*Hepatic therapeutic procedures*		*Hepatic embolisation*	10056203
To HLT	*Arterial therapeutic procedures (excl aortic)*		From HLT	
			Hepatic therapeutic procedures	10019704
			To HLT	
			Arterial therapeutic procedures (excl aortic)	10003167

MSSO Comment: The proposal to move the PT Hepatic embolisation from HLT Hepatic therapeutic procedures to HLT Arterial therapeutic procedures (excl aortic) is approved as requested. For better alignment consistency of vascular embolisation terms, PT Hepatic embolisation will be moved from site/organ specific HLT to relevant arterial/vascular HLT.

Supplemental Update Report

CR Number: 2022277095 **Implementation Date:** 07-Oct-22 Related CR: 2022277095

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Uterine artery embolisation*	Approved as Requested	Proposed PT	
			Uterine artery embolisation	10085781
From HLT	*Uterine therapeutic procedures*		From HLT	
			Uterine therapeutic procedures	10046808
To HLT	*Arterial therapeutic procedures (excl aortic)*		To HLT	
			Arterial therapeutic procedures (excl aortic)	10003167

MSSO Comment: The proposal to move the PT Uterine artery embolisation from HLT Uterine therapeutic procedures to HLT Arterial therapeutic procedures (excl aortic) is approved as requested. For better alignment consistency, PT Uterine artery embolisation will be moved from site/organ specific HLT to arterial/vascular HLT. In a related change, the recently added PT Prostatic artery embolisation will be moved from HLT Prostatic therapeutic procedures to HLT Arterial therapeutic procedures (excl aortic) for the same reason.

CR Number: 2022280010 **Implementation Date:** 07-Oct-22 Related CR: 2022277095

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Prostatic artery embolisation*	Approved as Requested	Proposed PT	
			Prostatic artery embolisation	10088271
From HLT	*Prostatic therapeutic procedures*		From HLT	
			Prostatic therapeutic procedures	10036967
To HLT	*Arterial therapeutic procedures (excl aortic)*		To HLT	
			Arterial therapeutic procedures (excl aortic)	10003167

MSSO Comment:

Supplemental Update Report

CR Number: 2022277096 **Implementation Date:** 07-Oct-22 Related CR: 2022277096

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Transcatheter arterial chemoembolisation*	Approved as Requested	Proposed PT	
From HLT	*Hepatic therapeutic procedures*		*Transcatheter arterial chemoembolisation*	10076242
To HLT	*Chemotherapies*		From HLT	
			Hepatic therapeutic procedures	10019704
			To HLT	
			Chemotherapies	10008442

MSSO Comment: The proposal to move the PT Transcatheter arterial chemoembolisation from HLT Hepatic therapeutic procedures to HLT Chemotherapies is approved as requested. Transarterial chemoembolization therapy involves administration of chemotherapy directly to the liver tumor via a catheter. With this technique, the chemotherapy targets the tumor while sparing the patient many side effects of traditional chemotherapy that is given to the whole body. Although the transcatheter administration aspect of this procedure is important, chemotherapy can be considered the principal conceptual element of this procedure.

CR Number: 2022277097 **Implementation Date:** 07-Oct-22 Related CR: 2022277097

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Portal vein embolisation*	Approved as Requested	Proposed PT	
From HLT	*Hepatic therapeutic procedures*		*Portal vein embolisation*	10076941
To HLT	*Venous therapeutic procedures*		From HLT	
			Hepatic therapeutic procedures	10019704
			To HLT	
			Venous therapeutic procedures	10047231

MSSO Comment: The proposal to move the PT Portal vein embolisation from HLT Hepatic therapeutic procedures to HLT Venous therapeutic procedures is approved as requested. For better alignment consistency, PT Portal vein embolisation will be moved from site/organ specific HLT to arterial/vascular HLT.

Supplemental Update Report

CR Number: 2022277098 **Implementation Date:** 07-Oct-22 Related CR: 2022277098

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Subclavian vein thrombosis*	Rejected		
To PT	*Deep vein thrombosis*			

MSSO Comment: The proposal to demote the PT Subclavian vein thrombosis under PT Deep vein thrombosis is not approved. MedDRA is not a taxonomy, therefore, unlike botany or zoology, terms of different specificity can be in the same level (e.g., the general PT Pneumonia and any of the many pathogen specific pneumonias also found at the PT level, without the latter having to be demoted). This diversity and specificity at the PT level does not disperse signaling if frequencies associated to each PT are added up at the HLT level. This does not increase counts (number of cases remain the same), but it does enlarge the list of "unique concepts" (the PTs and LLTs representing them) that depict the safety profile of a drug. Thus the variety of PT and LLT levels increases the information and accuracy of the medical information reported at the same time that grouping terms (HLTs and HLGTs) warrant adding up frequencies to avoid dispersion during analysis. Based on this, it is not appropriate to demote the highly specific and clinically important PT Subclavian vein thrombosis under the general PT Deep vein thrombosis. Subclavian vein thrombosis may be of special interest as well for etiology and treatment. Furthermore, the concept is in MedDRA since v3.1 at PT level and demoting under the umbrella PT may have negative impact of legacy data.

CR Number: 2022277099 **Implementation Date:** 07-Oct-22 Related CR: 2022277099

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Axillary vein thrombosis*	Rejected		
To PT	*Deep vein thrombosis*			

MSSO Comment: The proposal to demote the PT Axillary vein thrombosis under PT Deep vein thrombosis is not approved. MedDRA is not a taxonomy, therefore, unlike botany or zoology, terms of different specificity can be in the same level (e.g., the general PT Pneumonia and any of the many pathogen specific pneumonias also found at the PT level, without the latter having to be demoted). This diversity and specificity at the PT level does not disperse signaling if frequencies associated to each PT are added up at the HLT level. This does not increase counts (number of cases remain the same), but it does enlarge the list of "unique concepts" (the PTs and LLTs representing them) that depict the safety profile of a drug. Thus the variety of PT and LLT levels increases the information and accuracy of the medical information reported at the same time that grouping terms (HLTs and HLGTs) warrant adding up frequencies to avoid dispersion during analysis. Based on this, it is not appropriate to demote the highly specific and clinically important PT Axillary vein thrombosis under the general PT Deep vein thrombosis. Axillary vein thrombosis may be of special interest as well for etiology and treatment. Furthermore, the concept is in MedDRA since v3.1 at PT level and demoting under the umbrella PT may have negative impact of legacy data.

CR Number: 2022278001 **Implementation Date:** 07-Oct-22 Related CR: 2022278001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*CT cerebral angiogram*	Approved as Requested	Proposed LLT	
			CT cerebral angiogram	10088571 Current
			To PT	
			Computerised tomogram head	10054003

MSSO Comment: The proposal to add a new term CT cerebral angiogram is approved as requested. A cerebral angiogram is a test that looks for problems with blood vessels and blood flow in the brain. Computerised tomogram of brain (CT angiography) combines a CT scan with the injection of dye. This technique is able to create pictures of the blood vessels in the brain. Proposed term will be added as LLT CT cerebral angiogram under PT Computerised tomogram head.

Supplemental Update Report

CR Number: **2022278002** **Implementation Date:** 07-Oct-22 Related CR: 2022278002

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Wound*	Rejected		
To PT	*Skin laceration*			

MSSO Comment: The proposal to demote the PT Wound under PT Skin laceration is not approved. The concept of wound may represent a number of cases of injury that may not be a laceration event. Generally all lacerations refer to the external surface of the body-skin. As such, the two concepts are appropriately each represented at PT level. The concept of LLT Cut wound may represent a deeper injury aside from skin.

CR Number: **2022279001** **Implementation Date:** 12-Oct-22 Related CR: 2022279001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Barley allergy*	Approved as Requested	Proposed LLT	
			Barley allergy	10088576 Current
			To PT	
			Food allergy	10016946

MSSO Comment: The proposal to add a new term Barley allergy is approved as requested. Barley allergy can cause coeliac disease, triggered by the gluten-like proteins, as well as IgE-mediated cereal allergy, caused by the antibody IgE binding to other barley proteins different than gluten. Barley allergy will be added as an LLT to PT Food allergy.

CR Number: **2022279002** **Implementation Date:** 12-Oct-22 Related CR: 2022279002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Oat allergy*	Approved as Requested	Proposed LLT	
			Oat allergy	10088578 Current
			To PT	
			Food allergy	10016946

MSSO Comment: The proposal to add a new term Oat allergy is approved as requested. Other than cross-contamination, people can react to the protein in oats called avenin. Avenin is similar to gluten in wheat and causes the same allergic reactions. Allergy to oat protein can present with both respiratory and skin symptoms ranging from mild to severe, and can often be delayed. Oat allergy will be added as an LLT to PT Food allergy.

Supplemental Update Report

CR Number: 2022279003 **Implementation Date:** 12-Oct-22 Related CR: 2022279003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Lupin allergy*	Approved as Requested	Proposed LLT *Lupin allergy* To PT *Food allergy*	10088577 Current 10016946

MSSO Comment: The proposal to add a new term Lupin allergy is approved as requested. Lupin is a protein containing food like peanut and soybean, that may trigger an allergic reaction in a small percentage of the population. Some people who are allergic to peanuts may also react to lupin. Lupin allergy will be added as an LLT to PT Food allergy.

CR Number: 2022279004 **Implementation Date:** 12-Oct-22 Related CR: 2022279004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Distal radius fracture*	Approved as Requested	Proposed LLT *Distal radius fracture* To PT *Radius fracture*	10088579 Current 10037802

MSSO Comment: The proposal to add a new term Distal radius fracture is approved as requested. A fracture of the distal radius occurs when the radius breaks close to the wrist. Proposed term will be added as LLT Distal radius fracture under PT Radius fracture.

CR Number: 2022279005 **Implementation Date:** 12-Oct-22 Related CR: 2022279005

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Post transplant distal limb syndrome*	Approved Not as Requested	Proposed PT *Post transplant distal limb syndrome* With LLT *Calcineurin inhibitor induced pain syndrome*	10068179 Current 10068183
Replacement term	*Calcineurin-inhibitor related distal limb syndrome*			

MSSO Comment: The proposal to rename PT/LLT Post transplant distal limb syndrome to Calcineurin-inhibitor related distal limb syndrome is approved but not as requested. As the indication for tacrolimus widens to include primary membranous nephropathy, the current PT Post transplant distal limb syndrome will be swapped with LLT Calcineurin inhibitor induced pain syndrome to represent the broader concept at PT level.

Supplemental Update Report

CR Number: 2022279008 **Implementation Date:** 12-Oct-22 Related CR: 2022279008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Allergy patch test*	Approved as Requested	Proposed LLT	
			Allergy patch test	10088580 Current
			To PT	
			Skin test	10040929

MSSO Comment: The proposal to add a new term Allergy patch test is approved as requested. Allergy patch testing is used to screen substances to determine the cause of an allergic skin reaction. Proposed term will be added as synonym LLT Allergy patch test to PT Skin test.

CR Number: 2022280001 **Implementation Date:** 14-Oct-22 Related CR: 2022280001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Neck Hematomas*	Approved Not as Requested	Proposed LLT	
			Neck hematoma	10088581 Current
			To PT	
			Haematoma	10018852

MSSO Comment: The proposal to add a new term Neck Hematomas is approved but not as requested. Neck hematoma may result several causalities such as blunt trauma, from recent surgery, after percutaneous interventions, spontaneous as with ruptured thyroidal cyst, tumors and others. The requested term will be modified according to MedDRA capitalization conventions and in singular form as LLT Neck hematoma and together with the British English spelled counterpart LLT Neck haematoma will be both added to PT Haematoma.

CR Number: 2022287003 **Implementation Date:** 14-Oct-22 Related CR: 2022280001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Neck haematoma*	Approved as Requested	Proposed LLT	
To PT	*Haematoma*		*Neck haematoma*	10088582 Current
			To PT	
			Haematoma	10018852

MSSO Comment:

Supplemental Update Report

CR Number: 2022280002 **Implementation Date:** 14-Oct-22 Related CR: 2022280002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*PERIPHERAL PULMONARY EMBOLISM*	Approved Not as Requested	Proposed LLT	
To PT	*Pulmonary embolism*		*Peripheral pulmonary embolism*	10088583 Current
			To PT	
			Pulmonary embolism	10037377

MSSO Comment: The proposal to add a new LLT PERIPHERAL PULMONARY EMBOLISM to PT Pulmonary embolism is approved but not as requested. Peripheral pulmonary embolism is when an embolus is lodged in segmental or subsegmental arteries. Emboli lodged in the central pulmonary arteries carry a worse prognosis than more peripheral emboli and diagnosis may be challenging to distinguish from other causes of pleuritic pain, such as pneumonia, tuberculosis, pericarditis, and pleurisy due to viral infection. The requested term will be modified according to MedDRA capitalisation conventions and added as LLT Peripheral pulmonary embolism to PT Pulmonary embolism.

CR Number: 2022280003 **Implementation Date:** 14-Oct-22 Related CR: 2022280003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Symptomatic COVID-19*	Approved as Requested	Proposed LLT	
To PT	*COVID-19*		*Symptomatic COVID-19*	10088584 Current
			To PT	
			COVID-19	10084268

MSSO Comment: The proposal to add a new LLT Symptomatic COVID-19 to PT COVID-19 is approved as requested. People with COVID-19 may have a wide range of symptoms reported such as fever, fatigue, cough etc. – ranging from mild symptoms to severe illness. Symptoms may appear 2-14 days after exposure to the virus. In a related change, PT Asymptomatic COVID-19 will be demoted under PT COVID-19. In both situations, symptomatic or asymptomatic, the infection is confirmed and therefore represents the same concept.

CR Number: 2022287004 **Implementation Date:** 14-Oct-22 Related CR: 2022280003

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Asymptomatic COVID-19*	Approved as Requested	PT to merge	
To PT	*COVID-19*		*Asymptomatic COVID-19*	10084459 Current
			To PT	
			COVID-19	10084268

MSSO Comment:

Supplemental Update Report

CR Number: 2022280004 **Implementation Date:** 14-Oct-22 Related CR: 2022280004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Abdominal aortic aneurysm repair*	Approved as Requested	Proposed LLT	
			Abdominal aortic aneurysm repair	10088585 Current
			To PT	
			Aortic aneurysm repair	10002885

MSSO Comment: The proposal to add a new term Abdominal aortic aneurysm repair is approved as requested. In an abdominal aortic aneurysm the aneurysm is in part of the aorta that is in the abdomen. Repair of an abdominal aortic aneurysm may be done as an open repair or as endovascular aneurysm repair. Abdominal aortic aneurysm repair will be added as an LLT to PT Aortic aneurysm repair. In a related changed Intra-thoracic aortic aneurysm repair will be demoted under PT Aortic aneurysm repair.

CR Number: 2022287005 **Implementation Date:** 14-Oct-22 Related CR: 2022280004

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Intra-thoracic aortic aneurysm repair*	Approved as Requested	PT to merge	
To PT	*Aortic aneurysm repair*		*Intra-thoracic aortic aneurysm repair*	10022743 Current
			To PT	
			Aortic aneurysm repair	10002885

MSSO Comment:

CR Number: 2022280005 **Implementation Date:** 14-Oct-22 Related CR: 2022280005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*CT Upper limb*	Approved Not as Requested	Proposed LLT	
			CT upper limb	10088588 Current
			To PT	
			Computerised tomogram limb	10088586

MSSO Comment: The proposal to add a new term CT Upper limb is approved but not as requested. A CT of the upper extremities is an exam that takes very thin slice (2-5mm) images of a specified portion of your arm(s), from the shoulder girdle to the tips of your fingers. Proposed term will be modified for MedDRA capitalization conventions and added as LLT CT upper limb under new PT Computerised tomogram limb. In a related change, new PT Computerised tomogram limb will be added under HLT Musculoskeletal and soft tissue imaging procedures. In addition, the American English spelled counterpart LLT Computerized tomogram limb will also be added under PT Computerised tomogram limb.

Supplemental Update Report

CR Number: 2022287006 **Implementation Date:** 14-Oct-22 Related CR: 2022280005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Computerised tomogram limb*	Approved as Requested	Proposed PT	
HLT primary	*Musculoskeletal and soft tissue imaging procedures*		*Computerised tomogram limb*	10088586
SOC primary	*Investigations*		HLT primary	
			Musculoskeletal and soft tissue imaging procedures	10028386
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022287007 **Implementation Date:** 14-Oct-22 Related CR: 2022280005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Computerized tomogram limb*	Approved as Requested	Proposed LLT	
To PT	*Computerised tomogram limb*		*Computerized tomogram limb*	10088587 Current
			To PT	
			Computerised tomogram limb	10088586

MSSO Comment:

CR Number: 2022280006 **Implementation Date:** 14-Oct-22 Related CR: 2022280006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Abdominal Aortography*	Approved Not as Requested	Proposed LLT	
			Abdominal aortography	10088590 Current
			To PT	
			Aortogram	10057775

MSSO Comment: The proposal to add a new term Abdominal Aortography is approved but not as requested. Conventional abdominal aortography is usually performed by positioning the catheter in the lumen of the aorta at the level of T12–L1 to “flush” contrast in order to visualize the vasculature of the vessel and to determine the presence or absence of relevant pathology. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as LLT Abdominal aortography to PT Aortogram.

Supplemental Update Report

CR Number: 2022280007 **Implementation Date:** 14-Oct-22 Related CR: 2022280007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Robotic-assisted thoracoscopic surgery*	Approved as Requested	Proposed LLT	
			Robotic-assisted thoracoscopic surgery	10088589 Current
			To PT	
			Thoracic operation	10052703

MSSO Comment: The proposal to add a new term Robotic-assisted thoracoscopic surgery is approved as requested. Robotic thoracic surgery is a type of minimally invasive surgery used in thoracic procedures for some lung cancer and mediastinal masses. The proposed term will be added as an LLT Robotic-assisted thoracoscopic surgery to PT Thoracic operation.

CR Number: 2022280008 **Implementation Date:** 14-Oct-22 Related CR: 2022280008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*FOCAL CEREBRAL ISCHEMIA*	Approved Not as Requested	Proposed LLT	
			Focal cerebral ischemia	10088591 Current
			To PT	
			Cerebral ischaemia	10008120

MSSO Comment: The proposal to add a new term FOCAL CEREBRAL ISCHEMIA is approved but not as requested. There are two types of ischemia: focal ischemia, which is confined to a specific region of the brain; and global ischemia, which encompasses wide areas of brain tissue. Focal cerebral ischemia represents a deficiency of blood or oxygen in a circumscribed part of the brain, usually due to functional constriction or actual obstruction of a cerebrovascular or carotid artery. The proposed term will be modified to comply with MedDRA capitalization conventions and added as LLT Focal cerebral ischemia to PT Cerebral ischaemia. In a related change, its British homolog LLT Focal cerebral ischaemia will also be added under the PT Cerebral ischaemia.

CR Number: 2022287008 **Implementation Date:** 14-Oct-22 Related CR: 2022280008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Focal cerebral ischaemia*	Approved as Requested	Proposed LLT	
To PT	*Cerebral ischaemia*		*Focal cerebral ischaemia*	10088592 Current
			To PT	
			Cerebral ischaemia	10008120

MSSO Comment:

Supplemental Update Report

CR Number: 2022283001 **Implementation Date:** 14-Oct-22 Related CR: 2022283001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Embryo demise*	Approved as Requested	Proposed LLT *Embryo demise* To PT *Abortion spontaneous*	10088593 Current 10000234

MSSO Comment: The proposal to add a new term Embryo demise is approved as requested. Early pregnancy loss, sometimes termed embryonic demise, refers to the death of the embryo and therefore, miscarriage. Embryo demise will be added as a LLT to PT Abortion spontaneous aligned with the synonym LLT Early miscarriage.

CR Number: 2022284001 **Implementation Date:** 12-Oct-22 Related CR: 2022284001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Non-pitting legs oedema*	Rejected		
To PT	*Non-pitting oedema*			

MSSO Comment: The proposal to add a new LLT Non-pitting legs oedema to PT Non-pitting oedema is not approved. To avoid the overpopulation of the terminology, the MSSO refrains from adding every disease and condition associated with every possible anatomical site. Please consider section 3.7 Body Site vs. Event Specificity of the MedDRA Term Selection: Points to Consider.

CR Number: 2022284033 **Implementation Date:** 14-Oct-22 Related CR: 2022284033

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Nicotinism*	Approved as Requested	Proposed LLT	
To PT	*Nicotine dependence*		*Nicotinism*	10088594 Current
			To PT	
			Nicotine dependence	10057852

MSSO Comment: The proposal to add a new LLT Nicotinism to PT Nicotine dependence is approved as requested. Even if Nicotinism is sometimes used as a synonym of nicotine poisoning, it most often used internationally synonymously to nicotine dependence.

Supplemental Update Report

CR Number: 2022284034 **Implementation Date:** 14-Oct-22 Related CR: 2022284034

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Composite resection*	Approved as Requested	Proposed LLT	
To PT	*Maxillofacial operation*		*Composite resection*	10088595 Current
			To PT	
			Maxillofacial operation	10054806

MSSO Comment: The proposal to add a new LLT Composite resection to PT Maxillofacial operation is approved as requested. Composite resection, the standard surgical approach for treating cancer of the oral cavity and oropharynx, involves en bloc resection of primary tumor, cervical nodes, and part of mandible if tumor lies close to bone.

CR Number: 2022284035 **Implementation Date:** 14-Oct-22 Related CR: 2022284035

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Non-Epileptic paroxysmal event*	Approved Not as Requested	Proposed PT	
HLT primary	*Neurological signs and symptoms NEC*		*Non-epileptic paroxysmal event*	10088598
SOC primary	*Nervous system disorders*		HLT primary	
			Neurological signs and symptoms NEC	10029306
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Infancy, childhood and adolescence psychiatric disorders NEC	10037177
			SOC secondary	
			Psychiatric disorders	10037175

MSSO Comment: The proposal to add a new PT Non-Epileptic paroxysmal event to primary HLT Neurological signs and symptoms NEC in SOC Nervous system disorders and secondary HLT Infancy, childhood and adolescence psychiatric disorders NEC in SOC Psychiatric disorders is approved but not as requested. Non-epileptic paroxysmal events (NEPE) include a group of disorders manifesting as alterations in motor and/or behavioral activity that can mimic and therefore be easily confused with epileptic seizures. The requested term will be modified according to MedDRA capitalisation conventions and added as PT Non-epileptic paroxysmal event to primary HLT Neurological signs and symptoms NEC and secondary HLT Infancy, childhood and adolescence psychiatric disorders NEC.

Supplemental Update Report

CR Number: 2022284036 **Implementation Date:** 14-Oct-22 Related CR: 2022284036

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Killip class II*	Approved as Requested	Proposed LLT	
To PT	*Acute myocardial infarction*		*Killip class II*	10088599 Current
			To PT	
			Acute myocardial infarction	10000891

MSSO Comment: The proposal to add a new LLT Killip class II to PT Acute myocardial infarction is approved as requested. The addition of this term completes the representation of Killip classification in MedDRA.

CR Number: 2022284037 **Implementation Date:** 14-Oct-22 Related CR: 2022284037

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Killip class III*	Approved as Requested	Proposed LLT	
To PT	*Acute myocardial infarction*		*Killip class III*	10088600 Current
			To PT	
			Acute myocardial infarction	10000891

MSSO Comment: The proposal to add a new LLT Killip class III to PT Acute myocardial infarction is approved as requested. The addition of this term completes the representation of Killip classification in MedDRA.

CR Number: 2022284038 **Implementation Date:** 14-Oct-22 Related CR: 2022284038

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Killip class IV*	Approved as Requested	Proposed LLT	
To PT	*Acute myocardial infarction*		*Killip class IV*	10088601 Current
			To PT	
			Acute myocardial infarction	10000891

MSSO Comment: The proposal to add a new LLT Killip class IV to PT Acute myocardial infarction is approved as requested. The addition of this term completes the representation of Killip classification in MedDRA.

Supplemental Update Report

CR Number: 2022284039 **Implementation Date:** 14-Oct-22 Related CR: 2022284039

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Persistent taste disorder*	Approved Not as Requested	Proposed LLT *Persistent taste disorder* To PT *Taste disorder*	 10088596 Current 10082490

MSSO Comment: The proposal to add a new PT Persistent taste disorder is approved but not as requested. Persistent taste disorder will be added as a sub-concept LLT to PT Taste disorder.

CR Number: 2022284093 **Implementation Date:** 14-Oct-22 Related CR: 2022284093

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Core Decompression*	Approved Not as Requested	Proposed PT *Femoral core decompression* HLT primary *Bone therapeutic procedures NEC* SOC primary *Surgical and medical procedures*	 10088597 Current 10006000 10042613

MSSO Comment: The proposal to add a new term Core Decompression is approved but not as requested. Femoral core decompression is a prophylactic surgery indicated to treat initial stages of a vascular necrosis of the femur. The proposed term will be modified for a greater clarity and added as PT Femoral core decompression to HLT Bone therapeutic procedures NEC.

CR Number: 2022285001 **Implementation Date:** 19-Oct-22 Related CR: 2022285001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Methylmalonic acidemia*	Approved as Requested	Proposed LLT *Methylmalonic acidemia* To PT *Methylmalonic aciduria*	 10088603 Current 10059521 Current

MSSO Comment: The proposal to add a new LLT Methylmalonic acidemia is approved as requested. Methylmalonic acidemia also called methylmalonic aciduria is the elevation of methylmalonic acid in the blood and/or the urine (generally it is seen in both). The proposed term will be added as synonym LLT Methylmalonic acidemia under PT Methylmalonic aciduria. In a related change, the British English counterpart LLT Methylmalonic acidaemia will also be added under PT Methylmalonic aciduria. Furthermore, the LLT Methylmalonic acidaemia will be swapped with PT Methylmalonic aciduria to represent the condition term at PT level.

Supplemental Update Report

CR Number: 2022292003 **Implementation Date:** 19-Oct-22 Related CR: 2022285001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Methylmalonic acidaemia*	Approved as Requested	Proposed LLT	
To PT	*Methylmalonic aciduria*		*Methylmalonic acidaemia*	10088602
			To PT	
			Methylmalonic aciduria	10059521 Current

MSSO Comment:

CR Number: 2022292008 **Implementation Date:** 19-Oct-22 Related CR: 2022285001

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Methylmalonic aciduria*	Approved as Requested	Proposed PT	
With LLT	*Methylmalonic acidaemia*		*Methylmalonic aciduria*	10059521 Current
			With LLT	
			Methylmalonic acidaemia	10088602

MSSO Comment:

CR Number: 2022285002 **Implementation Date:** 19-Oct-22 Related CR: 2022285002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Methylmalonic acidemia*	Rejected		
HLT primary	*Inborn errors of amino acid metabolism*			
SOC primary	*Congenital, familial and genetic disorders*			

MSSO Comment: The proposal to add a new PT Methylmalonic acidemia to primary HLT Inborn errors of amino acid metabolism in SOC Congenital, familial and genetic disorders is not approved. Technical rejection as proposed term was added as PT Methylmalonic acidaemia in change request 2022285001.

Supplemental Update Report

CR Number: 2022285003 **Implementation Date:** 19-Oct-22 Related CR: 2022285003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Propionic acidemia*	Approved Not as Requested	Proposed LLT	
From PT	*Hyperglycinaemia*		*Propionic acidaemia*	10080607
To PT	*Propionic acidemia*		From PT	
			Hyperglycinaemia	10080883
			HLT primary	
			Inborn errors of amino acid metabolism	10021602
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Inborn errors of amino acid metabolism	10021602
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to move the LLT Propionic acidemia from PT Hyperglycinaemia to PT Propionic acidemia is approved but not as requested. LLT Propionic acidaemia is caused by a different enzyme deficiency and therefore will be promoted from PT Hyperglycinaemia to a PT level and linked to bi-axial HLT Inborn errors of amino acid metabolism to primary SOC Congenital, familial and genetic disorders and to secondary SOC Metabolism and nutrition disorders. In a related change, LLT Propionic acidemia will be moved from PT Hyperglycinaemia to the newly promoted PT Propionic acidaemia. Furthermore, the following LLTs will also be moved from PT Hyperglycinaemia to the promoted PT Propionic acidaemia; LLT Ketotic glycinaemia, LLT Ketotic glycinemia, and LLT Propionyl-CoA carboxylase deficiency for better alignment.

CR Number: 2022292004 **Implementation Date:** 19-Oct-22 Related CR: 2022285003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Propionic acidemia*	Approved as Requested	Proposed LLT	
From PT	*Hyperglycinaemia*		*Propionic acidemia*	10080615 Current
To PT	*Propionic acidaemia*		From PT	
			Hyperglycinaemia	10080883
			To PT	
			Propionic acidaemia	10080607

MSSO Comment:

Supplemental Update Report

CR Number: 2022292005 **Implementation Date:** 19-Oct-22 Related CR: 2022285003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Ketotic glycinaemia*	Approved as Requested	Proposed LLT		
From PT	*Hyperglycinaemia*		*Ketotic glycinaemia*	10080616	Current
To PT	*Propionic acidaemia*		From PT		
			Hyperglycinaemia	10080883	
			To PT		
			Propionic acidaemia	10080607	

MSSO Comment:

CR Number: 2022292006 **Implementation Date:** 19-Oct-22 Related CR: 2022285003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Ketotic glycinemia*	Approved as Requested	Proposed LLT		
From PT	*Hyperglycinaemia*		*Ketotic glycinemia*	10080611	Current
To PT	*Propionic acidaemia*		From PT		
			Hyperglycinaemia	10080883	
			To PT		
			Propionic acidaemia	10080607	

MSSO Comment:

CR Number: 2022292007 **Implementation Date:** 19-Oct-22 Related CR: 2022285003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Propionyl-CoA carboxylase deficiency*	Approved as Requested	Proposed LLT		
From PT	*Hyperglycinaemia*		*Propionyl-CoA carboxylase deficiency*	10080617	Current
To PT	*Propionic acidaemia*		From PT		
			Hyperglycinaemia	10080883	
			To PT		
			Propionic acidaemia	10080607	

MSSO Comment:

Supplemental Update Report

CR Number: 2022285006 **Implementation Date:** 19-Oct-22 Related CR: 2022285006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Papular dermatitis of pregnancy*	Approved Not as Requested	Proposed LLT	
HLT primary	*Rashes, eruptions and exanthems NEC*		*Papular dermatitis of pregnancy*	10088605 Current
SOC primary	*Skin and subcutaneous tissue disorders*		To PT	
			Prurigo of pregnancy	10088604

MSSO Comment: The proposal to add a new PT Papular dermatitis of pregnancy to primary HLT Rashes, eruptions and exanthems NEC in SOC Skin and subcutaneous tissue disorders and secondary HLT Normal pregnancy, labour and delivery in SOC Pregnancy, puerperium and perinatal conditions is approved but not as requested. Prurigo of pregnancy is one of the dermatoses found in pregnant women and defined as a benign non-specific itchy pruritic rash seen during pregnancy. It is referred to with several different terms such as prurigo gestationis, early onset prurigo of pregnancy, papular dermatitis, and pruritic folliculitis of pregnancy. The cause for prurigo of pregnancy is idiopathic i.e. not yet known, but thought to have a close association with atopic dermatitis. Papular dermatitis of pregnancy will be added as LLT to new PT Prurigo of pregnancy, which is the term more commonly used in literature. In related changes, PT Prurigo of pregnancy will be added as PT to primary HLT Dermatitis and eczema and secondary HLT Maternal complications of pregnancy NEC. Also, primary HLT for PT Polymorphic eruption of pregnancy will be changed from HLT Pruritus NEC to HLT Dermatitis and eczema for better alignment of related terms.

CR Number: 2022292009 **Implementation Date:** 19-Oct-22 Related CR: 2022285006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Prurigo of pregnancy*	Approved as Requested	Proposed PT	
HLT primary	*Dermatitis and eczema*		*Prurigo of pregnancy*	10088604
SOC primary	*Skin and subcutaneous tissue disorders*		HLT primary	
			Dermatitis and eczema	10012435
			SOC primary	
			Skin and subcutaneous tissue disorders	10040785
			HLT secondary	
			Maternal complications of pregnancy NEC	10026909
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment:

Supplemental Update Report

CR Number: 2022292010 **Implementation Date:** 19-Oct-22 Related CR: 2022285006

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Polymorphic eruption of pregnancy*	Approved as Requested	Proposed PT	
From HLT	*Pruritus NEC*		*Polymorphic eruption of pregnancy*	10066100
To HLT	*Dermatitis and eczema*		From HLT	
			Pruritus NEC	10049293
			To HLT	
			Dermatitis and eczema	10012435

MSSO Comment:

CR Number: 2022286001 **Implementation Date:** 19-Oct-22 Related CR: 2022286001

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Uterine cervix lymphoma*	Approved as Requested	Proposed PT	
To SMQ	*Haematological malignant tumours (SMQ)*		*Uterine cervix lymphoma*	10088190
Term scope	*Narrow*		To SMQ	
			Haematological malignant tumours (SMQ)	20000227
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Uterine cervix lymphoma to Haematological malignant tumours (SMQ) as a narrow term is approved as requested. PT Uterine cervix lymphoma added in version 26.0 which fits inclusion criterion for Haematological malignant tumours (SMQ) in narrow scope term. Lymphomas are part of the haematological system.

Supplemental Update Report

CR Number: 2022286002 **Implementation Date:** 19-Oct-22 Related CR: 2022286002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hypnic Headache*	Approved Not as Requested	Proposed PT	
			Hypnic headache	10088606
			HLT primary	
			Headaches NEC	10019233
			SOC primary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new LLT Hypnic Headache is approved but not as requested. Hypnic headache is characterized by frequently recurring headache attacks developing only during sleep, causing wakening and lasting for up to four hours, without characteristic associated symptoms and not attributed to other pathology. Once modified according to MedDRA capitalization conventions, Hypnic headache will be added as a new PT to HLT Headaches NEC.

CR Number: 2022286003 **Implementation Date:** 19-Oct-22 Related CR: 2022286003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Foramen of Winslow hernia*	Approved as Requested	Proposed LLT	
			Foramen of Winslow hernia	10088607 Current
			To PT	
			Internal hernia	10051989

MSSO Comment: The proposal to add a new term Foramen of Winslow hernia is approved as requested. Foramen of Winslow hernia can be defined as peculiar variant of internal abdominal hernia, since it is a normal peritoneal orifice kept closed by normal intra-abdominal pressure that may be permeated by the intra-abdominal viscera. Proposed term will be added as subconcept LLT Foramen of Winslow hernia under PT Internal hernia.

CR Number: 2022287001 **Implementation Date:** 19-Oct-22 Related CR: 2022287001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Acromioclavicular joint fracture*	Approved as Requested	Proposed LLT	
			Acromioclavicular joint fracture	10088608 Current
			To PT	
			Shoulder fracture	10049128

MSSO Comment: The proposal to add a new LLT Acromioclavicular joint fracture is approved as requested. The acromioclavicular joint is located where the clavicle meets the highest point of the acromion and a fracture of this joint is an injury that occurs when a break occurs in a bone in the joint area. Proposed term will be added as LLT Acromioclavicular joint fracture under PT Shoulder fracture. In a related change, the LLT Shoulder fracture will be promoted from PT Upper limb fracture to a PT level to primary HLT Limb fractures and dislocations and to secondary HLT Limb fractures.

Supplemental Update Report

CR Number: 2022292011 **Implementation Date:** 19-Oct-22 Related CR: 2022287001

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Shoulder fracture*	Approved as Requested	Proposed LLT	
From PT	*Upper limb fracture*		*Shoulder fracture*	10049128
HLT primary	*Limb fractures and dislocations*		From PT	
			Upper limb fracture	10061394
			HLT primary	
			Limb fractures and dislocations	10075886
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Limb fractures	10075885
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment:

CR Number: 2022287002 **Implementation Date:** 19-Oct-22 Related CR: 2022287002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Urinary squamous epithelial cell increased*	Approved Not as Requested	Proposed PT	
			Urinary squamous epithelial cells increased	10088609
			HLT primary	
			Urinalysis NEC	10046512
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Urinary squamous epithelial cell increased is approved but not as requested. Large numbers of squamous epithelial cells in the urine can represent contamination or may indicate urinary tract infection, kidney or liver disease, or certain types of cancer. Proposed term will be modified in plural form and added as new PT Urinary squamous epithelial cells increased under HLT Urinalysis NEC.

Supplemental Update Report

CR Number: 2022289002 **Implementation Date:** 19-Oct-22 Related CR: 2022289002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Heated Intraperitoneal Chemoperfusion*	Rejected		
To PT	*Hyperthermic chemotherapy*			

MSSO Comment: The proposal to add a new LLT Heated Intraperitoneal Chemoperfusion to PT Hyperthermic chemotherapy is not approved. The proposed concept is represented by existing LLT Intraperitoneal hyperthermic chemotherapy.

CR Number: 2022290001 **Implementation Date:** 19-Oct-22 Related CR: 2022290001

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed PT	*Basedow's disease*	Approved as Requested	Proposed PT		
With LLT	*Graves' disease*		*Basedow's disease*	10004161	Current
			With LLT		
			Graves' disease	10018706	

MSSO Comment: The proposal to swap the PT Basedow's disease with the LLT Graves' disease is approved as requested. Basedow's disease, also known as Graves' disease is a diffuse hyperplasia of the thyroid usually with an autoimmune etiology and has been linked to autoimmune thyroiditis. Basedow's disease is the lesser-known synonym and is uncommonly used, compared to the more widely used term Graves' disease.

CR Number: 2022290002 **Implementation Date:** 19-Oct-22 Related CR: 2022290002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*ANKYLOGLOSSIA*	Approved Not as Requested	Proposed LLT		
To PT	*Ankyloglossia congenital*		*Ankyloglossia*	10088611	Current
			To PT		
			Ankyloglossia congenital	10049244	

MSSO Comment: The proposal to add a new LLT ANKYLOGLOSSIA to PT Ankyloglossia congenital is approved but not as requested. Ankyloglossia, also known as tongue-tie, is generally a congenital oral anomaly that may decrease the mobility of the tongue tip and is caused by an unusually short, thick lingual frenulum. The proposed term will be modified in accordance with MedDRA capitalization conventions as LLT Ankyloglossia to PT Ankyloglossia congenital.

