

Supplemental Update Report

CR Number: 2022272001 **Implementation Date:** 19-Oct-23 **Related CR:** 2022272001

[Change Requested](#) Add a New HLT

[Final Disposition](#)

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Proposed HLT *Capripox viral infections*

Rejected After Suspension

MSSO Comment: The proposal to add a new HLT Capripox viral infections is not approved after suspension. The genus of Capripox viruses mainly affect animals and are reported sporadically in humans. It is not practical for MedDRA to create grouping terms for all microbial species especially if infections in humans are rare.

CR Number: 2022334008 **Implementation Date:** 07-Aug-23 **Related CR:** 2022334008

[Change Requested](#) Add a New HLG

[Final Disposition](#)

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Proposed HLG *Persistent ADR*

Rejected After Suspension

MSSO Comment: The proposal to add a new HLG Persistent ADR is not approved after suspension. Generally, it is out of the scope of MedDRA to provide terms which relay time, duration or temporally related qualifiers. From a global perspective, the definition of the duration of "persistent" or other time related qualifiers would vary depending on region or organization. The methodology to capture "persistent" or similar concepts might be well accomplished with the case report form design. When the chronicity or persistence of a particular disease concept is itself a disease/condition concept entity, it is given a MedDRA term such as in your examples provided LLT Persistent headache, LLT Persistent cough, etc.

CR Number: 2022364847 **Implementation Date:** 19-Oct-23 **Related CR:** 2022364847

[Change Requested](#) Add a New HLG

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Proposed HLG *Drug implant issues*

Rejected After Suspension

To SOC *Product issues*

MSSO Comment: The proposal to add a new HLG Drug implant issues to SOC Product issues is not approved after suspension. As specified in the MedDRA Introductory Guide, device terms are generally event based, not device type based. Terms related to ocular implant concepts have been added to MedDRA, but creating grouping terms to gather them is beyond the specificity with which devices are treated in the current MedDRA structure. To implement separate HLTs and HLGs for drug implants would change the entire philosophy of the existing structure. In addition, there were comments received from MedDRA users against making these changes.

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CR Number: 2022364848 **Implementation Date:** 19-Oct-23 **Related CR:** 2022364848

Change Requested Add a New HLT Final Disposition Final Placement MedDRA Code #

Proposed HLT *Ocular drug implant issue* Rejected After Suspension

MSSO Comment: The proposal to add a new HLT Ocular drug implant issue is not approved after suspension. As specified in the MedDRA Introductory Guide, device terms are generally event based, not device type based. Terms related to ocular implant concepts have been added to MedDRA, but creating grouping terms to gather them is beyond the specificity with which devices are treated in the current MedDRA structure. To implement separate HLTs and HLGTS for drug implants would change the entire philosophy of the existing structure. In addition, there were comments received from MedDRA users against making these changes.

CR Number: 2022364853 **Implementation Date:** 19-Oct-23 **Related CR:** 2022364853

Change Requested Add a New HLT Final Disposition Final Placement MedDRA Code #

Proposed HLT *Complication associated with ocular drug implant* Rejected After Suspension

MSSO Comment: The proposal to add a new HLT Complication associated with ocular drug implant is not approved after suspension. As specified in the MedDRA Introductory Guide, device terms are generally event based, not device type based. Terms related to ocular implant concepts have been added to MedDRA, but creating grouping terms to gather them is beyond the specificity with which devices are treated in the current MedDRA structure. To implement separate HLTs and HLGTS for drug implants would change the entire philosophy of the existing structure. In addition, there were comments received from MedDRA users against making these changes.

CR Number: 2022364854 **Implementation Date:** 19-Oct-23 **Related CR:** 2022364854

Change Requested Add a New HLGTS Final Disposition Final Placement MedDRA Code #

Proposed HLGTS *Eye complications associated with ocular drug implant* Rejected After Suspension

To SOC *General disorders and administration site conditions*

MSSO Comment: The proposal to add a new HLGTS Eye complications associated with ocular drug implant to SOC General disorders and administration site conditions is not approved after suspension. As specified in the MedDRA Introductory Guide, device terms are generally event based, not device type based. Terms related to ocular implant concepts have been added to MedDRA, but creating grouping terms to gather them is beyond the specificity with which devices are treated in the current MedDRA structure. To implement separate HLTs and HLGTS for drug implants would change the entire philosophy of the existing structure. In addition, there were comments received from MedDRA users against making these changes.

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CR Number: 2023144056 **Implementation Date:** 27-Nov-23 **Related CR:** 2023144056

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Term to modify	Rename HLT <i>Application and instillation site reactions</i>	Approved Not as Requested After Suspension	Term to modify <i>Application and instillation site reactions</i>	10003057
Replacement term	<i>HLT Application site reactions AND HLT Instillation site reactions</i>		Replacement term <i>Application site reactions</i>	10003057

MSSO Comment: The proposal to rename the HLT Application and instillation site reactions to HLT Application site reactions AND HLT Instillation site reactions is approved but not as requested after suspension. Existing HLT Application and instillation site reactions will be split into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. HLT Application and instillation site reactions will be renamed HLT Application site reactions, which was the original name of this term from MedDRA Version 2.1 to Version 4.0. In a related change, a new HLT Instillation site reactions will be added under HLGT Administration site reactions. The "installation site" PTs under renamed HLT Application site reactions will be moved to new HLT Instillation site reactions in follow-on change requests. The majority of users that provided feedback on this request were in favor of making these changes.

CR Number: 2023292036 **Implementation Date:** 27-Nov-23 **Related CR:** 2023144056

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed HLT	Add a New HLT <i>Instillation site reactions</i>	Approved as Requested	Proposed HLT <i>Instillation site reactions</i>	10090509
To HLGT	<i>Administration site reactions</i>		To HLGT <i>Administration site reactions</i>	10001316

MSSO Comment:

CR Number: 2023153001 **Implementation Date:** 03-Jul-23 **Related CR:** 2023153001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Pincer Nail Deformity</i>	Approved Not as Requested	Proposed LLT <i>Pincer nail deformity</i>	10089946 Current
			To PT <i>Nail deformation</i>	10028690

MSSO Comment: The proposal to add a new term Pincer Nail Deformity is approved but not as requested. A pincer nail is a common nail deformity (PND) of toenails and is characterized by nail thickening and nail plate deformation. PND's cause is not known but is suspected to be hereditary or acquired. The requested term will be modified according to MedDRA capitalisation conventions and added as LLT Pincer nail deformity to PT Nail deformation. In a related change LLT Nail deformation will be promoted from PT Nail disorder and linked to HLT Nail and nail bed conditions (excl infections and infestations).

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CR Number: 2023184052 Implementation Date: 03-Jul-23 Related CR: 2023153001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Promote an LLT	Approved as Requested	Proposed LLT	
From PT	<i>Nail deformation</i>		<i>Nail deformation</i>	10028690
HLT primary	<i>Nail disorder</i>		From PT	
	<i>Nail and nail bed conditions (excl infections and infestations)</i>		<i>Nail disorder</i>	10028694
			HLT primary	
			<i>Nail and nail bed conditions (excl infections and infestations)</i>	10028685
			SOC primary	
			<i>Skin and subcutaneous tissue disorders</i>	10040785

MSSO
Comment:

CR Number: 2023153002 Implementation Date: 03-Jul-23 Related CR: 2023153002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term	Rejected		
	<i>Dry Sinuses</i>			

MSSO The proposal to add a new term Dry Sinuses is not approved. The requested term can be represented by LLT Paranasal sinus dryness
Comment:

Supplemental Update Report

CR Number: 2023153003 Implementation Date: 03-Jul-23 Related CR: 2023153003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Moving toes syndrome</i>	Approved Not as Requested	Proposed PT <i>Painful legs-moving toes syndrome</i>	10089938
			HLT primary <i>Sensory abnormalities NEC</i>	10040021
			SOC primary <i>Nervous system disorders</i>	10029205
			HLT secondary <i>Peripheral nerve injuries</i>	10011302
			SOC secondary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new term Moving toes syndrome is approved but not as requested. The syndrome of painful legs-moving toes (PLMT) is an adult-onset, rare disorder characterized by pain, typically of a neuropathic quality, in the feet or legs, associated with writhing movements of one or more toes. The requested term will be modified to how it is most often referred to in literature and added as PT Painful legs-moving toes syndrome to primary HLT Sensory abnormalities NEC and secondary HLT Peripheral nerve injuries.

CR Number: 2023153004 Implementation Date: 03-Jul-23 Related CR: 2023153004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Toe Twitching</i>	Approved Not as Requested	Proposed LLT <i>Toe twitching</i>	10089942 Current
			To PT <i>Muscle twitching</i>	10028347

MSSO Comment: The proposal to add a new term Toe Twitching is approved but not as requested. Toe twitching, also called a tremor or a spasm, can be caused by a variety of conditions. Poor peripheral blood circulation can lead to a lack of oxygen supply to toe muscles. The requested term will be modified according to MedDRA capitalization conventions and added as LLT Toe twitching to PT Muscle twitching.

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CR Number: 2023153005 **Implementation Date:** 03-Jul-23 **Related CR:** 2023153005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Pulsed field ablation</i>	Approved Not as Requested	Proposed LLT <i>Cardiac pulsed field ablation</i>	10089943 Current
			To PT <i>Cardiac ablation</i>	10059864

MSSO Comment: The proposal to add a new term Pulsed field ablation is approved but not as requested. Pulsed electric fields (PEFs) have emerged as an ideal cardiac ablation modality. At present numerous clinical trials in humans are exploring PEF as an ablation strategy for both atrial and ventricular arrhythmias, with early data showing significant promise. The proposed term will be modified for clarity and added as the sub concept LLT Cardiac pulsed field ablation to PT Cardiac ablation.