Supplemental Update Report

CR Number: 2022290003 **Implementation Date:** 19-Oct-22 Related CR: 2022290003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Claw toe*	Approved Not as Requested	Proposed LLT	
To PT	*Congenital claw toe*		*Claw toe*	10088610 Current
			To PT	
			Foot deformity	10061159

MSSO Comment: The proposal to add a new LLT Claw toe to PT Congenital claw toe is approved but not as requested. Based on medical literature research and associated frequencies in regulatory databases, claw toe more often relates to acquired etiologies and therefore Claw toe will be added as an LLT to PT Foot deformity. In related change, PT Acquired claw toe will be demoted under PT Foot deformity aligned with closely related LLT Claw foot, acquired and LLT Curly toe.

CR Number: 2022292012 **Implementation Date:** 19-Oct-22 Related CR: 2022290003

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Acquired claw toe*	Approved as Requested	PT to merge	
To PT	*Foot deformity*		*Acquired claw toe*	10057689 Current
			To PT	
			Foot deformity	10061159

MSSO Comment:

CR Number: 2022290004 **Implementation Date:** 21-Oct-22 Related CR: 2022290004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Liver fluke lgG antibody positive*	Approved as Requested	Proposed LLT	
			Liver fluke lgG antibody positive	10088613 Current
			To PT	
			Fasciola test positive	10088612

MSSO Comment: The proposal to add a new term Liver fluke lgG antibody positive is approved as requested. Antibody detection assays for flukes are particularly useful in the early stages of infection before eggs are produced (egg production typically begins at least 3 to 4 months after exposure), and also during chronic infection when egg production is sporadic or low. LLT Liver fluke lgG antibody positive will be added to the broader new PT Fasciola test positive which will be added, in a related change, to HLT Parasite identification and serology.

Supplemental Update Report

CR Number: 2022294008 **Implementation Date:** 21-Oct-22 Related CR: 2022290004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Fasciola test positive*	Approved as Requested	Proposed PT	
HLT primary	*Parasite identification and serology*		*Fasciola test positive*	10088612
SOC primary	*Investigations*		HLT primary	
			Parasite identification and serology	10033903
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022291001 **Implementation Date:** 21-Oct-22 Related CR: 2022291001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Megaloureter*	Approved Not as Requested	Proposed LLT	
HLT primary	*Ureteric disorders NEC*		*Megaloureter*	10088618 Current
SOC primary	*Renal and urinary disorders*		To PT	
			Congenital megaureter	10010540

MSSO Comment: The proposal to add a new PT Megaloureter to primary HLT Ureteric disorders NEC in SOC Renal and urinary disorders is approved but not as requested. A congenital (primary) megaureter encompasses causes of an enlarged ureter which are intrinsic to the ureter, rather than as a result of a more distal abnormality; e.g. bladder, urethra. Megaloureter will be added as a synonym LLT to PT Congenital megaureter

---

CR Number: 2022291002 **Implementation Date:** 21-Oct-22 Related CR: 2022291002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dyskalemia*	Approved Not as Requested	Proposed LLT	
HLT primary	*Potassium imbalance*		*Dyskalemia*	10088617 Current
SOC primary	*Metabolism and nutrition disorders*		To PT	
			Dyskalaemia	10088614

MSSO Comment: The proposal to add a new PT Dyskalemia to primary HLT Potassium imbalance in SOC Metabolism and nutrition disorders is approved but not as requested. Dyskalemia is a term used in the context of pathologic states such as chronic renal failure, in which potassium imbalance can manifest either as a decreased (hypokalemia) or as increased (hyperkalemia) concentration of potassium in serum. The proposed term will be added as LLT Dyskalemia to a new British English spelled PT Dyskalaemia, in accordance with MedDRA spelling conventions. In a related change, this new PT Dyskalaemia will be added to HLT Potassium imbalance in SOC Metabolism and nutrition disorders.

Supplemental Update Report

CR Number: 2022294009 **Implementation Date:** 21-Oct-22 Related CR: 2022291002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dyskalaemia*	Approved as Requested	Proposed PT	
HLT primary	*Potassium imbalance*		*Dyskalaemia*	10088614
SOC primary	*Metabolism and nutrition disorders*		HLT primary	
			Potassium imbalance	10036451
			SOC primary	
			Metabolism and nutrition disorders	10027433

MSSO Comment:

CR Number: 2022291003 **Implementation Date:** 21-Oct-22 Related CR: 2022291003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Canalicular Infection*	Approved Not as Requested	Proposed LLT	
To PT	*Dacryocanaliculitis*		*Canaliculitis*	10088615 Current
			To PT	
			Dacryocanaliculitis	10011843

MSSO Comment: The proposal to add a new LLT Canalicular Infection to PT Dacryocanaliculitis is approved but not as requested. Canaliculitis, which is an infection of the lacrimal canaliculus, typically occurs in individuals over 40 of age. Obstruction of the canaliculus, foreign body in the canaliculus (such as a punctal plug or dacryolith), or even a diverticulum can promote bacterial growth causing this condition. The proposed term will be modified to reflect more common clinical useage and added as synonym LLT Canaliculitis to PT Dacryocanaliculitis.

CR Number: 2022291004 **Implementation Date:** 21-Oct-22 Related CR: 2022291004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Typhoid arthritis*	Approved Not as Requested	Proposed LLT	
To PT	*Arthritis bacterial*		*Septic typhoid arthritis*	10088616 Current
			To PT	
			Arthritis salmonella	10003271

MSSO Comment: The proposal to add a new LLT Typhoid arthritis to PT Arthritis bacterial is approved but not as requested. Typhoid fever is a systemic disease caused by the gram-negative bacterium Salmonella enterica serotype Typhi. Arthritis is an uncommon but possible manifestation of typhoid fever. The requested term will be modified for clarity and differentiation from the reactive form and will be added as LLT Septic typhoid arthritis to PT Arthritis salmonella.

Supplemental Update Report

CR Number: 2022291005 **Implementation Date:** 21-Oct-22 Related CR: 2022291005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Infant/children with high risk*	Approved Not as Requested	Proposed PT	
			High risk infant	10088619
			HLT primary	
			Newborn complications NEC	10010168
			SOC primary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new term Infant/children with high risk is approved but not as requested. There is no definitve definition of high risk baby/infant. However in a policy statement from the American Academy of Pediatrics high-risk infants were defined broadly as including the preterm infant; the infant with special healthcare needs or dependence on technology; the infant at risk because of family issues; and the infant with anticipated early death. The requested term will be modified and added as PT High risk infant to HLT Newborn complications NEC.

CR Number: 2022291006 **Implementation Date:** 21-Oct-22 Related CR: 2022291006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Subependymal cyst*	Approved as Requested	Proposed PT	
			Subependymal cyst	10088620
			HLT primary	
			Nervous system cysts and polyps	10068205
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Nervous system cysts and polyps	10068205
			SOC secondary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104

MSSO Comment: The proposal to add a new term Subependymal cyst is approved as requested. Subependymal cysts may either be postnatally acquired post-hemorrhagic cysts or may be congenital (germinolytic). The congenital cysts may result from infection, ischemic injury, or hemorrhage. Subependymal cyst will be added as PT to bi-axial HLT Nervous system cysts and polyps to primary SOC Nervous system disorders and secondary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and to secondary HLT Neonatal neurological system disorders NEC.

Supplemental Update Report

CR Number: 2022294007 **Implementation Date:** 21-Oct-22 Related CR: 2022291006

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Subependymal cyst*	Approved as Requested	Proposed PT	
To HLT	*Neonatal neurological system disorders NEC*		*Subependymal cyst*	10088620
			To HLT	
			Neonatal neurological system disorders NEC	10028964

MSSO Comment:

CR Number: 2022291007 **Implementation Date:** 21-Oct-22 Related CR: 2022291007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pituitary stalk interruption syndrome*	Approved as Requested	Proposed PT	
			Pituitary stalk interruption syndrome	10088621
			HLT primary	
			Endocrine disorders congenital NEC	10027671
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Hypothalamic and pituitary disorders NEC	10021109
			SOC secondary	
			Endocrine disorders	10014698

MSSO Comment: The proposal to add a new term Pituitary stalk interruption syndrome is approved as requested. Pituitary stalk interruption syndrome is a congenital abnormality of the pituitary gland characterized by the triad of a very thin or interrupted pituitary stalk, a misplaced (ectopic) or absent posterior pituitary and a small or absent anterior pituitary, with permanent growth hormone deficit. Pituitary stalk interruption syndrome will be added as PT to primary HLT Endocrine disorders congenital NEC and secondary HLT Hypothalamic and pituitary disorders NEC.

CR Number: 2022292001 **Implementation Date:** 21-Oct-22 Related CR: 2022292001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*PROZOLONE THERAPY*	Rejected		

MSSO Comment: The proposal to add a new LLT PROZOLONE THERAPY is not approved. The requested term PROZOLONE THERAPY is misspelled; However the correct spelled Prolozone therapy represents a registered trade mark. The MSSO does not include trade marks or trade names. Please consider related concepts in MedDRA such as LLT/PT Ozone therapy or LLT/PT Proliferative injection therapy.

Supplemental Update Report

CR Number: 2022292002 **Implementation Date:** 21-Oct-22 Related CR: 2022292002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dysphagia management*	Approved as Requested	Proposed PT	
			Dysphagia management	10088622
HLT primary	*Therapeutic procedures NEC*		HLT primary	
			Therapeutic procedures NEC	10027700
SOC primary	*Surgical and medical procedures*		SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Dysphagia management to primary HLT Therapeutic procedures NEC in SOC Surgical and medical procedures is approved as requested. Thickening agents are vital for the medical management of people with dysphagia. The main therapeutic pillar of dysphagia management is the modification of foods and drinks to ensure they can be swallowed safely and efficiently without entering or lodging in the airway.

CR Number: 2022292013 **Implementation Date:** 21-Oct-22 Related CR: 2022292013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Subungual abscess*	Approved Not as Requested	Proposed PT	
			Subungual abscess	10088623
			HLT primary	
			Skin structures and soft tissue infections	10040786
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Skin and subcutaneous tissue infections NEC	10040793
			SOC secondary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new LLT Subungual abscess is approved but not as requested. An untreated nail infection or paronychia may evolve into a subungual abscess, with pain and inflammation of the nail matrix. As a consequence, transient or permanent dystrophy of the nail plate may occur. Proposed term will be added as new PT Subungual abscess to primary HLT Skin structures and soft tissue infections and to secondary HLT Skin and subcutaneous tissue infections NEC.

Supplemental Update Report

CR Number: 2022292014 **Implementation Date:** 04-Nov-22 Related CR: 2022292014

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*ASTCT neurological toxicities consensus grade*	Rejected After Suspension		

MSSO Comment: The proposal to add a new term ASTCT neurological toxicities consensus grade is not approved after suspension. The proposed term can be represented by the concept PT Immune effector cell encephalopathy score.

CR Number: 2022292015 **Implementation Date:** 26-Oct-22 Related CR: 2022292015

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pseudoneutropenia*	Approved Not as Requested	Proposed LLT	
HLT primary	*Neutropenias*		*Pseudoneutropenia*	10088624 Current
SOC primary	*Blood and lymphatic system disorders*		To PT	
			False positive investigation result	10070748

MSSO Comment: The proposal to add a new PT Pseudoneutropenia to primary HLT Neutropenias in SOC Blood and lymphatic system disorders is approved but not as requested. In pseudoneutropenia, a normal neutrophil population may be shifted toward the marginating compartment, leaving fewer cells in the circulating compartment. Pseudoneutropenia is not a true disease entity, but a consequence of the laboratory measurement process. Pseudoneutropenia will be added as an LLT to PT False positive investigation result.

Supplemental Update Report

CR Number: 2022293001 **Implementation Date:** 26-Oct-22 Related CR: 2022293001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Delayed passage of meconium*	Approved Not as Requested	Proposed PT	
HLT primary	*Neonatal gastrointestinal disorders*		*Delayed passage of meconium*	10088625
SOC primary	*Pregnancy, puerperium and perinatal conditions*		HLT primary	
			Duodenal and small intestinal stenosis and obstruction	10013811
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Neonatal gastrointestinal disorders	10028940
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new PT Delayed passage of meconium to primary HLT Neonatal gastrointestinal disorders in SOC Pregnancy, puerperium and perinatal conditions is approved but not as requested. Delayed passage of meconium, defined as failure of the newborn to pass meconium within 24-48 hours, is an important symptom in the neonate and warrants evaluation for disorders that lead to neonatal intestinal obstruction. Delayed passage of meconium will be added as a PT to primary HLT Duodenal and small intestinal stenosis and obstruction and to secondary HLT Neonatal gastrointestinal disorders.

CR Number: 2022293002 **Implementation Date:** 26-Oct-22 Related CR: 2022293002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spinal stabilization*	Approved Not as Requested	Proposed LLT	
HLT primary	*Spine and spinal cord therapeutic procedures*		*Spinal stabilization*	10088627 Current
SOC primary	*Surgical and medical procedures*		To PT	
			Spinal stabilisation	10088626

MSSO Comment: The proposal to add a new PT Spinal stabilization to primary HLT Spine and spinal cord therapeutic procedures in SOC Surgical and medical procedures is approved but not as requested. Spine stabilization refers to the surgical procedures that correct spinal instability and deformity while optimizing the physiological weight-bearing function and mobility of the spinal column. Spinal stabilization will be added as LLT to a new PT Spinal stabilisation, the British English counterpart, which will be added in a related change and linked to HLT Spine and spinal cord therapeutic procedures.

Supplemental Update Report

CR Number: 2022299001 **Implementation Date:** 26-Oct-22 Related CR: 2022293002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spinal stabilisation*	Approved as Requested	Proposed PT	
HLT primary	*Spine and spinal cord therapeutic procedures*		*Spinal stabilisation*	10088626
SOC primary	*Surgical and medical procedures*		HLT primary	
			Spine and spinal cord therapeutic procedures	10041590
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment:

CR Number: 2022293003 **Implementation Date:** 26-Oct-22 Related CR: 2022293003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*H63D mutation*	Approved as Requested	Proposed PT	
HLT primary	*Gene mutations and other alterations NEC*		*H63D mutation*	10088628
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Gene mutations and other alterations NEC	10083625
			SOC primary	
			Congenital, familial and genetic disorders	10010331

MSSO Comment: The proposal to add a new PT H63D mutation to primary HLT Gene mutations and other alterations NEC in SOC Congenital, familial and genetic disorders is approved as requested. The H63D mutation is a histidine-to-aspartic acid substitution at amino acid position 63. It has been associated with hemochromatosis, but to a lesser extent than C282Y.

CR Number: 2022293004 **Implementation Date:** 26-Oct-22 Related CR: 2022293004

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Xerophthalmia*	Rejected		
To PT	*Vitamin A deficiency eye disorder*			

MSSO Comment: The proposal to demote the PT Xerophthalmia under PT Vitamin A deficiency eye disorder is not approved. Even though xerophthalmia is used synonymously to vitamin A deficiency in some literature references, in others it is used as a synonym of keratoconjunctivitis sicca and therefore it is preferable to keep PT Xerophthalmia as a stand alone concept. In addition, there are other causes of xeropthalmia aside from vitamin A deficiency.

Supplemental Update Report

CR Number: 2022293005 **Implementation Date:** 26-Oct-22 Related CR: 2022293005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Couvelaire uterus*	Approved as Requested	Proposed LLT *Couvelaire uterus* To PT *Premature separation of placenta*	 10088629 Current 10036608

MSSO Comment: The proposal to add a new LLT Couvelaire uterus is approved as requested. Couvelaire uterus is a life-threatening condition in which loosening of the placenta (abruptio placentae) causes bleeding that penetrates into the uterine myometrium forcing its way into the peritoneal cavity. Proposed term will be added as sub-concept LLT Couvelaire uterus under PT Premature separation of placenta.

CR Number: 2022293006 **Implementation Date:** 26-Oct-22 Related CR: 2022293006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Precursor to white skin cancer*	Rejected		
To PT	*Bowen's disease*			

MSSO Comment: The proposal to add a new LLT Precursor to white skin cancer to PT Bowen's disease is not approved. Proposed term is ambiguous and non-specific. Many conditions may serve as precursors of skin cancer, such as actinic keratosis.

CR Number: 2022293007 **Implementation Date:** 26-Oct-22 Related CR: 2022293007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Intestinal catarrh*	Approved as Requested	Proposed LLT *Intestinal catarrh* To PT *Enteritis*	 10088630 Current 10014866

MSSO Comment: The proposal to add a new LLT Intestinal catarrh is approved as requested. Intestinal catarrh is a term used to mean enteritis and refers to the mucousal inflammation of intestine. Proposed term will be added as synonym LLT Intestinal catarrh under PT Enteritis.

Supplemental Update Report

CR Number: 2022293008 **Implementation Date:** 28-Oct-22 Related CR: 2022293008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*FASCIOCUTANEOUS ROTATION FLAP*	Approved Not as Requested	Proposed PT	
			Fasciocutaneous rotation flap	10088632
			HLT primary	
			Soft tissue therapeutic procedures NEC	10052876
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT FASCIOCUTANEOUS ROTATION FLAP is approved but not as requested. Fasciocutaneous flaps are tissue flaps that include skin, subcutaneous tissue and the underlying fascia, and they are used to provide coverage when a skin graft or random skin flap is insufficient for wound coverage (eg, in coverage over tendon or bones). The proposed term will be modified in accordance with MedDRA capitalization conventions and added as an PT Fasciocutaneous rotation flap to HLT Soft tissue therapeutic procedures NEC.

CR Number: 2022293009 **Implementation Date:** 28-Oct-22 Related CR: 2022293009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Skin laser therapy*	Approved Not as Requested	Proposed PT	
			Skin laser therapy	10088633
			HLT primary	
			Skin and subcutaneous tissue therapeutic procedures NEC	10040794
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Skin laser therapy is approved but not as requested. Skin is an organ where there is an ample variety of techniques in relation with laser procedures appliance. Ablative lasers vaporize the top layers of damaged skin, while non-ablative lasers work deeper in the skin without removing or damaging the top layers. Skin laser therapy will be added as a PT to HLT Skin and subcutaneous tissue therapeutic procedures NEC.

Supplemental Update Report

CR Number: 2022293010 **Implementation Date:** 28-Oct-22 Related CR: 2022293010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Skin resurfacing*	Approved as Requested	Proposed PT	
			Skin resurfacing	10088634
HLT primary	*Skin and subcutaneous tissue therapeutic procedures NEC*		HLT primary	
			Skin and subcutaneous tissue therapeutic procedures NEC	10040794
SOC primary	*Surgical and medical procedures*		SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Skin resurfacing to primary HLT Skin and subcutaneous tissue therapeutic procedures NEC in SOC Surgical and medical procedures is approved as requested. Skin resurfacing treatments help to restore skin complexion by removing the most damaged outer layers though the use of a variety of techniques, such as laser skin resurfacing, chemical peels, microdermabrasion, dermabrasion, microneedling, etc. In a related change, PT Photorejuvenation will be moved from HLT Phototherapies to HLT Skin and subcutaneous tissue therapeutic procedures NEC for better alignment with related concept of skin resurfacing.

CR Number: 2022301002 **Implementation Date:** 28-Oct-22 Related CR: 2022293010

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Photorejuvenation*	Approved as Requested	Proposed PT	
			Photorejuvenation	10082247
From HLT	*Phototherapies*		From HLT	
			Phototherapies	10034976
To HLT	*Skin and subcutaneous tissue therapeutic procedures NEC*		To HLT	
			Skin and subcutaneous tissue therapeutic procedures NEC	10040794

MSSO Comment:

CR Number: 2022293011 **Implementation Date:** 28-Oct-22 Related CR: 2022293011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Gastrointestinal melanoma excision*	Approved Not as Requested	Proposed LLT	
			Non-cutaneous melanoma excision	10088631 Current
			To PT	
			Cancer surgery	10074431

MSSO Comment: The proposal to add a new term Gastrointestinal melanoma excision is approved but not as requested. To represent resection of melanomas occurred in organs different than skin, and in order to add a broader concept beyond the high specificity of the one requested, a new Non-cutaneous melanoma excision will be added as an LLT to PT Cancer surgery.

Supplemental Update Report

CR Number: 2022293012 **Implementation Date:** 28-Oct-22 Related CR: 2022293012

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Asymptomatic hyperglycemia*	Rejected		

MSSO Comment: The proposal to add a new term Asymptomatic hyperglycemia is not approved. To avoid overpopulation of the terminology, MedDRA cannot add an asymptomatic qualified term for every possible condition. Besides, except in cases of very high levels of blood glucose, hyperglycemia is usually asymptomatic, and can be assumed as such by default without needing to add the proposed qualified term.

CR Number: 2022294001 **Implementation Date:** 28-Oct-22 Related CR: 2022294001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Anastomotic obstruction*	Approved as Requested	Proposed PT	
			Anastomotic obstruction	10088635
			HLT primary	
			Non-site specific procedural complications	10029559
			SOC primary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new term Anastomotic obstruction is approved as requested. Anastomoses can become blocked or clogged both in the early and late postoperative recovery due to adhesions, internal strangulation, fibrosis bridles, or bleeding clots. Anastomotic obstruction will be added as PT to HLT Non-site specific procedural complications.

CR Number: 2022294002 **Implementation Date:** 28-Oct-22 Related CR: 2022294002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Systemic Hypertension*	Approved Not as Requested	Proposed LLT	
			Systemic hypertension	10088636 Current
			To PT	
			Hypertension	10020772

MSSO Comment: The proposal to add a new term Systemic Hypertension is approved but not as requested. Systemic hypertension refers to an elevated pressure in the systemic circulation, understood as the part of the vascular system that carries blood from the left ventricle to organs and tissues of the body. It is used synonymously with the non-qualified hypertension, which generally refers to high pressure in the systemic circulation, as opposed to the necessarily qualified pulmonary hypertension. Systemic hypertension will be modified in accordance with MedDRA capitalization conventions and added as LLT to PT Hypertension.

Supplemental Update Report

CR Number: 2022294003 **Implementation Date:** 28-Oct-22 Related CR: 2022294003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hydrocele testis*	Approved as Requested	Proposed LLT	
To PT	*Hydrocele*		*Hydrocele testis*	10088637 Current
			To PT	
			Hydrocele	10020488

MSSO Comment: The proposal to add a new LLT Hydrocele testis to PT Hydrocele is approved as requested. Hydrocele testis is a synonym of existing PT Hydrocele.

CR Number: 2022294004 **Implementation Date:** 28-Oct-22 Related CR: 2022294004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Traumatic rib injury*	Rejected		

MSSO Comment: The proposal to add a new term Traumatic rib injury is not approved. Proposed term exists in unqualified form as LLT Rib injury which is linked to HLT Chest and respiratory tract injuries NEC.

CR Number: 2022294005 **Implementation Date:** 28-Oct-22 Related CR: 2022294005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cyanotic spell*	Approved Not as Requested	Proposed LLT	
			Neonatal cyanotic spell	10088638 Current
			To PT	
			Cyanosis neonatal	10011705

MSSO Comment: The proposal to add a new PT Cyanotic spell is approved but not as requested. Cyanotic spells are paroxysmal hypoxic events in a child due to decreased pulmonary blood flow and right to left shunting such as in ventricular septal defect. Proposed term will be modified for clarity and added as a sub-concept LLT Neonatal cyanotic spell to PT Cyanosis neonatal.

Supplemental Update Report

CR Number: 2022294006 **Implementation Date:** 28-Oct-22 Related CR: 2022294006

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Alveolar bone defect*	Approved as Requested	Proposed PT	
		Alveolar bone defect	10088639
		HLT primary	
		Dental disorders NEC	10044037
		SOC primary	
		Gastrointestinal disorders	10017947
		HLT secondary	
		Bone disorders NEC	10027658
		SOC secondary	
		Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new term Alveolar bone defect is approved as requested. An alveolar bone defect represents the partial loss of the bony ridge in the jaw that holds the teeth and supports its roots. Alveolar bone defect will be added as a PT to primary HLT Dental disorders NEC and to secondary HLT Bone disorders NEC.

CR Number: 2022297001 **Implementation Date:** 28-Oct-22 Related CR: 2022297001

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Intraocular lens user*	Approved as Requested	Proposed LLT	
		Intraocular lens user	10088640 Current
		To PT	
		Eye prosthesis user	10050865

MSSO Comment: The proposal to add a new term Intraocular lens user is approved as requested. Knowing somebody is an intraocular lens user can help in the follow-up and differentiation of certain conditions more frequently associated with an intraocular lens implantation and its possible complications. Intraocular lens user will be added as sub-concept LLT to PT Eye prosthesis user.

Supplemental Update Report

CR Number: 2022297002 **Implementation Date:** 28-Oct-22 Related CR: 2022297002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Transient hepatic attenuation differences*	Approved as Requested	Proposed PT	
			Transient hepatic attenuation differences	10088641
			HLT primary	
			Hepatobiliary signs and symptoms	10019709
			SOC primary	
			Hepatobiliary disorders	10019805

MSSO Comment: The proposal to add a new term Transient hepatic attenuation differences is approved as requested. Transient hepatic attenuation differences refer to areas of parenchymal enhancement visible during the hepatic artery phase on helical CT. They are thought to be a physiological phenomenon caused by the dual hepatic blood supply or they may be associated with other pathologies. Proposed term will be added as new PT Transient hepatic attenuation differences under HLT Hepatobiliary signs and symptoms.

CR Number: 2022297003 **Implementation Date:** 28-Oct-22 Related CR: 2022297003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*DUAL-CHAMBER PACEMAKER IMPLANTATION*	Approved Not as Requested	Proposed LLT	
			Dual-chamber pacemaker implantation	10088642 Current
			To PT	
			Cardiac pacemaker insertion	10007598

MSSO Comment: The proposal to add a new term DUAL-CHAMBER PACEMAKER IMPLANTATION is approved but not as requested. Dual chamber pacemakers stimulate both the right atrium and the right ventricle. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as LLT Dual-chamber pacemaker implantation to PT Cardiac pacemaker insertion.

CR Number: 2022298001 **Implementation Date:** 01-Nov-22 Related CR: 2022298001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Embolic renal infarction*	Approved as Requested	Proposed LLT	
			Embolic renal infarction	10088643 Current
			To PT	
			Renal infarct	10038470

MSSO Comment: The proposal to add a new term Embolic renal infarction is approved as requested. Renal infarction secondary to thromboembolism,or embolic renal infarction, is usually a sequel of cardiac disease; the three major causes are atrial fibrillation, acute myocardial infarction, and rheumatic mitral stenosis. Embolic renal infarction will be added as an LLT to PT Renal infarct. In a related change, the secondary HLT for PT Renal infarct will be changed from HLT Renal necrosis and vascular insufficiency to HLT Renal embolism and thrombosis.

Supplemental Update Report

CR Number: 2022305004 **Implementation Date:** 01-Nov-22 Related CR: 2022298001

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Renal infarct*	Approved as Requested	Proposed PT	
From HLT	*Renal necrosis and vascular insufficiency*		*Renal infarct*	10038470
To HLT	*Renal embolism and thrombosis*		From HLT	
			Renal necrosis and vascular insufficiency	10038482
			To HLT	
			Renal embolism and thrombosis	10038434

MSSO Comment:

CR Number: 2022298002 **Implementation Date:** 01-Nov-22 Related CR: 2022298002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Vascular access site infiltration*	Approved as Requested	Proposed LLT		
To PT	*Vascular access site extravasation*		*Vascular access site infiltration*	10088644	Current
			To PT		
			Vascular access site extravasation	10087974	

MSSO Comment: The proposal to add a new LLT Vascular access site infiltration to PT Vascular access site extravasation is approved as requested as a sub-concept. The word infiltration in this context is understood as an extravasation or leakage and not as a cellular infiltrate.

CR Number: 2022298003 **Implementation Date:** 01-Nov-22 Related CR: 2022298003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vascular access site allergy*	Rejected		
To PT	*Vascular access site hypersensitivity*			

MSSO Comment: The proposal to add a new LLT Vascular access site allergy to PT Vascular access site hypersensitivity is not approved. To avoid overpopulation of the terminology, MedDRA cannot add combination terms for every possible condition occurring at every administration or accessory site. The proposed concept can be represented by LLT/PT Vascular access site hypersensitivity.

Supplemental Update Report

CR Number: 2022298004 **Implementation Date:** 01-Nov-22 Related CR: 2022298004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vascular access site burning*	Approved as Requested	Proposed LLT	
To PT	*Vascular access site pain*		*Vascular access site burning*	10088645 Current
			To PT	
			Vascular access site pain	10077762

MSSO Comment: The proposal to add a new LLT Vascular access site burning to PT Vascular access site pain is approved as requested. In MedDRA term placement, burning sensation is generally considered to be an expression related to pain at a named body site.

CR Number: 2022298005 **Implementation Date:** 01-Nov-22 Related CR: 2022298005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vascular access site tingling*	Rejected		
To PT	*Vascular access site paraesthesia*			

MSSO Comment: The proposal to add a new LLT Vascular access site tingling to PT Vascular access site paraesthesia is not approved. In MedDRA term placement, tingling sensation is generally considered to be an expression related to paraesthesia at a named body site.

CR Number: 2022298006 **Implementation Date:** 01-Nov-22 Related CR: 2022298006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vascular access site thrombophlebitis*	Approved as Requested	Proposed LLT	
To PT	*Vascular access site thrombosis*		*Vascular access site thrombophlebitis*	10088646 Current
			To PT	
			Vascular access site thrombosis	10078675

MSSO Comment: The proposal to add a new LLT Vascular access site thrombophlebitis to PT Vascular access site thrombosis is approved as requested. Thrombophlebitis can be considered a form of thrombosis.

Supplemental Update Report

CR Number: 2022298007 **Implementation Date:** 01-Nov-22 Related CR: 2022298007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vascular access site stinging*	Rejected		
To PT	*Vascular access site pain*			

MSSO Comment: The proposal to add a new LLT Vascular access site stinging to PT Vascular access site pain is not approved. Stinging sensations are generally considered in MedDRA as an expression in relation with pain.

CR Number: 2022298008 **Implementation Date:** 01-Nov-22 Related CR: 2022298008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hemispherectomy*	Approved as Requested	Proposed PT *Hemispherectomy*	10088647
HLT primary	*Skull and brain therapeutic procedures*		HLT primary *Skull and brain therapeutic procedures*	10040957
SOC primary	*Surgical and medical procedures*		SOC primary *Surgical and medical procedures*	10042613

MSSO Comment: The proposal to add a new PT Hemispherectomy to primary HLT Skull and brain therapeutic procedures in SOC Surgical and medical procedures is approved as requested. Hemispherectomy is a neurosurgical procedure in which a cerebral hemisphere (half of the upper brain, or cerebrum) is removed or disconnected that is used to treat a variety of refractory or drug-resistant seizure disorders. Proposed term will be added as new PT Hemispherectomy under HLT Skull and brain therapeutic procedures.

CR Number: 2022298009 **Implementation Date:** 01-Nov-22 Related CR: 2022298009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Klebsella renal infection*	Rejected		

MSSO Comment: The proposal to add a new LLT Klebsella renal infection is not approved. It is not feasible to add all possible combinations of specific agents with anatomical sites - please see the recently added broader concept of PT Klebsiella urinary tract infection and/or PT Bacterial pyelonephritis as options.

Supplemental Update Report

CR Number: 2022299002 **Implementation Date:** 01-Nov-22 Related CR: 2022299002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Lipohaemarthrosis*	Approved Not as Requested	Proposed PT	
HLT primary	*Arthropathies NEC*		*Lipohaemarthrosis*	10088648
SOC primary	*Musculoskeletal and connective tissue disorders*		HLT primary	
			Bone and joint injuries NEC	10074485
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Arthropathies NEC	10003284
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Lipohaemarthrosis to primary HLT Arthropathies NEC in SOC Musculoskeletal and connective tissue disorders is approved but not as requested. Lipohemarthrosis results from an intra-articular fracture when fat and blood from the bone marrow is extruded into the joint space. Proposed term will be added as new PT Lipohaemarthrosis under primary HLT Bone and joint injuries NEC and secondary HLT Arthropathies NEC and secondary HLT Haemorrhages NEC. In a related change, the American English spelled counterpart LLT Lipohemarthrosis will also be added under PT Lipohaemarthrosis.

CR Number: 2022305005 **Implementation Date:** 01-Nov-22 Related CR: 2022299002

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Lipohaemarthrosis*	Approved as Requested	Proposed PT	
To HLT	*Haemorrhages NEC*		*Lipohaemarthrosis*	10088648
			To HLT	
			Haemorrhages NEC	10018987

MSSO Comment:

Supplemental Update Report

CR Number: 2022305006 **Implementation Date:** 01-Nov-22 Related CR: 2022299002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Lipohemarthrosis*	Approved as Requested	Proposed LLT	
To PT	*Lipohaemarthrosis*		*Lipohemarthrosis*	10088649 Current
			To PT	
			Lipohaemarthrosis	10088648

MSSO Comment:

CR Number: 2022300001 **Implementation Date:** 04-Nov-22 Related CR: 2022300001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Denali vena cava filter*	Rejected		

MSSO Comment: The proposal to add a new term Denali vena cava filter is not approved. An inferior vena cava filter is a small, wiry device. When the filter is placed in the inferior vena cava, the blood flows past the filter and catches blood clots and stops them from moving up to the heart and lungs to prevent a pulmonary embolism. The proposed term represents a trade name and based on MedDRA conventions is represented as a general concept with existing LLT/PT Vena cava filter insertion.

Supplemental Update Report

CR Number: 2022300002 **Implementation Date:** 04-Nov-22 Related CR: 2022300002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Duodenal stump fistula*	Approved as Requested	Proposed PT	
			Duodenal stump fistula	10088660
			HLT primary	
			Gastrointestinal and hepatobiliary procedural complications	10017927
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Gastrointestinal fistulae	10017952
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Duodenal stump fistula is approved as requested. Duodenal stump fistula is the most severe surgical complication after gastrectomy. Iatrogenic or traumatic injury, malnutrition, cancer, tuberculosis, Crohn's disease are also common causes of duodenal fistula. Proposed term will be added as new PT Duodenal stump fistula under primary HLT Gastrointestinal and hepatobiliary procedural complications and secondary HLT Gastrointestinal fistulae.

CR Number: 2022300003 **Implementation Date:** 04-Nov-22 Related CR: 2022300003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Duodenal leak*	Approved as Requested	Proposed LLT	
			Duodenal leak	10088664 Current
			To PT	
			Fistula of small intestine	10065850

MSSO Comment: The proposal to add a new term Duodenal leak is approved as requested. A duodenal leak most frequently occurs from one of three sources: perforated peptic ulcer disease, traumatic injury, and postsurgical suture or staple line dehiscence. A majority of duodenal leaks are a result of surgical complication; only 13 percent are caused by perforated ulcers. Duodenal leak will be added as an LLT to PT Fistula of small intestine. In a related change, PT Fistula of small intestine will be linked to secondary HLT Gastrointestinal and hepatobiliary procedural complications.

Supplemental Update Report

CR Number: 2022308009 **Implementation Date:** 04-Nov-22 Related CR: 2022300003

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Fistula of small intestine*	Approved as Requested	Proposed PT	
			Fistula of small intestine	10065850
To HLT	*Gastrointestinal and hepatobiliary procedural complications*		To HLT	
			Gastrointestinal and hepatobiliary procedural complications	10017927

MSSO Comment:

CR Number: 2022300004 **Implementation Date:** 04-Nov-22 Related CR: 2022300004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pulsed echo doppler flowmeter*	Approved Not as Requested	Proposed LLT	
			Pulsed echo doppler flowmetry	10088661 Current
			To PT	
			Ultrasound Doppler	10045412

MSSO Comment: The proposal to add a new term Pulsed echo doppler flowmeter is approved but not as requested. The development of pulsed doppler flowmetry has provided an indispensable resource for the noninvasive evaluation of vascular structures. Proposed term will be modified to the most common form found in literature and added as sub-concept LLT Pulsed echo doppler flowmetry under PT Ultrasound Doppler.

CR Number: 2022300005 **Implementation Date:** 04-Nov-22 Related CR: 2022300005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pulsed doppler echocardiography*	Approved as Requested	Proposed LLT	
			Pulsed doppler echocardiography	10088666 Current
			To PT	
			Echocardiogram	10014113

MSSO Comment: The proposal to add a new term Pulsed doppler echocardiography is approved as requested. The pulsed wave doppler can analyze sound waves reflected from a specific location. This is the main advantage of pulsed wave Doppler, namely its ability to determine the location of the measured velocities. Proposed term will be added as sub-concept LLT Pulsed doppler echocardiography under PT Echocardiogram.

Supplemental Update Report

CR Number: **2022300006** **Implementation Date:** 04-Nov-22 Related CR: 2022300006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Pathway anti-her2 (4b5) antibody assay*	Approved Not as Requested	Proposed LLT		
			Anti-HER2 (4B5) antibody assay	10088662	Current
			To PT		
			Human epidermal growth factor receptor test	10088659	

MSSO Comment: The proposal to add a new term Pathway anti-her2 (4b5) antibody assay is approved but not as requested. Anti-HER2 (4B5) antibody assay detects a rabbit monoclonal antibody intended for laboratory use for the semi-quantitative detection of HER2 antigen in sections of formalin-fixed, paraffin-embedded normal and neoplastic breast tissue. This diagnostic assay aids in identifying breast cancer patients who are eligible for treatment with appropriate therapies. Proposed term is a trademark name and based on MedDRA conventions, will be modified to represent the generic concept equivalent and added as LLT Anti-HER2 (4B5) antibody assay to a new PT Human epidermal growth factor receptor test which will be added, in a related change, to HLT Cell marker analyses.

CR Number: **2022308010** **Implementation Date:** 04-Nov-22 Related CR: 2022300006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Human epidermal growth factor receptor test*	Approved as Requested	Proposed PT	
HLT primary	*Cell marker analyses*		*Human epidermal growth factor receptor test*	10088659
SOC primary	*Investigations*		HLT primary	
			Cell marker analyses	10072981
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: **2022300007** **Implementation Date:** 04-Nov-22 Related CR: 2022300007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Oncomine dx target test*	Approved Not as Requested	Proposed LLT		
			Next generation sequencing oncology panel	10088663	Current
			To PT		
			Oncotype test	10079623	

MSSO Comment: The proposal to add a new term Oncomine dx target test is approved but not as requested. Patient cancer tissue is sent to a lab which isolates DNA and RNA from the sample. These are mixed with chemical substances called reagents that find and test the DNA and RNA sequences of the patient's RET genes. Identifying these mutations can help patients with these cancers receive personalized treatment targeting these genetic changes. Proposed term is a trademark name and based on MedDRA conventions, will be modified to represent the generic concept equivalent as LLT Next generation sequencing oncology panel to PT Oncotype test.

Supplemental Update Report

CR Number: 2022300008 **Implementation Date:** 04-Nov-22 Related CR: 2022300008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pascal precision transcatheter valve repair system*	Approved Not as Requested	Proposed LLT	
			Transcatheter mitral valve repair	10088667 Current
			To PT	
			Mitral valve repair	10062202

MSSO Comment: The proposal to add a new term Pascal precision transcatheter valve repair system is approved but not as requested. Transcatheter mitral valve repair is indicated for the percutaneous reduction of significant, symptomatic mitral regurgitation due to primary abnormality of the mitral apparatus in patients who have been determined to be at prohibitive risk for mitral valve surgery. Proposed term will be modified for the generic representation of concept as proprietary trade names are not within the scope of MedDRA and added as new LLT Transcatheter mitral valve repair to PT Mitral valve repair.

CR Number: 2022300009 **Implementation Date:** 04-Nov-22 Related CR: 2022300009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Accelstim bone growth stimulator*	Approved Not as Requested	Proposed LLT	
			Noninvasive bone growth stimulation	10088665 Current
			To PT	
			Bone growth stimulation	10088658

MSSO Comment: The proposal to add a new term Accelstim bone growth stimulator is approved but not as requested. Noninvasive bone growth stimulation treatment delivers a high frequency sound wave (ultrasound signal) to encourage bone growth and help heal bone fractures. Proposed term will be modified for the generic representation of the concept as proprietary trade names are not within the scope of MedDRA and added as LLT Noninvasive bone growth stimulation to the new PT Bone growth stimulation which will be added, in a related change, HLT Fracture treatments (excl skull and spine). Furthermore, PT Bone electrostimulation therapy will be demoted under the new PT Bone growth stimulation.

CR Number: 2022308011 **Implementation Date:** 04-Nov-22 Related CR: 2022300009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Bone growth stimulation*	Approved as Requested	Proposed PT	
HLT primary	*Fracture treatments (excl skull and spine)*		*Bone growth stimulation*	10088658
SOC primary	*Surgical and medical procedures*		HLT primary	
			Fracture treatments (excl skull and spine)	10044556
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment:

Supplemental Update Report

CR Number: 2022308012 **Implementation Date:** 04-Nov-22 Related CR: 2022300009

Change Requested		Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*Bone electrostimulation therapy*	Approved as Requested	PT to merge		
To PT	*Bone growth stimulation*		*Bone electrostimulation therapy*	10057606	Current
			To PT		
			Bone growth stimulation	10088658	

MSSO Comment:

CR Number: 2022300010 **Implementation Date:** 01-Nov-22 Related CR: 2022300010

Change Requested		Final Disposition	Final Placement	MedDRA Code #	
Add a New Term					
Proposed Term	*Aortic root replacement*	Approved as Requested	Proposed LLT		
			Aortic root replacement	10088650	Current
			To PT		
			Aortic aneurysm repair	10002885	

MSSO Comment: The proposal to add a new term Aortic root replacement is approved as requested. Aortic root replacement is a procedure to treat an aneurysm of the ascending aorta in order to prevent rupture or aortic wall dissection. Aortic root replacement will be added as LLT to PT Aortic aneurysm repair.

CR Number: 2022300011 **Implementation Date:** 01-Nov-22 Related CR: 2022300011

Change Requested		Final Disposition	Final Placement	MedDRA Code #	
Add a New Term					
Proposed Term	*Valve-sparing root replacement*	Approved as Requested	Proposed LLT		
			Valve-sparing root replacement	10088651	Current
			To PT		
			Aortic aneurysm repair	10002885	

MSSO Comment: The proposal to add a new term Valve-sparing root replacement is approved as requested. During valve sparing root replacement, the patient's aortic valve is kept (although it may be repaired and reimplanted) and reconnected to a new section of aortic tissue, thus avoiding the need for lifelong anticoagulation. Valve-sparing root replacement will be added as LLT to PT Aortic aneurysm repair.

Supplemental Update Report

CR Number: 2022300012 **Implementation Date:** 01-Nov-22 Related CR: 2022300012

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*GASTROESOPHAGEAL REFLUX IN NEONATE*	Approved Not as Requested	Proposed LLT		
			Gastroesophageal reflux in neonate	10088654	Current
			To PT		
			Gastrooesophageal reflux in neonate	10088653	

MSSO Comment: The proposal to add a new term GASTROESOPHAGEAL REFLUX IN NEONATE is approved but not as requested. Gastroesophageal reflux occurs in almost all infants, manifesting as wet burps after feeding. Gastroesophageal reflux in infants causes complications such as irritability, respiratory problems, and poor growth. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as LLT Gastroesophageal reflux in neonate to the British English spelled new PT Gastrooesophageal reflux in neonate, which will be added, in a related change, to primary HLT Gastrointestinal atonic and hypomotility disorders NEC and to secondary HLT Neonatal gastrointestinal disorders.

CR Number: 2022305007 **Implementation Date:** 01-Nov-22 Related CR: 2022300012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gastrooesophageal reflux in neonate*	Approved as Requested	Proposed PT	
HLT primary	*Gastrointestinal atonic and hypomotility disorders NEC*		*Gastrooesophageal reflux in neonate*	10088653
SOC primary	*Gastrointestinal disorders*		HLT primary	
			Gastrointestinal atonic and hypomotility disorders NEC	10017933
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Neonatal gastrointestinal disorders	10028940
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment:

Supplemental Update Report

CR Number: 2022300013 **Implementation Date:** 01-Nov-22 Related CR: 2022300013

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*INFANTILE DIARRHEA*	Approved Not as Requested	Proposed LLT *Infantile diarrhea*	10088655 Current
			To PT *Infantile diarrhoea*	10088652

MSSO Comment: The proposal to add a new term INFANTILE DIARRHEA is approved but not as requested. The proposed term will be modified in accordance to MedDRA capitalization standards and added as LLT Infantile diarrhea to the British English spelled PT Infantile diarrhoea, which will be added in a related change, to primary HLT Diarrhoea (excl infective) and to secondary HLT Neonatal gastrointestinal disorders. Furthermore, PT Diarrhoea neonatal will be demoted under new PT Infantile diarrhoea.

CR Number: 2022305009 **Implementation Date:** 01-Nov-22 Related CR: 2022300013

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Diarrhoea neonatal*	Approved as Requested	PT to merge *Diarrhoea neonatal*	10012743 Current
To PT	*Infantile diarrhoea*		To PT *Infantile diarrhoea*	10088652

MSSO Comment:

Supplemental Update Report

CR Number: 2022305010 **Implementation Date:** 01-Nov-22 Related CR: 2022300013

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Infantile diarrhoea*	Approved as Requested	Proposed PT	
HLT primary	*Diarrhoea (excl infective)*		*Infantile diarrhoea*	10088652
SOC primary	*Gastrointestinal disorders*		HLT primary	
			Diarrhoea (excl infective)	10012736
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Neonatal gastrointestinal disorders	10028940
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment:

CR Number: 2022300014 **Implementation Date:** 01-Nov-22 Related CR: 2022300014

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*PATHOLOGICAL JAUNDICE*	Rejected		

MSSO Comment: The proposal to add a new term PATHOLOGICAL JAUNDICE is not approved. The proposed term is not needed provided that jaundice is virtually always pathological, except in infants, where unconjugated hyperbilirubinemia reflects a normal transitional phenomenon.

Supplemental Update Report

CR Number: 2022300015 **Implementation Date:** 01-Nov-22 Related CR: 2022300015

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*WET LUNG OF NEWBORN*	Approved Not as Requested	Proposed LLT	
			Wet lung of newborn	10088656 Current
			To PT	
			Transient tachypnoea of the newborn	10044403

MSSO Comment: The proposal to add a new term WET LUNG OF NEWBORN is approved but not as requested. Transient tachypnea of the newborn (also called "wet lung of newborn") affects premature infants, term infants delivered by elective cesarean delivery without labor, and infants born with respiratory depression, all of whom may have delayed clearance of fetal lung fluid. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as a synonym LLT Wet lung of newborn under PT Transient tachypnoea of the newborn.

CR Number: 2022300016 **Implementation Date:** 01-Nov-22 Related CR: 2022300016

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Otomycosis*	Approved as Requested	Proposed LLT	
			Otomycosis	10088657 Current
			To PT	
			Otitis externa fungal	10052557

MSSO Comment: The proposal to add a new term Otomycosis is approved as requested. Otomycosis is an inflammatory process of the external ear canal due to infection with fungi and is responsible for roughly 10% of the diagnoses of otitis externa. Otomycosis will be added as synonym LLT to PT Otitis externa fungal.

CR Number: 2022301001 **Implementation Date:** 01-Nov-22 Related CR: 2022301001

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Xerophthalmia*	Rejected		
To PT	*Dry eye*			

MSSO Comment: The proposal to demote the PT Xerophthalmia under PT Dry eye is not approved. Generally, xerophthalmia may be caused by a number of conditions such as vitamin A deficiency; zinc deficiency, certain medications; and diseases such as diabetes, arthritis, and Sjogren's syndrome. In addition, the high frequency of the term in regulatory databases also makes it preferable to keep it as a stand alone concept at PT level.

Supplemental Update Report

CR Number: 2022301003 **Implementation Date:** 07-Nov-22 Related CR: 2022301003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Flap reinforcement of bronchial stump*	Approved as Requested	Proposed PT	
			Flap reinforcement of bronchial stump	10088681
			HLT primary	
			Bronchial and pulmonary therapeutic procedures	10006412
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Flap reinforcement of bronchial stump is approved as requested. Bronchial stump reinforcement with the intercostal muscle flap is only one of the many types of flaps used after pulmonary resection involving lower and lower-middle lobectomy. The role of the flap reinforcement of the bronchial stump (FRBS) is to enhance the blood supply to the level of the bronchial stump, thus preventing the dehiscence of the stump. Flap reinforcement of bronchial stump will be added as PT to HLT Bronchial and pulmonary therapeutic procedures.

CR Number: 2022303001 **Implementation Date:** 04-Nov-22 Related CR: 2022303001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Sputum suction operation*	Approved Not as Requested	Proposed LLT		
			Sputum suction procedure	10088668	Current
			To PT		
			Airway secretion clearance therapy	10074363	

MSSO Comment: The proposal to add a new LLT Sputum suction operation is approved but not as requested. Suctioning clears mucus accumulating in the airway, which is essential for proper breathing and to avoid contamination of secretions that favor a subsequent infection. The proposed term will be modified in accordance with MedDRA conventions, and added as a new sub-concept LLT Sputum suction procedure to the PT Airway secretion clearance therapy.

CR Number: 2022303002 **Implementation Date:** 04-Nov-22 Related CR: 2022303002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*RECURRENT LARYNGEAL NERVE INJURY*	Approved Not as Requested	Proposed LLT		
			Recurrent laryngeal nerve injury	10088669	Current
			To PT		
			Paralysis recurrent laryngeal nerve	10033830	

MSSO Comment: The proposal to add a new LLT RECURRENT LARYNGEAL NERVE INJURY is approved but not as requested. Recurrent laryngeal nerve injuries are a common cause of vocal cord paresis resulting in voice changes or hoarseness. Laryngeal nerve injuries virtually always manifest as palsy or paralysis. The proposed term will be renamed in accordance with MedDRA capitalization conventions, and added as the sub-concept LLT Recurrent laryngeal nerve injury under PT Paralysis recurrent laryngeal nerve. In a related change, secondary HLT Neurological and psychiatric procedural complications will be added to PT Paralysis recurrent laryngeal nerve.

Supplemental Update Report

CR Number: 2022308013 **Implementation Date:** 04-Nov-22 Related CR: 2022303002

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Paralysis recurrent laryngeal nerve*	Approved as Requested	Proposed PT	
			Paralysis recurrent laryngeal nerve	10033830
To HLT	*Neurological and psychiatric procedural complications*		To HLT	
			Neurological and psychiatric procedural complications	10029294

MSSO Comment:

CR Number: 2022304001 **Implementation Date:** 04-Nov-22 Related CR: 2022304001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Percutaneous Dilational Tracheostomy*	Approved Not as Requested	Proposed LLT	
			Percutaneous dilational tracheostomy	10088670 Current
			To PT	
			Tracheostomy	10044320

MSSO Comment: The proposal to add a new term Percutaneous Dilational Tracheostomy is approved but not as requested. Percutaneous dilational tracheostomy (PDT), also referred to as bedside tracheostomy, is the placement of a tracheostomy tube without direct surgical visualization of the trachea. This is considered a minimally invasive, bedside procedure that may be easily performed in the intensive care unit or at the patient's bedside – with continuous monitoring of the patient's vital signs. Percutaneous dilational tracheostomy, modified in accordance with MedDRA capitalisation conventions, will be added as sub-concept LLT to PT Tracheostomy.

CR Number: 2022304002 **Implementation Date:** 04-Nov-22 Related CR: 2022304002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Circulating Tumor Cell Count*	Approved Not as Requested	Proposed LLT	
			Circulating tumor cell count	10088674 Current
			To PT	
			Circulating tumour cell count	10088673

MSSO Comment: The proposal to add a new LLT Circulating Tumor Cell Count is approved but not as requested. Demonstration of circulating tumor cells is an important prognostic marker for metastatic cancers and of potential utility in early clinical development of drugs. Circulating tumor cell count, modified according to MedDRA capitalization conventions, will be added as LLT to the British spelled counterpart PT Circulating tumour cell count which will be added to HLT Cell marker analyses in a related change. Furthermore, PT Liquid biopsy will be demoted under the new PT Circulating tumour cell count.

Supplemental Update Report

CR Number: 2022308014 **Implementation Date:** 04-Nov-22 Related CR: 2022304002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Circulating tumour cell count*	Approved as Requested	Proposed PT	
HLT primary	*Cell marker analyses*		*Circulating tumour cell count*	10088673
SOC primary	*Investigations*		HLT primary	
			Cell marker analyses	10072981
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022308015 **Implementation Date:** 04-Nov-22 Related CR: 2022304002

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Liquid biopsy*	Approved as Requested	PT to merge	
To PT	*Circulating tumour cell count*		*Liquid biopsy*	10088130 Current
			To PT	
			Circulating tumour cell count	10088673

MSSO Comment:

CR Number: 2022304003 **Implementation Date:** 04-Nov-22 Related CR: 2022304003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Circulating Tumor Cell Count positive*	Approved Not as Requested	Proposed LLT	
			Circulating tumor cell count positive	10088675 Current
			To PT	
			Circulating tumour cell count positive	10088672

MSSO Comment: The proposal to add a new LLT Circulating Tumor Cell Count positive is approved but not as requested. Demonstration of circulating tumor cells is an important prognostic marker for metastatic cancers and of potential utility in early clinical development of drugs. Circulating tumor cell count positive, modified according to MedDRA capitalization conventions, will be added as LLT to the British spelled counterpart PT Circulating tumour cell count positive which will be added to HLT Cell marker analyses in a related change.

Supplemental Update Report

CR Number: 2022308016 **Implementation Date:** 04-Nov-22 Related CR: 2022304003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Circulating tumour cell count positive*	Approved as Requested	Proposed PT	
HLT primary	*Cell marker analyses*		*Circulating tumour cell count positive*	10088672
SOC primary	*Investigations*		HLT primary	
			Cell marker analyses	10072981
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022304004 **Implementation Date:** 04-Nov-22 Related CR: 2022304004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Circulating Tumor Cell Count negative*	Approved Not as Requested	Proposed LLT	
			Circulating tumor cell count negative	10088676 Current
			To PT	
			Circulating tumour cell count negative	10088671

MSSO Comment: The proposal to add a new LLT Circulating Tumor Cell Count negative is approved but not as requested. Demonstration of circulating tumor cells is an important prognostic marker for metastatic cancers and of potential utility in early clinical development of drugs. Circulating tumor cell count negative, modified according to MedDRA capitalization conventions, will be added as LLT to the British spelled counterpart PT Circulating tumour cell count negative which will be added to HLT Cell marker analyses in a related change.

CR Number: 2022308017 **Implementation Date:** 04-Nov-22 Related CR: 2022304004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Circulating tumour cell count negative*	Approved as Requested	Proposed PT	
HLT primary	*Cell marker analyses*		*Circulating tumour cell count negative*	10088671
SOC primary	*Investigations*		HLT primary	
			Cell marker analyses	10072981
			SOC primary	
			Investigations	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2022304005 **Implementation Date:** 04-Nov-22 Related CR: 2022304005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cholecystolithotomy*	Approved as Requested	Proposed LLT *Cholecystolithotomy*	10088678 Current
			To PT *Cholelithotomy*	10052925

MSSO Comment: The proposal to add a new term Cholecystolithotomy is approved as requested. Cholecystolithotomy, the incision of the gallbladder for removal of gallstones, will be added as sub-concept LLT to PT Cholelithotomy. In a related change, PT Choledocholithotomy will be demoted under PT Cholelithotomy as a sub-concept.

CR Number: 2022308018 **Implementation Date:** 04-Nov-22 Related CR: 2022304005

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Choledocholithotomy*	Approved as Requested	PT to merge *Choledocholithotomy*	10057601 Current
To PT	*Cholelithotomy*		To PT *Cholelithotomy*	10052925

MSSO Comment:

CR Number: 2022304006 **Implementation Date:** 04-Nov-22 Related CR: 2022304006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tonsil stones*	Approved as Requested	Proposed LLT *Tonsil stones*	10088679 Current
			To PT *Tonsillolith*	10063957

MSSO Comment: The proposal to add a new term Tonsil stones is approved as requested. Tonsil stones will be added as synonym LLT to PT Tonsillolith.

Supplemental Update Report

CR Number: 2022304007 **Implementation Date:** 04-Nov-22 Related CR: 2022304007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Teeth retainer*	Approved Not as Requested	Proposed LLT	
			Teeth retainer appliance	10088677 Current
			To PT	
			Oral appliance	10085270

MSSO Comment: The proposal to add a new term Teeth retainer is approved but not as requested. Teeth retainers are removable dental devices that fit over a person's upper or lower teeth, most often used to keep teeth in their correct alignment after braces. The requested term will be modified for clarification as a procedural concept and added as LLT Teeth retainer appliance to the recently added PT Oral appliance, which will be available for v26.1.

CR Number: 2022304125 **Implementation Date:** 04-Nov-22 Related CR: 2022304125

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Laparoscopic ovarian cystectomy*	Approved as Requested	Proposed LLT	
			Laparoscopic ovarian cystectomy	10088680 Current
			To PT	
			Ovarian cystectomy	10033137

MSSO Comment: The proposal to add a new term Laparoscopic ovarian cystectomy is approved as requested. Laparoscopic ovarian cystectomy is a type of keyhole surgery to remove a cyst from the ovary. The aim is to have minimal blood loss, to perform efficient surgery and to preserve ovarian tissue. Proposed term will be added as sub-concept LLT Laparoscopic ovarian cystectomy under PT Ovarian cystectomy.

CR Number: 2022304126 **Implementation Date:** 07-Nov-22 Related CR: 2022304126

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tear duct Calculus*	Approved Not as Requested	Proposed LLT	
			Tear duct calculus	10088682 Current
			To PT	
			Dacryolith	10011848

MSSO Comment: The proposal to add a new term Tear duct Calculus is approved but not as requested. Tear duct calculus or dacryoliths, are encountered in the canaliculi and sometimes in the excretory ducts of the lacrimal gland. Proposed term will be modified for MedDRA capitalization conventions and added as synonym LLT Tear duct calculus under PT Dacryolith.

Supplemental Update Report

CR Number: 2022305001 **Implementation Date:** 07-Nov-22 Related CR: 2022305001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ingrowing eye lash*	Approved as Requested	Proposed LLT	
			Ingrowing eye lash	10088683 Current
			To PT	
			Trichiasis	10044604

MSSO Comment: The proposal to add a new LLT Ingrowing eye lash is approved as requested. Trichiasis is when the eyelashes grow inward toward the eye. Proposed term will be added as synonym LLT Ingrowing eye lash under PT Trichiasis.

CR Number: 2022305002 **Implementation Date:** 07-Nov-22 Related CR: 2022305002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Combined CHF*	Approved Not as Requested	Proposed LLT	
			Combined congestive cardiac failure	10088684 Current
			To PT	
			Cardiac failure congestive	10007559

MSSO Comment: The proposal to add a new LLT Combined CHF is approved but not as requested. In systolic congestive heart failure, the ventricles cannot produce enough pressure in the contraction phase to push blood into circulation while in diastolic congestive heart failure, the ventricles cannot relax, expand, or fill with enough blood. Combined congestive heart failure is a combination of systolic and diastolic heart failure. Proposed term will be modified for MedDRA conventions and added as sub-concept LLT Combined congestive cardiac failure under PT Cardiac failure congestive.

CR Number: 2022305003 **Implementation Date:** 07-Nov-22 Related CR: 2022305003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Penicillin-susceptible staphylococcus aureus bacteremia*	Approved as Requested	Proposed LLT	
			Penicillin-susceptible staphylococcus aureus bacteremia	10088685 Current
			To PT	
			Staphylococcal bacteraemia	10051017

MSSO Comment: The proposal to add a new term Penicillin-susceptible staphylococcus aureus bacteremia is approved as requested. The requested term provides important information regarding treatment possibilities with antibiotics and will be added as LLT Penicillin-susceptible staphylococcus aureus bacteremia under PT Staphylococcal bacteraemia. In addition, the British English counterpart LLT Penicillin-susceptible staphylococcus aureus bacteraemia will also be added under PT Staphylococcal bacteraemia.

Supplemental Update Report

CR Number: 2022311004 **Implementation Date:** 07-Nov-22 Related CR: 2022305003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Penicillin-susceptible staphylococcus aureus bacteraemia*	Approved as Requested	Proposed LLT *Penicillin-susceptible staphylococcus aureus bacteraemia*	10088686	Current
To PT	*Staphylococcal bacteraemia*		To PT *Staphylococcal bacteraemia*	10051017	

MSSO Comment:

CR Number: 2022305008 **Implementation Date:** 07-Nov-22 Related CR: 2022305008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Complement activation-related pseudoallergy (CARPA)*	Approved Not as Requested	Proposed LLT *Complement activation-related pseudoallergy*	10088687	Current
			To PT *Anaphylactoid reaction*	10002216	

MSSO Comment: The proposal to add a new term Complement activation-related pseudoallergy (CARPA) is approved but not as requested. There is growing awareness of numerous drug-induced immediate hypersensitivity reactions which are not IgE mediated Type I category of drug allergies. Such non-IgE-mediated "pseudoallergic" reactions are primarily caused by certain Intravenous injection of a variety of nanotechnology enhanced (liposomal, micellar, polymer-conjugated) and protein-based (antibodies, enzymes) drugs and iodinated radiocontrast media with limited solubility in water. Since common features of those "pseudoallergens" include the capacity to activate the complement (C) system, these reactions have been called "C activation-related pseudoallergy" (CARPA). Complement activation-related pseudoallergy will be added as an LLT to PT Anaphylactoid reaction. In a related change, PT Pseudoallergic reaction will be demoted under PT Anaphylactoid reaction as a quasi synonym.

CR Number: 2022311001 **Implementation Date:** 07-Nov-22 Related CR: 2022305008

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*Pseudoallergic reaction*	Approved as Requested	PT to merge *Pseudoallergic reaction*	10084859	Current
To PT	*Anaphylactoid reaction*		To PT *Anaphylactoid reaction*	10002216	

MSSO Comment:

Supplemental Update Report

CR Number: 2022306001 **Implementation Date:** 07-Nov-22 Related CR: 2022306001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Serpentine supravenous hyperpigmentation*	Approved Not as Requested	Proposed PT	
To PT	*Skin hyperpigmentation*		*Serpentine supravenous hyperpigmentation*	10088688
			HLT primary	
			Hyperpigmentation disorders	10020713
			SOC primary	
			Skin and subcutaneous tissue disorders	10040785
			HLT secondary	
			Allergies to foods, food additives, drugs and other chemicals	10001737
			SOC secondary	
			Immune system disorders	10021428

MSSO Comment: The proposal to add a new LLT Serpentine supravenous hyperpigmentation to PT Skin hyperpigmentation is approved but not as requested. Serpentine supravenous hyperpigmentation is a peculiar cutaneous eruption that follows the path of vein after intravenous injection of the chemotherapeutic agent. The lesions gradually resolve spontaneously if administration of the offending agent is stopped through the affected limb. Serpentine supravenous hyperpigmentation warrants PT level and will be added as a PT with a primary link to HLT Hyperpigmentation disorders and a secondary link to HLT Allergies to foods, food additives, drugs and other chemicals.

CR Number: 2022307001 **Implementation Date:** 07-Nov-22 Related CR: 2022307001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*T rex appliance*	Rejected		

MSSO Comment: The proposal to add a new term T rex appliance is not approved. MedDRA refrains from adding trade-mark names. The type of treatment action performed by a T-rex appliance is already represented by the LLT/PT Maxillary expansion which was recently added and will be available for version 26.0.

Supplemental Update Report

CR Number: 2022307002 **Implementation Date:** 07-Nov-22 Related CR: 2022307002

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Obturators*	Approved Not as Requested	Proposed PT	
		Palatal obturator	10088689
		HLT primary	
		Palatal therapeutic procedures	10033527
		SOC primary	
		Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Obturators is approved but not as requested. An obturator is an prosthesis made for the upper jaw to close a defect in the palate. Removal of oral and sinus cancers will often result in an opening from the mouth into the sinus or nose. An obturator covers this areas and protects the opening from food and liquid. The proposed term will modified for greater clarity and its singular form as PT Palatal obturator to HLT Palatal therapeutic procedures.

CR Number: 2022307003 **Implementation Date:** 07-Nov-22 Related CR: 2022307003

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Pendex appliance*	Approved as Requested	Proposed LLT	
		Pendex appliance	10088690 Current
		To PT	
		Oral appliance	10085270

MSSO Comment: The proposal to add a new term Pendex appliance is approved as requested. Pendex is an appliance which corrects the transverse deficiency of maxillary teeth in addition to distalizing the upper molars. Once is fixed in place it uses an expansion screw to widen the upper jaw and push the upper teeth in a backward direction. Pendex appliance will be added as an LLT to PT Oral appliance.

CR Number: 2022307004 **Implementation Date:** 07-Nov-22 Related CR: 2022307004

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Lingual braces*	Approved as Requested	Proposed LLT	
		Lingual braces	10088691 Current
		To PT	
		Oral appliance	10085270

MSSO Comment: The proposal to add a new term Lingual braces is approved as requested. Lingual braces have the same components as conventional braces, but they are fixed in the lingual side of teeth arcade, which makes them nearly invisible for patients concerned with the esthetic impact caused with conventional braces. Lingual braces will be added as an LLT to PT Oral appliance. In a related change, Dental braces will also be added as an LLT to PT Oral appliance.

Supplemental Update Report

CR Number: 2022311002 **Implementation Date:** 07-Nov-22 Related CR: 2022307004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Dental braces*	Approved as Requested	Proposed LLT	
To PT	*Oral appliance*		*Dental braces*	10088692 Current
			To PT	
			Oral appliance	10085270

MSSO Comment:

CR Number: 2022307005 **Implementation Date:** 07-Nov-22 Related CR: 2022307005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Congenital toe deformity*	Approved as Requested	Proposed LLT	
			Congenital toe deformity	10088694 Current
			To PT	
			Congenital foot malformation	10062332

MSSO Comment: The proposal to add a new LLT Congenital toe deformity is approved as requested. Congenital foot deformities can affect feet, toes and/or ankles. Congenital toe deformity will be added as anatomical sub-concept LLT to the broad PT Congenital foot malformation.

CR Number: 2022307006 **Implementation Date:** 07-Nov-22 Related CR: 2022307006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cystic hygroma excision*	Rejected		

MSSO Comment: The proposal to add a new LLT Cystic hygroma excision is not approved. It is not feasible to add all possible combinations of lesion concepts with the associated surgical removal/excision as this may lead to overgranulation at PT level. Please see the Points to Consider section 3.13 Medical and Surgical Procedures for coding options of such combination terms.

Supplemental Update Report

CR Number: 2022307007 **Implementation Date:** 07-Nov-22 Related CR: 2022307007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Overgrowth syndrome*	Approved Not as Requested	Proposed PT	
			Overgrowth syndrome	10088693
			HLT primary	
			Congenital disorders NEC	10010445
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Cell metabolism disorders NEC	10057187
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to add a new LLT Overgrowth syndrome is approved but not as requested. Overgrowth syndromes are a heterogeneous group of rare disorders characterized by generalized or segmental excessive growth commonly associated with additional features, such as visceromegaly, macrocephaly and a large range of various symptoms. The grouping concept of Overgrowth syndrome will be added as PT to primary HLT Congenital disorders NEC, to secondary HLT Cell metabolism disorders NEC and to secondary HLT Soft tissue disorders NEC.

CR Number: 2022311003 **Implementation Date:** 07-Nov-22 Related CR: 2022307007

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Overgrowth syndrome*	Approved as Requested	Proposed PT	
To HLT	*Soft tissue disorders NEC*		*Overgrowth syndrome*	10088693
			To HLT	
			Soft tissue disorders NEC	10041288

MSSO Comment:

Supplemental Update Report

CR Number: 2022307008 **Implementation Date:** 09-Nov-22 Related CR: 2022307008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Purulent sinusitis*	Approved as Requested	Proposed LLT	
			Purulent sinusitis	10088712 Current
			To PT	
			Sinusitis	10040753

MSSO Comment: The proposal to add a new term Purulent sinusitis is approved as requested. Purulent sinusitis has symptoms as nasal congestion causing difficulty breathing due to blocked and obstructed nose, usually occurs on both sides, accompanied by runny nose. LLT Purulent sinusitis will be added under PT Sinusitis.

CR Number: 2022307009 **Implementation Date:** 09-Nov-22 Related CR: 2022307009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Milwaukee Shoulder Syndrome*	Approved Not as Requested	Proposed LLT	
HLT primary	*Crystal arthropathic disorders*		*Milwaukee shoulder syndrome*	10088713 Current
SOC primary	*Musculoskeletal and connective tissue disorders*		To PT	
			Hydroxyapatite crystal deposition disease	10085378

MSSO Comment: The proposal to add a new PT Milwaukee Shoulder Syndrome to primary HLT Crystal arthropathic disorders in SOC Musculoskeletal and connective tissue disorders is approved but not as requested. Milwaukee shoulder syndrome is the marked destruction of a joint within months after the onset of symptoms. Proposed term will be modified for MedDRA capitalization conventions and added as sub-concept LLT Milwaukee shoulder syndrome to PT Hydroxyapatite crystal deposition disease.

CR Number: 2022307010 **Implementation Date:** 09-Nov-22 Related CR: 2022307010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*T wave changes*	Approved as Requested	Proposed LLT	
			T wave changes	10088704 Current
			To PT	
			Electrocardiogram T wave abnormal	10050380

MSSO Comment: The proposal to add a new LLT T wave changes is approved as requested. Changes in T wave morphology can be indicative of various benign or pathologic conditions affecting the myocardium. T wave changes is a frequent expression in electrocardiography interpretation to refer to these changes. T wave changes will be added as LLT to PT Electrocardiogram T wave abnormal.

Supplemental Update Report

CR Number: 2022307011 **Implementation Date:** 09-Nov-22 Related CR: 2022307011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Bacterial haematological infection*	Approved Not as Requested	Proposed LLT *Bacterial haematological infection* To PT *Bacteraemia*	10088706 Current 10003997

MSSO Comment: The proposal to add a new PT Bacterial haematological infection is approved but not as requested. LLT Bacterial haematological infection and its American English spelled counterpart LLT Bacterial hematological infection will both be added under PT Bacteraemia as a quasi synonym.

CR Number: 2022313007 **Implementation Date:** 09-Nov-22 Related CR: 2022307011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT To PT	*Bacterial hematological infection* *Bacteraemia*	Approved as Requested	Proposed LLT *Bacterial hematological infection* To PT *Bacteraemia*	10088709 Current 10003997

MSSO Comment:

CR Number: 2022307012 **Implementation Date:** 09-Nov-22 Related CR: 2022307012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Fungal haematological infection*	Approved Not as Requested	Proposed LLT *Fungal haematological infection* To PT *Fungaemia*	10088707 Current 10017523

MSSO Comment: The proposal to add a new PT Fungal haematological infection is approved but not as requested. LLT Fungal haematological infection and its American English spelled counterpart LLT Fungal hematological infection will both be added under PT Fungaemia as a quasi synonym.

Supplemental Update Report

CR Number: 2022313008 **Implementation Date:** 09-Nov-22 Related CR: 2022307012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Fungal hematological infection*	Approved as Requested	Proposed LLT	
To PT	*Fungaemia*		*Fungal hematological infection*	10088710 Current
			To PT	
			Fungaemia	10017523

MSSO Comment:

CR Number: 2022307013 **Implementation Date:** 09-Nov-22 Related CR: 2022307013

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Viral haematological infection*	Approved Not as Requested	Proposed LLT	
			Viral haematological infection	10088705 Current
			To PT	
			Viraemia	10058874

MSSO Comment: The proposal to add a new PT Viral haematological infection is approved but not as requested. LLT Viral haematological infection and its American English spelled counterpart LLT Viral hematological infection will both be added under PT Viraemia as a quasi synonym.

CR Number: 2022313009 **Implementation Date:** 09-Nov-22 Related CR: 2022307013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Viral hematological infection*	Approved as Requested	Proposed LLT	
To PT	*Viraemia*		*Viral hematological infection*	10088711 Current
			To PT	
			Viraemia	10058874

MSSO Comment:

Supplemental Update Report

CR Number: 2022307014 **Implementation Date:** 09-Nov-22 Related CR: 2022307014

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site coldness*	Approved as Requested	Proposed PT	
			Vascular access site coldness	10088703
			HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Vascular complications associated with device	10069789
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Vascular access site coldness is approved as requested. Vascular access site coldness will be added as PT to primary HLT Cardiac and vascular procedural complications and secondary HLT Vascular complications associated with device to complement the set of vascular access site terms for coding purposes.

Supplemental Update Report

CR Number: 2022307015 **Implementation Date:** 09-Nov-22 Related CR: 2022307015

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site discomfort*	Approved as Requested	Proposed PT	
			Vascular access site discomfort	10088701
			HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Vascular complications associated with device	10069789
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Vascular access site discomfort is approved as requested. Vascular access site discomfort will be added as PT to primary HLT Cardiac and vascular procedural complications and secondary HLT Vascular complications associated with device to complement the set of vascular access site terms for coding purposes.

Supplemental Update Report

CR Number: 2022307016 **Implementation Date:** 09-Nov-22 Related CR: 2022307016

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site hyperaesthesia*	Approved as Requested	Proposed PT	
			Vascular access site hyperaesthesia	10088702
			HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Vascular complications associated with device	10069789
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Vascular access site hyperaesthesia is approved as requested. Vascular access site hyperaesthesia will be added as PT to primary HLT Cardiac and vascular procedural complications, secondary HLT Vascular complications associated with device and secondary HLT Paraesthesias and dysaesthesias to complement the set of vascular access site terms for coding purposes. In a related change, American spelled counterpart LLT Vascular access site hyperesthesia will be added to the new PT Vascular access site hyperaesthesia

CR Number: 2022313006 **Implementation Date:** 09-Nov-22 Related CR: 2022307016

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vascular access site hyperesthesia*	Approved as Requested	Proposed LLT	
To PT	*Vascular access site hyperaesthesia*		*Vascular access site hyperesthesia*	10088708 Current
			To PT	
			Vascular access site hyperaesthesia	10088702

MSSO Comment:

Supplemental Update Report

CR Number: 2022313029 **Implementation Date:** 09-Nov-22 Related CR: 2022307016

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site hyperaesthesia*	Approved as Requested	Proposed PT	
To HLT	*Paraesthesias and dysaesthesias*		*Vascular access site hyperaesthesia*	10088702
			To HLT	
			Paraesthesias and dysaesthesias	10033788

MSSO Comment:

CR Number: 2022307017 **Implementation Date:** 09-Nov-22 Related CR: 2022307017

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site scar*	Approved as Requested	Proposed PT	
			Vascular access site scar	10088695
			HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Vascular complications associated with device	10069789
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Vascular access site scar is approved as requested. Vascular access site scar will be added as PT to primary HLT Cardiac and vascular procedural complications and secondary HLT Vascular complications associated with device and HLT Skin injuries and mechanical dermatoses to complement the set of vascular access site terms for coding purposes.

Supplemental Update Report

CR Number: 2022313026 **Implementation Date:** 09-Nov-22 Related CR: 2022307017

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site scar*	Approved as Requested	Proposed PT	
To HLT	*Skin injuries and mechanical dermatoses*		*Vascular access site scar*	10088695
			To HLT	
			Skin injuries and mechanical dermatoses	10040877

MSSO Comment:

CR Number: 2022307018 **Implementation Date:** 09-Nov-22 Related CR: 2022307018

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site pallor*	Approved as Requested	Proposed PT	
			Vascular access site pallor	10088699
			HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Vascular complications associated with device	10069789
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Vascular access site pallor is approved as requested. Vascular access site pallor will be added as PT to primary HLT Cardiac and vascular procedural complications and secondary HLT Vascular complications associated with device and secondary HLT Dermal and epidermal conditions NEC to complement the set of vascular access site terms for coding purposes.

Supplemental Update Report

CR Number: 2022313027 **Implementation Date:** 09-Nov-22 Related CR: 2022307018

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site pallor*	Approved as Requested	Proposed PT	
To HLT	*Dermal and epidermal conditions NEC*		*Vascular access site pallor*	10088699
			To HLT	
			Dermal and epidermal conditions NEC	10012424

MSSO Comment:

CR Number: 2022307019 **Implementation Date:** 09-Nov-22 Related CR: 2022307019

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site laceration*	Approved as Requested	Proposed PT	
			Vascular access site laceration	10088696
			HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Vascular complications associated with device	10069789
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Vascular access site laceration is approved as requested. Vascular access site laceration will be added as PT to primary HLT Cardiac and vascular procedural complications and secondary HLT Vascular complications associated with device and HLT Skin injuries and mechanical dermatoses to complement the set of vascular access site terms for coding purposes.