CR Number: 2023153006 **Implementation Date:** 03-Jul-23 **Related CR:** 2023153006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Supernumerary breast</i>	Approved as Requested	Proposed LLT <i>Supernumerary breast</i>	10089944 Current
			To PT <i>Accessory breast</i>	10049786

MSSO Comment: The proposal to add a new term Supernumerary breast is approved as requested. Supernumerary breast will be added as synonym LLT to PT Accessory breast aligned with LLT Polymastia.

CR Number: 2023153007 **Implementation Date:** 03-Jul-23 **Related CR:** 2023153007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Annessiectomy</i>	Approved as Requested	Proposed LLT <i>Annessiectomy</i>	10089947 Current
			To PT <i>Salpingo-oophorectomy</i>	10039464

MSSO Comment: The proposal to add a new term Annessiectomy is approved as requested. Annessiectomy, the removal of the ovaries and fallopian tubes, is a rarely used synonym of and will be added as LLT to PT Salpingo-oophorectomy.

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CR Number: 2023153008	Implementation Date: 03-Jul-23	Related CR: 2023153008	MedDRA Code #
<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	
Add a New Term			
Proposed Term <i>Heterogeneously dense breasts</i>	Approved as Requested	Proposed PT <i>Heterogeneously dense breasts</i>	10089939
		HLT primary <i>Breast disorders NEC</i>	10040675
		SOC primary <i>Reproductive system and breast disorders</i>	10038604

MSSO Comment: The proposal to add a new term Heterogeneously dense breasts is approved as requested. Dense breast tissue refers to the amount of fibroglandular and fibrous connective tissue as compared to fatty tissue. Heterogeneously dense breasts will be added as PT to HLT Breast disorders NEC.

CR Number: 2023153009	Implementation Date: 03-Jul-23	Related CR: 2023153009	MedDRA Code #
<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	
Add a New Term			
Proposed Term <i>Ureter Ligation</i>	Approved Not as Requested	Proposed PT <i>Ureter ligation</i>	10089940
		HLT primary <i>Ureteric therapeutic procedures</i>	10046407
		SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new term Ureter Ligation is approved but not as requested. Laparoscopic ureter ligation (clipping) is a surgical procedure e.g. in the treatment of incontinence due to an ectopic ureter. The requested term will be modified in accordance with MedDRA capitalisation conventions and added as PT Ureter ligation to HLT Ureteric therapeutic procedures.

CR Number: 2023153010	Implementation Date: 03-Jul-23	Related CR: 2023153010	MedDRA Code #
<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	
Add a New Term			
Proposed Term <i>Matrix metalloproteinase inhibitor-1 increased</i>	Approved as Requested	Proposed PT <i>Matrix metalloproteinase inhibitor-1 increased</i>	10089941
		HLT primary <i>Tissue enzyme analyses NEC</i>	10043891
		SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new term Matrix metalloproteinase inhibitor-1 increased is approved as requested. Matrix metalloproteinases (MMPs) and their inhibitors (TIMPs) play a major role in the maintenance of extracellular matrix homeostasis. Alterations of MMP and TIMP expressions have been found in several malignant tumour entities. Matrix metalloproteinase inhibitor-1 increased will be added as PT to HLT Tissue enzyme analyses NEC

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CR Number: 2023153011 Implementation Date: 03-Jul-23 Related CR: 2023153011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Sinonasal polyposis</i>	Approved as Requested	Proposed LLT <i>Sinonasal polyposis</i>	10089945 Current
			To PT <i>Nasal polyps</i>	10028756

MSSO Comment: The proposal to add a new term Sinonasal polyposis is approved as requested. Sinonasal polyposis refers to the presence of multiple benign polyps in the nasal cavity and paranasal sinuses. The polyps are most commonly encountered in adults and rare in children. Polyps are the most common expansile lesions of the nasal cavity. Sinonasal polyposis will be added as LLT to PT Nasal polyps.

CR Number: 2023153012 Implementation Date: 07-Aug-23 Related CR: 2023153012

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Heart failure with reduced ejection fraction</i>	Approved After Suspension	Proposed LLT <i>Heart failure with reduced ejection fraction</i>	10078289
From PT	<i>Cardiac failure</i>		From PT <i>Left ventricular failure</i>	10024119
			HLT primary <i>Left ventricular failures</i>	10024120
			SOC primary <i>Cardiac disorders</i>	10007541

MSSO Comment: The proposal to promote the LLT Heart failure with reduced ejection fraction from PT Cardiac failure is approved as requested after suspension. After reconsideration, this ,and the other two related LLTs in this batch, will be promoted based on the following assumptions: 1) the wide acceptance of the use of left ventricle ejection fraction in the classification of the severity of heart failure because of its ability in differing prognosis and response to treatments and because most clinical trials select patients based on these ejection fraction phenotypes; 2) though promotion of these terms was judged initially incoherent with the current presence of NYHA at the LLT level - as it is also the case of many severity classifications in MedDRA - it is also true that NYHA is a subjective assessment by a clinician and thus can change over time with a limited reproducibility and validity; and 3) although heart failure is mainly based on left ventricular failure, it may also involve functional and structural changes in the atrium, specially at the stage of "heart failure with preserved ejection fraction", which makes current subordination to PT Left ventricular failure acceptable but not totally correct. Therefore, LLT Heart failure with reduced ejection fraction will be promoted from PT Left ventricular failure to HLT Left ventricular failures.

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CR Number: 2023153013 Implementation Date: 07-Aug-23 Related CR: 2023153013

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Promote an LLT	Approved After Suspension	Proposed LLT	
From PT	<i>Heart failure with preserved ejection fraction</i>		<i>Heart failure with preserved ejection fraction</i>	10076396
	<i>Cardiac failure</i>		From PT	
			<i>Left ventricular failure</i>	10024119
			HLT primary	
			<i>Left ventricular failures</i>	10024120
			SOC primary	
			<i>Cardiac disorders</i>	10007541

MSSO Comment: The proposal to promote the LLT Heart failure with preserved ejection fraction from PT Cardiac failure is approved as requested after suspension. The diagnosis of chronic heart failure with preserved ejection fraction, especially in the typical elderly patient with co-morbidities and no obvious signs of central fluid overload, is difficult to the point that a validated gold standard is missing. To improve the specificity of its diagnose, the clinical diagnosis needs to be supported by objective measures of cardiac dysfunction at rest or during exercise. Therefore, after reconsideration, the LLT Heart failure with preserved ejection fraction represents a well individualized clinical context, and thus will be promoted from PT Left ventricular failure to HLT Left ventricular failures.

CR Number: 2023153014 Implementation Date: 07-Aug-23 Related CR: 2023153014

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Promote an LLT	Approved After Suspension	Proposed LLT	
From PT	<i>Heart failure with midrange ejection fraction</i>		<i>Heart failure with midrange ejection fraction</i>	10086366
	<i>Cardiac failure</i>		From PT	
			<i>Left ventricular failure</i>	10024119
			HLT primary	
			<i>Left ventricular failures</i>	10024120
			SOC primary	
			<i>Cardiac disorders</i>	10007541

MSSO Comment: The proposal to promote the LLT Heart failure with midrange ejection fraction from PT Cardiac failure is approved as requested after suspension. Heart failure with mid-range ejection fraction (also called "Heart failure mild-range ejection fraction") is defined as an ejection fraction of 41% to 49% per European guidelines and 40 to 49% per the US guidelines. Patients with HFmrEF are usually in a dynamic trajectory to improvement from HFrEF or to deterioration to HFrEF. This class represents the grey area between the "preserved" and "reduced" heart failure ejection fractions, and has become accepted as a distinct entity; thus LLT Heart failure with midrange ejection fraction will be promoted from PT Heart failure with mid-range ejection fraction (also called "Heart failure mild-range ejection fraction") is defined as an ejection fraction of 41% to 49% per European guidelines and 40 to 49% per the US guidelines. Patients with HFmrEF are usually in a dynamic trajectory to improvement from HFrEF or to deterioration to HFrEF. This class represents the grey area between the "preserved" and "reduced" heart failure ejection fractions, and has become accepted as a distinct entity; thus LLT Heart failure with midrange ejection fraction will be promoted from PT Left ventricular failure to HLT Left ventricular failures.

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CR Number: 2023155001 **Implementation Date:** 30-Jun-23 **Related CR:** 2023155001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Corneal epithelial edema	Approved Not as Requested	Proposed LLT Corneal epithelial edema	10089912 Current
			To PT Corneal oedema	10011033

MSSO Comment: The proposal to add a new PT Corneal epithelial edema is approved but not as requested. Corneal epithelial edema causes a hazy microcystic appearance to occur in the epithelium in mild-to-moderate cases of corneal edema, significantly decreasing vision, and increasing glare. It can also cause the development of large painful, subepithelial bullae in severe cases. Corneal epithelial edema will be added as an LLT to PT Corneal oedema, in line with the related LLT Corneal microcystic edema. In a related change, the British English counterpart LLT Corneal epithelial oedema will also be added to PT Corneal oedema.