Supplemental Update Report

CR Number: 2022313028 **Implementation Date:** 09-Nov-22 Related CR: 2022307019

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site laceration*	Approved as Requested	Proposed PT	
To HLT	*Skin injuries and mechanical dermatoses*		*Vascular access site laceration*	10088696
			To HLT	
			Skin injuries and mechanical dermatoses	10040877

MSSO Comment:

CR Number: 2022307020 **Implementation Date:** 09-Nov-22 Related CR: 2022307020

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site warmth*	Approved as Requested	Proposed PT	
			Vascular access site warmth	10088697
			HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Vascular complications associated with device	10069789
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Vascular access site warmth is approved as requested. Vascular access site warmth will be added as PT to primary HLT Cardiac and vascular procedural complications and secondary HLT Vascular complications associated with device to complement the set of vascular access site terms for coding purposes.

Supplemental Update Report

CR Number: 2022307021 **Implementation Date:** 09-Nov-22 Related CR: 2022307021

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site fibrosis*	Approved as Requested	Proposed PT	
			Vascular access site fibrosis	10088698
			HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Vascular complications associated with device	10069789
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Vascular access site fibrosis is approved as requested. Vascular access site fibrosis will be added as PT to primary HLT Cardiac and vascular procedural complications and secondary HLT Vascular complications associated with device to complement the set of vascular access site terms for coding purposes.

Supplemental Update Report

CR Number: 2022307022 **Implementation Date:** 09-Nov-22 Related CR: 2022307022

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site injury*	Approved as Requested	Proposed PT	
			Vascular access site injury	10088700
			HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Vascular complications associated with device	10069789
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Vascular access site injury is approved as requested. Vascular access site injury will be added as PT to primary HLT Cardiac and vascular procedural complications and secondary HLT Vascular complications associated with device to complement the set of vascular access site terms for coding purposes.

CR Number: 2022307023 **Implementation Date:** 09-Nov-22 Related CR: 2022307023

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Red blood cell macrocytes*	Rejected		
Replacement term	*Red blood cell macrocytes test*			

MSSO Comment: The proposal to rename PT/LLT Red blood cell macrocytes to Red blood cell macrocytes test is not approved. The names alone for investigative terms are appropriate and do not need always "test" or essay etc. see MedDRA Introductory Guide - 6.13.2 Conventions and Exceptions; Unqualified terms (e.g., PT Blood glucose) are intended to be used to record test names and point to an actual value in a separate database field.

Supplemental Update Report

CR Number: **2022307024** **Implementation Date:** 09-Nov-22 Related CR: 2022307024

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Urinary occult blood test*	Rejected		
From PT	*Urinary occult blood*			

MSSO Comment: The proposal to promote the LLT Urinary occult blood test from PT Urinary occult blood is not approved. As occult blood only can be detected through the chemicals used in occult blood tests, the existing PT Urinary occult blood, linked to HLT Urinalysis NEC to the SOC Investigations is not to be seen as an adverse event. In addition, the LLT Urinary occult blood test under the PT Urinary occult blood provides clarity of the concept as a test term.

CR Number: **2022307025** **Implementation Date:** 09-Nov-22 Related CR: 2022307025

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*V-Y advancement flap*	Approved as Requested	Proposed LLT	
From PT	*Hand repair operation*		*V-Y advancement flap*	10087653 Current
To PT	*Soft tissue flap operation*		From PT	
			Hand repair operation	10019118
			To PT	
			Soft tissue flap operation	10072998

MSSO Comment: The proposal to move the LLT V-Y advancement flap from PT Hand repair operation to PT Soft tissue flap operation is approved as requested. The V-Y advancement flap is often used not only for facial circular defects but also for defects of the trunk and extremities. Its advantages are less scarring and superior aesthetic results as compared with other local flap methods, because of less scarification of adjacent tissue.

CR Number: **2022307026** **Implementation Date:** 09-Nov-22 Related CR: 2022307026

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cervical decompression surgery*	Approved as Requested	Proposed LLT	
			Cervical decompression surgery	10088723 Current
			To PT	
			Spinal decompression	10041563

MSSO Comment: The proposal to add a new term Cervical decompression surgery is approved as requested. Cervical decompression surgery is a procedure that removes any structures compressing the nerves in the cervical section of the spine. Proposed term will be added as subconcept LLT Cervical decompression surgery under PT Spinal decompression.

Supplemental Update Report

CR Number: 2022307027 **Implementation Date:** 09-Nov-22 Related CR: 2022307027

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*RIF test*	Approved Not as Requested	Proposed LLT	
			MTB/RIF	10088724 Current
			To PT	
			Mycobacterium tuberculosis complex test	10070472

MSSO Comment: The proposal to add a new term RIF test is approved but not as requested. Mycobacterium tuberculosis complex-rifampin resistant test is an automated diagnostic test that can identify mycobacterium tuberculosis complex and genetic mutations associated with resistance to rifampin. The proposed term will be modified and added as LLT MTB/RIF test to PT Mycobacterium tuberculosis complex test. In a related change, the spelled out concept will be added as LLT Mycobacterium tuberculosis complex-rifampin resistant test to PT Mycobacterium tuberculosis complex test.

CR Number: 2022313019 **Implementation Date:** 09-Nov-22 Related CR: 2022307027

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Mycobacterium tuberculosis complex-rifampin resistant test*	Approved as Requested	Proposed LLT	
			Mycobacterium tuberculosis complex-rifampin resistant test	10088725 Current
To PT	*Mycobacterium tuberculosis complex test*		To PT	
			Mycobacterium tuberculosis complex test	10070472

MSSO Comment:

CR Number: 2022307028 **Implementation Date:** 09-Nov-22 Related CR: 2022307028

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tongue base mucosectomy*	Approved as Requested	Proposed PT	
			Tongue base mucosectomy	10088726
			HLT primary	
			Tongue therapeutic procedures	10043968
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Tongue base mucosectomy is approved as requested. In tongue base mucosectomy laser microsurgery or transoral robotic surgery of the base of tongue are two modalities that are being increasingly utilized to help identify the site of the primary tumor in cases of metastatic cervical lymphadenopathy from an unknown primary origin, in order to minimize the potential morbidity from treatment by reducing the radiation field. Tongue base mucosectomy will be added as PT to HLT Tongue therapeutic procedures.

Supplemental Update Report

CR Number: 2022308001 **Implementation Date:** 09-Nov-22 Related CR: 2022308001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Fecal immunochemical test*	Approved as Requested	Proposed LLT	
To PT	*Occult blood*		*Fecal immunochemical test*	10088719 Current
			To PT	
			Occult blood	10061878

MSSO Comment: The proposal to add a new LLT Fecal immunochemical test to PT Occult blood is approved as requested. Fecal immunochemical test and the British English spelled counterpart LLT Faecal immunochemical test will be added as sub-concept LLTs to PT Occult blood.

CR Number: 2022313030 **Implementation Date:** 09-Nov-22 Related CR: 2022308001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Faecal immunochemical test*	Approved as Requested	Proposed LLT	
To PT	*Occult blood*		*Faecal immunochemical test*	10088722 Current
			To PT	
			Occult blood	10061878

MSSO Comment:

CR Number: 2022308002 **Implementation Date:** 09-Nov-22 Related CR: 2022308002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*CD4 lymphocyte percentage*	Approved as Requested	Proposed PT	
			CD4 lymphocyte percentage	10088715
			HLT primary	
			White blood cell analyses	10047938
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT CD4 lymphocyte percentage is approved as requested. CD4 lymphocyte percentage will be added as PT to HLT White blood cell analyses to provide the unqualified test term.

Supplemental Update Report

CR Number: 2022308003 **Implementation Date:** 09-Nov-22 Related CR: 2022308003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Globotriaosylsphingosine*	Approved as Requested	Proposed PT	
			Globotriaosylsphingosine	10088718
			HLT primary	
			Lysosomal enzyme analyses	10025368
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Globotriaosylsphingosine is approved as requested. Globotriaosylsphingosine, as a biomarker for cardiac variant of Fabry disease, will be added as PT to HLT Lysosomal enzyme analyses to provide the unqualified test term.

CR Number: 2022308004 **Implementation Date:** 09-Nov-22 Related CR: 2022308004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Jugular venous wave*	Approved Not as Requested	Proposed LLT	
To PT	*Pulse waveform*		*Jugular venous waveform*	10088721 Current
			To PT	
			Pulse waveform	10061488

MSSO Comment: The proposal to add a new LLT Jugular venous wave to PT Pulse waveform is approved but not as requested. The requested term will be modified and added as sub-concept LLT Jugular venous waveform to PT Pulse waveform.

CR Number: 2022308005 **Implementation Date:** 09-Nov-22 Related CR: 2022308005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Stenotrophomonas test*	Approved as Requested	Proposed PT	
			Stenotrophomonas test	10088716
			HLT primary	
			Bacteria identification and serology (excl mycobacteria)	10004000
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Stenotrophomonas test is approved as requested. Stenotrophomonas test will be added as PT to HLT Bacteria identification and serology (excl mycobacteria) to provide the unqualified test term.

Supplemental Update Report

CR Number: 2022308006 **Implementation Date:** 09-Nov-22 Related CR: 2022308006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Stenotrophomonas maltophilia test*	Approved Not as Requested	Proposed LLT	
			Stenotrophomonas maltophilia test	10088720 Current
			To PT	
			Stenotrophomonas test	10088716

MSSO Comment: The proposal to add a new PT Stenotrophomonas maltophilia test is approved but not as requested. Stenotrophomonas maltophilia test will be added as LLT to the newly added PT Stenotrophomonas test, added in change request 2022308005.

CR Number: 2022308007 **Implementation Date:** 09-Nov-22 Related CR: 2022308007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Thrombomodulin*	Approved as Requested	Proposed PT	
			Thrombomodulin	10088714
			HLT primary	
			Coagulation and bleeding analyses	10009728
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Thrombomodulin is approved as requested. Thrombomodulin will be added as a PT to HLT Coagulation and bleeding analyses to provide the unqualified test term.

CR Number: 2022308008 **Implementation Date:** 09-Nov-22 Related CR: 2022308008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*CD19 antigen*	Approved as Requested	Proposed PT	
			CD19 antigen	10088717
			HLT primary	
			Cell marker analyses	10072981
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT CD19 antigen is approved as requested. CD19 antigen will be added as PT to HLT Cell marker analyses to provide the unqualified test term.

Supplemental Update Report

CR Number: 2022308019 **Implementation Date:** 09-Nov-22 Related CR: 2022308019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tecartherapy*	Approved as Requested	Proposed LLT *Tecartherapy*	10088731 Current
			To PT *Diathermy*	10012762

MSSO Comment: The proposal to add a new LLT Tecartherapy is approved as requested. Tecartherapy or Capacitive-resistive electric transfer is a electrophysical energy within the radiofrequency spectrum which consists of oscillating energy at specific frequencies generating therapeutic heat in body tissues, a technique known as diathermy. Tecartherapy will be added as an LLT to PT Diathermy. In a related change, Capacitive-resistive electric transfer will also be added as an LLT to PT Diathermy.

CR Number: 2022313020 **Implementation Date:** 09-Nov-22 Related CR: 2022308019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Capacitive-resistive electric transfer*	Approved as Requested	Proposed LLT *Capacitive-resistive electric transfer*	10088732 Current
To PT	*Diathermy*		To PT *Diathermy*	10012762

MSSO Comment:

CR Number: 2022308020 **Implementation Date:** 09-Nov-22 Related CR: 2022308020

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Odontoplerosis*	Approved as Requested	Proposed LLT *Odontoplerosis*	10088729 Current
			To PT *Tooth restoration*	10085637

MSSO Comment: The proposal to add a new term Odontoplerosis is approved as requested. Odontoplerosis, is a rarely used term, defined as the operation of filling or plugging a cavity in a tooth, and will be added as an LLT to PT Tooth restoration.

Supplemental Update Report

CR Number: 2022308021 **Implementation Date:** 09-Nov-22 Related CR: 2022308021

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Hypersplenotrophy*	Approved as Requested	Proposed LLT	
			Hypersplenotrophy	10088730 Current
			To PT	
			Splenomegaly	10041660

MSSO Comment: The proposal to add a new term Hypersplenotrophy is approved as requested. Hypersplenotrophy is an infrequently used synonym of splenomegaly, and will be placed as LLT to PT Splenomegaly.

CR Number: 2022308022 **Implementation Date:** 09-Nov-22 Related CR: 2022308022

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Bile duct transection*	Approved as Requested	Proposed PT	
			Bile duct transection	10088727
			HLT primary	
			Gastrointestinal and hepatobiliary procedural complications	10017927
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Structural and other bile duct disorders	10042257
			SOC secondary	
			Hepatobiliary disorders	10019805

MSSO Comment: The proposal to add a new term Bile duct transection is approved as requested. Complete transection of the common bile duct is a dramatic and often extremely difficult-to-repair event after surgery. Abdominal biliary fluid collection or jaundice is the initial symptom, and ERCP is the determinant for diagnosis. Bile duct transection will be added as a PT with a primary link to HLT Gastrointestinal and hepatobiliary procedural complications and a secondary link to HLT Structural and other bile duct disorders.

Supplemental Update Report

CR Number: 2022308023 **Implementation Date:** 09-Nov-22 Related CR: 2022308023

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Core decompression*	Approved as Requested	Proposed PT	
			Core decompression	10088728
			HLT primary	
			Bone therapeutic procedures NEC	10006000
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Core decompression is approved as requested. Core decompression is a surgical procedure that involves surgical drilling into the area of dead bone near the joint. This reduces pressure, allows for increased blood flow, and slows or stops bone and/or joint destruction. Core decompression is commonly performed to treat osteonecrosis. Core decompression will be added as PT linked to HLT Bone therapeutic procedures NEC. In a related change, the recently added PT Femoral core decompression will be demoted under this new PT Core decompression.

CR Number: 2022313031 **Implementation Date:** 09-Nov-22 Related CR: 2022308023

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Femoral core decompression*	Approved as Requested	PT to merge	
To PT	*Core decompression*		*Femoral core decompression*	10088597 Current
			To PT	
			Core decompression	10088728

MSSO Comment:

CR Number: 2022308024 **Implementation Date:** 09-Nov-22 Related CR: 2022308024

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Allergic rhinitis aggravated*	Rejected		

MSSO Comment: The proposal to add a new term Allergic rhinitis aggravated is not approved. MedDRA cannot accommodate a separate term for an aggravated state of every potential disease or condition.

Supplemental Update Report

CR Number: 2022308025 **Implementation Date:** 11-Nov-22 Related CR: 2022308025

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ataxia with Vitamin E Deficiency*	Approved Not as Requested	Proposed PT	
			Ataxia with vitamin E deficiency	10088735
			HLT primary	
			Neurological disorders congenital NEC	10029300
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Coordination and balance disturbances	10072984
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Ataxia with Vitamin E Deficiency is approved but not as requested. Ataxia with vitamin E deficiency is a progressive disease affecting motor control and movement. Symptoms include dysarthria, ataxia, numbness in the hands and feet (peripheral neuropathy), and progressive leg weakness. Some patients may experience vision loss. Ataxia with vitamin E deficiency is caused by a genetic change to the TTPA gene. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as PT Ataxia with vitamin E deficiency with primary link to HLT Neurological disorders congenital NEC and secondary links to HLT Coordination and balance disturbances and HLT Fat soluble vitamin deficiencies and disorders.

CR Number: 2022315017 **Implementation Date:** 11-Nov-22 Related CR: 2022308025

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ataxia with vitamin E deficiency*	Approved as Requested	Proposed PT	
To HLT	*Fat soluble vitamin deficiencies and disorders*		*Ataxia with vitamin E deficiency*	10088735
			To HLT	
			Fat soluble vitamin deficiencies and disorders	10016250

MSSO Comment:

Supplemental Update Report

CR Number: 2022312001 **Implementation Date:** 11-Nov-22 Related CR: 2022312001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Nasal cavity lesion excision*	Rejected		

MSSO Comment: The proposal to add a new term Nasal cavity lesion excision is not approved. MedDRA cannot provide for all possible lesion terms procedural equivalent for removal/excision as this may lead to overgranularity at PT level. Furthermore, external nose lesion excision is an inherited term from older terminologies and would not have been accepted for a later addition to MedDRA.

CR Number: 2022312003 **Implementation Date:** 11-Nov-22 Related CR: 2022312003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Hypervascular liver lesions*	Rejected		

MSSO Comment: The proposal to add a new term Hypervascular liver lesions is not approved. Hypervascular liver lesions are a radiological finding which may refer to different pathologies. The MSSO generally refrains from adding imprecise 'lesion' terms.

CR Number: 2022312004 **Implementation Date:** 11-Nov-22 Related CR: 2022312004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Intraoperative cardiac valve injury*	Approved as Requested	Proposed LLT	
			Intraoperative cardiac valve injury	10088741 Current
To PT	*Cardiac procedure complication*		To PT	
			Cardiac procedure complication	10057461

MSSO Comment: The proposal to add a new LLT Intraoperative cardiac valve injury to PT Cardiac procedure complication is approved as requested. Injuries to cardiac valves may occur during transcatheter heart valve surgery, for example, iatrogenic injury to the mitral valve during transcatheter aortic valve replacement.

Supplemental Update Report

CR Number: 2022312005 **Implementation Date:** 11-Nov-22 Related CR: 2022312005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anterior capsule opacification*	Approved as Requested	Proposed PT	
HLT primary	*Lens structural change, deposit and degeneration (excl cataracts)*		*Anterior capsule opacification*	10088740
SOC primary	*Eye disorders*		HLT primary	
			Lens structural change, deposit and degeneration (excl cataracts)	10024210
			SOC primary	
			Eye disorders	10015919
			HLT secondary	
			Eye and ear procedural complications	10015908
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Anterior capsule opacification to primary HLT Lens structural change, deposit and degeneration (excl cataracts) and secondary HLT Eye and ear procedural complications is approved as requested. Residual lens epithelial cells can proliferate and cause opacification in the anterior or posterior lens capsule. Opacification of the residual anterior capsule occurs by the first postoperative month and continues until 6 months, frequently in association with Anterior capsule contraction (also a PT in MedDRA with the same mapping). It is distinct from posterior capsule opacification (referred to as 'secondary cataract' or 'after cataract'), which develops over the clear posterior capsule a few months to a few years after an uneventful cataract surgery. PT Posterior capsule opacification is already in MedDRA.

CR Number: 2022313001 **Implementation Date:** 11-Nov-22 Related CR: 2022313001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Sporothrix Antibody Test*	Approved Not as Requested	Proposed LLT	
			Sporothrix antibody test	10088738 Current
			To PT	
			Sporothrix test	10088736

MSSO Comment: The proposal to add a new LLT Sporothrix Antibody Test is approved but not as requested. Sporotrichosis is an endemic fungal infection caused by the dimorphic fungus Sporothrix schenckii. Extracutaneous infections, including disseminated and articular infections, produce positive antibody tests. The requested term will be modified according to MedDRA capitalization conventions and added as LLT Sporothrix antibody test to a new PT Sporothrix test, which will be added, in a related change to HLT Fungus identification and serology.

Supplemental Update Report

CR Number: 2022315018 **Implementation Date:** 11-Nov-22 Related CR: 2022313001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Sporothrix test*	Approved as Requested	Proposed PT	
HLT primary	*Fungus identification and serology*		*Sporothrix test*	10088736
SOC primary	*Investigations*		HLT primary	
			Fungus identification and serology	10017545
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022313002 **Implementation Date:** 11-Nov-22 Related CR: 2022313002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Sporothrix Antibody Positive*	Approved Not as Requested	Proposed LLT		
			Sporothrix antibody positive	10088739	Current
			To PT		
			Sporothrix test positive	10088737	

MSSO Comment: The proposal to add a new LLT Sporothrix Antibody Positive is approved but not as requested. Sporotrichosis is an endemic fungal infection caused by the dimorphic fungus Sporothrix schenckii. Extracutaneous infections, including disseminated and articular infections, produce positive antibody tests. The requested term will be modified according to MedDRA capitalization conventions and added as LLT Sporothrix antibody positive to a new PT Sporothrix test positive, which will be added, in a related change to HLT Fungus identification and serology.

CR Number: 2022315019 **Implementation Date:** 11-Nov-22 Related CR: 2022313002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Sporothrix test positive*	Approved as Requested	Proposed PT	
HLT primary	*Fungus identification and serology*		*Sporothrix test positive*	10088737
SOC primary	*Investigations*		HLT primary	
			Fungus identification and serology	10017545
			SOC primary	
			Investigations	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2022313003 **Implementation Date:** 11-Nov-22 Related CR: 2022313003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spinal arteriovenous fistula*	Approved Not as Requested	Proposed LLT	
			Spinal arteriovenous fistula	10088734 Current
			To PT	
			Dural arteriovenous fistula	10074462

MSSO Comment: The proposal to add a new PT Spinal arteriovenous fistula is approved but not as requested. Spinal arteriovenous fistula is a type of dural arteriovenous fistula, which is an abnormal connection between an artery and a vein in the dura mater. Proposed term will be added as subconcept LLT Spinal arteriovenous fistula under PT Dural arteriovenous fistula.

CR Number: 2022313004 **Implementation Date:** 11-Nov-22 Related CR: 2022313004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Enterococcus test negative*	Approved as Requested	Proposed PT	
			Enterococcus test negative	10088733
			HLT primary	
			Bacteria identification and serology (excl mycobacteria)	10004000
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Enterococcus test negative is approved as requested. Proposed term will be added as PT Enterococcus test negative under HLT Bacteria identification and serology (excl mycobacteria) to represent a negative test result.

CR Number: 2022313005 **Implementation Date:** 11-Nov-22 Related CR: 2022313005

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Broken Capillary*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Broken Capillary to non-current is not approved. Even if it is most times used to refer to either the hair or the smallest blood vessels, the word capillary is also used to refer to very thin structures (thin as a hair). Therefore, in the case of the LLT Capillary fracture, the word “capillary” is acting as a qualifier of the central fracture concept fracture (a very thin fracture, without separation). On the contrary, in the LLT Broken capillary, the word “capillary” is the central concept, referring to the smallest blood vessels; the word “broken” being the qualifier here. In sum, “capillary” is a modifier in the first case and a name in the second, making changes around status or addition of new terms unnecessary.

Supplemental Update Report

CR Number: 2022313010 **Implementation Date:** 15-Nov-22 Related CR: 2022313010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tongue bifurcation*	Approved Not as Requested	Proposed LLT	
			Deliberate tongue bifurcation	10088755 Current
			To PT	
			Body modification	10085246

MSSO Comment: The proposal to add a new term Tongue bifurcation is approved but not as requested. Tongue bifurcation, splitting or forking, is a type of body modification in which the tongue is cut centrally from its tip to as far back as the underside base, forking the end. Deliberate tongue splitting is a cosmetic body modification procedure that results in a 'lizard-like' bifid tongue. The requested term will be modified to distinguish from e.g. congenital bifid tongues or as a complication of piercing and added as an LLT Deliberate tongue bifurcation to PT Body modification.

CR Number: 2022313011 **Implementation Date:** 15-Nov-22 Related CR: 2022313011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ligament reconstruction and tendon interposition*	Approved as Requested	Proposed LLT	
			Ligament reconstruction and tendon interposition	10088753 Current
			To PT	
			Ligament operation	10065122

MSSO Comment: The proposal to add a new term Ligament reconstruction and tendon interposition is approved as requested. Ligament reconstruction and tendon interposition is standard technique for carpometacarpal arthroplasty. Ligament reconstruction and tendon interposition will be added as sub-concept LLT to PT Ligament operation.

CR Number: 2022313012 **Implementation Date:** 15-Nov-22 Related CR: 2022313012

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Intentional partial odontectomy*	Approved as Requested	Proposed LLT	
			Intentional partial odontectomy	10088757 Current
			To PT	
			Coronectomy	10088756

MSSO Comment: The proposal to add a new term Intentional partial odontectomy is approved as requested. Intentional partial odontectomy is defined as removing the crown of the lower wisdom tooth, whilst keeping the roots in place. To reduce the risk of inferior alveolar nerve injury, Intentional partial odontectomy, may be chosen alternatively to complete surgical extraction of the third molars. Intentional partial odontectomy will be added as LLT to a new PT Coronectomy, the more prevalent term for this concept, which will be added in a related change and linked to HLT Dental and gingival therapeutic procedures.

Supplemental Update Report

CR Number: 2022319021 **Implementation Date:** 15-Nov-22 Related CR: 2022313012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Coronectomy*	Approved as Requested	Proposed PT	
			Coronectomy	10088756
HLT primary	*Dental and gingival therapeutic procedures*		HLT primary	
			Dental and gingival therapeutic procedures	10012317
SOC primary	*Surgical and medical procedures*		SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment:

CR Number: 2022313013 **Implementation Date:** 15-Nov-22 Related CR: 2022313013

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Endometrial thinning*	Approved as Requested	Proposed PT	
			Endometrial thinning	10088752
			HLT primary	
			Uterine disorders NEC	10013376
			SOC primary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new term Endometrial thinning is approved as requested. Estrogen hormone is extremely vital in keeping endometrium thick, salutary and blood-rich. Inadequate level of estrogen results in thin endometrium. If a uterine lining or endometrium is a minimum thickness of 8 mm, it is considered satisfactory. Anything less than 7 mm is called thin endometrium. Endometrial thinning will be added as PT to HLT Uterine disorders NEC, aligned with PT Endometrial thickening.

CR Number: 2022313014 **Implementation Date:** 15-Nov-22 Related CR: 2022313014

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Sacral insufficiency fractures*	Approved Not as Requested	Proposed LLT	
			Sacral insufficiency fracture	10088754 Current
			To PT	
			Stress fracture	10042212

MSSO Comment: The proposal to add a new term Sacral insufficiency fractures is approved but not as requested. Sacral insufficiency fractures are a subtype of stress fractures, which are the result of normal stresses on abnormal bone, most frequently seen in the setting of osteoporosis. They fall under the broader group of pelvic insufficiency fractures. The requested term will be added in the singular form as LLT Sacral insufficiency fracture to PT Stress fracture, aligned with LLT Pelvic insufficiency fracture.

Supplemental Update Report

CR Number: 2022313015 **Implementation Date:** 15-Nov-22 Related CR: 2022313015

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Retropharyngeal hematoma*	Approved as Requested	Proposed LLT *Retropharyngeal hematoma* To PT *Pharyngeal haematoma*	10088750 Current 10068121

MSSO Comment: The proposal to add a new term Retropharyngeal hematoma is approved as requested. A retropharyngeal hematoma forms when blood collects in the retropharyngeal space. It can be an immediate life-threatening emergency, with potential for airway compromise. Retropharyngeal hematoma will be added as LLT to PT Pharyngeal haematoma. In a related change, the British spelled LLT Retropharyngeal haematoma will also be added to PT Pharyngeal haematoma.

CR Number: 2022319018 **Implementation Date:** 15-Nov-22 Related CR: 2022313015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT To PT	*Retropharyngeal haematoma* *Pharyngeal haematoma*	Approved as Requested	Proposed LLT *Retropharyngeal haematoma* To PT *Pharyngeal haematoma*	10088751 Current 10068121

MSSO Comment:

CR Number: 2022313016 **Implementation Date:** 15-Nov-22 Related CR: 2022313016

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Paeniclostridium sordellii infection*	Approved as Requested	Proposed LLT *Paeniclostridium sordellii infection* To PT *Clostridial infection*	10088749 Current 10061043

MSSO Comment: The proposal to add a new term Paeniclostridium sordellii infection is approved as requested. Paeniclostridium sordellii (previously Clostridium sordellii) is a rare anaerobic, gram-positive, spore-forming rod capable of causing pneumonia, endocarditis, arthritis, peritonitis, and myonecrosis. It has also been described in post-partum females and medically induced abortions with very high mortality rate. Paeniclostridium sordellii infection will be added as LLT under PT Clostridial infection. In a related change, the spelling for LLT C.sordelli colitis will be replaced with LLT C.sordellii colitis and LLT Clostridium sordelli colitis will be replaced with LLT Clostridium sordellii colitis.

Supplemental Update Report

CR Number: 2022319019 **Implementation Date:** 15-Nov-22 Related CR: 2022313016

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Rename PT/LLT				
Term to modify	*Clostridium sordelli colitis*	Approved as Requested	Term to modify	
			Clostridium sordelli colitis	10009662
Replacement term	*Clostridium sordellii colitis*		Replacement term	
			Clostridium sordellii colitis	10009662 Current

MSSO Comment:

CR Number: 2022319020 **Implementation Date:** 15-Nov-22 Related CR: 2022313016

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Rename PT/LLT				
Term to modify	*C.sordelli colitis*	Approved as Requested	Term to modify	
			C.sordelli colitis	10006839
Replacement term	*C.sordellii colitis*		Replacement term	
			C.sordellii colitis	10006839 Current

MSSO Comment:

Supplemental Update Report

CR Number: 2022313017 **Implementation Date:** 15-Nov-22 Related CR: 2022313017

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Mucocutaneous separation*	Approved Not as Requested	Proposed PT	
			Stoma site mucocutaneous separation	10088747
			HLT primary	
			Stoma complications	10074475
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Skin and subcutaneous conditions NEC	10042356
			SOC secondary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new term Mucocutaneous separation is approved but not as requested. A stoma mucoutaneous separation is the separation of the sutured junction between the stoma and the skin, which occurs more frequently in patients with compromised healing due to steroid therapy, diabetes, infection, radiation to the abdominal area, etc. The proposed term will be modified for greater clarity and added as PT Stoma site mucocutaneous separation with to primary HLT Stoma complications and to secondary HLT Skin and subcutaneous conditions NEC.

CR Number: 2022313018 **Implementation Date:** 15-Nov-22 Related CR: 2022313018

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Intestinal xanthoma*	Approved as Requested	Proposed PT	
			Intestinal xanthoma	10088748
			HLT primary	
			Gastrointestinal disorders NEC	10017948
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Lipid metabolism and deposit disorders NEC	10024581
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to add a new term Intestinal xanthoma is approved as requested. Intestinal xanthomatosis is an uncommon nonneoplastic lesion that may cause small bowel obstruction. Intestinal xanthoma will be added as a PT with a primary link to HLT Gastrointestinal disorders NEC and a secondary link to HLT Lipid metabolism and deposit disorders NEC.

Supplemental Update Report

CR Number: 2022313021 **Implementation Date:** 11-Nov-22 Related CR: 2022313021

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Onychomycosis*	Rejected		
From HLT	*Fungal infections NEC*			
To HLT	*Tinea Infections*			

MSSO Comment: The proposal to move the PT Onychomycosis from HLT Fungal infections NEC to HLT Tinea Infections is not approved. About 60 to 80% of cases are caused by dermatophytes (eg, Trichophyton rubrum); dermatophyte infection of the nails is called tinea unguium. Many of the remaining cases are caused by nondermatophyte molds (eg, Aspergillus, Scopulariopsis, Fusarium). Immunocompromised patients and those with chronic mucocutaneous candidiasis may have candidal onychomycosis (which is more common on the fingers).

CR Number: 2022313087 **Implementation Date:** 15-Nov-22 Related CR: 2022313087

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Rabson Mendenhall Syndrome*	Approved Not as Requested	Proposed PT	
HLT primary	*Endocrine disorders congenital NEC*		*Rabson Mendenhall syndrome*	10088742
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Endocrine disorders congenital NEC	10027671
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Hyperglycaemic conditions NEC	10020638
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to add a new PT Rabson Mendenhall Syndrome to primary HLT Endocrine disorders congenital NEC in SOC Congenital, familial and genetic disorders is approved but not as requested. Rabson–Mendenhall syndrome is a rare autosomal recessive disorder characterized by severe insulin resistance. The disorder is caused by mutations in the insulin receptor gene. The requested term will be modified according to MedDRA capitalisation conventions and added as PT Rabson Mendenhall syndrome to primary HLT Endocrine disorders congenital NEC and to secondary HLT Hyperglycaemic conditions NEC and to secondary HLT Skin hyperplasias and hypertrophies. In a related change, the HLT for PT Donohue syndrome will be changed from HLT Hypoglycaemic conditions NEC to HLT Hyperglycaemic conditions NEC for better alignment.

Supplemental Update Report

CR Number: 2022319015 **Implementation Date:** 15-Nov-22 Related CR: 2022313087

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Rabson Mendenhall syndrome*	Approved as Requested	Proposed PT	
To HLT	*Skin hyperplasias and hypertrophies*		*Rabson Mendenhall syndrome*	10088742
			To HLT	
			Skin hyperplasias and hypertrophies	10040866

MSSO Comment:

CR Number: 2022319016 **Implementation Date:** 15-Nov-22 Related CR: 2022313087

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Donohue syndrome*	Approved as Requested	Proposed PT	
From HLT	*Hypoglycaemic conditions NEC*		*Donohue syndrome*	10081896
To HLT	*Hyperglycaemic conditions NEC*		From HLT	
			Hypoglycaemic conditions NEC	10021001
			To HLT	
			Hyperglycaemic conditions NEC	10020638

MSSO Comment:

CR Number: 2022313088 **Implementation Date:** 15-Nov-22 Related CR: 2022313088

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Autosomal recessive hypercholesterolemia*	Approved as Requested	Proposed LLT		
To PT	*Type IIa hyperlipidaemia*		*Autosomal recessive hypercholesterolemia*	10088744	Current
			To PT		
			Type IIa hyperlipidaemia	10045261	

MSSO Comment: The proposal to add a new LLT Autosomal recessive hypercholesterolemia to PT Type IIa hyperlipidaemia is approved as requested. Autosomal recessive hypercholesterolemia presents with a clinical phenotype similar to that of classical homozygous familial hypercholesterolemia, caused by defects in the low-density lipoprotein receptor gene. It is more variable, generally less severe, and more responsive to lipid-lowering therapy than homozygous familial hypercholesterolemia. In a related change, the British spelled equivalent term LLT Autosomal recessive hypercholesterolaemia will also be added to PT Type IIa hyperlipidaemia.

Supplemental Update Report

CR Number: 2022319014 **Implementation Date:** 15-Nov-22 Related CR: 2022313088

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Autosomal recessive hypercholesterolaemia*	Approved as Requested	Proposed LLT		
To PT	*Type IIa hyperlipidaemia*		*Autosomal recessive hypercholesterolaemia*	10088745	Current
			To PT		
			Type IIa hyperlipidaemia	10045261	

MSSO Comment:

CR Number: 2022313089 **Implementation Date:** 15-Nov-22 Related CR: 2022313089

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed PT	*Biologically Inactive Leptin*	Approved Not as Requested	Proposed LLT		
HLT primary	*Protein analyses NEC*		*Biologically inactive leptin*	10088743	Current
SOC primary	*Investigations*		To PT		
			Congenital leptin deficiency	10087061	

MSSO Comment: The proposal to add a new PT Biologically Inactive Leptin to primary HLT Protein analyses NEC in SOC Investigations and secondary HLT Inborn errors of metabolism NEC in SOC Congenital, familial and genetic disorders is approved but not as requested. Although classical congenital leptin deficiency is characterized by the absence or very low levels of the hormone in the circulation, sequence analysis of the LEP gene revealed a small subset of patients with a bioinactive form of leptin, which may exhibit normal or even high hormone levels. After modification in accordance with MedDRA capitalization conventions and for greater clarity of the term, Biologically inactive leptin will be added as an LLT to PT Congenital leptin deficiency. In a related change, Functional leptin deficiency will also be added as an LLT to PT Congenital leptin deficiency.

CR Number: 2022319017 **Implementation Date:** 15-Nov-22 Related CR: 2022313089

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Functional leptin deficiency*	Approved as Requested	Proposed LLT		
To PT	*Congenital leptin deficiency*		*Functional leptin deficiency*	10088746	Current
			To PT		
			Congenital leptin deficiency	10087061	

MSSO Comment:

Supplemental Update Report

CR Number: 2022313090 **Implementation Date:** 15-Nov-22 Related CR: 2022313090

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Undetermined stroke*	Approved as Requested	Proposed LLT		
			Undetermined stroke	10088760	Current
			To PT		
			Cerebrovascular accident	10008190	

MSSO Comment: The proposal to add a new term Undetermined stroke is approved as requested. Undetermined stroke refers to stroke of unknown etiology/source and that is not classified as ischaemic or haemorrhagic. It is often defined as an acute onset of neurological signs or symptoms persisting > 24 h or until death but without sufficient neuroimaging or pathology evidence to be classified. Undetermined stroke will be added as LLT to PT Cerebrovascular accident.

CR Number: 2022313091 **Implementation Date:** 15-Nov-22 Related CR: 2022313091

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Aggravated pregnancy conditions*	Approved Not as Requested	Proposed PT	
			Maternal disease complicating pregnancy	10088758
			HLT primary	
			Pregnancy complicated by maternal disorders	10052745
			SOC primary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new term Aggravated pregnancy conditions is approved but not as requested. Aggravated pregnancy conditions is too broad and unprecise as it may refer to many underlying chronic diseases which may worsen during a prgnancy with complication for mother and foetus. However, in line with existing PT Diabetes complicating pregnancy new PT Maternal disease complicating pregnancy will be added to HLT Pregnancy complicated by maternal disorders as it may affect mother and the foetus.

CR Number: 2022313092 **Implementation Date:** 15-Nov-22 Related CR: 2022313092

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Aggravated Pregnancy conditions secondary to pre-existing health disorders*	Approved Not as Requested	Proposed LLT		
			Maternal pre-existing disease complicating pregnancy	10088762	Current
			To PT		
			Maternal disease complicating pregnancy	10088758	

MSSO Comment: The proposal to add a new LLT Aggravated Pregnancy conditions secondary to pre-existing health disorders is approved but not as requested. The proposed term will be modified for clarity as Maternal pre-existing disease complicating pregnancy and added as an LLT to PT Maternal disease complicating pregnancy, added in change request 2022313091.

Supplemental Update Report

CR Number: 2022313093 **Implementation Date:** 15-Nov-22 Related CR: 2022313093

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Peripheral vein hematoma*	Approved as Requested	Proposed LLT *Peripheral vein hematoma*	10088761 Current
			To PT *Vascular access site haematoma*	10077647

MSSO Comment: The proposal to add a new term Peripheral vein hematoma is approved as requested. Peripheral vein hematoma and the the British spelled Peripheral vein haematoma will both be added as LLTs to PT Vascular access site haematoma. In a related change, PT Peripheral artery haematoma will be demoted under PT Vascular access site haematoma for better alignment.

CR Number: 2022319022 **Implementation Date:** 15-Nov-22 Related CR: 2022313093

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Peripheral vein haematoma*	Approved as Requested	Proposed LLT *Peripheral vein haematoma*	10088763 Current
To PT	*Vascular access site haematoma*		To PT *Vascular access site haematoma*	10077647

MSSO Comment:

CR Number: 2022319023 **Implementation Date:** 15-Nov-22 Related CR: 2022313093

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Peripheral artery haematoma*	Approved as Requested	PT to merge *Peripheral artery haematoma*	10081077 Current
To PT	*Vascular access site haematoma*		To PT *Vascular access site haematoma*	10077647

MSSO Comment:

Supplemental Update Report

CR Number: 2022313094 **Implementation Date:** 15-Nov-22 Related CR: 2022313094

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Femoral vein hematoma*	Approved as Requested	Proposed LLT *Femoral vein hematoma*	10088759 Current
			To PT *Vascular access site haematoma*	10077647

MSSO Comment: The proposal to add a new LLT Femoral vein hematoma is approved as requested. Femoral vein hematoma and the British English counterpart Femoral vein haematoma both will be added as LLTs to the PT Vascular access site haematoma.

CR Number: 2022319024 **Implementation Date:** 15-Nov-22 Related CR: 2022313094

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Femoral vein haematoma*	Approved as Requested	Proposed LLT *Femoral vein haematoma*	10088764 Current
To PT	*Vascular access site haematoma*		To PT *Vascular access site haematoma*	10077647

MSSO Comment:

CR Number: 2022314001 **Implementation Date:** 15-Nov-22 Related CR: 2022314001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Vocal cord hemorrhage*	Approved as Requested	Proposed LLT *Vocal cord hemorrhage*	10088767 Current
			To PT *Vocal cord haemorrhage*	10088766

MSSO Comment: The proposal to add a new term Vocal cord hemorrhage is approved as requested. Vocal fold hemorrhage occurs after a traumatic voice event such as screaming or yelling, singing loudly, coughing, voice overuse or misuse. Vocal cord hemorrhage will be added as LLT to the British English counterpart PT Vocal cord haemorrhage, which will be added in a related change and linked to primary HLT Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) and secondary HLT Haemorrhages NEC and secondary HLT Chest and respiratory tract injuries NEC.

Supplemental Update Report

CR Number: 2022319025 **Implementation Date:** 15-Nov-22 Related CR: 2022314001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vocal cord haemorrhage*	Approved as Requested	Proposed PT	
			Vocal cord haemorrhage	10088766
HLT primary	*Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)*		HLT primary	
			Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	10023819
SOC primary	*Respiratory, thoracic and mediastinal disorders*		SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738
			HLT secondary	
			Haemorrhages NEC	10018987
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment:

CR Number: 2022319026 **Implementation Date:** 15-Nov-22 Related CR: 2022314001

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vocal cord haemorrhage*	Approved as Requested	Proposed PT	
			Vocal cord haemorrhage	10088766
To HLT	*Chest and respiratory tract injuries NEC*		To HLT	
			Chest and respiratory tract injuries NEC	10080710

MSSO Comment:

Supplemental Update Report

CR Number: 2022314002 **Implementation Date:** 15-Nov-22 Related CR: 2022314002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*FEMUR RESECTION*	Approved Not as Requested	Proposed PT	
			Femur resection	10088765
			HLT primary	
			Bone therapeutic procedures NEC	10006000
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term FEMUR RESECTION is approved but not as requested. Femur resection (distal, proximal or total) is a limb-sparing surgical intervention for conditions such as primary or secondary bone tumors. Proximal resection of the femoral head and a portion of the femur is also a procedure after failed hip replacement surgery. The requested term will be modified according to MedDRA capitalisation conventions and added as PT Femur resection to HLT Bone therapeutic procedures NEC.

CR Number: 2022314003 **Implementation Date:** 15-Nov-22 Related CR: 2022314003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Sclerosing epithelioid fibrosarcoma*	Approved as Requested	Proposed PT	
			Sclerosing epithelioid fibrosarcoma	10088768
			HLT primary	
			Fibrosarcomas malignant	10016634
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Malignant musculoskeletal and connective tissue neoplasms	10025681
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new term Sclerosing epithelioid fibrosarcoma is approved as requested. Sclerosing epithelioid fibrosarcoma (SEF) is a rare and distinctive deep-seated variant of fibrosarcoma typically occurring in adults. Sclerosing epithelioid fibrosarcoma will be added as a PT to primary HLT Fibrosarcomas malignant and to secondary HLT Malignant musculoskeletal and connective tissue neoplasms.

Supplemental Update Report

CR Number: 2022314004 **Implementation Date:** 15-Nov-22 Related CR: 2022314004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Adult acne*	Approved as Requested	Proposed LLT *Adult acne* To PT *Acne*	10088769 Current 10000496

MSSO Comment: The proposal to add a new term Adult acne is approved as requested. Not only teenagers in puberty fight against unsightly pimples and skin blemishes, but also women over 30 sometimes suffer from it. Adult acne, or post-adolescent acne, is acne that occurs after age 25. Adult acne will be added as LLT to PT Acne.

CR Number: 2022314005 **Implementation Date:** 15-Nov-22 Related CR: 2022314005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Acne Tarda*	Approved Not as Requested	Proposed LLT *Acne tarda* To PT *Acne*	10088770 Current 10000496

MSSO Comment: The proposal to add a new LLT Acne Tarda is approved but not as requested. Acne tarda, modified according to MedDRA capitalization conventions, a synonym of LLT Adult acne, will be added as LLT to PT Acne.

CR Number: 2022314006 **Implementation Date:** 15-Nov-22 Related CR: 2022314006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Neurofibromatosis type 6*	Approved Not as Requested	Proposed LLT *Neurofibromatosis type 6*	10088775 Current
To PT	*Cafe au lait spots*		To PT *Neurofibromatosis*	10029268

MSSO Comment: The proposal to add a new LLT Neurofibromatosis type 6 to PT Cafe au lait spots is approved but not as requested. Although neurofibromatosis type 6 only presents with café-au-lait lesions, the contrary is not true, since café-au-lait lesions are present in high number in other types of neurofibromatosis (specially type 1), as well as in healthy children. Therefore the proposed term Neurofibromatosis type 6 will be added as an LLT to PT Neurofibromatosis. In a related change, PT Neurofibromatosis will also be linked to secondary HLT Hyperpigmentation disorders.

Supplemental Update Report

CR Number: 2022319011 **Implementation Date:** 15-Nov-22 Related CR: 2022314006

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neurofibromatosis*	Approved as Requested	Proposed PT	
To HLT	*Hyperpigmentation disorders*		*Neurofibromatosis*	10029268
			To HLT	
			Hyperpigmentation disorders	10020713

MSSO Comment:

CR Number: 2022314007 **Implementation Date:** 15-Nov-22 Related CR: 2022314007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Arthritis-dermatitis syndrome*	Approved as Requested	Proposed PT	
			Arthritis-dermatitis syndrome	10088771
			HLT primary	
			Neisseria infections	10028909
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Infectious arthritis	10021904
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new term Arthritis-dermatitis syndrome is approved as requested. Arthritis-dermatitis syndrome manifests as constitutional symptoms (during the acute phase of disseminated gonorrhea), migrating polyarthralgia, tenosynovitis, and cutaneous lesions, which most often involve the posterior distal extremities and are characterized by hemorrhagic papulo-pustules, vesicles, or bullae. Arthritis-dermatitis syndrome will be added as a PT with a primary link to HLT Neisseria infections and secondary links to HLT Infectious arthritis and HLT Skin and subcutaneous tissue bacterial infections.

Supplemental Update Report

CR Number: 2022319012 **Implementation Date:** 15-Nov-22 Related CR: 2022314007

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Arthritis-dermatitis syndrome*	Approved as Requested	Proposed PT	
To HLT	*Skin and subcutaneous tissue bacterial infections*		*Arthritis-dermatitis syndrome*	10088771
			To HLT	
			Skin and subcutaneous tissue bacterial infections	10040788

MSSO Comment:

CR Number: 2022314008 **Implementation Date:** 15-Nov-22 Related CR: 2022314008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Disseminated gonococcal infection*	Approved as Requested	Proposed PT	
			Disseminated gonococcal infection	10088773
			HLT primary	
			Neisseria infections	10028909
			SOC primary	
			Infections and infestations	10021881

MSSO Comment: The proposal to add a new term Disseminated gonococcal infection is approved as requested. Disseminated gonococcal infection is an uncommon, but severe, complication of untreated gonorrhea, which occurs when the sexually transmitted pathogen Neisseria gonorrhoeae invades the bloodstream and spreads to distant sites, leading to clinical manifestations such as septic arthritis, polyarthralgia, tenosynovitis, petechial/pustular skin lesions, bacteremia, or, on rare occasions, endocarditis or meningitis. Disseminated gonococcal infection will be added as a PT liked to HLT Neisseria infections.

CR Number: 2022314009 **Implementation Date:** 15-Nov-22 Related CR: 2022314009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Urticaria factitia*	Approved as Requested	Proposed LLT		
To PT	*Mechanical urticaria*		*Urticaria factitia*	10088774	Current
			To PT		
			Mechanical urticaria	10068773	

MSSO Comment: The proposal to add a new LLT Urticaria factitia to PT Mechanical urticaria is approved as requested. Urticaria factitia is a synonym of Mechanical urticaria, a variant of chronic urticaria which presents as linear erythema and intensely pruritic wheals at sites of trauma, friction with clothing or after scratching the skin.

Supplemental Update Report

CR Number: 2022314010 **Implementation Date:** 15-Nov-22 Related CR: 2022314010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Exposure of impacted teeth*	Approved Not as Requested	Proposed PT	
			Impacted tooth exposure	10088772
			HLT primary	
			Dental and gingival therapeutic procedures	10012317
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Exposure of impacted teeth is approved but not as requested. Impacted teeth exposure is a procedure involving a gingivectomy and occasionally bone removal in order to expose a buried tooth. The proposed term will be modified according to MedDRA naming conventions and added as PT Impacted tooth exposure to HLT Dental and gingival therapeutic procedures.

CR Number: 2022314011 **Implementation Date:** 15-Nov-22 Related CR: 2022314011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Hepatic steatosis alcoholic*	Approved as Requested	Proposed LLT		
			Hepatic steatosis alcoholic	10088776	Current
			To PT		
			Fatty liver alcoholic	10016262	

MSSO Comment: The proposal to add a new LLT Hepatic steatosis alcoholic is approved as requested. Hepatic steatosis alcoholic will be added as synonym LLT to PT Fatty liver alcoholic. Please note that PT Fatty liver alcoholic is in MedDRA since version 2.1 and demoting to a new PT Hepatic steatosis alcoholic (or swapping) only for consistency reasons at PT level presentation may have a negative impact on legacy data.

CR Number: 2022314012 **Implementation Date:** 15-Nov-22 Related CR: 2022314012

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #	
Term to modify	*Esophageal bayonet*	Approved as Requested	Term to modify		
			Esophageal bayonet	10088306	
Replacement term	*Esophageal bayonet sign*		Replacement term		
			Esophageal bayonet sign	10088306	Current

MSSO Comment: The proposal to rename PT/LLT Esophageal bayonet to Esophageal bayonet sign is approved as requested. The originating batch to add the British English counterpart for this term was added as Oesophageal bayonet sign in CR# 2022215009. Renaming of the American spelled counterpart LLT Esophageal bayonet will correct an error in intended term addition.

Supplemental Update Report

CR Number: 2022314013 **Implementation Date:** 15-Nov-22 Related CR: 2022314013

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Hypertriglycaeridemic waist phenotype*	Approved as Requested	Term to modify	
Replacement term	*Hypertriglyceridaemic waist phenotype*		*Hypertriglycaeridemic waist phenotype*	10088156
			Replacement term	
			Hypertriglyceridaemic waist phenotype	10088156

MSSO Comment: The proposal to rename PT/LLT Hypertriglycaeridemic waist phenotype to Hypertriglyceridaemic waist phenotype is approved as requested to correct the UK spelling for the -emic/-aemic suffix.

CR Number: 2022314014 **Implementation Date:** 15-Nov-22 Related CR: 2022314014

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Electrocardiogram depolarisation abnormality*	Approved as Requested	Proposed LLT		
To PT	*Electrocardiogram abnormal*		*Electrocardiogram depolarisation abnormality*	10088777	Current
			To PT		
			Electrocardiogram abnormal	10014363	

MSSO Comment: The proposal to add a new LLT Electrocardiogram depolarisation abnormality to PT Electrocardiogram abnormal is approved as requested. The proposed term is the British spelled counterpart to recently added American spelled LLT Electrocardiogram depolarization abnormality (CR# 2022235001).

Supplemental Update Report

CR Number: 2022315001 **Implementation Date:** 17-Nov-22 Related CR: 2022315001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Idiopathic histaminergic angioedema*	Approved Not as Requested	Proposed PT	
			Idiopathic histaminergic angioedema	10088780
			HLT primary	
			Angioedemas	10002425
			SOC primary	
			Skin and subcutaneous tissue disorders	10040785
			HLT secondary	
			Laryngeal spasm, oedema and obstruction	10023855
			SOC secondary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new LLT Idiopathic histaminergic angioedema is approved but not as requested. Idiopathic histaminergic angioedema is a common cause of recurrent angioedema without wheals. It is a mast cell-mediated disease thought to belong to the same clinical entity as chronic urticaria. Idiopathic histaminergic angioedema will be added as PT to primary HLT Angioedemas and to secondary HLT Laryngeal spasm, oedema and obstruction.

CR Number: 2022315002 **Implementation Date:** 17-Nov-22 Related CR: 2022315002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Lateral rectus recession*	Approved as Requested	Proposed LLT	
			Lateral rectus recession	10088789 Current
			To PT	
			Eye muscle recession	10015954

MSSO Comment: The proposal to add a new LLT Lateral rectus recession is approved as requested. Lateral rectus recession is a surgical procedure to correct small and moderate-angle exotropia. Lateral rectus recession will be added as sub-concept LLT to PT Eye muscle recession.

Supplemental Update Report

CR Number: 2022315003 **Implementation Date:** 17-Nov-22 Related CR: 2022315003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tubular proteinuria*	Approved as Requested	Proposed LLT *Tubular proteinuria* To PT *Proteinuria*	10088790 Current 10037032

MSSO Comment: The proposal to add a new LLT Tubular proteinuria is approved as requested. Tubular proteinuria is proteinuria (excessive protein in the urine) caused by renal tubular dysfunction. Proteins of low molecular weight are normally filtered at the glomerulus of the kidney and are then normally reabsorbed by the tubular cells, so that less than 150 mg per day should appear in the urine. Tubular proteinuria will be added as LLT to PT Proteinuria. In a related change, LLT Glomerular proteinuria will also be added under PT Proteinuria.

CR Number: 2022321012 **Implementation Date:** 17-Nov-22 Related CR: 2022315003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Glomerular proteinuria*	Approved as Requested	Proposed LLT *Glomerular proteinuria* To PT *Proteinuria*	10088784 Current 10037032
To PT	*Proteinuria*			

MSSO Comment:

CR Number: 2022315004 **Implementation Date:** 17-Nov-22 Related CR: 2022315004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pediatric trigger thumb*	Approved as Requested	Proposed LLT *Pediatric trigger thumb* To PT *Trigger finger*	10088787 Current 10044654

MSSO Comment: The proposal to add a new LLT Pediatric trigger thumb is approved as requested. Pediatric trigger finger is condition that affects the movement of the thumb in children. The thumb gets stuck in a flexed position.The exact cause of pediatric trigger finger is not known. Children are not born with it. It does not occur from overuse, trauma, or injury. There is a mismatch in size between the tendon that moves the thumb and the ligament through which the tendon glides. Pediatric trigger thumb and the British English equivalent Paediatric trigger thumb will be both added as LLTs to PT Trigger finger.

Supplemental Update Report

CR Number: 2022321013 **Implementation Date:** 17-Nov-22 Related CR: 2022315004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Paediatric trigger thumb*	Approved as Requested	Proposed LLT		
To PT	*Trigger finger*		*Paediatric trigger thumb*	10088786	Current
			To PT		
			Trigger finger	10044654	

MSSO Comment:

CR Number: 2022315005 **Implementation Date:** 17-Nov-22 Related CR: 2022315005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Muenke syndrome*	Approved Not as Requested	Proposed PT	
			Muenke syndrome	10088781
			HLT primary	
			Musculoskeletal and connective tissue disorders of skull congenital	10028382
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Musculoskeletal and connective tissue disorders of skull congenital	10028382
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new LLT Muenke syndrome is approved but not as requested. Muenke Syndrome is a condition characterized by the premature closure of the coronal suture of the skull (coronal craniosynostosis) during development. This affects the shape of the head and face. Other variable features include abnormalities of the hands or feet, hearing loss and developmental delay. Muenke Syndrome is caused by genetic changes in the FGFR3 gene. It is inherited in an autosomal dominant pattern. Muenke syndrome will be added as a PT to bi-axial HLT Musculoskeletal and connective tissue disorders of skull congenital (primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders).

Supplemental Update Report

CR Number: 2022315006 **Implementation Date:** 17-Nov-22 Related CR: 2022315006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Lactobacillus bacteremia*	Approved as Requested	Proposed LLT *Lactobacillus bacteremia*	10088792 Current
			To PT *Lactobacillus bacteraemia*	10088783

MSSO Comment: The proposal to add a new LLT Lactobacillus bacteremia is approved as requested. Risk factors related to Lactobacillus bacteremia include impaired host defenses and severe underlying diseases, as well as prior surgery and prolonged antibiotic therapy ineffective for lactobacilli. Proposed term will be added as LLT Lactobacillus bacteremia to new PT Lactobacillus bacteraemia. In a related change, new PT Lactobacillus bacteraemia will be added under HLT Bacterial infections NEC.

CR Number: 2022321014 **Implementation Date:** 17-Nov-22 Related CR: 2022315006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Lactobacillus bacteraemia*	Approved as Requested	Proposed PT *Lactobacillus bacteraemia*	10088783
HLT primary	*Bacterial infections NEC*		HLT primary *Bacterial infections NEC*	10004047
SOC primary	*Infections and infestations*		SOC primary *Infections and infestations*	10021881

MSSO Comment:

CR Number: 2022315007 **Implementation Date:** 17-Nov-22 Related CR: 2022315007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cardiac mapping*	Approved Not as Requested	Proposed PT *Cardiac mapping*	10088778
			HLT primary *Cardiac imaging procedures*	10007574
			SOC primary *Investigations*	10022891

MSSO Comment: The proposal to add a new LLT Cardiac mapping is approved but not as requested. Cardiac mapping is a method by which electrical activity is recorded directly from the myocardium, analyzed, and then displayed in a manner similar to a geographic map. Proposed term will be added as new PT Cardiac mapping under HLT Cardiac imaging procedures.

Supplemental Update Report

CR Number: 2022315008 **Implementation Date:** 17-Nov-22 Related CR: 2022315008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Fibroblast growth factor receptor 3 gene mutation*	Approved as Requested	Proposed LLT	
			Fibroblast growth factor receptor 3 gene mutation	10088791 Current
			To PT	
			FGFR3 gene mutation	10088779

MSSO Comment: The proposal to add a new LLT Fibroblast growth factor receptor 3 gene mutation is approved as requested. The FGFR3 gene provides instructions for making a protein called fibroblast growth factor receptor 3. Mutations in this gene lead to craniosynostosis and multiple types of skeletal dysplasia. Proposed term will be added as LLT Fibroblast growth factor receptor 3 gene mutation under new PT FGFR3 gene mutation, added in change request 2022315009.

CR Number: 2022315009 **Implementation Date:** 17-Nov-22 Related CR: 2022315009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*FGFR3 gene mutation*	Approved Not as Requested	Proposed PT	
			FGFR3 gene mutation	10088779
			HLT primary	
			Gene mutations and other alterations NEC	10083625
			SOC primary	
			Congenital, familial and genetic disorders	10010331

MSSO Comment: The proposal to add a new LLT FGFR3 gene mutation is approved but not as requested. The FGFR3 gene provides instructions for making a protein called fibroblast growth factor receptor 3. Mutations in this gene lead to craniosynostosis and multiple types of skeletal dysplasia. Proposed term will be added as new PT FGFR3 gene mutation under HLT Gene mutations and other alterations NEC.

CR Number: 2022315010 **Implementation Date:** 17-Nov-22 Related CR: 2022315010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Paediatric trigger finger*	Approved as Requested	Proposed LLT	
			Paediatric trigger finger	10088788 Current
			To PT	
			Trigger finger	10044654

MSSO Comment: The proposal to add a new LLT Paediatric trigger finger is approved as requested. Paediatric trigger finger (PTF) is a rare disorder occurring up to ten times less frequently than its counterpart, paediatric trigger thumb.1 Though prevalence rates specific to PTF are scarce, triggering of any digit, thumb or finger, is reported to affect less than 0.05% of children. Paediatric trigger finger and the American English counterpart Pediatric trigger finger will both be added as LLTs to PT Trigger finger.

Supplemental Update Report

CR Number: 2022321015 **Implementation Date:** 17-Nov-22 Related CR: 2022315010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pediatric trigger finger*	Approved as Requested	Proposed LLT	
To PT	*Trigger finger*		*Pediatric trigger finger*	10088785 Current
			To PT	
			Trigger finger	10044654

MSSO Comment:

CR Number: 2022315011 **Implementation Date:** 17-Nov-22 Related CR: 2022315011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Incomplete thymus involution*	Approved Not as Requested	Proposed PT	
			Incomplete thymus involution	10088782
			HLT primary	
			Thymus disorders	10043677
			SOC primary	
			Blood and lymphatic system disorders	10005329
			HLT secondary	
			Autoimmune disorders NEC	10027657
			SOC secondary	
			Immune system disorders	10021428

MSSO Comment: The proposal to add a new LLT Incomplete thymus involution is approved but not as requested. Thymic involution normally occurs with age. Incomplete thymus involution is defined as a residual thymic tissue more than 7 mm thick. Findings show that two autoimmune diseases, Rheumatoid Arthritis and Systemic Sclerosis, are associated with incomplete thymus involution. Proposed term will be added as new PT Incomplete thymus involution under primary HLT Thymus disorders and secondary HLT Autoimmune disorders NEC.

Supplemental Update Report

CR Number: 2022315012 **Implementation Date:** 17-Nov-22 Related CR: 2022315012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene amplification*	Approved Not as Requested	Proposed PT	
			NTRK gene amplification	10088796
			HLT primary	
			Gene mutations and other alterations NEC	10083625
			SOC primary	
			Congenital, familial and genetic disorders	10010331

MSSO Comment: The proposal to add a new LLT NTRK gene amplification is approved but not as requested. Gene amplification is defined as an increase in the copy number of a restricted region of a chromosome arm. NTRK amplification is an oncogenic driver, which is defined by the presence of ≥4.0 gen copies. NTRK inhibitors show promise to provide an effective treatment for cancers involving NTRK amplification. NTRK gene amplification will be added as a PT with a primary link to HLT Gene mutations and other alterations NEC.

CR Number: 2022315013 **Implementation Date:** 17-Nov-22 Related CR: 2022315013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion test*	Approved Not as Requested	Proposed PT	
			NTRK gene fusion test	10088793
			HLT primary	
			Gene analyses	10071950
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new LLT NTRK gene fusion test is approved but not as requested. There are several technologies that can test for NTRK gene fusions. However, only immunohistochemistry, DNA fluorescence in situ hybridization (FISH), reverse transcription polymerase chain reaction (RT-PCR) and next-generation sequencing (NGS) are sensitive, specific, and multiplexing assays which can reliably detect NTRK gene fusions. NTRK gene fusion test will be added as PT to HLT Gene analyses.

CR Number: 2022315014 **Implementation Date:** 17-Nov-22 Related CR: 2022315014

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive*	Approved Not as Requested	Proposed PT	
			NTRK gene fusion positive	10088797
			HLT primary	
			Gene analyses	10071950
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive is approved but not as requested. NTRK gene fusion positive will be added as a PT to represent positive results of NTRK gene fusion test added in change request 2022315013. NTRK gene fusion positive will be added as a PT to HLT Gene analyses.

Supplemental Update Report

CR Number: 2022315015 **Implementation Date:** 17-Nov-22 Related CR: 2022315015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion negative*	Approved Not as Requested	Proposed PT	
			NTRK gene fusion negative	10088794
			HLT primary	
			Gene analyses	10071950
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new LLT NTRK gene fusion negative is approved but not as requested. NTRK gene fusion negative will be added as a PT to represent negative results of NTRK gene fusion test, added in change request 2022315013. NTRK gene fusion negative will be added as a PT to HLT Gene analyses.

CR Number: 2022315016 **Implementation Date:** 17-Nov-22 Related CR: 2022315016

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion cancer*	Approved Not as Requested	Proposed PT	
			NTRK gene fusion cancer	10088795
			HLT primary	
			Neoplasms malignant site unspecified NEC	10029105
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104

MSSO Comment: The proposal to add a new LLT NTRK gene fusion cancer is approved but not as requested. NTRK genes tend to fuse with housekeeping genes. Once fused, they are constitutively active due to the genetic alteration. Therefore, NTRK gene fusions can lead to the development of solid tumors in a variety of tissue types. NTRK gene fusion cancer will be added as PT to HLT Neoplasms malignant site unspecified NEC.

CR Number: 2022315020 **Implementation Date:** 17-Nov-22 Related CR: 2022315020

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Compressive atelectasis*	Approved as Requested	Proposed LLT	
			Compressive atelectasis	10088798 Current
			To PT	
			Atelectasis	10003598

MSSO Comment: The proposal to add a new LLT Compressive atelectasis is approved as requested. Compressive atelectasis refers to a form of lung atelectasis due to compression by a space-occupying process. Compressive atelectasis will be added as sub-concept LLT to PT Atelectasis. In a related change, LLT Obstructive atelectasis will also be added to PT Atelectasis. Resorptive or obstructive atelectasis is a form of lung collapse that is due to obstruction of the airways supplying a lung segment or lobe. It is a term used to distinguish atelectasis identified on imaging based on the underlying pathophysiology to guide diagnosis.

Supplemental Update Report

CR Number: 2022321016 **Implementation Date:** 17-Nov-22 Related CR: 2022315020

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Obstructive atelectasis*	Approved as Requested	Proposed LLT	
To PT	*Atelectasis*		*Obstructive atelectasis*	10088799 Current
			To PT	
			Atelectasis	10003598

MSSO Comment:

CR Number: 2022317001 **Implementation Date:** 17-Nov-22 Related CR: 2022317001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Parotid gland nodules*	Rejected		

MSSO Comment: The proposal to add a new term Parotid gland nodules is not approved. The MSSO generally refrains from adding “nodule” terms except when a nodule represents a full diagnostic expression e.g. PT Milker’s nodules. Nodules can generally be represented with the most appropriate “mass” or “disorder” term.

CR Number: 2022317002 **Implementation Date:** 17-Nov-22 Related CR: 2022317002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Visible blue light therapy*	Approved Not as Requested	Proposed PT	
			Blue light therapy	10088800
			HLT primary	
			Phototherapies	10034976
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Visible blue light therapy is approved but not as requested. Visible light is absorbed by photoacceptors in pigmented and non-pigmented mammalian cells, activating signaling cascades and downstream mechanisms that lead to the modulation of cellular processes. There is shown that Blue light is beneficial in the treatment of inflammatory skin conditions. The requested term will be modified and added as PT Blue light therapy to HLT Phototherapies.

Supplemental Update Report

CR Number: 2022318001 **Implementation Date:** 17-Nov-22 Related CR: 2022318001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Endoscopic tattooing*	Approved Not as Requested	Proposed PT	
			Endoscopic tattooing	10088801
			HLT primary	
			Gastrointestinal therapeutic procedures NEC	10018013
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Endoscopic tattooing is approved but not as requested. Endoscopic tattooing or marking of lesions is performed when a gastroenterologist or surgeon sees a lesion in the GI tract, it is tattooed to mark lesion location so that it can later be found on subsequent screening or for surgical resection. Proposed term will be added as PT Endoscopic tattooing under HLT Gastrointestinal therapeutic procedures NEC.

CR Number: 2022318002 **Implementation Date:** 17-Nov-22 Related CR: 2022318002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Dry needling*	Approved Not as Requested	Proposed PT	
			Dry needling	10088802
			HLT primary	
			Muscle therapeutic procedures	10028321
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Dry needling is approved but not as requested. Dry needling is the use of a small needle to penetrate a “trigger point” in an area of muscle that is tight and/or causing pain or decreased performance. The intent of dry needling is to cause the muscle to contract, then relax, therefore releasing the trigger point. Proposed term will be added as new PT Dry needling under HLT Muscle therapeutic procedures. In a related change, Trigger point dry needling will be added as an LLT to PT Dry needling.

CR Number: 2022321017 **Implementation Date:** 17-Nov-22 Related CR: 2022318002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Trigger point dry needling*	Approved as Requested	Proposed LLT	
To PT	*Dry needling*		*Trigger point dry needling*	10088804 Current
			To PT	
			Dry needling	10088802

MSSO Comment:

Supplemental Update Report

CR Number: 2022318003 **Implementation Date:** 17-Nov-22 Related CR: 2022318003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ultrasound-guided infiltration*	Approved Not as Requested	Proposed LLT *Ultrasound-guided joint infiltration* To PT *Joint injection*	10088803 Current 10023218

MSSO Comment: The proposal to add a new LLT Ultrasound-guided infiltration is approved but not as requested. Ultrasound-guided infiltration involves injecting an anti-inflammatory drug into joints, bursae or tendons to relieve pain and reduce inflammation. The radiologist uses an ultrasound machine as a guide and to see the infiltration site clearly. Proposed term will be modified and added as new LLT Ultrasound-guided joint infiltration under PT Joint injection.

CR Number: 2022318004 **Implementation Date:** 17-Nov-22 Related CR: 2022318004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Epicapsular star/ chicken tracks*	Approved Not as Requested	Proposed LLT *Epicapsular star* To PT *Persistent pupillary membrane*	10088805 Current 10070872

MSSO Comment: The proposal to add a new term Epicapsular star/ chicken tracks is approved but not as requested. Epicapsular stars (or congenital epicapsular pigmentation) are very small, stellate, pigment deposits on the anterior lens capsule. Called “epicapsular stars, they are the remnants of the tunica vasculosa lentis, an embryonic vascular network surrounding the lens. The requested term will be modified and added as LLT Epicapsular star to PT Persistent pupillary membrane.

CR Number: 2022318005 **Implementation Date:** 17-Nov-22 Related CR: 2022318005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Use of error-prone abbreviation*	Approved as Requested	Proposed LLT *Use of error-prone abbreviation* To PT *Circumstance or information capable of leading to medication error*	10088806 Current 10064385

MSSO Comment: The proposal to add a new LLT Use of error-prone abbreviation is approved as requested. Abbreviations and symbols are often used to save time when communicating medication orders, especially in handwritten communication. However, abbreviations and nonstandard dose designations are frequently misinterpreted, and they often lead to errors resulting in patient harm. Use of error-prone abbreviation will be added as LLT to PT Circumstance or information capable of leading to medication error.

Supplemental Update Report

CR Number: 2022318006 **Implementation Date:** 17-Nov-22 Related CR: 2022318006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Computerized tomogram thorax and abdomen*	Rejected		

MSSO Comment: The proposal to add a new LLT Computerized tomogram thorax and abdomen is not approved. The requested term includes two anatomical regions which are both available for CT imaging in MedDRA - see LLT Computerised tomogram thorax and LLT Computerised tomogram abdomen. However, Thoracic CT is a computed tomography scan of the chest and upper abdomen, so LLT Computerised tomogram thorax may be a coding option for this combination report depending upon the context.

CR Number: 2022318007 **Implementation Date:** 17-Nov-22 Related CR: 2022318007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Gag reflex*	Approved Not as Requested	Proposed PT	
			Gag reflex test	10088807
			HLT primary	
			Neurologic diagnostic procedures	10029285
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Gag reflex is approved but not as requested. The gag reflex, also known as the pharyngeal reflex, is an involuntary reflex involving bilateral pharyngeal muscle contraction and elevation of the soft palate. It is an essential component of evaluating the medullary brainstem and plays a role in the declaration of brain death. Gag reflex test will be added as a PT to primary HLT Neurologic diagnostic procedures

CR Number: 2022318008 **Implementation Date:** 17-Nov-22 Related CR: 2022318008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Palatal expander*	Approved as Requested	Proposed LLT		
			Palatal expander	10088808	Current
			To PT		
			Oral appliance	10085270	

MSSO Comment: The proposal to add a new term Palatal expander is approved as requested. A palatal expander is an appliance that fits into the roof of the mouth and widens palate to improve the way the upper and lower jaws and teeth fit together. Palatal expander will be added as an LLT to PT Oral appliance. In a related change, PT Palatal expander insertion will be demoted under PT Maxillary expansion for better alignment.

Supplemental Update Report

CR Number: 2022321020 **Implementation Date:** 17-Nov-22 Related CR: 2022318008

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Palatal expander insertion*	Approved as Requested	PT to merge	
To PT	*Maxillary expansion*		*Palatal expander insertion*	10086424 Current
			To PT	
			Maxillary expansion	10088479

MSSO Comment:

CR Number: 2022318009 **Implementation Date:** 17-Nov-22 Related CR: 2022318009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Modified bluegrass appliance*	Approved as Requested	Proposed LLT	
			Modified bluegrass appliance	10088809 Current
			To PT	
			Oral appliance	10085270

MSSO Comment: The proposal to add a new term Modified bluegrass appliance is approved as requested. Bluegrass appliances are an aversive approach, often felt as a punitive therapy, but which have been moderately effective. A modified bluegrass appliance is characterized by the addition of acrylic roller or beads which results in a better accepted and nonpunitive therapy to treat sucking habits, acting as a habit reversal technique and installing positive reinforcement in children. Modified bluegrass appliance will be added as LLT to PT Oral appliance.

CR Number: 2022318010 **Implementation Date:** 17-Nov-22 Related CR: 2022318010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Dental flossing*	Approved as Requested	Proposed LLT	
			Dental flossing	10088810 Current
			To PT	
			Dental cleaning	10051047

MSSO Comment: The proposal to add a new term Dental flossing is approved as requested. Dental flossing is a cleaning procedure to get rid of plaque and prevents it from building up. Dental flossing will be added as an LLT to PT Dental cleaning.

Supplemental Update Report

CR Number: **2022318011** **Implementation Date:** 17-Nov-22 Related CR: 2022318011

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Tingling in feet*	Rejected		

MSSO Comment: The proposal to add a new term Tingling in feet is not approved. Tingling is a colloquial expression of the medical term paresthesia. To avoid unnecessary overpopulation of the terminology, MedDRA refrains from adding a tingling related term for every possible anatomical location. Existing LLTs (such as Paraesthesia foot, Paresthesia foot and Tingling feet/hands) can represent the proposed concept.

CR Number: **2022319001** **Implementation Date:** 17-Nov-22 Related CR: 2022319001

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Thymus nodule*	Rejected		

MSSO Comment: The proposal to add a new term Thymus nodule is not approved. As per the Introductory Guide MedDRA Version 25.1, in general, new terms containing “nodule” are not added to MedDRA, except when a nodule represents a full diagnostic expression.

CR Number: **2022319002** **Implementation Date:** 17-Nov-22 Related CR: 2022319002

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New LLT			
Proposed LLT *ARTERY BALLOON DILATATION*	Approved Not as Requested	Proposed LLT	
		Balloon dilatation of artery	10088811 Current
		To PT	
		Arterial angioplasty	10081731

MSSO Comment: The proposal to add a new LLT ARTERY BALLOON DILATATION is approved but not as requested. Balloon dilatation involves positioning the deflated balloon across the stenotic site and subsequent inflation, stretching the intimal and medial layers of the vessel. Proposed term will be modified for MedDRA capitalization conventions and clarity and added as LLT Balloon dilatation of artery to PT Arterial angioplasty.

Supplemental Update Report

CR Number: 2022319003 **Implementation Date:** 17-Nov-22 Related CR: 2022319003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Closed reduction of fracture with external fixation*	Rejected		
To PT	*Closed fracture manipulation*			

MSSO Comment: The proposal to add a new LLT Closed reduction of fracture with external fixation to PT Closed fracture manipulation is not approved. The proposed term can be represented by LLT External fixation of closed fracture.

CR Number: 2022319004 **Implementation Date:** 17-Nov-22 Related CR: 2022319004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*ABO HEMOLYTIC ANEMIA OF NEWBORN*	Approved Not as Requested	Proposed LLT		
			ABO hemolytic anemia of newborn	10088812	Current
			To PT		
			ABO haemolytic disease of newborn	10000205	

MSSO Comment: The proposal to add a new term ABO HEMOLYTIC ANEMIA OF NEWBORN is approved but not as requested. The clinical course of ABO haemolytic disease of newborn is relatively benign, characterized by high serum bilirubin, moderately severe anemia, reticulocytosis and spherocytosis. Proposed term will be modified for MedDRA capitalization conventions and added as subconcept LLT ABO hemolytic anemia of newborn under PT ABO haemolytic disease of newborn. In a related change, the British English counterpart LLT ABO haemolytic anaemia of newborn will also be added under PT ABO haemolytic disease of newborn.

CR Number: 2022321021 **Implementation Date:** 17-Nov-22 Related CR: 2022319004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*ABO haemolytic anaemia of newborn*	Approved as Requested	Proposed LLT		
To PT	*ABO haemolytic disease of newborn*		*ABO haemolytic anaemia of newborn*	10088813	Current
			To PT		
			ABO haemolytic disease of newborn	10000205	

MSSO Comment:

Supplemental Update Report

CR Number: 2022319005 **Implementation Date:** 17-Nov-22 Related CR: 2022319005

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *BREAST MILK DIARRHEA*	Rejected		

MSSO Comment: The proposal to add a new term BREAST MILK DIARRHEA is not approved. The MSSO considers this term to be a “due to” type of term. Causality or cause /effect can be determined by the reporter/investigator or by the sponsor in a separate field of a transmittal form.