CR Number: 2023181005 **Implementation Date:** 30-Jun-23 **Related CR:** 2023155001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Corneal epithelial oedema	Approved as Requested	Proposed LLT Corneal epithelial oedema	10089915 Current
To PT	Corneal oedema		To PT Corneal oedema	10011033

MSSO Comment:

CR Number: 2023155002 **Implementation Date:** 30-Jun-23 **Related CR:** 2023155002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Corneal Honeycombing	Approved Not as Requested	Proposed LLT Corneal honeycombing	10089911 Current
			To PT Corneal oedema	10011033

MSSO Comment: The proposal to add a new LLT Corneal Honeycombing is approved but not as requested. Honeycomb-type reticular epithelial corneal edema leading to a sudden-onset decrease in visual acuity is a novel side effect produced by rho-kinase inhibitors in the treatment of glaucoma. The propose term will be modified in accordance with MedDRA capitalization conventions to Corneal honeycombing, which will be added as an LLT to PT Corneal oedema. In an associated change, its synonym Reticular epithelial corneal edema - as well as its British spelled synonym Reticular epithelial corneal oedema - will both be added as LLTs to PT Corneal oedema.

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CR Number: 2023181006	Implementation Date: 30-Jun-23	Related CR: 2023155002		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Reticular epithelial corneal edema</i>	Approved as Requested	Proposed LLT	
To PT	<i>Corneal oedema</i>		<i>Reticular epithelial corneal edema</i>	10089913 Current
			To PT	
			<i>Corneal oedema</i>	10011033

MSSO
Comment:

CR Number: 2023181007	Implementation Date: 30-Jun-23	Related CR: 2023155002		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Reticular epithelial corneal oedema</i>	Approved as Requested	Proposed LLT	
To PT	<i>Corneal oedema</i>		<i>Reticular epithelial corneal oedema</i>	10089914 Current
			To PT	
			<i>Corneal oedema</i>	10011033

MSSO
Comment:

CR Number: 2023155003	Implementation Date: 30-Jun-23	Related CR: 2023155003		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Antibody mediated hypersensitivity reactions</i>	Approved Not as Requested	Proposed LLT	
			<i>Antibody mediated cytotoxic hypersensitivity reaction</i>	10089910 Current
			To PT	
			<i>Type II hypersensitivity</i>	10054000

MSSO
Comment: The proposal to add a new LLT Antibody mediated hypersensitivity reactions is approved but not as requested. Antibody-dependent cytotoxic hypersensitivity is a synonym of type II hypersensitivity, which results when an antibody binds to a cell surface antigen or to a molecule coupled to a cell surface. The proposed term will be modified to its more specific name not to be confounded with IgE-mediated immune responses or immune complex diseases, in which antibodies are also involved. Once expressed in singular, it will be added as the LLT Antibody mediated cytotoxic hypersensitivity reaction to PT Type II hypersensitivity.

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CR Number: 2023155004 Implementation Date: 30-Jun-23 Related CR: 2023155004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Autoimmune Polyglandular Syndrome Type 1</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Autoimmune Polyglandular Syndrome Type 1 is not approved. The proposed concept is already represented in MedDRA by PT/LLT Polyglandular autoimmune syndrome type I.

CR Number: 2023155005 Implementation Date: 30-Jun-23 Related CR: 2023155005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Suspected prostatitis</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Suspected prostatitis is not approved. Except for a few terms of particular interest in pharmacovigilance, MedDRA does not add terms representing conditions not yet confirmed. As per section "3.1 Definitive and Provisional Diagnoses with or without Signs and Symptoms" of the Term Selection Points to Consider document, the preferred option for a provisional diagnosis is to select a term for the diagnosis, i.e. in this case, LLT/PT Prostatitis.

CR Number: 2023156001 Implementation Date: 03-Jul-23 Related CR: 2023156001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Parasitic test negative</i>	Approved as Requested	Proposed PT <i>Parasitic test negative</i>	10089948
			HLT primary <i>Parasite identification and serology</i>	10033903
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new term Parasitic test negative is approved as requested. Parasitic test negative will be added as PT to HLT Parasite identification and serology, aligned with PT Parasitic blood test negative. In related change PT Parasitic blood test negative will be demoted under the new PT Parasitic test negative to have specimens at LLT level.

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CR Number: 2023184055 Implementation Date: 03-Jul-23 Related CR: 2023156001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
PT to merge	Demote a PT <i>Parasitic blood test negative</i>	Approved as Requested	PT to merge	
To PT	<i>Parasitic test negative</i>		<i>Parasitic blood test negative</i>	10059992 Current
			To PT	
			<i>Parasitic test negative</i>	10089948

MSSO
Comment:

CR Number: 2023156002 Implementation Date: 30-Jun-23 Related CR: 2023156002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Thigh lift</i>	Approved as Requested	Proposed LLT	
To PT	<i>Skin cosmetic procedure</i>		<i>Thigh lift</i>	10089916 Current
			To PT	
			<i>Skin cosmetic procedure</i>	10052608

MSSO Comment: The proposal to add a new LLT Thigh lift to PT Skin cosmetic procedure is approved as requested. A crural lift or a thigh lift is a surgery to remove excess cutaneous, subcutaneous and adipose tissue (dermal-adipose lipectomy) located in the internal part of the thighs to harmonize the lower limbs with the rest of the body and improve movements.

CR Number: 2023156003 Implementation Date: 30-Jun-23 Related CR: 2023156003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Crural lifting</i>	Approved as Requested	Proposed LLT	
To PT	<i>Skin cosmetic procedure</i>		<i>Crural lifting</i>	10089917 Current
			To PT	
			<i>Skin cosmetic procedure</i>	10052608

MSSO Comment: The proposal to add a new LLT Crural lifting to PT Skin cosmetic procedure is approved as requested. A crural lift or a thigh lift is a surgery to remove excess cutaneous, subcutaneous and adipose tissue (dermal-adipose lipectomy) located in the internal part of the thighs to harmonize the lower limbs with the rest of the body and improve movements.

Supplemental Update Report

CR Number: 2023157001 Implementation Date: 03-Jul-23 Related CR: 2023157001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Total Leukocyte Count	Approved Not as Requested	Proposed LLT	
To PT	White blood cell count		Total leukocyte count	10089949 Current
			To PT	
			White blood cell count	10047939

MSSO Comment: The proposal to add a new LLT Total Leukocyte Count to PT White blood cell count is approved but not as requested. The term will be modified to follow MedDRA rules of capitalization. LLT Total leukocyte count will be added to PT White blood cell count. In a related change, due to the ambiguity of the acronyms, (in the book of Medical abbreviations TLC is cited; total lung capacity, or total lymphocyte count) the following LLTs will be flagged non-current: LLT TLC; LLT TLC abnormal; LLT TLC decreased; LLT TLC normal.

CR Number: 2023184047 Implementation Date: 03-Jul-23 Related CR: 2023157001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
LLT to change	TLC	Approved as Requested	LLT to change	
Status	Non-current		TLC	10043896 Non-Current
			Status	
			Non-current	

MSSO Comment:

CR Number: 2023184048 Implementation Date: 03-Jul-23 Related CR: 2023157001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
LLT to change	TLC abnormal	Approved as Requested	LLT to change	
Status	Non-current		TLC abnormal	10043897 Non-Current
			Status	
			Non-current	

MSSO Comment:

Supplemental Update Report

CR Number: 2023184049 **Implementation Date:** 03-Jul-23 **Related CR:** 2023157001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
LLT to change	<i>TLC decreased</i>	Approved as Requested	LLT to change	
Status	<i>Non-current</i>		<i>TLC decreased</i>	10043898 Non-Current
			Status	
			<i>Non-current</i>	

MSSO
Comment:

CR Number: 2023184050 **Implementation Date:** 03-Jul-23 **Related CR:** 2023157001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
LLT to change	<i>TLC normal</i>	Approved as Requested	LLT to change	
Status	<i>Non-current</i>		<i>TLC normal</i>	10043899 Non-Current
			Status	
			<i>Non-current</i>	

MSSO
Comment:

CR Number: 2023157011 **Implementation Date:** 03-Jul-23 **Related CR:** 2023157011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Duodenal bulbar ulcer</i>	Approved Not as Requested	Proposed LLT	
			<i>Duodenal bulb ulcer</i>	10089950 Current
			To PT	
			<i>Duodenal ulcer</i>	10013836

MSSO The proposal to add a new term Duodenal bulbar ulcer is approved but not as requested. The proposed term will be rephrased to Duodenal bulb ulcer in accordance with MedDRA
Comment: naming conventions and will be added as an LLT under PT Duodenal ulcer.

Supplemental Update Report

CR Number: 2023158001	Implementation Date: 30-Jun-23	Related CR: 2023158001		<u>MedDRA Code #</u>
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	
Proposed Term	<i>Self-rating anxiety scale score</i>	Approved as Requested	Proposed LLT <i>Self-rating anxiety scale score</i>	10089919 Current
			To PT <i>Anxiety rating scale score</i>	10089918

MSSO Comment: The proposal to add a new term Self-rating anxiety scale score is approved as requested. The self-rating anxiety scale is a 20-item self-report assessment device built to measure anxiety levels, based on scoring in 4 groups of manifestations: cognitive, autonomic, motor and central nervous system symptoms. Self-rating anxiety scale score will be added as an LLT to new PT Anxiety rating scale score, which will be added, in a related change, to HLT Psychiatric investigations.

CR Number: 2023181008	Implementation Date: 30-Jun-23	Related CR: 2023158001		<u>MedDRA Code #</u>
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	
Proposed PT	<i>Anxiety rating scale score</i>	Approved as Requested	Proposed PT <i>Anxiety rating scale score</i>	10089918
HLT primary	<i>Psychiatric investigations</i>		HLT primary <i>Psychiatric investigations</i>	10067226
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO Comment:

CR Number: 2023158003	Implementation Date: 30-Jun-23	Related CR: 2023158003		<u>MedDRA Code #</u>
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	
Proposed PT	<i>Dengue-like illness</i>	Rejected		
HLT primary	<i>General signs and symptoms NEC</i>			
SOC primary	<i>General disorders and administration site conditions</i>			

MSSO Comment: The proposal to add a new PT Dengue-like illness to primary HLT General signs and symptoms NEC in SOC General disorders and administration site conditions is not approved. The MSSO refrains from adding further 'like illnesses' to the terminology. As well, there is no global unified case definition for Dengue-like illness.

Supplemental Update Report

CR Number: 2023158004 Implementation Date: 30-Jun-23 Related CR: 2023158004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Systemic post-immunization reaction	Approved as Requested	Proposed LLT	
To PT	Immunisation reaction		Systemic post-immunization reaction	10089920 Current
			To PT	
			Immunisation reaction	10021432

MSSO Comment: The proposal to add a new LLT Systemic post-immunization reaction to PT Immunisation reaction is approved as requested. The systemic reactions post vaccination include fever, headache, body aches, fatigue, etc. In a related change, the British spelled LLT Systemic post-immunisation reaction will also be added to PT Immunisation reaction.

CR Number: 2023181012 Implementation Date: 30-Jun-23 Related CR: 2023158004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Systemic post-immunisation reaction	Approved as Requested	Proposed LLT	
To PT	Immunisation reaction		Systemic post-immunisation reaction	10089921 Current
			To PT	
			Immunisation reaction	10021432

MSSO Comment:

CR Number: 2023159001 Implementation Date: 30-Jun-23 Related CR: 2023159001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Perforated viscus	Approved as Requested	Proposed LLT	
To PT	Intestinal perforation		Perforated viscus	10089923 Current
			To PT	
			Intestinal perforation	10022694

MSSO Comment: The proposal to add a new LLT Perforated viscus to PT Intestinal perforation is approved as requested as a synonym LLT. A perforated viscus, also known as an intestinal or bowel perforation, is a life-threatening condition that occurs when the wall of the gastrointestinal tract ruptures and the enteric contents leak into the peritoneal cavity.

Supplemental Update Report

CR Number: 2023159002		Implementation Date: 30-Jun-23	Related CR: 2023159002	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Transvaginal ultrasound aspiration</i>	Approved as Requested	Proposed LLT <i>Transvaginal ultrasound aspiration</i>	10089922 Current
			To PT <i>Oocyte harvest</i>	10051936

MSSO Comment: The proposal to add a new term Transvaginal ultrasound aspiration is approved as requested. Transvaginal ultrasound aspiration is used to retrieve eggs. During this procedure, an ultrasound probe is inserted into the vagina to identify follicles, and a needle is guided through the vagina and into the follicles. The eggs are removed from the follicles through the needle, which is connected to a suction device. Transvaginal ultrasound aspiration will be added as LLT to PT Oocyte harvest.

CR Number: 2023159003		Implementation Date: 30-Jun-23	Related CR: 2023159003	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Bile duct margin resection</i>	Approved Not as Requested	Proposed PT <i>Bile duct tumour margin resection</i>	10089924
			HLT primary <i>Biliary tract and gallbladder therapeutic procedures</i>	10004675
			SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new term Bile duct margin resection is approved but not as requested. Ensuring an adequate resection margin of of extra-hepatic cholangiocarcinomas is of utmost importance, because both high-grade dysplasia and carcinoma in situ of the biliary duct tumor margin are negative prognostic factors, especially between patients with early stages of extra-hepatic cholangiocarcinoma. The proposed term will be modified for a greater clarity and added as the PT Bile duct tumour margin resection to the HLT Biliary tract and gallbladder therapeutic procedures. In a related change, the American spelled counterpart Bile duct tumor margin resection will be added as LLT to the new PT Bile duct tumour margin resection.

CR Number: 2023181013		Implementation Date: 30-Jun-23	Related CR: 2023159003	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Bile duct tumor margin resection</i>	Approved as Requested	Proposed LLT <i>Bile duct tumor margin resection</i>	10089925 Current
To PT	<i>Bile duct tumour margin resection</i>		To PT <i>Bile duct tumour margin resection</i>	10089924

MSSO Comment:

Supplemental Update Report

CR Number: 2023159004 Implementation Date: 30-Jun-23 Related CR: 2023159004

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT <i>Pleural fluid lactate dehydrogenase increased</i>	Approved Not as Requested	Proposed PT <i>Lactate dehydrogenase pleural fluid increased</i>	10089926
		HLT primary <i>Tissue enzyme analyses NEC</i>	10043891
		SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new LLT Pleural fluid lactate dehydrogenase increased is approved but not as requested. Elevated levels of LDH may indicate various conditions, including stroke, some cancers, heart attack, and infections. Measurement of LDH in pleural fluids is primarily indicated to aid in the differentiation of transudative and exudative effusions as LDH activity is considered an indicator of the extent of inflammation. Elevated levels as well may be an indicator for some cancers. The requested term will be modified and added in reverse order as PT Lactate dehydrogenase pleural fluid increased to HLT Tissue enzyme analyses NEC.

CR Number: 2023159005 Implementation Date: 30-Jun-23 Related CR: 2023159005

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT <i>Pleural fluid leukocyte count increased</i>	Approved as Requested	Proposed LLT <i>Pleural fluid leukocyte count increased</i>	10089927 Current
		To PT <i>White blood cell count increased</i>	10047943

MSSO Comment: The proposal to add a new LLT Pleural fluid leukocyte count increased is approved as requested. The most common aetiologies which produce leukocytic (lymphocytic) effusions are tuberculosis, malignancy and congestive cardiac failure. Other aetiologies include lymphoma and post-cardiac bypass graft, renal or liver failure, rheumatoid arthritis and rarely parapneumonic effusions. Pleural fluid leukocyte count increased will be added as an LLT to PT White blood cell count increased.

CR Number: 2023160005 Implementation Date: 04-Jul-23 Related CR: 2023160005

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Bradbury-Eggleston syndrome</i>	Approved as Requested	Proposed LLT <i>Bradbury-Eggleston syndrome</i>	10089970 Current
		To PT <i>Autonomic failure syndrome</i>	10056339

MSSO Comment: The proposal to add a new term Bradbury-Eggleston syndrome is approved as requested. Pure autonomic failure (PAF) is a neurodegenerative disorder of the autonomic nervous system clinically characterized by orthostatic hypotension. The disorder has also been known as Bradbury-Eggleston syndrome. Patients typically present in midlife or later with orthostatic hypotension or syncope. Autonomic failure may also manifest as genitourinary, bowel, and thermoregulatory dysfunction. With widespread involvement, patients may present to a variety of different specialties and require multidisciplinary treatment approaches. Pathologically, PAF is characterized by predominantly peripheral deposition of α -synuclein. Bradbury-Eggleston syndrome will be added as LLT under PT Autonomic failure syndrome.

Supplemental Update Report

CR Number: 2023160006	Implementation Date: 04-Jul-23	Related CR: 2023160006	
Change Requested	Add a New Term	Final Disposition	MedDRA Code #
Proposed Term	<i>Pure autonomic failure</i>	Approved as Requested	Proposed LLT <i>Pure autonomic failure</i> 10089971 Current To PT <i>Autonomic failure syndrome</i> 10056339

MSSO Comment: The proposal to add a new term Pure autonomic failure is approved as requested. Pure autonomic failure is a neurodegenerative disorder of the autonomic nervous system clinically characterized by orthostatic hypotension. The disorder has also been known as Bradbury-Eggleston syndrome. Patients typically present in midlife or later with orthostatic hypotension or syncope. Autonomic failure may also manifest as genitourinary, bowel, and thermoregulatory dysfunction. With widespread involvement, patients may present to a variety of different specialties and require multidisciplinary treatment approaches. Pathologically, PAF is characterized by predominantly peripheral deposition of α -synuclein. Pure autonomic failure will be added as LLT under PT Autonomic failure syndrome.

CR Number: 2023160007	Implementation Date: 04-Jul-23	Related CR: 2023160007	
Change Requested	Add a New Term	Final Disposition	MedDRA Code #
Proposed Term	<i>Idiopathic orthostatic hypotension</i>	Approved as Requested	Proposed LLT <i>Idiopathic orthostatic hypotension</i> 10089972 Current To PT <i>Autonomic failure syndrome</i> 10056339

MSSO Comment: The proposal to add a new term Idiopathic orthostatic hypotension is approved as requested. Pure autonomic failure is a neurodegenerative disorder of the autonomic nervous system clinically characterized by orthostatic hypotension. The disorder has also been known as Bradbury-Eggleston syndrome. Patients typically present in midlife or later with orthostatic hypotension or syncope. Autonomic failure may also manifest as genitourinary, bowel, and thermoregulatory dysfunction. With widespread involvement, patients may present to a variety of different specialties and require multidisciplinary treatment approaches. Pathologically, PAF is characterized by predominantly peripheral deposition of α -synuclein. Idiopathic orthostatic hypotension will be added as LLT under PT Autonomic failure syndrome.

CR Number: 2023160008	Implementation Date: 30-Jun-23	Related CR: 2023160008	
Change Requested	Add a New Term	Final Disposition	MedDRA Code #
Proposed Term	<i>HYPERCUPREMIA</i>	Approved Not as Requested	Proposed LLT <i>Hypercupremia</i> 10089929 Current To PT <i>Hypercupraemia</i> 10089928

MSSO Comment: The proposal to add a new term HYPERCUPREMIA is approved but not as requested. Hypercupremia is the presence of an excess of copper in the blood. It may occur from consuming excess copper salts, but most commonly is the result of the genetic condition Wilson's disease and Menke's disease, which are associated with mismanaged transport and storage of copper ions. The requested term will be modified according to MedDRA capitalisation conventions and added as LLT Hypercupremia to a new PT Hypercupraemia which will be added, in a related change, to HLT Copper metabolism disorders.