CR Number: 2022319006 **Implementation Date:** 17-Nov-22 Related CR: 2022319006

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New LLT			
Proposed LLT *NEWBORN ABO HEMOLYTIC JAUNDICE*	Rejected		

MSSO Comment: The proposal to add a new LLT NEWBORN ABO HEMOLYTIC JAUNDICE is not approved. The requested term is a combintion between two concepts - LLT/PT ABO haemolytic disease of newborn and LLT Jaundice of newborn. The MSSO refrains from adding combination concepts of a "due to" nature.

CR Number: 2022319007 **Implementation Date:** 17-Nov-22 Related CR: 2022319007

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *SEPTICEMIA OF NEWBORN*	Approved Not as Requested	Proposed LLT	
		Neonatal septicemia	10088814 Current
		To PT	
		Sepsis neonatal	10040049

MSSO Comment: The proposal to add a new term SEPTICEMIA OF NEWBORN is approved but not as requested. Neonatal septicemia is defined as a syndrome of clinical features of disseminated infection and presence of bacteremia in first four weeks of life. The requested term will be modified according to MedDRA capitalisation and naming conventions and added as LLT Neonatal septicemia to PT Sepsis neonatal. In a related change, the British English spelled LLT Neonatal septicaemia will also be added to PT Sepsis neonatal.

Supplemental Update Report

CR Number: 2022321022 **Implementation Date:** 17-Nov-22 Related CR: 2022319007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Neonatal septicaemia*	Approved as Requested	Proposed LLT	
To PT	*Sepsis neonatal*		*Neonatal septicaemia*	10088815 Current
			To PT	
			Sepsis neonatal	10040049

MSSO Comment:

CR Number: 2022319009 **Implementation Date:** 22-Nov-22 Related CR: 2022319009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Healthy volunteer*	Approved Not as Requested	Proposed LLT	
			Clinical trial healthy volunteer	10088820 Current
			To PT	
			Clinical trial participant	10076055

MSSO Comment: The proposal to add a new term Healthy volunteer is approved but not as requested. A clinical trial healthy volunteer is someone with no known significant health problems who participates in research to test a new drug, device, or intervention. The proposed term will be modified for a greater specificity and clarity of the concept. A new LLT Clinical trial healthy volunteer will be added to PT Clinical trial participant.

CR Number: 2022319010 **Implementation Date:** 22-Nov-22 Related CR: 2022319010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cut wound*	Rejected		
From PT	*Wound*			
To PT	*Cut wound*			

MSSO Comment: The proposal to move the LLT Cut wound from PT Wound to PT Cut wound is not approved. LLT Cut wound needs to remain at the LLT level to avoid overpopulation at the PT level. Certain terms of high specificity must be represented at the LLT level.

Supplemental Update Report

CR Number: 2022319013 **Implementation Date:** 22-Nov-22 Related CR: 2022319013

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*CANOMAD Syndrome*	Approved Not as Requested	Proposed PT *CANOMAD syndrome*	10088816
			HLT primary *Chronic polyneuropathies*	10036107
			SOC primary *Nervous system disorders*	10029205
			HLT secondary *Nervous system autoimmune disorders*	10074484
			SOC secondary *Immune system disorders*	10021428

MSSO Comment: The proposal to add a new term CANOMAD Syndrome is approved but not as requested. CANOMAD (chronic ataxic neuropathy, ophthalmoplegia, immunoglobulin M [IgM] paraprotein, cold agglutinins, and disialosyl antibodies) is a rare syndrome characterized by chronic neuropathy with sensory ataxia, ocular, and/or bulbar motor weakness in the presence of a monoclonal IgM reacting against gangliosides containing disialosyl epitopes. Proposed term will be modified for MedDRA capitalization conventions and added as new PT CANOMAD syndrome under primary HLT Chronic polyneuropathies and secondary HLT Nervous system autoimmune disorders and secondary HLT Ocular nerve and muscle disorders. In a related change, the spelled out acronym LLT Chronic ataxic neuropathy, ophthalmoplegia, IgM paraprot, cold agglutinins, disialosyl Ab syndrome will be added to new PT CANOMAD syndrome.

CR Number: 2022326017 **Implementation Date:** 22-Nov-22 Related CR: 2022319013

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*CANOMAD syndrome*	Approved as Requested	Proposed PT *CANOMAD syndrome*	10088816
To HLT	*Ocular nerve and muscle disorders*		To HLT *Ocular nerve and muscle disorders*	10030059

MSSO Comment:

Supplemental Update Report

CR Number: 2022326019 **Implementation Date:** 22-Nov-22 Related CR: 2022319013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Chronic ataxic neuropathy, ophthalmoplegia, IgM paraprot, cold agglutinins, disialosyl Ab syndrome*	Approved as Requested	Proposed LLT *Chronic ataxic neuropathy, ophthalmoplegia, IgM paraprot, cold agglutinins, disialosyl Ab syndrome*	10088817 Current
To PT	*CANOMAD syndrome*		To PT *CANOMAD syndrome*	10088816

MSSO Comment:

CR Number: 2022319028 **Implementation Date:** 22-Nov-22 Related CR: 2022319028

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*ULTRASOUND SHOULDER*	Approved Not as Requested	Proposed LLT *Ultrasound shoulder*	10088818 Current
			To PT *Ultrasound joint*	10063568

MSSO Comment: The proposal to add a new term ULTRASOUND SHOULDER is approved but not as requested. Ultrasound of the shoulder is a fast, relatively cheap, and dynamic way to examine the rotator cuff and is particularly useful in diagnosing: shoulder impingement, shoulder instability, rotator cuff disorders. The requested term will be modified according to MedDRA capitalisation conventions and added as LLT Ultrasound shoulder to PT Ultrasound joint.

CR Number: 2022320001 **Implementation Date:** 22-Nov-22 Related CR: 2022320001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Fontan-Associated Liver Disease*	Approved Not as Requested	Proposed LLT *Fontan-associated liver disease*	10088819 Current
			To PT *Cardiac cirrhosis*	10054936

MSSO Comment: The proposal to add a new term Fontan-Associated Liver Disease is approved but not as requested. Patients with congenital heart disease with a single ventricle anomaly, who require creation of a Fontan circulation, are particularly vulnerable as they have elevated venous filling pressures with chronic liver congestion. Progression to liver fibrosis and eventually cirrhosis may occur, with its associated risks of liver failure and hepatocellular carcinoma. The requested term will be modified according to MedDRA capitalisation conventions and added as LLT Fontan-associated liver disease to PT Cardiac cirrhosis.

Supplemental Update Report

CR Number: 2022320002 **Implementation Date:** 22-Nov-22 Related CR: 2022320002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*PERIODONTAL ENDODONTIC SYNDROME*	Approved Not as Requested	Proposed PT	
			Periodontic-endodontic disease	10088821
			HLT primary	
			Dental and oral soft tissue infections	10012326
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Dental and periodontal infections and inflammations	10012325
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term PERIODONTAL ENDODONTIC SYNDROME is approved but not as requested. Combined periodontic-endodontic lesions are localized, circumscribed areas of bacterial infection originating from either dental pulp, periodontal tissues surrounding the involved tooth or both. The requested term will be modified according to MedDRA capitalisation conventions and in its most cited form as PT Periodontic-endodontic disease to primary HLT Dental and oral soft tissue infections and secondary HLT Dental and periodontal infections and inflammations.

CR Number: 2022320003 **Implementation Date:** 22-Nov-22 Related CR: 2022320003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*TUMOR NECROSIS FACTOR BETA INCREASED*	Approved Not as Requested	Proposed PT	
			Beta tumour necrosis factor increased	10088822
			HLT primary	
			Immune response protein analyses NEC	10021421
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term TUMOR NECROSIS FACTOR BETA INCREASED is approved but not as requested. Tumor Necrosis Factor beta (TNF-beta, TNFß), also known as lymphotoxin-alpha, is produced predominantly by mitogen-stimulated T-lymphocytes and leukocytes. It is cytotoxic for a wide range of tumor cells both in vitro and in vivo. Proposed term will be modified for MedDRA capitalization conventions and alignment with existing PT Alpha tumour necrosis factor increased and added as new PT Beta tumour necrosis factor increased under HLT Immune response protein analyses NEC. In a related change, the American English spelled counterpart LLT Beta tumor necrosis factor increased will also be added to new PT Beta tumour necrosis factor increased.

Supplemental Update Report

CR Number: 2022326038 **Implementation Date:** 22-Nov-22 Related CR: 2022320003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Beta tumor necrosis factor increased*	Approved as Requested	Proposed LLT	
To PT	*Beta tumour necrosis factor increased*		*Beta tumor necrosis factor increased*	10088823 Current
			To PT	
			Beta tumour necrosis factor increased	10088822

MSSO Comment:

CR Number: 2022320004 **Implementation Date:** 22-Nov-22 Related CR: 2022320004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*TUMOR NECROSIS FACTOR BETA INCREASED*	Rejected		

MSSO Comment: The proposal to add a new term TUMOR NECROSIS FACTOR BETA INCREASED is not approved. The proposed concept is a duplicate of change request 2022320003 in which the concept was added.

CR Number: 2022320005 **Implementation Date:** 22-Nov-22 Related CR: 2022320005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Iris capture*	Approved as Requested	Proposed LLT	
			Iris capture	10088824 Current
			To PT	
			Pupillary capture	10088327

MSSO Comment: The proposal to add a new term Iris capture is approved as requested. In iris capture, the iris is trapped between IOL and lens capsule and becomes attached to the anterior lens capsule. Iris capture occurred in 23% in patients who underwent combined scleral IOL fixation and pars plana vitrectomy. Iris capture leads to blurred vision, photophobia, and dull pain. The rectangular loop suture technique is an effective, convenient, and minimally invasive method for iris capture of the IOL. Proposed term will be added as LLT Iris capture under PT Pupillary capture, which was recently added and will be available in v26.0.

Supplemental Update Report

CR Number: 2022320006 **Implementation Date:** 22-Nov-22 Related CR: 2022320006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*BCG related prostatitis*	Approved Not as Requested	Proposed LLT	
HLT primary	*Prostate and seminal vesicles infections and inflammations*		*BCG related prostatitis*	10088825 Current
			To PT	
SOC primary	*Reproductive system and breast disorders*		*Prostatitis*	10036978

MSSO Comment: The proposal to add a new PT BCG related prostatitis to primary HLT Prostate and seminal vesicles infections and inflammations in SOC Reproductive system and breast disorders is approved but not as requested. The reason for BCG-induced granulomatous prostatitis is a prostatic inflammatory reaction resulting from the intraprostatic reflux of BCG-contaminated urine in the bladder. It is a hypersensitivity reaction to BCG antigens when given as adjuvant treatment of patients with superficial bladder cancer. BCG related prostatitis will be added as an LLT to PT Prostatitis, aligned with LLT Granulomatous prostatitis.

CR Number: 2022320007 **Implementation Date:** 23-Nov-22 Related CR: 2022320007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Product closure leak*	Approved as Requested	Proposed LLT	
To PT	*Product closure issue*		*Product closure leak*	10088826 Current
			To PT	
			Product closure issue	10069295

MSSO Comment: The proposal to add a new LLT Product closure leak to PT Product closure issue is approved as requested. Addition of Product closure leak allows determining exactly where a leak is coming, thus facilitating its mitigation.

CR Number: 2022320008 **Implementation Date:** 23-Nov-22 Related CR: 2022320008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Shaving pimples*	Rejected		
To PT	*Pseudofolliculitis*			

MSSO Comment: The proposal to add a new LLT Shaving pimples to PT Pseudofolliculitis is not approved. Shaving pimples is an ambiguous term due to its colloquial nature, since it may refer to the very precise diagnosis of Pseudofolliculitis barbae or to any occasional foliculitis occurring after shaving. MedDRA already has PT Pseudofolliculitis, with several LLTs with differing wording to capture such situations.

Supplemental Update Report

CR Number: 2022320009 **Implementation Date:** 23-Nov-22 Related CR: 2022320009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Sinus swelling*	Approved as Requested	Proposed LLT *Sinus swelling* To PT *Sinus congestion*	10088827 Current 10040742

MSSO Comment: The proposal to add a new term Sinus swelling is approved as requested. Swelling of the lining of paranasal sinuses, is associated with blocked congested nose. Sinus swelling will be added as an LLT to PT Sinus congestion.

CR Number: 2022320010 **Implementation Date:** 23-Nov-22 Related CR: 2022320010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Rosacea-like dermatitis*	Rejected		
From PT	*Rosacea*			
To PT	*Dermatitis*			

MSSO Comment: The proposal to move the LLT Rosacea-like dermatitis from PT Rosacea to PT Dermatitis is not approved. Rosacea-like is often used to refer to steroid rosacea, a condition on the mid-face caused by potent topical steroids or their withdrawal. Rosacea-like is more specific as it indicates the mid-facial region where it most often appears. If placed under PT Dermatitis this information would not be reflected. Additionally, "condition-like" terms are generally placed under the corresponding condition in MedDRA.

CR Number: 2022320011 **Implementation Date:** 23-Nov-22 Related CR: 2022320011

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Penile fissure*	Rejected		
From PT	*Penis disorder*			
To PT	*Penis injury*			

MSSO Comment: The proposal to move the LLT Penile fissure from PT Penis disorder to PT Penis injury is not approved. Although friction and trauma could explain some penile fissures, there are also other non-injury causes that could cause it, such as some dermatopathies (contact dermatitis, psoriasis, fixed drug eruptions), sexually transmitted diseases, fungal infections (candida) or - more rarely - neoplastic conditions such as Bowen disease.

Supplemental Update Report

CR Number: 2022320012 **Implementation Date:** 23-Nov-22 Related CR: 2022320012

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Uvula pain*	Approved as Requested	Proposed LLT	
From PT	*Oropharyngeal pain*		*Uvula pain*	10083481 Current
To PT	*Oral pain*		From PT	
			Oropharyngeal pain	10068319
			To PT	
			Oral pain	10031009

MSSO Comment: The proposal to move the LLT Uvula pain from PT Oropharyngeal pain to PT Oral pain is approved as requested. Uvula can be considered either an oral or palatal structure. The new location provides a coincidental primary link within the Gastrointestinal SOC which is consistent with terms representing other uvular conditions, thus facilitating data analysis.

CR Number: 2022320013 **Implementation Date:** 23-Nov-22 Related CR: 2022320013

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Uvular erythema*	Approved as Requested	Proposed LLT	
From PT	*Pharyngeal erythema*		*Uvular erythema*	10067239 Current
To PT	*Oral mucosal erythema*		From PT	
			Pharyngeal erythema	10057009
			To PT	
			Oral mucosal erythema	10067418

MSSO Comment: The proposal to move the LLT Uvular erythema from PT Pharyngeal erythema to PT Oral mucosal erythema is approved as requested. Uvula can be considered either an oral or palatal structure. The new location provides a coincidental primary link within the Gastrointestinal SOC which is consistent with terms representing other uvular conditions, thus facilitating data analysis.

CR Number: 2022320014 **Implementation Date:** 23-Nov-22 Related CR: 2022320014

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Uvular ulceration*	Approved as Requested	Proposed LLT	
From PT	*Pharyngeal ulceration*		*Uvular ulceration*	10077521 Current
To PT	*Palatal ulcer*		From PT	
			Pharyngeal ulceration	10034834
			To PT	
			Palatal ulcer	10077519

MSSO Comment: The proposal to move the LLT Uvular ulceration from PT Pharyngeal ulceration to PT Palatal ulcer is approved as requested. Uvula can be considered either an oral or palatal structure. The new location provides a coincidental primary link within the Gastrointestinal SOC which is consistent with terms representing other uvular conditions, thus facilitating data analysis.

Supplemental Update Report

CR Number: 2022320015 **Implementation Date:** 23-Nov-22 Related CR: 2022320015

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Body hair increased*	Approved as Requested	Proposed LLT		
From PT	*Hypertrichosis*		*Body hair increased*	10053924	Current
To PT	*Hair growth abnormal*		From PT		
			Hypertrichosis	10020864	
			To PT		
			Hair growth abnormal	10019044	

MSSO Comment: The proposal to move the LLT Body hair increased from PT Hypertrichosis to PT Hair growth abnormal is approved as requested. Body hair increased could be used to refer to both Hypertrichosis and Hirsutism, and therefore the new location provides a more accurate placement, aligned with existing LLT Hair growth increased.

CR Number: 2022320016 **Implementation Date:** 23-Nov-22 Related CR: 2022320016

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Facial hair increased*	Approved as Requested	Proposed LLT		
From PT	*Hypertrichosis*		*Facial hair increased*	10083548	Current
To PT	*Hair growth abnormal*		From PT		
			Hypertrichosis	10020864	
			To PT		
			Hair growth abnormal	10019044	

MSSO Comment: The proposal to move the LLT Facial hair increased from PT Hypertrichosis to PT Hair growth abnormal is approved as requested. Apart from the adequacy of this rather colloquial expression under a diagnostic term as Hypertrichosis, Facial hair increased could be be used to refer to both Hypertrichosis and Hirsutism, and therefore the new location warrants a better alignment.

CR Number: 2022321001 **Implementation Date:** 23-Nov-22 Related CR: 2022321001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Vascular access site pressure sensation*	Approved as Requested	Proposed LLT		
To PT	*Vascular access site discomfort*		*Vascular access site pressure sensation*	10088829	Current
			To PT		
			Vascular access site discomfort	10088701	

MSSO Comment: The proposal to add a new LLT Vascular access site pressure sensation to PT Vascular access site discomfort is approved as requested. Vascular access site pressure sensation will be added as LLT to PT Vascular access site discomfort to complement the set of vascular access site subconcept terms for coding purposes.

Supplemental Update Report

CR Number: 2022321002 **Implementation Date:** 23-Nov-22 Related CR: 2022321002

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Product temperature excursion issue*	Approved Not as Requested	Proposed LLT	
Replacement term	*Manufacturing product temperature excursion issue*		*Product temperature deviation error*	10088831 Current
			To PT	
			Product storage error	10079843

MSSO Comment: The proposal to rename PT/LLT Product temperature excursion issue to Manufacturing product temperature excursion issue is approved but not as requested. The proposed term does not need to be modified as the HLT Product distribution and storage issues is intended to cover issues with the storage of products by manufacturers, distributors, wholesalers, etc. In contrast, product storage issues by end-users such as healthcare professionals, patients, and consumers are considered to be medication errors and are represented by appropriate medication error terms in SOC Injury, poisoning and procedural complications. Therefore a new LLT Product temperature deviation error will be added under PT Product storage error.

CR Number: 2022321003 **Implementation Date:** 23-Nov-22 Related CR: 2022321003

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Loss of personal independence in daily activities*	Rejected		
From HLT	*Disability issues*			
To HLT	*General signs and symptoms NEC*			

MSSO Comment: The proposal to move the PT Loss of personal independence in daily activities from HLT Disability issues to HLT General signs and symptoms NEC is not approved. PT Loss of personal independence in daily activities and PT Impaired self-care are closely related and both represent disability issues. Please see change request 2022321004 for the action taken.

CR Number: 2022321004 **Implementation Date:** 23-Nov-22 Related CR: 2022321004

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Impaired self-care*	Approved as Requested	PT to merge	
To PT	*Loss of personal independence in daily activities*		*Impaired self-care*	10052404 Current
			To PT	
			Loss of personal independence in daily activities	10079487

MSSO Comment: The proposal to demote the PT Impaired self-care under PT Loss of personal independence in daily activities is approved as requested. PT Loss of personal independence in daily activities and PT Impaired self-care are closely related and both represent disability issues.

Supplemental Update Report

CR Number: 2022321005 **Implementation Date:** 23-Nov-22 Related CR: 2022321005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Heart-type fatty acid-binding protein increased*	Approved as Requested	Proposed PT	
			Heart-type fatty acid-binding protein increased	10088828
			HLT primary	
			Skeletal and cardiac muscle analyses	10040768
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Heart-type fatty acid-binding protein increased is approved as requested. Heart-type fatty acid-binding protein (H-FABP) is a sensitive biomarker for myocardial infarction and can be detected in the blood within one to three hours of the pain. H-FABP as early marker and cardiac troponin I as late marker would be the ideal combination to cover the complete diagnostic window for AMI. Heart-type fatty acid-binding protein increased will be added as a PT under HLT Skeletal and cardiac muscle analyses. In a related change, the acronym LLT H-FABP increased will also be added under the new PT Heart-type fatty acid-binding protein increased.

CR Number: 2022326037 **Implementation Date:** 23-Nov-22 Related CR: 2022321005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*H-FABP increased*	Approved as Requested	Proposed LLT	
To PT	*Heart-type fatty acid-binding protein increased*		*H-FABP increased*	10088832 Current
			To PT	
			Heart-type fatty acid-binding protein increased	10088828

MSSO Comment:

CR Number: 2022321006 **Implementation Date:** 23-Nov-22 Related CR: 2022321006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypertensive uveitis*	Approved Not as Requested	Proposed LLT	
			Hypertensive uveitis	10088830 Current
			To PT	
			Uveitis	10046851

MSSO Comment: The proposal to add a new PT Hypertensive uveitis is approved but not as requested. Hypertensive uveitis is associated with rise of intraocular pressure along with mild infammation of the anterior chamber or uveitis. Proposed term will be added as new LLT Hypertensive uveitis under PT Uveitis.

Supplemental Update Report

CR Number: 2022321007 **Implementation Date:** 23-Nov-22 Related CR: 2022321007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*STING-associated vasculopathy with onset in infancy*	Approved Not as Requested	Proposed PT *STING-associated vasculopathy with onset in infancy*	10088833
HLT primary	*Autoimmune disorders NEC*		HLT primary *Immune system abnormalities congenital*	10021424
SOC primary	*Immune system disorders*		SOC primary *Congenital, familial and genetic disorders*	10010331
			HLT secondary *Autoinflammatory diseases*	10073080
			SOC secondary *Immune system disorders*	10021428

MSSO Comment: The proposal to add a new PT STING-associated vasculopathy with onset in infancy to primary HLT Autoimmune disorders NEC in SOC Immune system disorders is approved but not as requested. Stimulator of interferon genes (STING1) is a key intermediary in activating the type I IFN response. STING-associated vasculopathy with onset in infancy (SAVI) is a very rare autoinflammatory disease that is caused by heterozygous gain-of-function mutations in STING1. SAVI typically manifests as neonatal-onset systemic inflammation, interstitial lung disease (ILD), and severe cutaneous vasculopathy located in acral regions, including fingers, toes, ears, and nose. Severity of ILD and recurrent pulmonary infections are crucial for the prognosis. STING-associated vasculopathy with onset in infancy will be added as PT to primary HLT Immune system abnormalities congenital and secondary HLT Autoinflammatory diseases and secondary HLT Vasculitides NEC and secondary HLT Parenchymal lung disorders NEC.

CR Number: 2022327099 **Implementation Date:** 23-Nov-22 Related CR: 2022321007

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*STING-associated vasculopathy with onset in infancy*	Approved as Requested	Proposed PT *STING-associated vasculopathy with onset in infancy*	10088833
To HLT	*Vasculitides NEC*		To HLT *Vasculitides NEC*	10047113

MSSO Comment:

Supplemental Update Report

CR Number: 2022327100 **Implementation Date:** 23-Nov-22 Related CR: 2022321007

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*STING-associated vasculopathy with onset in infancy*	Approved as Requested	Proposed PT	
			STING-associated vasculopathy with onset in infancy	10088833
To HLT	*Parenchymal lung disorders NEC*		To HLT	
			Parenchymal lung disorders NEC	10033979

MSSO Comment:

CR Number: 2022321008 **Implementation Date:** 23-Nov-22 Related CR: 2022321008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Squamous cell carcinoma in situ*	Approved Not as Requested	Proposed LLT		
			Squamous cell carcinoma in situ	10088836	Current
To PT	*squamous cell carcinoma*		To PT		
			Squamous cell carcinoma	10041823	

MSSO Comment: The proposal to add a new LLT Squamous cell carcinoma in situ to PT squamous cell carcinoma is approved but not as requested. Squamous cell carcinoma in situ (or stage 0) is a squamous carcinoma which has not broken the epithelial basal membrane. Squamous cell carcinoma in situ will be added as an LLT to PT Squamous cell carcinoma, with capitalization corrected for how the concept is represented in MedDRA.

CR Number: 2022321009 **Implementation Date:** 23-Nov-22 Related CR: 2022321009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Glottic stenosis*	Approved as Requested	Proposed LLT		
			Glottic stenosis	10088834	Current
To PT	*Laryngeal stenosis*		To PT		
			Laryngeal stenosis	10023862	

MSSO Comment: The proposal to add a new LLT Glottic stenosis to PT Laryngeal stenosis is approved as requested. Glottic stenosis is narrowing of the larynx at the level of the glottis (ie, vocal cords). It is caused by webbing, fibrosis, or scarring and most often involves the posterior glottis. The most common cause of stenosis is prolonged endotracheal intubation. In a related change, PT Laryngeal stenosis will be linked to a secondary HLT Respiratory tract and thoracic cavity procedural complications.

Supplemental Update Report

CR Number: 2022327101 **Implementation Date:** 23-Nov-22 Related CR: 2022321009

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Laryngeal stenosis*	Approved as Requested	Proposed PT	
To HLT	*Respiratory tract and thoracic cavity procedural complications*		*Laryngeal stenosis*	10023862
			To HLT	
			Respiratory tract and thoracic cavity procedural complications	10052823

MSSO Comment:

CR Number: 2022321010 **Implementation Date:** 23-Nov-22 Related CR: 2022321010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Drug-induced heart failure*	Rejected		
HLT primary	*Heart failures NEC*			
SOC primary	*Cardiac disorders*			

MSSO Comment: The proposal to add a new PT Drug-induced heart failure to primary HLT Heart failures NEC in SOC Cardiac disorders is not approved. The proposed term implies a causal relationship between an event and a drug, and therefore represents a combination term. The MSSO refrains from adding further "drug-induced" terms. Please consider LLT Cardiotoxicity in addition to Cardiac failure to represent the causal relationship between causality and effect.

CR Number: 2022321011 **Implementation Date:** 23-Nov-22 Related CR: 2022321011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed PT	*Large intestinal resection*	Approved Not as Requested	Proposed LLT		
HLT primary	*Large intestine therapeutic procedures*		*Large intestine resection*	10088835	Current
SOC primary	*Surgical and medical procedures*		To PT		
			Colectomy	10061778	

MSSO Comment: The proposal to add a new PT Large intestinal resection to primary HLT Large intestine therapeutic procedures in SOC Surgical and medical procedures is approved but not as requested. The proposed term will be slightly modified and added as synonym LLT Large intestine resection to PT Colectomy.

Supplemental Update Report

CR Number: 2022321018 **Implementation Date:** 23-Nov-22 Related CR: 2022321018

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Intravenous injection formulation administered by other route*	Rejected		
To PT	*Incorrect route of product administration*			

MSSO Comment: The proposal to add a new LLT Intravenous injection formulation administered by other route to PT Incorrect route of product administration is not approved. The proposed term is represented by LLT Intravenous formulation administered by other route.

CR Number: 2022321019 **Implementation Date:** 23-Nov-22 Related CR: 2022321019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Intramuscular injection formulation administered by other route*	Rejected		
To PT	*Incorrect route of product administration*			

MSSO Comment: The proposal to add a new LLT Intramuscular injection formulation administered by other route to PT Incorrect route of product administration is not approved. The proposed term is represented by LLT Intramuscular formulation administered by other route.

CR Number: 2022321023 **Implementation Date:** 23-Nov-22 Related CR: 2022321023

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*High active antiretroviral therapy induced lipodystrophy*	Rejected		
To PT	*Lipodystrophy acquired*			

MSSO Comment: The proposal to add a new LLT High active antiretroviral therapy induced lipodystrophy to PT Lipodystrophy acquired is not approved. The proposed concept is the combination of the two existing LLTs Lipodystrophy and Antiretroviral therapy. Causal association between condition and drug therapy can also be explored through the adequate fields for each within the transmittal form. Please, also consider point 3.5.4 When to “split” into more than one MedDRA term, of the Term Selection: Points to Consider document.

Supplemental Update Report

CR Number: **2022321024** **Implementation Date:** 23-Nov-22 Related CR: 2022321024

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Localized lipodystrophy*	Approved Not as Requested	Proposed LLT	
HLT primary	*Lipodystrophies*		*Localized lipodystrophy*	10088838 Current
SOC primary	*Skin and subcutaneous tissue disorders*		To PT	
			Localised lipodystrophy	10088837

MSSO Comment: The proposal to add a new PT Localized lipodystrophy to primary HLT Lipodystrophies in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Localized lipodystrophies occur as a result of drug or vaccine injections, pressure, and panniculitis, as well as other unknown reasons. They present with subcutaneous fat loss from a focal region resulting in a dimple or a crater with overlying skin usually unaffected. In some patients, large contiguous or anatomically distinct areas on any region of the body may be involved. The proposed term will be added as LLT Localized lipodystrophy to new British English spelled PT Localised lipodystrophy which will be added in a related change under HLT Lipodystrophies.

CR Number: **2022327102** **Implementation Date:** 23-Nov-22 Related CR: 2022321024

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Localised lipodystrophy*	Approved as Requested	Proposed PT	
HLT primary	*Lipodystrophies*		*Localised lipodystrophy*	10088837
SOC primary	*Skin and subcutaneous tissue disorders*		HLT primary	
			Lipodystrophies	10024606
			SOC primary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment:

CR Number: **2022321025** **Implementation Date:** 23-Nov-22 Related CR: 2022321025

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Drug-induced lipodystrophy*	Rejected		
HLT primary	*Lipodystrophies*			
SOC primary	*Skin and subcutaneous tissue disorders*			

MSSO Comment: The proposal to add a new PT Drug-induced lipodystrophy to primary HLT Lipodystrophies in SOC Skin and subcutaneous tissue disorders is not approved. MedDRA refrains from adding new drug-induced terms. Terms of “due to” nature are generally not added to MedDRA because causality is determined by the reporter/investigator or sponsor. Please consider LLT Injection site lipodystrophy.

Supplemental Update Report

CR Number: 2022322001 **Implementation Date:** 23-Nov-22 Related CR: 2022322001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Little's disease*	Approved as Requested	Proposed LLT *Little's disease* To PT *Cerebral palsy*	10088839 Current 10008129

MSSO Comment: The proposal to add a new LLT Little's disease is approved as requested. Little's disease will be added as a sub-type LLT to PT Cerebral palsy. In a related change, LLT Spastic diplegia, a synonym of Little's disease will be moved from PT Diplegia to PT Cerebral palsy for better alignment.

CR Number: 2022327103 **Implementation Date:** 23-Nov-22 Related CR: 2022322001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Spastic diplegia*	Approved as Requested	Proposed LLT *Spastic diplegia*	10067130 Current
From PT	*Diplegia*		From PT *Diplegia*	10013033
To PT	*Cerebral palsy*		To PT *Cerebral palsy*	10008129

MSSO Comment:

CR Number: 2022322002 **Implementation Date:** 23-Nov-22 Related CR: 2022322002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Calcified granuloma*	Approved as Requested	Proposed LLT *Calcified granuloma* To PT *Granuloma*	10088842 Current 10018691

MSSO Comment: The proposal to add a new LLT Calcified granuloma is approved as requested. Calcified granulomas are small clumps of immune cells that have become filled with calcium. When something is referred to as “calcified,” it means that it contains deposits of the element calcium. Calcified granuloma will be added as LLT to PT Granuloma.

Supplemental Update Report

CR Number: 2022322003 **Implementation Date:** 23-Nov-22 Related CR: 2022322003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tigroid fundus*	Approved as Requested	Proposed LLT	
			Tigroid fundus	10088843 Current
			To PT	
			Tessellated fundus	10083502

MSSO Comment: The proposal to add a new term Tigroid fundus is approved as requested. Myopic maculopathy begins with the development of tessellated (or tigroid) fundus, and later other lesions, such as lacquer cracks, diffuse chorioretinal atrophy, and patchy chorioretinal atrophy, develop. Tigroid fundus will be added as LLT to PT Tessellated fundus aligned with LLT Leopard fundus.

CR Number: 2022322004 **Implementation Date:** 23-Nov-22 Related CR: 2022322004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Erosive pustular dermatosis of the scalp*	Approved as Requested	Proposed LLT	
			Erosive pustular dermatosis of the scalp	10088844 Current
			To PT	
			Erosive pustular dermatosis	10088153

MSSO Comment: The proposal to add a new term Erosive pustular dermatosis of the scalp is approved as requested. Erosive pustular dermatosis occurs in males and females; most affected individuals are over the age of 80 years and have actinic keratoses and a history of squamous cell carcinoma or (less often) basal cell carcinoma of the scalp. Erosive pustular dermatosis of the scalp will be added as LLT to the recently added PT Erosive pustular dermatosis which will be available for version 26.0.

CR Number: 2022322005 **Implementation Date:** 23-Nov-22 Related CR: 2022322005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Abnormal gene carrier*	Approved as Requested	Proposed PT	
			Abnormal gene carrier	10088840
			HLT primary	
			Abnormal gene carriers	10052636
			SOC primary	
			Congenital, familial and genetic disorders	10010331

MSSO Comment: The proposal to add a new term Abnormal gene carrier is approved as requested. Abnormal gene carrier will be added as PT to HLT Abnormal gene carriers to facilitate coding of reports where no specific gene abnormality is mentioned.

Supplemental Update Report

CR Number: 2022322006 **Implementation Date:** 23-Nov-22 Related CR: 2022322006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Disease carrier*	Rejected		

MSSO Comment: The proposal to add a new term Disease carrier is not approved. Disease carrier is ambiguous as it may refer to asymptomatic carrier of infectious diseases or to genetic carrier who has inherited a genetic trait or mutation, but displays no symptoms.

CR Number: 2022322007 **Implementation Date:** 23-Nov-22 Related CR: 2022322007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*ALG8 gene carrier*	Approved Not as Requested	Proposed PT	
			ALG8 gene mutation carrier	10088841
			HLT primary	
			Abnormal gene carriers	10052636
			SOC primary	
			Congenital, familial and genetic disorders	10010331

MSSO Comment: The proposal to add a new LLT ALG8 gene carrier is approved but not as requested. Mutations in this gene have been associated with congenital disorders of glycosylation. The requested term will be modified for clarity and added as PT ALG8 gene mutation carrier to HLT Abnormal gene carriers.

CR Number: 2022322159 **Implementation Date:** 28-Nov-22 Related CR: 2022322159

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive breast cancer*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive breast cancer is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

Supplemental Update Report

CR Number: 2022322160 **Implementation Date:** 28-Nov-22 Related CR: 2022322160

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive salivary gland cancer*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive salivary gland cancer is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

CR Number: 2022322161 **Implementation Date:** 28-Nov-22 Related CR: 2022322161

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive thyroid cancer*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive thyroid cancer is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

CR Number: 2022322162 **Implementation Date:** 28-Nov-22 Related CR: 2022322162

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive cholangiocarcinoma*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive cholangiocarcinoma is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

Supplemental Update Report

CR Number: **2022322163** **Implementation Date:** 28-Nov-22 Related CR: 2022322163

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive colorectal cancer*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive colorectal cancer is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

CR Number: **2022322164** **Implementation Date:** 28-Nov-22 Related CR: 2022322164

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive sarcoma*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive sarcoma is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

CR Number: **2022322165** **Implementation Date:** 28-Nov-22 Related CR: 2022322165

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive pancreatic cancer*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive pancreatic cancer is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

Supplemental Update Report

CR Number: 2022322166 **Implementation Date:** 28-Nov-22 Related CR: 2022322166

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive non-small cell lung cancer*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive non-small cell lung cancer is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

CR Number: 2022322167 **Implementation Date:** 28-Nov-22 Related CR: 2022322167

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive melanoma*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive melanoma is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

CR Number: 2022322168 **Implementation Date:** 28-Nov-22 Related CR: 2022322168

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive neuroendocrine tumour*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive neuroendocrine tumour is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

Supplemental Update Report

CR Number: 2022322169 **Implementation Date:** 28-Nov-22 Related CR: 2022322169

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive head and neck cancer*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive head and neck cancer is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

CR Number: 2022322170 **Implementation Date:** 28-Nov-22 Related CR: 2022322170

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive biliary tract cancer*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive biliary tract cancer is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

CR Number: 2022322171 **Implementation Date:** 28-Nov-22 Related CR: 2022322171

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive inflammatory myofibroblastic tumour*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive inflammatory myofibroblastic tumour is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

Supplemental Update Report

CR Number: **2022322172** **Implementation Date:** 28-Nov-22 Related CR: 2022322172

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive appendix cancer*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive appendix cancer is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

CR Number: **2022322173** **Implementation Date:** 28-Nov-22 Related CR: 2022322173

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive glioma*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive glioma is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

CR Number: **2022322174** **Implementation Date:** 28-Nov-22 Related CR: 2022322174

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive renal cell cancer*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive renal cell cancer is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

Supplemental Update Report

CR Number: 2022322175 **Implementation Date:** 28-Nov-22 Related CR: 2022322175

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive acute myeloid leukaemia*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive acute myeloid leukaemia is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

CR Number: 2022322176 **Implementation Date:** 28-Nov-22 Related CR: 2022322176

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive acute lymphoblastic leukaemia*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive acute lymphoblastic leukaemia is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

CR Number: 2022322177 **Implementation Date:** 28-Nov-22 Related CR: 2022322177

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive multiple myeloma*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive multiple myeloma is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

Supplemental Update Report

CR Number: **2022322178** **Implementation Date:** 28-Nov-22 Related CR: 2022322178

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*NTRK gene fusion positive dendritic cell neoplasm*	Rejected		

MSSO Comment: The proposal to add a new LLT NTRK gene fusion positive dendritic cell neoplasm is not approved. In order to avoid over-population at PT level, MedDRA cannot accept all possible combination NTRK gene fusion positive cancer type terms. In lieu of adding/submitting the proposed terms please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER (PTC) document specifically section 3.5.4 When to “split” into more than one MedDRA term. If splitting the reported ARs/AEs provides more clinical information, select more than one MedDRA term. For example, in the field of oncology, there may be situations in which it is important to capture information not only for the tumour type, but also for the associated genetic marker or abnormality because of the implications for aetiology, prognosis or treatment. If a combination term that describes a genetic marker or abnormality associated with a medical condition is not available, separate terms may be selected to represent the genetic marker or abnormality as well as the associated medical condition.