Supplemental Update Report

CR Number: 2023181014	Implementation Date: 30-Jun-23	Related CR: 2023160008	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>
			<u>MedDRA Code #</u>
Proposed PT	<i>Hypercupraemia</i>	Approved as Requested	Proposed PT
HLT primary	<i>Copper metabolism disorders</i>		<i>Hypercupraemia</i>
SOC primary	<i>Metabolism and nutrition disorders</i>		
			10089928
			HLT primary
			<i>Copper metabolism disorders</i>
			10010962
			SOC primary
			<i>Metabolism and nutrition disorders</i>
			10027433

MSSO
Comment:

CR Number: 2023160009	Implementation Date: 03-Jul-23	Related CR: 2023160009	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
			<u>MedDRA Code #</u>
Proposed Term	<i>Agrammatism</i>	Approved as Requested	Proposed PT
			<i>Agrammatism</i>
			10089951
			HLT primary
			<i>Cortical dysfunction NEC</i>
			10011168
			SOC primary
			<i>Nervous system disorders</i>
			10029205
			HLT secondary
			<i>Speech and language usage disturbances</i>
			10041461
			SOC secondary
			<i>Psychiatric disorders</i>
			10037175

MSSO
Comment: The proposal to add a new term Agrammatism is approved as requested. Agrammatism means difficulty with using basic grammar and syntax, or word order and sentence structure. It is a common feature in the speech of people with aphasia, especially Broca's aphasia. Agrammatism will be added as a PT with a primary link to HLT Cortical dysfunction NEC and a secondary link to HLT Speech and language usage disturbances.

Supplemental Update Report

CR Number: 2023160010 Implementation Date: 03-Jul-23 Related CR: 2023160010

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Ataxic dysarthria</i>	Approved as Requested	Proposed LLT <i>Ataxic dysarthria</i>	10089952 Current
			To PT <i>Dysarthria</i>	10013887

MSSO Comment: The proposal to add a new term Ataxic dysarthria is approved as requested. Ataxic dysarthria refers to the presence of slurred speech due to the poor coordination of movements involved in speech. Lesions to the cerebellum often give rise to ataxic dysarthria which is characterized by a primary disruption to articulation and prosody. Ataxic dysarthria will be added as sub-concept LLT to PT Dysarthria.

CR Number: 2023160011 Implementation Date: 03-Jul-23 Related CR: 2023160011

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Saccadic intrusions</i>	Approved as Requested	Proposed LLT <i>Saccadic intrusions</i>	10089953 Current
			To PT <i>Saccadic eye movement</i>	10053694

MSSO Comment: The proposal to add a new term Saccadic intrusions is approved as requested. Saccadic intrusions are unwanted saccades that intrude upon visual fixation and, thus, disrupt vision. Sustained saccadic intrusions (e.g. saccadic oscillations) may cause the patient to experience oscillopsia. Saccadic intrusions will be added as LLT under PT Saccadic eye movement. In a related change, the PT Saccadic eye movement will change its primary link from SOC Eye disorders to SOC Nervous system disorders, since saccadic movements are originated in neurological structures, such as parietal and frontal cortical regions, brainstem and cerebellum. Additionally, PT Nystagmus will be assigned a secondary link to SOC Ear and labyrinth disorders via HLT Inner ear signs and symptoms, since the general symptom of nystagmus is shared between central nervous system disorders (central) and vestibular disorders (peripheral), in labyrinthitis or BPPV with equal clinical relevance.

CR Number: 2023184057 Implementation Date: 03-Jul-23 Related CR: 2023160011

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Saccadic eye movement</i>	Approved as Requested	Proposed PT <i>Saccadic eye movement</i>	10053694
Old Primary SOC	<i>Eye disorders</i>		Old Primary SOC <i>Eye disorders</i>	10015919
New Primary SOC	<i>Nervous system disorders</i>		New Primary SOC <i>Nervous system disorders</i>	10029205

MSSO Comment:

Supplemental Update Report

CR Number: 2023184058	Implementation Date: 03-Jul-23	Related CR: 2023160011		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Nystagmus</i>	Approved as Requested	Proposed PT	
To HLT	<i>Inner ear signs and symptoms</i>		<i>Nystagmus</i>	10029864
			To HLT	
			<i>Inner ear signs and symptoms</i>	10022398

MSSO
Comment:

CR Number: 2023160012	Implementation Date: 10-Jul-23	Related CR: 2023160012		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Opsoclonus</i>	Approved After Suspension	Proposed PT	
			<i>Opsoclonus</i>	10090043
			HLT primary	
			<i>Coordination and balance disturbances</i>	10072984
			SOC primary	
			<i>Nervous system disorders</i>	10029205
			HLT secondary	
			<i>Ocular nerve and muscle disorders</i>	10030059
			SOC secondary	
			<i>Eye disorders</i>	10015919

MSSO
Comment: The proposal to add a new term Opsoclonus is approved as requested after suspension. Opsoclonus is an oculomotor dyskinesia characterized by rapid, repetitive conjugate eye movements that are involuntary, arrhythmic, chaotic, and multidirectional (horizontal, vertical, and torsional components) without intersaccadic intervals. It is most pronounced when the patient is awake and attempting fixation, often causing visual blur and oscillopsia because of the high frequency of the oscillations. Opsoclonus will be added as PT with a primary link to HLT Coordination and balance disturbances and secondary links to HLT Ocular nerve and muscle disorders, HLT Paraneoplastic syndromes NEC. In a related change, PT Opsoclonus myoclonus will change primary link from SOC Eye disorders to SOC Nervous system disorders. Additionally, PT Opsoclonus myoclonus will receive secondary link to HLT Paraneoplastic syndromes NEC.

Supplemental Update Report

CR Number: 2023191015	Implementation Date: 10-Jul-23	Related CR: 2023160012		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Opsoclonus</i>	Approved as Requested	Proposed PT	
To HLT	<i>Paraneoplastic syndromes NEC</i>		<i>Opsoclonus</i>	10090043
			To HLT	
			<i>Paraneoplastic syndromes NEC</i>	10067229

MSSO
Comment:

CR Number: 2023191016	Implementation Date: 10-Jul-23	Related CR: 2023160012		
<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Opsoclonus myoclonus</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Eye disorders</i>		<i>Opsoclonus myoclonus</i>	10053854
New Primary SOC	<i>Nervous system disorders</i>		Old Primary SOC	
			<i>Eye disorders</i>	10015919
			New Primary SOC	
			<i>Nervous system disorders</i>	10029205

MSSO
Comment:

CR Number: 2023191017	Implementation Date: 10-Jul-23	Related CR: 2023160012		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Opsoclonus myoclonus</i>	Approved as Requested	Proposed PT	
To HLT	<i>Paraneoplastic syndromes NEC</i>		<i>Opsoclonus myoclonus</i>	10053854
			To HLT	
			<i>Paraneoplastic syndromes NEC</i>	10067229

MSSO
Comment:

Supplemental Update Report

CR Number: 2023160013

Implementation Date: 03-Jul-23

Related CR: 2023160013

[Change Requested](#)

Add a New Term

[Final Disposition](#)

[Final Placement](#)

[MedDRA
Code #](#)

Proposed Term *Noncerebellar ataxia*

Rejected

MSSO Comment: The proposal to add a new term Noncerebellar ataxia is not approved. The proposed term is a term of an exclusionary nature based on diagnostic criteria. Non-cerebellar ataxias are generically called sensory ataxia. Please review PT Ataxia and its related LLTs.

CR Number: 2023163001

Implementation Date: 30-Jun-23

Related CR: 2023163001

[Change Requested](#)

Add a New PT

[Final Disposition](#)

[Final Placement](#)

[MedDRA
Code #](#)

Proposed PT *Dermatolymphangiadenitis*

Rejected

HLT primary *Dermal and epidermal conditions NEC*

SOC primary *Skin and subcutaneous tissue disorders*

MSSO Comment: The proposal to add a new PT Dermatolymphangiadenitis to primary HLT Dermal and epidermal conditions NEC in SOC Skin and subcutaneous tissue disorders and secondary HLT Lymphatic system disorders NEC in SOC Blood and lymphatic system disorders is not approved. The proposed term is a duplicate of a term added in change request 2023163002.

Supplemental Update Report

CR Number: 2023163002 Implementation Date: 30-Jun-23 Related CR: 2023163002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT	Approved Not as Requested	Proposed PT	
HLT primary	<i>Dermatolymphangioadenitis</i>		<i>Dermatolymphangioadenitis</i>	10089930
SOC primary	<i>Dermal and epidermal conditions NEC</i>		HLT primary	
	<i>Skin and subcutaneous tissue disorders</i>		<i>Bacterial infections NEC</i>	10004047
			SOC primary	
			<i>Infections and infestations</i>	10021881
			HLT secondary	
			<i>Lymphatic system disorders NEC</i>	10025198
			SOC secondary	
			<i>Blood and lymphatic system disorders</i>	10005329

MSSO Comment: The proposal to add a new PT *Dermatolymphangioadenitis* to primary HLT *Dermal and epidermal conditions NEC* in SOC *Skin and subcutaneous tissue disorders* and secondary HLT *Lymphatic system disorders NEC* in SOC *Blood and lymphatic system disorders* is approved but not as requested. *Dermatolymphangioadenitis* (also known as infectious cellulitis) is a common and serious bacterial infection of the deeper layers of the skin, due to obstructive peripheral lymphedema. The presentation may be a combination of lymphangitis, lymphadenitis, cellulitis and abscess formation. *Dermatolymphangioadenitis* will be added as a PT with a primary link to HLT *Bacterial infections NEC* and secondary links to HLT *Lymphatic system disorders NEC*, HLT *Skin and subcutaneous tissue bacterial infections* and HLT *Lymphoedemas*. In a related change, LLT *Acute dermatolymphangioadenitis* will be added to new PT *Dermatolymphangioadenitis* because of its clinical importance.