CR Number: **2022324001** **Implementation Date:** 28-Nov-22 Related CR: 2022324001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*CORONARY ARTERY BALLOON DILATATION*	Rejected		

MSSO Comment: The proposal to add a new term CORONARY ARTERY BALLOON DILATATION is not approved. The proposed coronary intervention is already represented by the LLT Balloon coronary angioplasty.

CR Number: **2022324002** **Implementation Date:** 28-Nov-22 Related CR: 2022324002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*GASTROINTESTINAL POLYPECTOMY*	Rejected		

MSSO Comment: The proposal to add a new term GASTROINTESTINAL POLYPECTOMY is not approved. The proposed term is too broad and unlikely to be used without a more concrete anatomical location within the gastrointestinal tract, as it is the case of the many different polypectomies already found under HLGT Gastrointestinal therapeutic procedures. Should you have any special need to add this general term, please justify it in a new change request.

Supplemental Update Report

CR Number: **2022324003** **Implementation Date:** 28-Nov-22 Related CR: 2022324003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Closed reduction of fracture external fixation*	Rejected		
To PT	*Closed fracture manipulation*			

MSSO Comment: The proposal to add a new LLT Closed reduction of fracture external fixation to PT Closed fracture manipulation is not approved. This type of fracture reduction is already represented by LLT External fixation of closed fracture.

CR Number: **2022324004** **Implementation Date:** 28-Nov-22 Related CR: 2022324004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Spinal implantation*	Approved as Requested	Proposed PT	
			Spinal implantation	10088845
			HLT primary	
			Spine and spinal cord therapeutic procedures	10041590
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Spinal implantation is approved as requested. Spinal implants are used to stabilize the unstable spine caused by trauma or by slipped vertebrae (spondylolisthesis) originating from degenerative intervertebral disks. Surgical stabilization can be achieved from either the anterior or posterior approach. Spinal implantation will be added as PT to HLT Spine and spinal cord therapeutic procedures. In a related change, current PT Spinal rod insertion will be demoted under the new PT Spinal implantation for better alignment.

CR Number: **2022332053** **Implementation Date:** 28-Nov-22 Related CR: 2022324004

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Spinal rod insertion*	Approved as Requested	PT to merge	
To PT	*Spinal implantation*		*Spinal rod insertion*	10053002 Current
			To PT	
			Spinal implantation	10088845

MSSO Comment:

Supplemental Update Report

CR Number: 2022324005 **Implementation Date:** 28-Nov-22 Related CR: 2022324005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Vaginal cuff*	Approved as Requested	Proposed PT	
			Vaginal cuff	10088846
			HLT primary	
			Uterine therapeutic procedures	10046808
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Vaginal cuff is approved as requested. A vaginal cuff is a closure made at the top of the vagina, near where the cervix is usually located. It is created after a hysterectomy by suturing the edges of the vagina together and then to the uterosacral ligaments to prevent prolapse. Vaginal cuff will be added as PT to HLT Uterine therapeutic procedures.

CR Number: 2022324006 **Implementation Date:** 28-Nov-22 Related CR: 2022324006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Papilla base incision*	Approved Not as Requested	Proposed PT	
			Interdental papilla base incision	10088847
			HLT primary	
			Dental and gingival therapeutic procedures	10012317
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Papilla base incision is approved but not as requested. The papilla base incision consists of a shallow first incision at the base of the gingival papilla and a second incision directed to the crestal bone, creating a split thickness flap in the area of the papilla base used in the treatment of persisting apical periodontitis free of periodontal disease. The proposed term will will be modified for clarity and added as PT Interdental papilla base incision to HLT Dental and gingival therapeutic procedures.

CR Number: 2022324007 **Implementation Date:** 28-Nov-22 Related CR: 2022324007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Interdental aids*	Approved Not as Requested	Proposed LLT	
			Interdental cleaning aid	10088848 Current
			To PT	
			Dental cleaning	10051047

MSSO Comment: The proposal to add a new term Interdental aids is approved but not as requested. Interdental cleaning aid play a vital role in optimising gingival health and preventing oral disease. Based on the results of this review, interdental brushes provide a significant benefit over brushing as a monotherapy. The requested term will be modified for clarity and added as LLT Interdental cleaning aid to PT Dental cleaning.

Supplemental Update Report

CR Number: 2022324008 **Implementation Date:** 28-Nov-22 Related CR: 2022324008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Open bite*	Approved as Requested	Proposed LLT *Open bite* To PT *Malocclusion*	 10088849 Current 10061274

MSSO Comment: The proposal to add a new term Open bite is approved as requested. Open bite is a type of malocclusion that is mainly characterized by a vertical gap. Open bite will be added as LLT to PT Malocclusion.

CR Number: 2022325001 **Implementation Date:** 29-Nov-22 Related CR: 2022325001

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Drug eruption*	Rejected		
Old Primary SOC	*Skin and subcutaneous tissue disorders*			
New Primary SOC	*Immune system disorders*			

MSSO Comment: The proposal to reassign the primary SOC of PT Drug eruption from current SOC Skin and subcutaneous tissue disorders to SOC Immune system disorders is not approved. In general, anatomical site prevails over etiology in MedDRA term placements. Most conditions being mapped to both Skin and subcutaneous tissue disorders SOC and Immune system disorders SOCs are primarily linked to the former.

CR Number: 2022325002 **Implementation Date:** 29-Nov-22 Related CR: 2022325002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Postprocedural fatigue*	Rejected		
HLT primary	*Non-site specific procedural complications*			
SOC primary	*Injury, poisoning and procedural complications*			

MSSO Comment: The proposal to add a new PT Postprocedural fatigue to primary HLT Non-site specific procedural complications in SOC Injury, poisoning and procedural complications is not approved. The requested term represents a combination concept with a temporal or causal relationship. Despite the existence of numerous post procedural terms already, the MSSO refrains from adding further post procedural complication concepts as the continued addition of such combinations could overpopulate MedDRA and lead to signal dilution. Please consider representing the reported event with an appropriate combination of existing terms such as LLT Post procedural complication and LLT Fatigue.

Supplemental Update Report

CR Number: 2022325003 **Implementation Date:** 29-Nov-22 Related CR: 2022325003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tendon edema*	Rejected		
HLT primary	*Tendon disorders*			
SOC primary	*Musculoskeletal and connective tissue disorders*			

MSSO Comment: The proposal to add a new PT Tendon edema to primary HLT Tendon disorders in SOC Musculoskeletal and connective tissue disorders is not approved. Although, Tendon edema is found in a few literature references as an extracellular liquid accumulation between tendocytes, it is basically a synonym expression of tendonitis.

CR Number: 2022325004 **Implementation Date:** 29-Nov-22 Related CR: 2022325004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Postprocedural dysuria*	Rejected		
HLT primary	*Urinary tract procedural complications*			
SOC primary	*Injury, poisoning and procedural complications*			

MSSO Comment: The proposal to add a new PT Postprocedural dysuria to primary HLT Urinary tract procedural complications in SOC Injury, poisoning and procedural complications is not approved. The requested term represents a combination concept with a temporal or causal relationship. Despite the existence of numerous post procedural terms already, the MSSO refrains from adding further post procedural complication concepts as the continued addition of such combinations could overpopulate MedDRA and lead to signal dilution. Please consider representing the reported event with an appropriate combination of existing terms such as LLT Post procedural complication and LLT Dysuria.

CR Number: 2022325005 **Implementation Date:** 29-Nov-22 Related CR: 2022325005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Postprocedural Hypovolemic shock*	Rejected		
HLT primary	*Cardiac and vascular procedural complications*			
SOC primary	*Injury, poisoning and procedural complications*			

MSSO Comment: The proposal to add a new PT Postprocedural Hypovolemic shock to primary HLT Cardiac and vascular procedural complications in SOC Injury, poisoning and procedural complications is not approved. The requested term represents a combination concept with a temporal or causal relationship. Despite the existence of numerous post procedural terms already, the MSSO refrains from adding further post procedural complication concepts as the continued addition of such combinations could overpopulate MedDRA and lead to signal dilution. Please consider representing the reported event with an appropriate combination of existing terms such as LLT Post procedural complication and LLT Hypovolemic shock.

Supplemental Update Report

CR Number: 2022325006 **Implementation Date:** 29-Nov-22 Related CR: 2022325006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Postprocedural hepatic failure*	Rejected		
HLT primary	*Gastrointestinal and hepatobiliary procedural complications*			
SOC primary	*Injury, poisoning and procedural complications*			

MSSO Comment: The proposal to add a new PT Postprocedural hepatic failure to primary HLT Gastrointestinal and hepatobiliary procedural complications in SOC Injury, poisoning and procedural complications is not approved. The requested term represents a combination concept with a temporal or causal relationship. Despite the existence of numerous post procedural terms already, the MSSO refrains from adding further post procedural complication concepts as the continued addition of such combinations could overpopulate MedDRA and lead to signal dilution. Please consider representing the reported event with an appropriate combination of existing terms such as LLT Post procedural complication and LLT Hepatic failure.

CR Number: 2022325007 **Implementation Date:** 29-Nov-22 Related CR: 2022325007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Transforaminal lumbar interbody fusion*	Approved Not as Requested	Proposed LLT	
HLT primary	*Spine and spinal cord therapeutic procedures*		*Transforaminal lumbar interbody fusion*	10088887 Current
SOC primary	*Surgical and medical procedures*		To PT	
			Spinal fusion surgery	10050505

MSSO Comment: The proposal to add a new PT Transforaminal lumbar interbody fusion to primary HLT Spine and spinal cord therapeutic procedures in SOC Surgical and medical procedures is approved but not as requested. A Transforaminal interbody lumbar fusion is a particular type of fusion, or surgical procedure that permanently fuses, or unites, bones of the spine. Transforaminal lumbar interbody fusion will be added as LLT to PT Spinal fusion surgery.

CR Number: 2022325008 **Implementation Date:** 29-Nov-22 Related CR: 2022325008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hyper-reflexive rhinopathy*	Approved Not as Requested	Proposed LLT	
HLT primary	*Abnormal reflexes*		*Hyper-reflexive rhinopathy*	10088886 Current
SOC primary	*Nervous system disorders*		To PT	
			Vasomotor rhinitis	10047145

MSSO Comment: The proposal to add a new PT Hyper-reflexive rhinopathy to primary HLT Abnormal reflexes in SOC Nervous system disorders is approved but not as requested. Vasomotor rhinitis, also called nonallergic rhinitis or hyper-reflexive rhinopathy, is a chronic condition in which intermittent vascular engorgement of the nasal mucous membrane leads to watery rhinorrhea and sneezing. Hyper-reflexive rhinopathy will be added as synonym LLT to PT Vasomotor rhinitis.

Supplemental Update Report

CR Number: 2022325009 **Implementation Date:** 29-Nov-22 Related CR: 2022325009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Idiopathic pancreatitis*	Approved as Requested	Proposed PT	
HLT primary	*Acute and chronic pancreatitis*		*Idiopathic pancreatitis*	10088882
SOC primary	*Gastrointestinal disorders*		HLT primary	
			Acute and chronic pancreatitis	10033646
			SOC primary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new PT Idiopathic pancreatitis to primary HLT Acute and chronic pancreatitis in SOC Gastrointestinal disorders is approved as requested. Diagnosis of idiopathic pancreatitis is applied to cases of pancreatitis where a diagnosis cannot be made through a thorough history, physical examination, laboratory studies, and noninvasive imaging modalities such as abdominal ultrasonography/computerized tomography.

CR Number: 2022325010 **Implementation Date:** 29-Nov-22 Related CR: 2022325010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Phakectomy*	Approved Not as Requested	Proposed LLT	
To PT	*Cataract Operation*		*Phakectomy*	10088890 Current
			To PT	
			Cataract operation	10063797

MSSO Comment: The proposal to add a new LLT Phakectomy to PT Cataract Operation is approved but not as requested. Phakectomy is a synonym of existing LLT Cataract extraction and will be placed as an LLT under PT Cataract operation, with corrected capitalization. In a related change, LLT Phacoemulsification will be moved from PT Lens extraction to PT Cataract operation for better alignment.

CR Number: 2022333024 **Implementation Date:** 29-Nov-22 Related CR: 2022325010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Phacoemulsification*	Approved as Requested	Proposed LLT	
From PT	*Lens extraction*		*Phacoemulsification*	10059285 Current
To PT	*Cataract operation*		From PT	
			Lens extraction	10071370
			To PT	
			Cataract operation	10063797

MSSO Comment:

Supplemental Update Report

CR Number: 2022325011 **Implementation Date:** 29-Nov-22 Related CR: 2022325011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Benzodiazepine Use Disorder*	Rejected		
To PT	*Drug use disorder*			

MSSO Comment: The proposal to add a new LLT Benzodiazepine Use Disorder to PT Drug use disorder is not approved. In addition to the many specific LLTs under PT Drug dependence, it is not feasible to add every possible drug class represented as a "drug use disorder". Furthermore, the specific drug class can be documented in a specific field of the report.

CR Number: 2022325012 **Implementation Date:** 29-Nov-22 Related CR: 2022325012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Patent Foramen Ovale Closure*	Approved Not as Requested	Proposed LLT	
To PT	*Atrial septal defect repair*		*Patent foramen ovale closure*	10088889 Current
			To PT	
			Atrial septal defect repair	10003667

MSSO Comment: The proposal to add a new LLT Patent Foramen Ovale Closure to PT Atrial septal defect repair is approved but not as requested. Patent foramen ovale closure is a percutaneous procedure undertaken from the femoral vein with ultrasound guidance and adequate anticoagulation, most often to reduce a long-term risk of stroke. The proposed term will be modified to Patent foramen ovale closure, in accordance with MedDRA capitalization conventions, and added as LLT to PT Atrial septal defect repair.

CR Number: 2022325013 **Implementation Date:** 29-Nov-22 Related CR: 2022325013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Chromosomal microduplication*	Approved Not as Requested	Proposed PT	
To PT	*Cytogenetic abnormality*		*Chromosomal microduplication*	10088883
			HLT primary	
			Chromosomal abnormalities NEC	10008805
			SOC primary	
			Congenital, familial and genetic disorders	10010331

MSSO Comment: The proposal to add a new LLT Chromosomal microduplication to PT Cytogenetic abnormality is approved but not as requested. Chromosomal microduplications, or submicroscopic duplications, are chromosomal duplications that are too small to be detected by light microscopy using conventional cytogenetics methods. Chromosomal microduplication will be added as a PT under HLT Chromosomal abnormalities NEC.

Supplemental Update Report

CR Number: 2022325014 **Implementation Date:** 29-Nov-22 Related CR: 2022325014

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Borderline Hypothyroidism*	Approved Not as Requested	Proposed LLT	
To PT	*Hypothyroidism*		*Borderline hypothyroidism*	10088888 Current
			To PT	
			Hypothyroidism	10021114

MSSO Comment: The proposal to add a new LLT Borderline Hypothyroidism to PT Hypothyroidism is approved but not as requested. Borderline hypothyroidism typically is used when blood tests show that your body's level of TSH is slightly above normal, but your T3 and T4 levels are normal. Another name for this condition is subclinical hypothyroidism. Proposed term will be modified for MedDRA capitalization conventions and added as a sub-concept LLT Borderline hypothyroidism to existing PT Hypothyroidism, aligned with related LLT Subclinical hypothyroidism.

CR Number: 2022325015 **Implementation Date:** 29-Nov-22 Related CR: 2022325015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Allergy to Tuberculin*	Approved Not as Requested	Proposed LLT	
To PT	*Drug hypersensitivity*		*Systemic hypersensitivity to tuberculin*	10088891 Current
			To PT	
			Drug hypersensitivity	10013700

MSSO Comment: The proposal to add a new LLT Allergy to Tuberculin to PT Drug hypersensitivity is approved but not as requested. Systemic hypersensitivity reactions to tuberculin include anaphylaxis, urticaria, angio- and other edema, and throat swelling. The proposed term will be modified for clarity and for capitalization standards for MedDRA and will be added as LLT Systemic hypersensitivity to tuberculin to PT Drug hypersensitivity.

CR Number: 2022325016 **Implementation Date:** 29-Nov-22 Related CR: 2022325016

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pelvic Washing*	Approved Not as Requested	Proposed LLT	
HLT primary	*Abdominal therapeutic procedures NEC*		*Pelvic washing*	10088885 Current
SOC primary	*Surgical and medical procedures*		To PT	
			Peritoneal washing	10088884

MSSO Comment: The proposal to add a new PT Pelvic Washing to primary HLT Abdominal therapeutic procedures NEC in SOC Surgical and medical procedures is approved but not as requested. Pelvic washing is a procedure in which a salt-water solution is used to wash the pelvic peritoneal cavity and then is removed to check for cancer cells. The proposed term will modified for MedDRA capitalization standards and added as LLT Pelvic washing to PT Peritoneal washing which will be added, in a related change, under HLT Abdominal therapeutic procedures NEC.

Supplemental Update Report

CR Number: 2022333025 **Implementation Date:** 29-Nov-22 Related CR: 2022325016

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Peritoneal washing*	Approved as Requested	Proposed PT	
HLT primary	*Abdominal therapeutic procedures NEC*		*Peritoneal washing*	10088884
SOC primary	*Surgical and medical procedures*		HLT primary	
			Abdominal therapeutic procedures NEC	10027653
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment:

CR Number: 2022325017 **Implementation Date:** 29-Nov-22 Related CR: 2022325017

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Acute postprocedural respiratory failure*	Rejected		
HLT primary	*Respiratory tract and thoracic cavity procedural complications*			
SOC primary	*Injury, poisoning and procedural complications*			

MSSO Comment: The proposal to add a new PT Acute postprocedural respiratory failure to primary HLT Respiratory tract and thoracic cavity procedural complications in SOC Injury, poisoning and procedural complications is not approved. It is not feasible to add post procedural instances of all possible disease conditions. Please see section 3.5.4 When to “split” into more than one MedDRA term in the MedDRA® TERM SELECTION:POINTS TO CONSIDER document.

CR Number: 2022325018 **Implementation Date:** 28-Nov-22 Related CR: 2022325018

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Perioral inflammation*	Approved as Requested	Proposed LLT	
To PT	*Perioral dermatitis*		*Perioral inflammation*	10088850 Current
			To PT	
			Perioral dermatitis	10034541

MSSO Comment: The proposal to add a new LLT Perioral inflammation to PT Perioral dermatitis is approved as requested. Perioral dermatitis is an inflammatory rash involving the skin around your mouth.

Supplemental Update Report

CR Number: 2022325019 **Implementation Date:** 28-Nov-22 Related CR: 2022325019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*DAMP syndrome*	Approved Not as Requested	Proposed PT	
			DAMP syndrome	10088851
			HLT primary	
			Attention deficit and disruptive behaviour disorders	10003730
			SOC primary	
			Psychiatric disorders	10037175
			HLT secondary	
			Coordination and balance disturbances	10072984
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new LLT DAMP syndrome is approved but not as requested. Deficits in attention, motor control and perceptual abilities (DAMP) is used as an umbrella term to describe children with a combination of motor control, perceptual and attention problems. DAMP syndrome is defined as a combination of attention deficit/hyperactivity disorder and developmental coordination disorder. Proposed term will be added as new PT DAMP syndrome under primary HLT Attention deficit and disruptive behaviour disorders and secondary HLT Coordination and balance disturbances. In a related change, the spelled out form of the acronym will be added as LLT Deficits in attention, motor control and perceptual abilities syndrome under PT DAMP syndrome.

CR Number: 2022332054 **Implementation Date:** 28-Nov-22 Related CR: 2022325019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Deficits in attention, motor control and perceptual abilities syndrome*	Approved as Requested	Proposed LLT	
			Deficits in attention, motor control and perceptual abilities syndrome	10088855 Current
To PT	*DAMP syndrome*		To PT	
			DAMP syndrome	10088851

MSSO Comment:

Supplemental Update Report

CR Number: 2022325020 **Implementation Date:** 28-Nov-22 Related CR: 2022325020

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Motor activity abnormal*	Approved as Requested	Proposed LLT *Motor activity abnormal* To PT *Motor dysfunction*	10088852 Current 10061296

MSSO Comment: The proposal to add a new LLT Motor activity abnormal is approved as requested. Proposed term will be added as sub-concept LLT Motor activity abnormal under PT Motor dysfunction.

CR Number: 2022325021 **Implementation Date:** 28-Nov-22 Related CR: 2022325021

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Clotting time abnormal*	Approved as Requested	Proposed LLT *Clotting time abnormal* To PT *Coagulation time abnormal*	10088853 Current 10009791

MSSO Comment: The proposal to add a new LLT Clotting time abnormal is approved as requested. Clotting time is the time required for blood to clot in a glass tube. Proposed term will be added as synonym LLT Clotting time abnormal under PT Coagulation time abnormal.

CR Number: 2022325022 **Implementation Date:** 28-Nov-22 Related CR: 2022325022

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Closed loop bowel obstruction*	Approved as Requested	Proposed LLT *Closed loop bowel obstruction* To PT *Intestinal obstruction*	10088854 Current 10022687

MSSO Comment: The proposal to add a new LLT Closed loop bowel obstruction is approved as requested. A closed loop obstruction is a specific type of bowel obstruction in which two points along the course of a bowel are obstructed, usually but not always with the transition points adjacent to each other at a single location. Proposed term will be added as subconcept LLT Closed loop bowel obstruction under PT Intestinal obstruction.

Supplemental Update Report

CR Number: 2022325023 **Implementation Date:** 28-Nov-22 Related CR: 2022325023

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Delayed onset of lactation*	Approved as Requested	Proposed PT	
HLT primary	*Lactation disorders*		*Delayed onset of lactation*	10088878
SOC primary	*Reproductive system and breast disorders*		HLT primary	
			Lactation disorders	10013316
			SOC primary	
			Reproductive system and breast disorders	10038604
			HLT secondary	
			Postpartum breast disorders	10006234
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new PT Delayed onset of lactation to primary HLT Lactation disorders in SOC Reproductive system and breast disorders and secondary HLT Postpartum breast disorders in SOC Pregnancy, puerperium and perinatal conditions is approved as requested. Delayed onset of lactation refers to the absence of copious milk secretion (onset of lactation) within the first 72 hours following childbirth. Late onset lactation can be the result of a variety of causes and may be associated with an increased risk of excessive neonatal weight loss and early cessation of breastfeeding.

CR Number: 2022325024 **Implementation Date:** 28-Nov-22 Related CR: 2022325024

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Primary lactation insufficiency*	Approved as Requested	Proposed LLT		
To PT	*Suppressed lactation*		*Primary lactation insufficiency*	10088880	Current
			To PT		
			Suppressed lactation	10042576	Current

MSSO Comment: The proposal to add a new LLT Primary lactation insufficiency to PT Suppressed lactation is approved as requested. This term is needed to capture a specific type of lactation insufficiency/ failure. Primary lactation insufficiency or low milk supply refers to the inadequate synthesis of breast milk to meet the nutritional needs of the infant. Primary causes include anatomical issues such as insufficient glandular tissue and prior breast surgery, medical conditions including hypothyroidism and hypertension, and maternal smoking. Many medications may also suppress lactation. In a related change, a new PT Lactation insufficiency will be added to primary HLT Lactation disorders and to secondary HLT Postpartum breast disorders. Furthermore, PT Suppressed lactation will be demoted under the more encompassing new PT Lactation insufficiency.

Supplemental Update Report

CR Number: 2022332061 **Implementation Date:** 28-Nov-22 Related CR: 2022325024

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Lactation insufficiency*	Approved as Requested	Proposed PT	
HLT primary	*Lactation disorders*		*Lactation insufficiency*	10088879
SOC primary	*Reproductive system and breast disorders*		HLT primary	
			Lactation disorders	10013316
			SOC primary	
			Reproductive system and breast disorders	10038604
			HLT secondary	
			Postpartum breast disorders	10006234
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment:

CR Number: 2022332062 **Implementation Date:** 28-Nov-22 Related CR: 2022325024

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Suppressed lactation*	Approved as Requested	PT to merge	
To PT	*Lactation insufficiency*		*Suppressed lactation*	10042576 Current
			To PT	
			Lactation insufficiency	10088879

MSSO Comment:

Supplemental Update Report

CR Number: 2022325025 **Implementation Date:** 28-Nov-22 Related CR: 2022325025

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Secondary lactation insufficiency*	Approved Not as Requested	Proposed LLT	
To PT	*Suppressed lactation*		*Secondary lactation insufficiency*	10088881 Current
			To PT	
			Lactation insufficiency	10088879

MSSO Comment: The proposal to add a new LLT Secondary lactation insufficiency to PT Suppressed lactation is approved but not as requested. This term is needed to capture a specific type of lactation insufficiency/ failure. Secondary lactation insufficiency refers to the inadequate transfer of breastmilk during breastfeeding. The most common cause is ineffective or inadequate milk removal. Breastfeeding management issues can interfere with milk drainage and include poor latching of the infant to the breast and use of supplemental formula. Medical conditions in the infant that are associated with weak or uncoordinated suckling may also result in low milk supply. Secondary lactation insufficiency will be added as an LLT to new PT Lactation insufficiency added in change request 2022325024.

CR Number: 2022325026 **Implementation Date:** 28-Nov-22 Related CR: 2022325026

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Left-to-right ventricular shunt*	Approved as Requested	Proposed LLT	
To PT	*Left-to-right cardiac shunt*		*Left-to-right ventricular shunt*	10088857 Current
			To PT	
			Left-to-right cardiac shunt	10077834

MSSO Comment: The proposal to add a new LLT Left-to-right ventricular shunt to PT Left-to-right cardiac shunt is approved as requested. Left-to-right ventricular shunt occurs due to a ventricular septal defect. In small (restrictive) cases, the direction and magnitude of the shunt depends on the pressure difference across the shunt, while in large cases the direction and magnitude of the shunt depends on the relative resistance in the pulmonary and systemic circuits.

CR Number: 2022325027 **Implementation Date:** 28-Nov-22 Related CR: 2022325027

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ventricular septal defect closure*	Approved as Requested	Proposed LLT	
To PT	*Ventricular septal defect repair*		*Ventricular septal defect closure*	10088856 Current
			To PT	
			Ventricular septal defect repair	10047301

MSSO Comment: The proposal to add a new LLT Ventricular septal defect closure to PT Ventricular septal defect repair is approved as requested. Ventricular septal defect closures are mainly performed by a transcatheter procedure through the implantation of an occluder device which comports little risk of embolism after implantation.

Supplemental Update Report

CR Number: 2022325028 **Implementation Date:** 28-Nov-22 Related CR: 2022325028

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Atrial septal defect closure*	Approved as Requested	Proposed LLT		
To PT	*Atrial septal defect repair*		*Atrial septal defect closure*	10088858	Current
			To PT		
			Atrial septal defect repair	10003667	

MSSO Comment: The proposal to add a new LLT Atrial septal defect closure to PT Atrial septal defect repair is approved as requested. An atrial septal defect closure is a minimally invasive procedure performed to repair a communication between the two atrial chambers.

CR Number: 2022325029 **Implementation Date:** 28-Nov-22 Related CR: 2022325029

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Prosthetic tricuspid valve central regurgitation*	Approved Not as Requested	Proposed LLT		
To PT	*Prosthetic cardiac valve central regurgitation*		*Prosthetic tricuspid valve central regurgitation*	10088859	Current
			To PT		
			Prosthetic cardiac valve regurgitation	10087802	

MSSO Comment: The proposal to add a new LLT Prosthetic tricuspid valve central regurgitation to PT Prosthetic cardiac valve central regurgitation is approved but not as requested. The prosthetic tricuspid valve central regurgitation is a known phenomenon after surgical or transcatheter tricuspid valve replacement. This could be due to failure of the right ventricle geometry to remodel or prosthetic valve leaflet dysfunction. Prosthetic tricuspid valve central regurgitation will be added as subconcept LLT to PT Prosthetic cardiac valve regurgitation.

CR Number: 2022325030 **Implementation Date:** 28-Nov-22 Related CR: 2022325030

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cardiac pseudoaneurysm*	Approved as Requested	Proposed PT	
To HLT	*Cardiac and vascular procedural complications*		*Cardiac pseudoaneurysm*	10048974
			To HLT	
			Cardiac and vascular procedural complications	10007602

MSSO Comment: The proposal to link the PT Cardiac pseudoaneurysm to the HLT Cardiac and vascular procedural complications is approved as requested. Patients with cardiac pseudoaneurysm often have a history of prior cardiac procedures, valvular heart disease, or myocardial infarction.

Supplemental Update Report

CR Number: 2022325031 **Implementation Date:** 28-Nov-22 Related CR: 2022325031

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New PT				
Proposed PT	*Pulmonary artery embolism*	Approved Not as Requested	Proposed LLT *Pulmonary artery embolism*	10088860 Current
			To PT *Pulmonary embolism*	10037377

MSSO Comment: The proposal to add a new PT Pulmonary artery embolism is approved but not as requested. Pulmonary embolism is a blockage of an artery in the lungs by a substance that has moved from elsewhere in the body through the bloodstream. Pulmonary artery embolism will be added as a synonym LLT to PT Pulmonary embolism.

CR Number: 2022326001 **Implementation Date:** 28-Nov-22 Related CR: 2022326001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*NSAID induced gastric ulcer*	Rejected		

MSSO Comment: The proposal to add a new LLT NSAID induced gastric ulcer is not approved. Terms that state or imply a causality relationship between a drug or drug class and a condition are generally not added to MedDRA because establishing causality is not inherent to the coded term, but is instead determined by the reporter/investigator or by the sponsor.

CR Number: 2022326002 **Implementation Date:** 28-Nov-22 Related CR: 2022326002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Drug induced gastric ulcer*	Rejected		

MSSO Comment: The proposal to add a new LLT Drug induced gastric ulcer is not approved. Terms that state or imply a drug-induced causality relationship with a condition are generally not added to MedDRA because establishing causality is not inherent to the coded term, but is instead determined by the reporter/investigator or by the sponsor.

Supplemental Update Report

CR Number: 2022326003 **Implementation Date:** 28-Nov-22 Related CR: 2022326003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Tender muscle knots*	Approved as Requested	Proposed LLT *Tender muscle knots* To PT *Trigger points*	10088865 Current 10087554

MSSO Comment: The proposal to add a new LLT Tender muscle knots is approved as requested. A muscle knot is a painful or tender highly contracted spot in a muscle. It feels tight and sore, and it often happens in the upper back or legs. Tender muscle knots will be added as an LLT to PT Trigger points.

CR Number: 2022326004 **Implementation Date:** 28-Nov-22 Related CR: 2022326004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Myofacial pain*	Rejected		

MSSO Comment: The proposal to add a new LLT Myofacial pain is not approved. The proposed term does not seem to represent a clear medical condition when sought in literature. In case an accidental typo had altered a request of Myofascial pain, please consider existing PT Myofascial pain syndrome.

CR Number: 2022326005 **Implementation Date:** 28-Nov-22 Related CR: 2022326005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Pacemaker endocarditis*	Rejected		

MSSO Comment: The proposal to add a new LLT Pacemaker endocarditis is not approved. The concept can be represented by a combination of PT Device related infection and PT Endocarditis.

Supplemental Update Report

CR Number: 2022326006 **Implementation Date:** 28-Nov-22 Related CR: 2022326006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Device endocarditis*	Rejected		

MSSO Comment: The proposal to add a new LLT Device endocarditis is not approved. The concept can be represented by a combination of PT Device related infection and PT Endocarditis.

CR Number: 2022326007 **Implementation Date:** 28-Nov-22 Related CR: 2022326007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Uncharacteristic behaviour*	Approved as Requested	Proposed LLT *Uncharacteristic behaviour* To PT *Abnormal behaviour*	10088866 Current 10061422

MSSO Comment: The proposal to add a new LLT Uncharacteristic behaviour is approved as requested. Uncharacteristic behaviour is used to describe a behavior that is unexpected or unusual for a given person, and will be added as an LLT to PT Abnormal behaviour. In a related change, the American spelling of the term will also be added as the LLT Uncharacteristic behavior under the PT Abnormal behaviour.

CR Number: 2022332057 **Implementation Date:** 28-Nov-22 Related CR: 2022326007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Uncharacteristic behavior*	Approved as Requested	Proposed LLT	
To PT	*Abnormal behaviour*		*Uncharacteristic behavior* To PT *Abnormal behaviour*	10088867 Current 10061422

MSSO Comment:

Supplemental Update Report

CR Number: **2022326008** **Implementation Date:** 28-Nov-22 Related CR: 2022326008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Reaction to pain*	Rejected		

MSSO Comment: The proposal to add a new LLT Reaction to pain is not approved. The requested term is very vague and ambiguous as to what type of reaction is meant.

CR Number: **2022326009** **Implementation Date:** 28-Nov-22 Related CR: 2022326009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pain at prosthesis site*	Rejected		

MSSO Comment: The proposal to add a new LLT Pain at prosthesis site is not approved. The requested term can be represented by the broader PT Medical device site pain.

CR Number: **2022326010** **Implementation Date:** 28-Nov-22 Related CR: 2022326010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Swelling at prosthesis site*	Rejected		

MSSO Comment: The proposal to add a new LLT Swelling at prosthesis site is not approved. The requested term can be represented by the broader LLT Medical device site swelling or LLT Medical device site joint swelling.

Supplemental Update Report

CR Number: 2022326011 **Implementation Date:** 28-Nov-22 Related CR: 2022326011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Swelling at transplant site*	Rejected		

MSSO Comment: The proposal to add a new PT Swelling at transplant site is not approved. Swelling at transplant site is a very broad term and without context of the type of tissue or organ transplanted.

CR Number: 2022326012 **Implementation Date:** 28-Nov-22 Related CR: 2022326012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ear lobe bleeding*	Rejected		

MSSO Comment: The proposal to add a new LLT Ear lobe bleeding is not approved. It is not feasible to add all possible anatomic site-specific bleeding/haemorrhage terms in MedDRA.Please consider the broader LLT Skin bleeding.

CR Number: 2022326013 **Implementation Date:** 28-Nov-22 Related CR: 2022326013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Bleeding from piercing*	Rejected		

MSSO Comment: The proposal to add a new LLT Bleeding from piercing is not approved. The requested term is too unspecific among all the possible sites associated with piercing. However, an umbrella PT Piercing associated complication will be added as PT to HLT Non-site specific procedural complications which than can be combined with a specific LLT for bleeding.

Supplemental Update Report

CR Number: 2022332055 **Implementation Date:** 28-Nov-22 Related CR: 2022326013

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Piercing associated complication*	Approved as Requested	Proposed PT	
HLT primary	*Non-site specific procedural complications*		*Piercing associated complication*	10088862
SOC primary	*Injury, poisoning and procedural complications*		HLT primary	
			Non-site specific procedural complications	10029559
			SOC primary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment:

CR Number: 2022326014 **Implementation Date:** 28-Nov-22 Related CR: 2022326014

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Endometriosis relapse*	Approved as Requested	Proposed LLT	
			Endometriosis relapse	10088864 Current
			To PT	
			Endometriosis	10014778

MSSO Comment: The proposal to add a new LLT Endometriosis relapse is approved as requested. Between 20% and 40% of women will experience recurrence of endometriosis within five years of their initial surgery. Endometriosis relapse will be added as LLT to PT Endometriosis.

Supplemental Update Report

CR Number: 2022326015 **Implementation Date:** 28-Nov-22 Related CR: 2022326015

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cutibacterium acnes infection*	Approved as Requested	Proposed PT *Cutibacterium acnes infection*	10088861
			HLT primary *Bacterial infections NEC*	10004047
			SOC primary *Infections and infestations*	10021881
			HLT secondary *Skin and subcutaneous tissue bacterial infections*	10040788
			SOC secondary *Skin and subcutaneous tissue disorders*	10040785

MSSO Comment: The proposal to add a new PT Cutibacterium acnes infection is approved as requested. The recent description of the genus Cutibacterium has altered the taxonomy of Propionibacterium species. These organisms still belong to the genera of the skin coryneform group, and the most-studied species remains Cutibacterium acnes. Cutibacterium avidum is also a known skin commensal. Cutibacterium acnes infection will be added as PT to primary HLT Bacterial infections NEC and secondary HLT Skin and subcutaneous tissue bacterial infections. In a related change, PT Propionibacterium infection will be demoted under the new PT Cutibacterium acnes infection, because of the updated taxonomy. Furthermore, a new PT Cutibacterium test positive will be added to HLT Bacteria identification and serology (excl mycobacteria) and PT Propionibacterium test positive will be demoted under PT Cutibacterium test positive for the same reason.

CR Number: 2022332056 **Implementation Date:** 28-Nov-22 Related CR: 2022326015

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Propionibacterium infection*	Approved as Requested	PT to merge *Propionibacterium infection*	10051946 Current
To PT	*Cutibacterium acnes infection*		To PT *Cutibacterium acnes infection*	10088861

MSSO Comment:

Supplemental Update Report

CR Number: 2022332058 **Implementation Date:** 28-Nov-22 Related CR: 2022326015

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cutibacterium test positive*	Approved as Requested	Proposed PT	
			Cutibacterium test positive	10088863
HLT primary	*Bacteria identification and serology (excl mycobacteria)*		HLT primary	
			Bacteria identification and serology (excl mycobacteria)	10004000
SOC primary	*Investigations*		SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022332059 **Implementation Date:** 28-Nov-22 Related CR: 2022326015

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Propionibacterium test positive*	Approved as Requested	PT to merge	
			Propionibacterium test positive	10070004 Current
To PT	*Cutibacterium test positive*		To PT	
			Cutibacterium test positive	10088863

MSSO Comment:

CR Number: 2022326016 **Implementation Date:** 28-Nov-22 Related CR: 2022326016

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cardiac pain*	Rejected		
From PT	*Angina pectoris*			
To PT	*Chest pain*			

MSSO Comment: The proposal to move the LLT Cardiac pain from PT Angina pectoris to PT Chest pain is not approved. Cardiac pain is under Angina pectoris since version 4.0 and moving under Chest pain is not appropriate as not reported as "chest" but as "cardiac".

Supplemental Update Report

CR Number: 2022326018 **Implementation Date:** 28-Nov-22 Related CR: 2022326018

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Culture negative septic shock*	Approved as Requested	Proposed LLT *Culture negative septic shock* To PT *Septic shock*	10088868 Current 10040070

MSSO Comment: The proposal to add a new term Culture negative septic shock is approved as requested. Sepsis without a microbiologically documented infection is called culture-negative sepsis/septic shock. The proportion of culture-negative cases is between 28 to 49% among all patients with sepsis. Proposed term will be added as LLT Culture negative septic shock under PT Septic shock.

CR Number: 2022327001 **Implementation Date:** 28-Nov-22 Related CR: 2022327001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Eosinophilic cholangitis*	Approved as Requested	Proposed PT *Eosinophilic cholangitis* HLT primary *Bile duct infections and inflammations* SOC primary *Hepatobiliary disorders* HLT secondary *Eosinophilic disorders* SOC secondary *Blood and lymphatic system disorders*	 10088869 10004607 10019805 10052828 10005329

MSSO Comment: The proposal to add a new term Eosinophilic cholangitis is approved as requested. Eosinophilic cholangitis (EC) is a rare inflammatory condition of the biliary tract that can result in biliary obstruction and can mimic malignancy. The precise pathogenesis of the disease is poorly understood and an allergic mechanism is thought to play a key role in the development of EC. Eosinophilic cholangitis will be added as PT to primary HLT Bile duct infections and inflammations and secondary HLT Eosinophilic disorders.

CR Number: 2022327002 **Implementation Date:** 28-Nov-22 Related CR: 2022327002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Donor nephrectomy*	Rejected		

MSSO Comment: The proposal to add a new term Donor nephrectomy is not approved. A donor nephectomy is a nephrectomy like any other; the social aspect of this concept maybe be captured by the combination of LLT Nephrectomy and LLT Kidney donor.

Supplemental Update Report

CR Number: 2022327003 **Implementation Date:** 28-Nov-22 Related CR: 2022327003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Perlman syndrome*	Approved as Requested	Proposed PT	
			Perlman syndrome	10088870
			HLT primary	
			Congenital disorders NEC	10010445
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Foetal growth complications	10010163
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new term Perlman syndrome is approved as requested. Perlman syndrome is a rare overgrowth syndrome characterized by polyhydramnios with neonatal macrosomia, nephromegaly, distinctive facial appearance, renal dysplasia, nephro-blastomatosis, and predisposition to Wilms tumor. Perlman syndrome will be added as PT to primary HLT Congenital disorders NEC to secondary HLT Foetal growth complications and secondary HLT Renal disorders NEC.

CR Number: 2022332060 **Implementation Date:** 28-Nov-22 Related CR: 2022327003

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Perlman syndrome*	Approved as Requested	Proposed PT	
To HLT	*Renal disorders NEC*		*Perlman syndrome*	10088870
			To HLT	
			Renal disorders NEC	10027695

MSSO Comment:

Supplemental Update Report

CR Number: 2022327004 **Implementation Date:** 28-Nov-22 Related CR: 2022327004

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Haber's syndrome*	Approved as Requested	Proposed PT	
		Haber's syndrome	10088871
		HLT primary	
		Skin and subcutaneous tissue disorders congenital NEC	10040834
		SOC primary	
		Congenital, familial and genetic disorders	10010331
		HLT secondary	
		Dermatitis and eczema	10012435
		SOC secondary	
		Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new term Haber's syndrome is approved as requested. Haber syndrome is a cutaneous disorder of hyperpigmentation characterized by reticulated pigmentation of the person's skin. A rare genodermatosis, its key features include "rosacea-like facial eruption, reticulated hyperpigmentation of major flexures, comedones on the back and neck, and pitted facial scars. Haber's syndrome will be added as PT to primary HLT Skin and subcutaneous tissue disorders congenital NEC and secondary HLT Dermatitis and eczema.

CR Number: 2022327005 **Implementation Date:** 28-Nov-22 Related CR: 2022327005

Change Requested	Final Disposition	Final Placement	MedDRA Code #	
Add a New Term				
Proposed Term *SAVI syndrome*	Approved as Requested	Proposed LLT		
		SAVI syndrome	10088872	Current
		To PT		
		STING-associated vasculopathy with onset in infancy	10088833	

MSSO Comment: The proposal to add a new term SAVI syndrome is approved as requested. SAVI syndrome will be added as synonym LLT to the recently added PT STING-associated vasculopathy with onset in infancy in change request 2022321007.

Supplemental Update Report

CR Number: 2022327006 **Implementation Date:** 28-Nov-22 Related CR: 2022327006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Preinfarction angina*	Approved as Requested	Proposed LLT	
			Preinfarction angina	10088874 Current
			To PT	
			Angina unstable	10002388

MSSO Comment: The proposal to add a new term Preinfarction angina is approved as requested. Unstable angina is also described as crescendo angina, preinfarction angina, and intermediate chest pain syndrome. In patients with acute myocardial infarction preceded by unstable angina, as compared with those without preinfarction angina, thrombolytic therapy resulted in more rapid reperfusion and smaller infarcts. Preinfarction angina will be added as an LLT to PT Angina unstable.

CR Number: 2022327007 **Implementation Date:** 28-Nov-22 Related CR: 2022327007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Morel lavellee seroma*	Approved Not as Requested	Proposed PT	
			Morel-Lavellee seroma	10088873
			HLT primary	
			Non-site specific injuries NEC	10029511
			SOC primary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new term Morel lavellee seroma is approved but not as requested. Morel-Lavallee seroma or post-traumatic pseudocyst is a soft tissue seroma developing due to closed degloving injury by a shearing force that causes separation of subcutaneous fatty layer from the deeper muscular fascia resulting in collection of fluid in the created space. The proposed term will be modified according to MedDRA capitalization conventions for proper names and added as the PT Morel-Lavallee seroma to HLT Non-site specific injuries NEC.

CR Number: 2022327008 **Implementation Date:** 28-Nov-22 Related CR: 2022327008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Harris platelet syndrome*	Approved as Requested	Proposed LLT	
			Harris platelet syndrome	10088875 Current
			To PT	
			Congenital thrombocyte disorder	10058896

MSSO Comment: The proposal to add a new term Harris platelet syndrome is approved as requested. Harris platelet syndrome is the most common inherited giant platelet disorder, which is identified among healthy blood donors in the north-eastern part of the Indian subcontinent, and characterized by absent bleeding symptoms, mild to severe thrombocytopenia with giant platelets and normal platelet aggregation studies with absent MYH9 mutation. Harris platelet syndrome will be added as an LLT to PT Congenital thrombocyte disorder along with its superordinate LLT Giant platelet disorder.

Supplemental Update Report

CR Number: **2022327009** **Implementation Date:** 28-Nov-22 Related CR: 2022327009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ahmed glaucoma valve implant*	Rejected		

MSSO Comment: The proposal to add a new term Ahmed glaucoma valve implant is not approved. Please consider PT Glaucoma drainage device placement and its LLTs, such as LLT Seton glaucoma surgery for your coding needs.

CR Number: **2022327010** **Implementation Date:** 29-Nov-22 Related CR: 2022327010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Obstructive laryngitis*	Rejected		

MSSO Comment: The proposal to add a new PT Obstructive laryngitis is not approved. The proposed term is a combination of laryngitis and laryngeal obstruction and without context may refer to different pathologies.

CR Number: **2022327057** **Implementation Date:** 30-Nov-22 Related CR: 2022327057

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation hepatic arteriovenous*	Rejected		
To PT	*Hepatic arteriovenous malformation*			

MSSO Comment: The proposal to add a new LLT Malformation hepatic arteriovenous to PT Hepatic arteriovenous malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

Supplemental Update Report

CR Number: **2022327058** **Implementation Date:** 30-Nov-22 Related CR: 2022327058

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation arteriovenous*	Rejected		
To PT	*Arteriovenous malformation*			

MSSO Comment: The proposal to add a new LLT Malformation arteriovenous to PT Arteriovenous malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: **2022327059** **Implementation Date:** 30-Nov-22 Related CR: 2022327059

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation retinal arteriovenous*	Rejected		
To PT	*Retinal arteriovenous malformation*			

MSSO Comment: The proposal to add a new LLT Malformation retinal arteriovenous to PT Retinal arteriovenous malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: **2022327060** **Implementation Date:** 30-Nov-22 Related CR: 2022327060

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation gastrointestinal arteriovenous*	Rejected		
To PT	*Gastrointestinal arteriovenous malformation*			

MSSO Comment: The proposal to add a new LLT Malformation gastrointestinal arteriovenous to PT Gastrointestinal arteriovenous malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

Supplemental Update Report

CR Number: **2022327061** **Implementation Date:** 30-Nov-22 Related CR: 2022327061

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation renal arteriovenous*	Rejected		
To PT	*Renal arteriovenous malformation*			

MSSO Comment: The proposal to add a new LLT Malformation renal arteriovenous to PT Renal arteriovenous malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: **2022327062** **Implementation Date:** 30-Nov-22 Related CR: 2022327062

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation breast*	Rejected		
To PT	*Breast malformation*			

MSSO Comment: The proposal to add a new LLT Malformation breast to PT Breast malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: **2022327063** **Implementation Date:** 30-Nov-22 Related CR: 2022327063

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vascular Dieulafoy's malformation*	Rejected		
To PT	*Dieulafoy's vascular malformation*			

MSSO Comment: The proposal to add a new LLT Vascular Dieulafoy's malformation to PT Dieulafoy's vascular malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

Supplemental Update Report

CR Number: 2022327064 **Implementation Date:** 30-Nov-22 Related CR: 2022327064

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation foetal*	Rejected		
To PT	*Foetal malformation*			

MSSO Comment: The proposal to add a new LLT Malformation foetal to PT Foetal malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327065 **Implementation Date:** 30-Nov-22 Related CR: 2022327065

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation gastrointestinal*	Rejected		
To PT	*Gastrointestinal malformation*			

MSSO Comment: The proposal to add a new LLT Malformation gastrointestinal to PT Gastrointestinal malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327066 **Implementation Date:** 30-Nov-22 Related CR: 2022327066

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation vascular*	Rejected		
To PT	*Vascular malformation*			

MSSO Comment: The proposal to add a new LLT Malformation vascular to PT Vascular malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

Supplemental Update Report

CR Number: 2022327067 **Implementation Date:** 30-Nov-22 Related CR: 2022327067

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation brain*	Rejected		
To PT	*Brain malformation*			

MSSO Comment: The proposal to add a new LLT Malformation brain to PT Brain malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327068 **Implementation Date:** 30-Nov-22 Related CR: 2022327068

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation urinary tract*	Rejected		
To PT	*Urinary tract malformation*			

MSSO Comment: The proposal to add a new LLT Malformation urinary tract to PT Urinary tract malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327069 **Implementation Date:** 30-Nov-22 Related CR: 2022327069

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Joint malformation congenital*	Rejected		
To PT	*Congenital joint malformation*			

MSSO Comment: The proposal to add a new LLT Joint malformation congenital to PT Congenital joint malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

Supplemental Update Report

CR Number: 2022327070 **Implementation Date:** 30-Nov-22 Related CR: 2022327070

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Jaw malformation congenital*	Rejected		
To PT	*Congenital jaw malformation*			

MSSO Comment: The proposal to add a new LLT Jaw malformation congenital to PT Congenital jaw malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327071 **Implementation Date:** 30-Nov-22 Related CR: 2022327071

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Eyelid malformation congenital*	Rejected		
To PT	*Congenital eyelid malformation*			

MSSO Comment: The proposal to add a new LLT Eyelid malformation congenital to PT Congenital eyelid malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327072 **Implementation Date:** 30-Nov-22 Related CR: 2022327072

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Genital malformation congenital*	Rejected		
To PT	*Congenital genital malformation*			

MSSO Comment: The proposal to add a new LLT Genital malformation congenital to PT Congenital genital malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

Supplemental Update Report

CR Number: **2022327073** **Implementation Date:** 30-Nov-22 Related CR: 2022327073

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hand malformation congenital*	Rejected		
To PT	*Congenital hand malformation*			

MSSO Comment: The proposal to add a new LLT Hand malformation congenital to PT Congenital hand malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: **2022327074** **Implementation Date:** 30-Nov-22 Related CR: 2022327074

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Coronary artery malformation congenital*	Rejected		
To PT	*Congenital coronary artery malformation*			

MSSO Comment: The proposal to add a new LLT Coronary artery malformation congenital to PT Congenital coronary artery malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: **2022327075** **Implementation Date:** 30-Nov-22 Related CR: 2022327075

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Male genital malformation congenital*	Rejected		
To PT	*Congenital genital malformation male*			

MSSO Comment: The proposal to add a new LLT Male genital malformation congenital to PT Congenital genital malformation male is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

Supplemental Update Report

CR Number: **2022327076** **Implementation Date:** 30-Nov-22 Related CR: 2022327076

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Nose malformation congenital*	Rejected		
To PT	*Congenital nose malformation*			

MSSO Comment: The proposal to add a new LLT Nose malformation congenital to PT Congenital nose malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: **2022327077** **Implementation Date:** 30-Nov-22 Related CR: 2022327077

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Female genital malformation congenital*	Rejected		
To PT	*Congenital genital malformation female*			

MSSO Comment: The proposal to add a new LLT Female genital malformation congenital to PT Congenital genital malformation female is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: **2022327078** **Implementation Date:** 30-Nov-22 Related CR: 2022327078

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Intestinal malformation congenital*	Rejected		
To PT	*Congenital intestinal malformation*			

MSSO Comment: The proposal to add a new LLT Intestinal malformation congenital to PT Congenital intestinal malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

Supplemental Update Report

CR Number: 2022327079 **Implementation Date:** 30-Nov-22 Related CR: 2022327079

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Laryngeal malformation congenital*	Rejected		
To PT	*Congenital laryngeal malformation*			

MSSO Comment: The proposal to add a new LLT Laryngeal malformation congenital to PT Congenital laryngeal malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327080 **Implementation Date:** 30-Nov-22 Related CR: 2022327080

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Arterial malformation congenital*	Rejected		
To PT	*Congenital arterial malformation*			

MSSO Comment: The proposal to add a new LLT Arterial malformation congenital to PT Congenital arterial malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327081 **Implementation Date:** 30-Nov-22 Related CR: 2022327081

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Foot malformation congenital*	Rejected		
To PT	*Congenital foot malformation*			

MSSO Comment: The proposal to add a new LLT Foot malformation congenital to PT Congenital foot malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

Supplemental Update Report

CR Number: 2022327082 **Implementation Date:** 30-Nov-22 Related CR: 2022327082

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Oral malformation congenital*	Rejected		
To PT	*Congenital oral malformation*			

MSSO Comment: The proposal to add a new LLT Oral malformation congenital to PT Congenital oral malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327083 **Implementation Date:** 30-Nov-22 Related CR: 2022327083

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation pulmonary*	Rejected		
To PT	*Pulmonary malformation*			

MSSO Comment: The proposal to add a new LLT Malformation pulmonary to PT Pulmonary malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327084 **Implementation Date:** 30-Nov-22 Related CR: 2022327084

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation spleen*	Rejected		
To PT	*Spleen malformation*			

MSSO Comment: The proposal to add a new LLT Malformation spleen to PT Spleen malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

Supplemental Update Report

CR Number: 2022327085 **Implementation Date:** 30-Nov-22 Related CR: 2022327085

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation respiratory tract*	Rejected		
To PT	*Respiratory tract malformation*			

MSSO Comment: The proposal to add a new LLT Malformation respiratory tract to PT Respiratory tract malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327086 **Implementation Date:** 30-Nov-22 Related CR: 2022327086

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation skin*	Rejected		
To PT	*Skin malformation*			

MSSO Comment: The proposal to add a new LLT Malformation skin to PT Skin malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327087 **Implementation Date:** 30-Nov-22 Related CR: 2022327087

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Biliary malformation*	Rejected		
To PT	*Malformation biliary*			

MSSO Comment: The proposal to add a new LLT Biliary malformation to PT Malformation biliary is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

Supplemental Update Report

CR Number: 2022327088 **Implementation Date:** 30-Nov-22 Related CR: 2022327088

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation ear*	Rejected		
To PT	*Ear malformation*			

MSSO Comment: The proposal to add a new LLT Malformation ear to PT Ear malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327089 **Implementation Date:** 30-Nov-22 Related CR: 2022327089

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation umbilical*	Rejected		
To PT	*Umbilical malformation*			

MSSO Comment: The proposal to add a new LLT Malformation umbilical to PT Umbilical malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327090 **Implementation Date:** 30-Nov-22 Related CR: 2022327090

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation kidney*	Rejected		
To PT	*Kidney malformation*			

MSSO Comment: The proposal to add a new LLT Malformation kidney to PT Kidney malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

Supplemental Update Report

CR Number: 2022327091 **Implementation Date:** 30-Nov-22 Related CR: 2022327091

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation thyroid*	Rejected		
To PT	*Thyroid malformation*			

MSSO Comment: The proposal to add a new LLT Malformation thyroid to PT Thyroid malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327092 **Implementation Date:** 30-Nov-22 Related CR: 2022327092

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Venous malformation*	Rejected		
To PT	*Malformation venous*			

MSSO Comment: The proposal to add a new LLT Venous malformation to PT Malformation venous is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327093 **Implementation Date:** 30-Nov-22 Related CR: 2022327093

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hereditary tooth malformation*	Rejected		
To PT	*Tooth malformation hereditary*			

MSSO Comment: The proposal to add a new LLT Hereditary tooth malformation to PT Tooth malformation hereditary is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

Supplemental Update Report

CR Number: 2022327094 **Implementation Date:** 30-Nov-22 Related CR: 2022327094

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Malformation cerebrovascular arteriovenous*	Rejected		
To PT	*Cerebrovascular arteriovenous malformation*			

MSSO Comment: The proposal to add a new LLT Malformation cerebrovascular arteriovenous to PT Cerebrovascular arteriovenous malformation is not approved. The proposed English language change in word order of existing LLT/PT of concept does not add value as an additional option for coding. The translation change does not necessarily require a corresponding English language change or addition of the term.

CR Number: 2022327095 **Implementation Date:** 28-Nov-22 Related CR: 2022327095

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site mass*	Approved as Requested	Proposed PT	
			Vascular access site mass	10088876
			HLT primary	
			Administration site reactions NEC	10057196
			SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Administration site reactions NEC	10057196
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Vascular access site mass is approved as requested. Vascular access site mass will be added as PT to primary HLT Administration site reactions NEC which is linked to bi-axial HLGT Administration site reactions (primary SOC General disorders and administration site conditions and secondary SOC Injury, poisoning and procedural complications) to complement the set of vascular access site terms.

Supplemental Update Report

CR Number: 2022327096 **Implementation Date:** 28-Nov-22 Related CR: 2022327096

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vascular access site irritation*	Approved as Requested	Proposed PT	
			Vascular access site irritation	10088877
			HLT primary	
			Administration site reactions NEC	10057196
			SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Administration site reactions NEC	10057196
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Vascular access site irritation is approved as requested. Vascular access site irritation will be added as PT to primary HLT Administration site reactions NEC which is linked to bi-axial HLGT Administration site reactions (primary SOC General disorders and administration site conditions and to secondary SOC Injury, poisoning and procedural complications) to complement the existing set of vascular access site terms.

CR Number: 2022327097 **Implementation Date:** 29-Nov-22 Related CR: 2022327097

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Jaw ankylosis*	Approved Not as Requested	Proposed PT	
			Temporomandibular joint ankylosis	10088892
			HLT primary	
			Joint related disorders NEC	10027685
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Jaw ankylosis is approved but not as requested. Temporomandibular joint ankylosis or jaw ankylosis is defined as bony or fibrous adhesion of the anatomic joint components accompanied by a limitation in opening the mouth, causing difficulties with mastication, speaking and oral hygiene as well as inadvertently influencing mandibular growth. The proposed term will be modified for better medical expression and added as PT Temporomandibular joint ankylosis to HLT Joint related disorders NEC.

Supplemental Update Report

CR Number: 2022327098 **Implementation Date:** 29-Nov-22 Related CR: 2022327098

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Fibrodysplasia ossificans progressiva (FOP) flare up*	Approved Not as Requested	Proposed LLT *Fibrodysplasia ossificans progressiva flare up* To PT *Fibrodysplasia ossificans progressiva*	10088893 Current 10068715

MSSO Comment: The proposal to add a new PT Fibrodysplasia ossificans progressiva (FOP) flare up is approved but not as requested. Patients with fibrodysplasia ossificans progressiva typically experience episodic flare-ups at an average of two flare-ups per year. Flare-ups are characterized by large painful swellings, which are usually red and warm to the touch. Proposed term will be added as subconcept LLT Fibrodysplasia ossificans progressiva flare up under PT Fibrodysplasia ossificans progressiva.

CR Number: 2022328001 **Implementation Date:** 29-Nov-22 Related CR: 2022328001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Reduced parasympathetic activity*	Approved Not as Requested	Proposed PT *Reduced parasympathetic activity* HLT primary *Autonomic nervous system disorders* SOC primary *Nervous system disorders*	 10088894 10003839 10029205

MSSO Comment: The proposal to add a new LLT Reduced parasympathetic activity is approved but not as requested. Nocturnal parasympathetic activity, reflected by heart rate variability, is diminished in individuals with chronic fatigue syndrome, suggesting hypervigilant sleep. Reduced parasympathetic activity will be added as a PT to HLT Autonomic nervous system disorders.

CR Number: 2022330001 **Implementation Date:** 30-Nov-22 Related CR: 2022330001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT To PT	*Skier's thumb* *Ligament sprain*	Approved as Requested	Proposed LLT *Skier's thumb* To PT *Ligament sprain*	 10088897 Current 10024453

MSSO Comment: The proposal to add a new LLT Skier's thumb to PT Ligament sprain is approved as requested. The ligament affected by skier's thumb is the ulnar collateral ligament at the base of the thumb on the pointer finger side. This ligament keeps the thumb stable when pinching or grasping objects. In skier's thumb, this ligament gets stretched or torn, resulting in pain and limited thumb movement.

Supplemental Update Report

CR Number: **2022331001** **Implementation Date:** 30-Nov-22 Related CR: 2022331001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*De-challenge response to specific drug positive.*	Rejected		
HLT primary	*Therapeutic and nontherapeutic responses*			
SOC primary	*General disorders and administration site conditions*			

MSSO Comment: The proposal to add a new PT De-challenge response to specific drug positive. to primary HLT Therapeutic and nontherapeutic responses in SOC General disorders and administration site conditions is not approved. The concept definition of de-challenge is understood to represent a response to a single drug/product. Please see change request 2022331004 for the addition of PT Drug dechallenge positive.

CR Number: **2022331002** **Implementation Date:** 30-Nov-22 Related CR: 2022331002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Re-challenge response positive.*	Approved Not as Requested	Proposed PT	
HLT primary	*Therapeutic and nontherapeutic responses*		*Drug rechallenge positive*	10088898
SOC primary	*General disorders and administration site conditions*		HLT primary	
			Therapeutic and nontherapeutic responses	10043409
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Re-challenge response positive. to primary HLT Therapeutic and nontherapeutic responses in SOC General disorders and administration site conditions is approved but not as requested. Challenge–dechallenge–rechallenge is a medical testing protocol in which a medicine or drug is administered, withdrawn, then re-administered, while being monitored for adverse effects at each stage. The requested term will be modified and added as PT Drug rechallenge positive to HLT Therapeutic and nontherapeutic responses.

CR Number: **2022331003** **Implementation Date:** 30-Nov-22 Related CR: 2022331003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Re-challenge response to specific drug positive.*	Rejected		
HLT primary	*Therapeutic and nontherapeutic responses*			
SOC primary	*General disorders and administration site conditions*			

MSSO Comment: The proposal to add a new PT Re-challenge response to specific drug positive. to primary HLT Therapeutic and nontherapeutic responses in SOC General disorders and administration site conditions is not approved. The concept definition of de-challenge is understood to represent a response to a single drug/product. Please see change request 2022331002 for the addition of PT Drug rechallenge positive.

Supplemental Update Report

CR Number: 2022331004 **Implementation Date:** 30-Nov-22 Related CR: 2022331004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*De-challenge response positive.*	Approved Not as Requested	Proposed PT	
HLT primary	*Therapeutic and nontherapeutic responses*		*Drug dechallenge positive*	10088899
SOC primary	*General disorders and administration site conditions*		HLT primary	
			Therapeutic and nontherapeutic responses	10043409
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT De-challenge response positive. to primary HLT Therapeutic and nontherapeutic responses in SOC General disorders and administration site conditions is approved but not as requested. Challenge–dechallenge–rechallenge is a medical testing protocol in which a medicine or drug is administered, withdrawn, then re-administered, while being monitored for adverse effects at each stage. The requested term will be modified and added as PT Drug dechallenge positive to HLT Therapeutic and nontherapeutic responses.

CR Number: 2022331005 **Implementation Date:** 30-Nov-22 Related CR: 2022331005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ear bone fracture*	Approved Not as Requested	Proposed PT	
To PT	*Ear injury*		*Ear ossicle fracture*	10088900
			HLT primary	
			Fractures and dislocations NEC	10027677
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Middle ear disorders NEC	10027687
			SOC secondary	
			Ear and labyrinth disorders	10013993

MSSO Comment: The proposal to add a new LLT Ear bone fracture to PT Ear injury is approved but not as requested. There are three tiny articulating bones in the middle ear known as ossicles: malleus; incus; stapes. The requested term will be modified and added as PT Ear ossicle fracture to primary HLT Fractures and dislocations NEC and secondary HLT Middle ear disorders NEC. In a related change, PT Stapes fracture will be demoted as sub-concept LLT to new PT Ear ossicle fracture.

Supplemental Update Report

CR Number: 2022334041 **Implementation Date:** 30-Nov-22 Related CR: 2022331005

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Stapes fracture*	Approved as Requested	PT to merge	
To PT	*Ear ossicle fracture*		*Stapes fracture*	10081442 Current
			To PT	
			Ear ossicle fracture	10088900

MSSO Comment:

CR Number: 2022331006 **Implementation Date:** 30-Nov-22 Related CR: 2022331006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Heart CT*	Approved Not as Requested	Proposed PT	
			Computerised tomogram heart	10088901
			HLT primary	
			Cardiac imaging procedures	10007574
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Heart CT is approved but not as requested. The requested term will be modified and added as PT Computerised tomogram heart to HLT Cardiac imaging procedures. In a related change, the American English spelled Computerized tomogram heart will be added as an LLT to new PT Computerised tomogram heart. Furthermore, PT Computerised tomogram coronary artery will be merged as sub-concept to PT Computerised tomogram heart. Additionally, New PTs: PT Computerised tomogram heart abnormal and PT Computerised tomogram heart normal will both be added to HLT Cardiac imaging procedures. In addition, the American spelled LLT Computerized tomogram heart abnormal will be added to PT Computerised tomogram heart abnormal. Then the American English spelled LLT Computerized tomogram heart normal will be added to PT Computerised tomogram heart normal. Then, PT Computerised tomogram coronary artery normal will be demoted PT Computerised tomogram heart normal. Finally, PT Computerised tomogram coronary artery abnormal will be demoted under PT Computerised tomogram heart abnormal.

CR Number: 2022334042 **Implementation Date:** 30-Nov-22 Related CR: 2022331006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Computerized tomogram heart*	Approved as Requested	Proposed LLT	
To PT	*Computerised tomogram heart*		*Computerized tomogram heart*	10088904 Current
			To PT	
			Computerised tomogram heart	10088901

MSSO Comment:

Supplemental Update Report

CR Number: 2022334043 **Implementation Date:** 30-Nov-22 Related CR: 2022331006

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Computerised tomogram coronary artery*	Approved as Requested	PT to merge	
To PT	*Computerised tomogram heart*		*Computerised tomogram coronary artery*	10060804 Current
			To PT	
			Computerised tomogram heart	10088901

MSSO Comment:

CR Number: 2022334044 **Implementation Date:** 30-Nov-22 Related CR: 2022331006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Computerised tomogram heart abnormal*	Approved as Requested	Proposed PT	
HLT primary	*Cardiac imaging procedures*		*Computerised tomogram heart abnormal*	10088902
SOC primary	*Investigations*		HLT primary	
			Cardiac imaging procedures	10007574
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2022334045 **Implementation Date:** 30-Nov-22 Related CR: 2022331006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Computerised tomogram heart normal*	Approved as Requested	Proposed PT	
HLT primary	*Cardiac imaging procedures*		*Computerised tomogram heart normal*	10088903
SOC primary	*Investigations*		HLT primary	
			Cardiac imaging procedures	10007574
			SOC primary	
			Investigations	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2022334046 **Implementation Date:** 30-Nov-22 Related CR: 2022331006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Computerized tomogram heart abnormal*	Approved as Requested	Proposed LLT		
To PT	*Computerised tomogram heart abnormal*		*Computerized tomogram heart abnormal*	10088905	Current
			To PT		
			Computerised tomogram heart abnormal	10088902	

MSSO Comment:

CR Number: 2022334047 **Implementation Date:** 30-Nov-22 Related CR: 2022331006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Computerized tomogram heart normal*	Approved as Requested	Proposed LLT		
To PT	*Computerised tomogram heart normal*		*Computerized tomogram heart normal*	10088906	Current
			To PT		
			Computerised tomogram heart normal	10088903	

MSSO Comment:

CR Number: 2022334048 **Implementation Date:** 30-Nov-22 Related CR: 2022331006

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*Computerised tomogram coronary artery normal*	Approved as Requested	PT to merge		
To PT	*Computerised tomogram heart normal*		*Computerised tomogram coronary artery normal*	10060805	Current
			To PT		
			Computerised tomogram heart normal	10088903	

MSSO Comment:

Supplemental Update Report

CR Number: 2022334049 **Implementation Date:** 30-Nov-22 Related CR: 2022331006

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*Computerised tomogram coronary artery abnormal*	Approved as Requested	PT to merge		
To PT	*Computerised tomogram heart abnormal*		*Computerised tomogram coronary artery abnormal*	10060806	Current
			To PT		
			Computerised tomogram heart abnormal	10088902	

MSSO Comment:

CR Number: 2022332006 **Implementation Date:** 30-Nov-22 Related CR: 2022332006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Endothelinum-derived relaxing factors*	Approved Not as Requested	Proposed PT	
HLT primary	*Metabolism tests NEC*		*Endothelinum-derived relaxing factor*	10088895
SOC primary	*Investigations*		HLT primary	
			Vascular tests NEC (incl blood pressure)	10047110
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Endothelinum-derived relaxing factors to primary HLT Metabolism tests NEC in SOC Investigations is approved but not as requested. Endothelium-derived relaxing factor (EDRF) is an endogenous vasodilator that endothelial cells produce and subsequently release in response to various changes in normal physiologic as well as pathophysiologic changes.The proposed term will be modified to the singular form as PT Endothelinum-derived relaxing factor to HLT Vascular tests NEC (incl blood pressure).

Supplemental Update Report

CR Number: 2022332007 **Implementation Date:** 30-Nov-22 Related CR: 2022332007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pertussis-like syndrome*	Approved as Requested	Proposed PT	
HLT primary	*Upper respiratory tract infections*		*Pertussis-like syndrome*	10088896
SOC primary	*Infections and infestations*		HLT primary	
			Upper respiratory tract infections	10046309
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Upper respiratory tract infections NEC	10045573
			SOC secondary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new PT Pertussis-like syndrome to primary HLT Upper respiratory tract infections in SOC Infections and infestations and secondary HLT Upper respiratory tract infections NEC in SOC Respiratory, thoracic and mediastinal disorders is approved as requested. Pertussis-like syndrome refers to a clinical syndrome compatible with pertussis infection but lacking laboratory confirmation or an epidemiological link to a confirmed case. The surge in pertussis like syndrome could be mainly related to viruses, other Bordetella species, or due to the waning pertussis immunity.

CR Number: 2022332063 **Implementation Date:** 30-Nov-22 Related CR: 2022332063

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*Drooping shoulder syndrome*	Approved as Requested	PT to merge		
To PT	*Dropped shoulder syndrome*		*Drooping shoulder syndrome*	10079746	Current
			To PT		
			Dropped shoulder syndrome	10088323	

MSSO Comment: The proposal to demote the PT Drooping shoulder syndrome under PT Dropped shoulder syndrome is approved as requested. Drooping shoulder syndrome is synonymously used for dropped shoulder syndrome.

Supplemental Update Report

CR Number: 2022332064 **Implementation Date:** 30-Nov-22 Related CR: 2022332064

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Kosaki overgrowth syndrome*	Rejected		
To PT	*Overgrowth syndrome*			

MSSO Comment: The proposal to demote the PT Kosaki overgrowth syndrome under PT Overgrowth syndrome is not approved. Overgrowth syndromes in children constitute a group of rare disorders that are characterized by tissue hypertrophy. Although they all have features in common, each one involves different organs and therefore need a different MedDRA mapping, which makes preferable to keep them as PTs. Apart from the one requested for demotion, examples of other overgrowth syndromes already represented in MedDRA as PTs are PIK3CA related overgrowth spectrum, Sotos' syndrome, Proteus syndrome or Acral overgrowth.

CR Number: 2022332065 **Implementation Date:** 30-Nov-22 Related CR: 2022332065

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Hepatocele*	Approved as Requested	PT to merge	
To PT	*Liver hernia*		*Hepatocele*	10080531 Current
			To PT	
			Liver hernia	10088554

MSSO Comment: The proposal to demote the PT Hepatocele under PT Liver hernia is approved as requested. In a related change, the PT Liver hernia will be linked to secondary HLT Diaphragmatic hernias.

CR Number: 2022334050 **Implementation Date:** 30-Nov-22 Related CR: 2022332065

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Liver hernia*	Approved as Requested	Proposed PT	
To HLT	*Diaphragmatic hernias*		*Liver hernia*	10088554
			To HLT	
			Diaphragmatic hernias	10012714

MSSO Comment:

Supplemental Update Report

CR Number: 2022332066 **Implementation Date:** 30-Nov-22 Related CR: 2022332066

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Viscocanalostomy*	Approved as Requested	PT to merge	
To PT	*Goniosynechialysis*		*Viscocanalostomy*	10077985 Current
			To PT	
			Goniosynechialysis	10088046

MSSO Comment: The proposal to demote the PT Viscocanalostomy under PT Goniosynechialysis is approved as requested. Goniosynechialysis is a surgical technique consisting of the mechanical release of peripheral anterior chamber synechiae. The synechiae are completely released and the the chamber angle enlarged by using a cohesive viscoelastic material.

CR Number: 2022333001 **Implementation Date:** 30-Nov-22 Related CR: 2022333001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pain crisis*	Approved as Requested	Proposed LLT	
			Pain crisis	10088907 Current
			To PT	
			Pain	10033371

MSSO Comment: The proposal to add a new term Pain crisis is approved as requested. Pain crisis is an expression generally used to refer to an episode of pain that range in severity from mild to severe, usually occurring very abruptly. Pain crisis will be added as an LLT under PT Pain.

CR Number: 2022333002 **Implementation Date:** 30-Nov-22 Related CR: 2022333002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Allergy to seeds*	Approved as Requested	Proposed LLT	
			Allergy to seeds	10088908 Current
			To PT	
			Food allergy	10016946

MSSO Comment: The proposal to add a new term Allergy to seeds is approved as requested. A seed allergy is any physical reaction after consuming seeds or their products. Allergy to seeds will be added as LLT to PT Food allergy.

Supplemental Update Report

CR Number: 2022333011 **Implementation Date:** 30-Nov-22 Related CR: 2022333011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*TRANSIENT PULMONARY ARTERIAL HYPERTENSION IN NEONATES*	Approved Not as Requested	Proposed LLT	
			Transient neonatal pulmonary arterial hypertension	10088910 Current
			To PT	
			Neonatal pulmonary hypertension	10088909

MSSO Comment: The proposal to add a new term TRANSIENT PULMONARY ARTERIAL HYPERTENSION IN NEONATES is approved but not as requested. Pulmonary hypertension in neonates, infants, children, adolescents, and young adults is a complex condition that can be associated with several cardiac, pulmonary, and systemic diseases contributing to morbidity and mortality. The requested term will be modified according to MedDRA capitalization conventions and added as LLT Transient neonatal pulmonary arterial hypertension to a new PT Neonatal pulmonary hypertension which will be added in a related change to primary HLT Pulmonary hypertensions and secondary HLT Neonatal respiratory disorders NEC.

CR Number: 2022334051 **Implementation Date:** 30-Nov-22 Related CR: 2022333011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal pulmonary hypertension*	Approved as Requested	Proposed PT	
			Neonatal pulmonary hypertension	10088909
HLT primary	*Pulmonary hypertensions*		HLT primary	
			Pulmonary hypertensions	10037401
SOC primary	*Respiratory, thoracic and mediastinal disorders*		SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738
			HLT secondary	
			Neonatal respiratory disorders NEC	10028972
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment:

Supplemental Update Report

CR Number: 2022333021 **Implementation Date:** 30-Nov-22 Related CR: 2022333021

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Mpox*	Approved as Requested	Proposed LLT	
To PT	*Monkeypox*		*Mpox*	10088911 Current
			To PT	
			Monkeypox	10069538

MSSO Comment: The proposal to add a new LLT Mpox to PT Monkeypox is approved as requested. New terminology has been recommended for monkeypox to use the term “mpox” as a synonym. “Monkeypox” has been considered to represent racist and stigmatizing language. This new term is being proposed as the new preferred nomenclature, mpox.

CR Number: 2022333022 **Implementation Date:** 30-Nov-22 Related CR: 2022333022

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Mpox immunisation*	Approved as Requested	Proposed LLT	
To PT	*Monkeypox immunisation*		*Mpox immunisation*	10088912 Current
			To PT	
			Monkeypox immunisation	10088234

MSSO Comment: The proposal to add a new LLT Mpox immunisation to PT Monkeypox immunisation is approved as requested. New terminology has been recommended for monkeypox to use the term “mpox” as a synonym. “Monkeypox” has been considered to represent racist and stigmatizing language. This new term is being proposed as the new preferred nomenclature, mpox.

CR Number: 2022333023 **Implementation Date:** 30-Nov-22 Related CR: 2022333023

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Mpox immunization*	Approved as Requested	Proposed LLT	
To PT	*Monkeypox immunisation*		*Mpox immunization*	10088913 Current
			To PT	
			Monkeypox immunisation	10088234

MSSO Comment: The proposal to add a new LLT Mpox immunization to PT Monkeypox immunisation is approved as requested. New terminology has been recommended for monkeypox to use the term “mpox” as a synonym. “Monkeypox” has been considered to represent racist and stigmatizing language. This new term is being proposed as the new preferred nomenclature, mpox.