CR Number: 2023181015 Implementation Date: 30-Jun-23 Related CR: 2023163002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT	Approved as Requested	Proposed PT	
To HLT	<i>Dermatolymphangioadenitis</i>		<i>Dermatolymphangioadenitis</i>	10089930
	<i>Lymphoedemas</i>		To HLT	
			<i>Lymphoedemas</i>	10052790

MSSO Comment:

Supplemental Update Report

CR Number: 2023181016		Implementation Date: 30-Jun-23	Related CR: 2023163002	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Dermatolymphangioadenitis</i>	Approved as Requested	Proposed PT	
To HLT	<i>Skin and subcutaneous tissue bacterial infections</i>		<i>Dermatolymphangioadenitis</i>	10089930
			To HLT	
			<i>Skin and subcutaneous tissue bacterial infections</i>	10040788

MSSO
Comment:

CR Number: 2023181017		Implementation Date: 30-Jun-23	Related CR: 2023163002	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Acute dermatolymphangioadenitis</i>	Approved as Requested	Proposed LLT	
To PT	<i>Dermatolymphangioadenitis</i>		<i>Acute dermatolymphangioadenitis</i>	10089931 Current
			To PT	
			<i>Dermatolymphangioadenitis</i>	10089930

MSSO
Comment:

CR Number: 2023163003		Implementation Date: 04-Jul-23	Related CR: 2023163003	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Chyliform pleural effusion</i>	Approved as Requested	Proposed LLT	
			<i>Chyliform pleural effusion</i>	10089982 Current
			To PT	
			<i>Chylothorax</i>	10051228

MSSO
Comment: The proposal to add a new term Chyliform pleural effusion is approved as requested. The presence of high amounts of cholesterol in a pleural effusion is termed a cholesterol pleural effusion, chyliform pleural effusion or pseudochylothorax. While chronic inflammation in the pleural membrane may be a risk factor for the development of a cholesterol effusion, the pathogenesis of cholesterol effusions is unknown. Chyliform pleural effusion will be added as a synonym LLT to PT Chylothorax.

Supplemental Update Report

CR Number: 2023163004 Implementation Date: 04-Jul-23 Related CR: 2023163004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Lienculus</i>	Approved as Requested	Proposed LLT	
To PT	<i>Accessory spleen</i>		<i>Lienculus</i>	10089986 Current
			To PT	
			<i>Accessory spleen</i>	10068059

MSSO Comment: The proposal to add a new LLT *Lienculus* to PT *Accessory spleen* is approved as requested. *Lienculus* is defined as one of the small nodules sometimes found in the neighborhood of the spleen; an accessory or supplementary spleen.

CR Number: 2023163005 Implementation Date: 04-Jul-23 Related CR: 2023163005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Small bowel angioectasias</i>	Approved as Requested	Proposed LLT	
			<i>Small bowel angioectasias</i>	10089987 Current
			To PT	
			<i>Gastrointestinal angiodysplasia</i>	10017928

MSSO Comment: The proposal to add a new term *Small bowel angioectasias* is approved as requested. *Small bowel angioectasias* are vascular malformations consisting of thin-walled, dilated capillaries located in the gastrointestinal mucosa. They are responsible for 10% of all causes of gastrointestinal bleeding and 60% of small bowel bleeding pathologies. *Small bowel angioectasias* will be added as an LLT to PT *Gastrointestinal angiodysplasia*. In a related change, PT *Gastrointestinal angiectasia* will be demoted under PT *Gastrointestinal angiodysplasia* as a synonymous concept.

CR Number: 2023185013 Implementation Date: 04-Jul-23 Related CR: 2023163005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Gastrointestinal angiectasia</i>	Approved as Requested	PT to merge	
To PT	<i>Gastrointestinal angiodysplasia</i>		<i>Gastrointestinal angiectasia</i>	10078142 Current
			To PT	
			<i>Gastrointestinal angiodysplasia</i>	10017928

MSSO Comment:

Supplemental Update Report

CR Number: 2023163006 Implementation Date: 04-Jul-23 Related CR: 2023163006

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Weightlifter's Shoulder (Distal Clavicular Osteolysis)</i>	Approved Not as Requested	Proposed PT <i>Distal clavicular osteolysis</i>	10089975
		HLT primary <i>Bone and joint injuries NEC</i>	10074485
		SOC primary <i>Injury, poisoning and procedural complications</i>	10022117
		HLT secondary <i>Metabolic bone disorders</i>	10027425
		SOC secondary <i>Musculoskeletal and connective tissue disorders</i>	10028395

MSSO Comment: The proposal to add a new term Weightlifter's Shoulder (Distal Clavicular Osteolysis) is approved but not as requested. Distal clavicular osteolysis is an atypical injury occurring most often in athletes and weight lifters, specifically those who perform repetitive overhead movements. It results from repetitive excess load to the acromioclavicular joint which causes micro-trauma to the subchondral bone of the distal clavicular head, resulting in subchondral cystic changes, disruption of the articular cartilage, and metaplastic bone formation with increased osteoclastic activity. Proposed term will be added as PT Distal clavicular osteolysis to primary HLT Bone and joint injuries NEC, to secondary HLT Metabolic bone disorders, and to secondary HLT Bone metabolism disorders. In a related change, and after modification for MedDRA capitalization conventions, the synonym LLT Weightlifter's shoulder will also be added under new PT Distal clavicular osteolysis.

CR Number: 2023185014 Implementation Date: 04-Jul-23 Related CR: 2023163006

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT <i>Distal clavicular osteolysis</i>	Approved as Requested	Proposed PT <i>Distal clavicular osteolysis</i>	10089975
To HLT <i>Bone metabolism disorders</i>		To HLT <i>Bone metabolism disorders</i>	10005992

MSSO Comment:

Supplemental Update Report

CR Number: 2023185015 Implementation Date: 04-Jul-23 Related CR: 2023163006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Weightlifter's shoulder</i>	Approved as Requested	Proposed LLT	
To PT	<i>Distal clavicular osteolysis</i>		<i>Weightlifter's shoulder</i>	10089978 Current
			To PT	
			<i>Distal clavicular osteolysis</i>	10089975

MSSO
Comment:

CR Number: 2023163007 Implementation Date: 04-Jul-23 Related CR: 2023163007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Sternoclavicular joint osteoarthritis</i>	Approved as Requested	Proposed LLT	
			<i>Sternoclavicular joint osteoarthritis</i>	10089985 Current
			To PT	
			<i>Osteoarthritis</i>	10031161

MSSO
Comment: The proposal to add a new term Sternoclavicular joint osteoarthritis is approved as requested. Primary osteoarthritis of the sternoclavicular joint is relatively common, occurring in 90% of people over age 60, and must be considered in the differential of chest wall pain. Conservative measures for sternoclavicular joint osteoarthritis are the mainstay of treatment as most symptoms are self-limiting. Sternoclavicular joint osteoarthritis will be added as sub-concept LLT under PT Osteoarthritis.

CR Number: 2023163008 Implementation Date: 04-Jul-23 Related CR: 2023163008

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Lis excision</i>	Rejected		

MSSO
Comment: The proposal to add a new term Lis excision is not approved. This is a rarely used term and better represented by the common and more easily translated term LLT Large loop excision of the transformation zone.

Supplemental Update Report

CR Number: 2023163009 Implementation Date: 04-Jul-23 Related CR: 2023163009

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Renal forniceal rupture or calyceal rupture</i>	Approved Not as Requested	Proposed PT <i>Renal forniceal rupture</i>	10089973
			HLT primary <i>Renal structural abnormalities and trauma</i>	10038529
			SOC primary <i>Renal and urinary disorders</i>	10038359
			HLT secondary <i>Renal and urinary tract injuries NEC</i>	10027694
			SOC secondary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new term Renal forniceal rupture or calyceal rupture is approved but not as requested. Renal forniceal rupture is a common finding in patients with ureteral obstruction. It is thought to be due to increased renal pelvis pressure from backup of urine, causing one or more renal fornices to leak urine. The most common aetiology of renal forniceal rupture is obstruction caused by distal ureteric stones followed by malignant extrinsic ureteric compression. Renal forniceal rupture will be added as a new PT to primary HLT Renal structural abnormalities and trauma, to secondary HLT Renal and urinary tract injuries NEC and to secondary HLT Oncologic complications and emergencies.

CR Number: 2023185016 Implementation Date: 04-Jul-23 Related CR: 2023163009

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Renal forniceal rupture</i>	Approved as Requested	Proposed PT <i>Renal forniceal rupture</i>	10089973
To HLT	<i>Oncologic complications and emergencies</i>		To HLT <i>Oncologic complications and emergencies</i>	10030315

MSSO Comment:

Supplemental Update Report

CR Number: 2023163010 Implementation Date: 04-Jul-23 Related CR: 2023163010

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Scoliosis Braces	Approved Not as Requested	Proposed LLT	
To PT	Spinal support		Scoliosis brace placement	10089984 Current
			To PT	
			Spinal support	10052920

MSSO Comment: The proposal to add a new LLT Scoliosis Braces to PT Spinal support is approved but not as requested. A scoliosis brace is a medical device used in children and adolescents with scoliosis. It helps slow or completely stop the sideways curve in the spine. Proposed term will be modified for MedDRA capitalization conventions and better alignment and added as LLT Scoliosis brace placement under PT Spinal support.

CR Number: 2023163011 Implementation Date: 04-Jul-23 Related CR: 2023163011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Subcortical stroke	Approved as Requested	Proposed PT	
			Subcortical stroke	10089974
			HLT primary	
			Central nervous system haemorrhages and cerebrovascular accidents	10007948
			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 term Subcortical stroke is approved as requested. A stroke may affect structures subcortically, below the cortex, including the internal capsule, thalamus, basal ganglia, brainstem and cerebellum. Lesions which are subcortical in the brainstem may present with signs and symptoms such as extraocular movement impairments, diplopia, dysphagia, dysarthria, nystagmus. A subcortical stroke in the cerebellum may present with nausea, vomiting, vertigo, imbalance. Subcortical stroke will be added as a new PT under primary HLT Central nervous system haemorrhages and cerebrovascular accidents and secondary HLT Cerebrovascular and spinal necrosis and vascular insufficiency.

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CR Number: 2023163012	Implementation Date: 04-Jul-23	Related CR: 2023163012	
Change Requested	Add a New Term	Final Disposition	Final Placement
			MedDRA Code #
Proposed Term	<i>Pericardial fluid culture</i>	Approved as Requested	Proposed LLT <i>Pericardial fluid culture</i>
			10089981 Current
			To PT <i>Culture</i>
			10061447

MSSO Comment: The proposal to add a new term Pericardial fluid culture is approved as requested. Pericardial fluid culture is a test performed on a sample of fluid from the sac surrounding the heart. It is done to identify organisms that cause infection. Pericardial fluid culture will be added as sub-concept LLT under PT Culture.

CR Number: 2023163013	Implementation Date: 04-Jul-23	Related CR: 2023163013	
Change Requested	Add a New Term	Final Disposition	Final Placement
			MedDRA Code #
Proposed Term	<i>Laryngomicrosurgery</i>	Approved as Requested	Proposed LLT <i>Laryngomicrosurgery</i>
			10089979 Current
			To PT <i>Vocal cord operation</i>
			10077452

MSSO Comment: The proposal to add a new term Laryngomicrosurgery is approved as requested. Microscopic laryngeal surgery, otherwise known as microlaryngoscopy or laryngomicrosurgery, is the most precise means of visualizing and operating on the vocal folds. Surgery is done through a laryngoscope and is used in the evaluation and removal of various lesions of the vocal folds, including (but not limited to): cancer, cysts, papilloma, polyps, and Reinke's edema. Laryngomicrosurgery will be added as sub-concept LLT under PT Vocal cord operation.

CR Number: 2023163014	Implementation Date: 04-Jul-23	Related CR: 2023163014	
Change Requested	Add a New Term	Final Disposition	Final Placement
			MedDRA Code #
Proposed Term	<i>Proliferating pilar tumor</i>	Approved as Requested	Proposed LLT <i>Proliferating pilar tumor</i>
			10089983 Current
			To PT <i>Proliferating pilar tumour</i>
			10089977

MSSO Comment: The proposal to add a new term Proliferating pilar tumor is approved as requested. A proliferating pilar tumor is a rare skin neoplasm that arises from the outer root sheath of a hair follicle. Presentation varies widely, as the tumor can be benign or malignant and has a high probability of recurring after excision. Proliferating pilar tumor will be added as the American spelled LLT under a new PT Proliferating pilar tumour, added in a related change to HLT Skin neoplasms malignant and unspecified (excl melanoma) which is bi-axial at HLT level (primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and secondary SOC Skin and subcutaneous tissue disorders).

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CR Number: 2023185017 Implementation Date: 04-Jul-23 Related CR: 2023163014

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT	Approved as Requested	Proposed PT	
HLT primary	<i>Proliferating pilar tumour</i>		<i>Proliferating pilar tumour</i>	10089977
SOC primary	<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		HLT primary	
	<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>		<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>	10040901
			SOC primary	
			<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary	
			<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>	10040901
			SOC secondary	
			<i>Skin and subcutaneous tissue disorders</i>	10040785

MSSO
Comment:

CR Number: 2023163015 Implementation Date: 04-Jul-23 Related CR: 2023163015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term	Approved as Requested	Proposed PT	
	<i>Cardiac myxoma resection</i>		<i>Cardiac myxoma resection</i>	10089976
			HLT primary	
			<i>Cardiac therapeutic procedures NEC</i>	10027660
			SOC primary	
			<i>Surgical and medical procedures</i>	10042613

MSSO
Comment: The proposal to add a new term Cardiac myxoma resection is approved as requested. Primary cardiac tumors are rare and approximately 70% are benign. Myxoma is the only relatively common primary heart neoplasm, which is often found on 2-dimensional echocardiography. A myxoma that grows inside the heart can block blood flow through the valve. Cardiac myxoma resection is the only treatment for myxomas and should be done promptly. Cardiac myxoma resection will be added as a new PT under HLT Cardiac therapeutic procedures NEC.

Supplemental Update Report

CR Number: 2023163016	Implementation Date: 04-Jul-23	Related CR: 2023163016		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Lower gastrointestinal endoscopy</i>	Approved Not as Requested	Proposed LLT <i>Endoscopy lower gastrointestinal tract</i>	10089980 Current
			To PT <i>Colonoscopy</i>	10010007

MSSO Comment: The proposal to add a new term Lower gastrointestinal endoscopy is approved but not as requested. Lower gastrointestinal endoscopy is a minimally invasive diagnostic technique that allows the clinician to evaluate the mucosal surfaces of the rectum, colon, ileocolic sphincter, cecum, and distal small intestine (ileum). Proposed term will be modified for better alignment and add with corrected spelling as LLT Endoscopy lower gastrointestinal tract to PT Colonoscopy.

CR Number: 2023163017	Implementation Date: 30-Jun-23	Related CR: 2023163017		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Bone fracture repair</i>	Rejected		

MSSO Comment: The proposal to add a new term Bone fracture repair is not approved. The requested concept is represented by LLT Fracture repair.

CR Number: 2023163018	Implementation Date: 30-Jun-23	Related CR: 2023163018		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Basal cell carcinoma nasal</i>	Approved as Requested	Proposed LLT <i>Basal cell carcinoma nasal</i>	10089934 Current
To PT	<i>Basal cell carcinoma</i>		To PT <i>Basal cell carcinoma</i>	10004146

MSSO Comment: The proposal to add a new LLT Basal cell carcinoma nasal to PT Basal cell carcinoma is approved as requested. The most common sites for nodular basal cells are the face, especially the nose, cheeks, forehead, nasolabial folds, and eyelids.

Supplemental Update Report

CR Number: 2023163019	Implementation Date: 30-Jun-23	Related CR: 2023163019		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Liquid nitrogen therapy	Approved Not as Requested	Proposed LLT	
To PT	Skin cryotherapy		Cutaneous liquid nitrogen therapy	10089933 Current
			To PT	
			Skin cryotherapy	10070473
MSSO Comment:	The proposal to add a new LLT Liquid nitrogen therapy to PT Skin cryotherapy is approved but not as requested. Liquid nitrogen therapy consists on the release of liquid nitrogen (at about -165°) in a controlled and local way on the skin lesion to treat (such as actinic keratoses, skin tags, warts, etc). The requested term will be modified for clarity and added as LLT Cutaneous liquid nitrogen therapy to PT Skin cryotherapy.			

CR Number: 2023163020	Implementation Date: 30-Jun-23	Related CR: 2023163020		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Nephrostomy tube dislocation	Approved as Requested	Proposed LLT	
To PT	Device dislocation		Nephrostomy tube dislocation	10089932 Current
			To PT	
			Device dislocation	10064684
MSSO Comment:	The proposal to add a new LLT Nephrostomy tube dislocation to PT Device dislocation is approved as requested. Nephrostomy tubes are commonly placed for urinary obstruction, urinary diversion, or future endourologic procedures. Nephrostomy tube failure, caused by kinking, dislodgment or migration can manifest with obstructive signs and symptoms.			

CR Number: 2023163022	Implementation Date: 30-Jun-23	Related CR: 2023163022		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	INTERSTITIAL GRANULOMA ANNULARE	Approved Not as Requested	Proposed LLT	
HLT primary	Granulomatous and deep cutaneous inflammatory conditions		Interstitial granuloma annulare	10089936 Current
SOC primary	Skin and subcutaneous tissue disorders		To PT	
			Granuloma annulare	10018692
MSSO Comment:	The proposal to add a new PT INTERSTITIAL GRANULOMA ANNULARE to primary HLT Granulomatous and deep cutaneous inflammatory conditions in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Interstitial granuloma annulare is variant of the classical granuloma annulare whose features are not fully developed, differing in morphology, histology and immunophenotype. Cases of interstitial granuloma annulare are paucicellular with scant to no mucin, with only a few scattered mononuclear cells and lacking well-formed granulomas with multinucleated giant cells. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as LLT Interstitial granuloma annulare, which - despite its differential aspects - can still be considered a sub-concept of PT Granuloma annulare.			

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CR Number: 2023163023 Implementation Date: 30-Jun-23 Related CR: 2023163023

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	INFUNDIBULAR DILATATION	Approved Not as Requested	Proposed PT	
HLT primary	Aneurysms and dissections site specific NEC		Cerebrovascular infundibular dilatation	10089935
SOC primary	Vascular disorders		HLT primary	
			Central nervous system vascular disorders NEC	10007962
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Cerebrovascular and spinal vascular disorders NEC	10008193
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT INFUNDIBULAR DILATATION to primary HLT Aneurysms and dissections site specific NEC in SOC Vascular disorders is approved but not as requested. An infundibulum is a conical, triangular, or funnel-shaped dilatation of the origin of a major branch of the internal carotid artery. Because infundibula have generally been viewed as nonpathological, distinguishing them from small or micro-aneurysms is important. The proposed term will be modified for clarity and in accordance with MedDRA capitalization standards and added as PT Cerebrovascular infundibular dilatation with a primary link to HLT Central nervous system vascular disorders NEC and secondary link to HLT Cerebrovascular and spinal vascular disorders NEC.

CR Number: 2023163024 Implementation Date: 03-Jul-23 Related CR: 2023163024

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Developmental concerns	Rejected		

MSSO Comment: The proposal to add a new term Developmental concerns is not approved. The proposed concept represents a non-specific and unconfirmed clinical condition. If a developmental delay is reported as being suspected, please refer to section "3.1 Definitive and Provisional Diagnoses with or without Signs and Symptoms" of the Term Selection Points to Consider document. The preferred option for a provisional diagnosis is to select a term for the diagnosis (PTs around development delay or disorder in this case).

Supplemental Update Report

CR Number: 2023163121	Implementation Date: 03-Jul-23	Related CR: 2023163121	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Hypophenylalaninaemia</i>	Approved Not as Requested	Proposed PT <i>Hypophenylalaninaemia</i>
			10089954
			HLT primary <i>Amino acid metabolism disorders NEC</i>
			10036999
			SOC primary <i>Metabolism and nutrition disorders</i>
			10027433
MSSO Comment:	The proposal to add a new term Hypophenylalaninaemia is approved but not as requested. The requested term will be modified and added with corrected spelling as PT Hypophenylalaninaemia to HLT Amino acid metabolism disorders NEC. In a related change, the American English counterpart LLT Hypophenylalaninemia will be added to the new PT Hypophenylalaninaemia.		

CR Number: 2023184053	Implementation Date: 03-Jul-23	Related CR: 2023163121	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Hypophenylalaninemia</i>	Approved as Requested	Proposed LLT <i>Hypophenylalaninemia</i>
To PT	<i>Hypophenylalaninaemia</i>		10089955 Current
			To PT <i>Hypophenylalaninaemia</i>
			10089954
MSSO Comment:			

CR Number: 2023163122	Implementation Date: 03-Jul-23	Related CR: 2023163122	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Parietal pain</i>	Approved as Requested	Proposed LLT <i>Parietal pain</i>
To PT	<i>abdominal pain</i>		10089956 Current
			To PT <i>Abdominal pain</i>
			10000081
MSSO Comment:	The proposal to add a new LLT Parietal pain to PT abdominal pain is approved as requested. Parietal pain occurs when there is an irritation of the peritoneal lining and is mediated by segmental nerves associated with specific dermatomes. The peritoneum has a high number of sensitive nerve fibers, so the pain is generally sharp, aggravated by movement and easy to localize. The patient will typically present in a guarded position with shallow breathing. Parietal pain will be added as an LLT to PT Abdominal pain.		

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CR Number: 2023163123 Implementation Date: 03-Jul-23 Related CR: 2023163123

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Schistosomiasis pulmonary	Approved as Requested	Proposed PT	
			Schistosomiasis pulmonary	10089957
			HLT primary	
			Trematode infections	10044560
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Parasitic lower respiratory tract infections	10033917
			SOC secondary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new PT Schistosomiasis pulmonary is approved as requested. Schistosomiasis is an infection caused by certain flatworms (flukes), called schistosomes. Schistosomiasis can affect other organs (such as the lungs, spinal cord, and brain). Eggs that reach the lungs can result in inflammation and increased blood pressure in the arteries of the lungs (pulmonary hypertension), which can result in a type of heart failure called cor pulmonale. The proposed term will be added as a PT and placed under primary HLT Trematode infections and secondary HLT Parasitic lower respiratory tract infections.

CR Number: 2023164001 Implementation Date: 03-Jul-23 Related CR: 2023164001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Cardia inflammation	Approved Not as Requested	Proposed LLT	
			Gastric cardia inflammation	10089958 Current
			To PT	
			Gastritis	10017853

MSSO Comment: The proposal to add a new term Cardia inflammation is approved but not as requested. Inflammation of the native gastric cardia is strongly associated with Helicobacter pylori infection, although there may be a second form of 'carditis' in which metaplastic cardiac-type mucosa becomes inflamed secondary to GERD. The requested term will be modified for clarity and added as LLT Gastric cardia inflammation to PT Gastritis.

Supplemental Update Report

CR Number: 2023164002	Implementation Date: 03-Jul-23	Related CR: 2023164002		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Metatarsophalangeal joint pain</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Metatarsophalangeal joint pain is not approved. The requested term is represented by existing term LLT/PT Metatarsalgia.

CR Number: 2023164003	Implementation Date: 03-Jul-23	Related CR: 2023164003		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Edema nerve</i>	Approved Not as Requested	Proposed LLT <i>Nerve edema</i>	10089960 Current
			To PT <i>Nerve oedema</i>	10089959

MSSO Comment: The proposal to add a new term Edema nerve is approved but not as requested. Nerve edema is a common response to the nerve injury seen in many peripheral neuropathies and is an important component of Wallerian degeneration. The requested term will be modified according MedDRA capitalization conventions and added in the natural word order as LLT Nerve edema to a new PT Nerve oedema, the British English counterpart, which will be added as a related change to HLT Nervous system disorders NEC.

CR Number: 2023184056	Implementation Date: 03-Jul-23	Related CR: 2023164003		
Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Nerve oedema</i>	Approved as Requested	Proposed PT <i>Nerve oedema</i>	10089959
HLT primary	<i>Nervous system disorders NEC</i>		HLT primary <i>Nervous system disorders NEC</i>	10057185
SOC primary	<i>Nervous system disorders</i>		SOC primary <i>Nervous system disorders</i>	10029205

MSSO Comment:

Supplemental Update Report

CR Number: 2023165001 Implementation Date: 04-Jul-23 Related CR: 2023165001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Vaccine exposed to high temperature administered to patient	Rejected		
To PT	Product storage error			

MSSO Comment: The proposal to add a new LLT Vaccine exposed to high temperature administered to patient to PT Product storage error is not approved. The requested term represents a combination concept and can be represented by more than one LLT such as LLT Product storage error temperature too high, LLT Poor quality vaccine administered, and LLT Product temperature excursion issue, depending on the case scenario and internal coding conventions.

CR Number: 2023165002 Implementation Date: 04-Jul-23 Related CR: 2023165002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Vaccine exposed to low temperature administered to patient	Rejected		
To PT	Product storage error			

MSSO Comment: The proposal to add a new LLT Vaccine exposed to low temperature administered to patient to PT Product storage error is not approved. The requested term represents a combination concept and can be represented by more than one LLT such as LLT Product storage error temperature too low, LLT Poor quality vaccine administered, and LLT Product temperature excursion issue, depending on the case scenario and internal coding conventions.

CR Number: 2023165003 Implementation Date: 04-Jul-23 Related CR: 2023165003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Scrofuloderma	Approved as Requested	Proposed LLT	
To PT	Cutaneous tuberculosis		Scrofuloderma	10089988 Current
			To PT	
			Cutaneous tuberculosis	10011684

MSSO Comment: The proposal to add a new LLT Scrofuloderma to PT Cutaneous tuberculosis is approved as requested. Scrofuloderma is the result of cutaneous infection adjacent to a tuberculous focus.

Supplemental Update Report

CR Number: 2023165004	Implementation Date: 03-Jul-23	Related CR: 2023165004		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>QuantiFERON-TB Gold Test</i>	Rejected		
To PT	<i>Interferon gamma release assay</i>			

MSSO Comment: The proposal to add a new LLT QuantiFERON-TB Gold Test to PT Interferon gamma release assay is not approved. QuantiFERON is a trade name which are generally not added to MedDRA.

CR Number: 2023165005	Implementation Date: 30-Jun-23	Related CR: 2023165005		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Hiatal hernia gangrenous</i>	Approved as Requested	Proposed PT	
To HLT	<i>Diaphragmatic hernias</i>		<i>Hiatal hernia gangrenous</i>	10089638
			To HLT	
			<i>Diaphragmatic hernias</i>	10012714

MSSO Comment: The proposal to link the PT Hiatal hernia gangrenous to the HLT Diaphragmatic hernias is approved as requested, for consistency with placement of PT Diaphragmatic hernia gangrenous.

CR Number: 2023165006	Implementation Date: 04-Jul-23	Related CR: 2023165006		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Myocardial perfusion PET stress test</i>	Approved as Requested	Proposed LLT	
			<i>Myocardial perfusion PET stress test</i>	10089990 Current
			To PT	
			<i>Scan myocardial perfusion</i>	10054082

MSSO Comment: The proposal to add a new term Myocardial perfusion PET stress test is approved as requested. This specific type of myocardial perfusion imaging will be added as LLT Myocardial perfusion PET stress test under PT Scan myocardial perfusion.

Supplemental Update Report

CR Number: 2023165007	Implementation Date: 04-Jul-23	Related CR: 2023165007	MedDRA Code #
Change Requested	Final Disposition	Final Placement	
Proposed Term <i>B-Type natriuretic peptide increase</i>	Approved Not as Requested	Proposed LLT <i>B-type natriuretic peptide increase</i>	10089989 Current
		To PT <i>Brain natriuretic peptide increased</i>	10053405

MSSO Comment: The proposal to add a new term B-Type natriuretic peptide increase is approved but not as requested. Brain natriuretic peptide 32 (BNP), also known as B-type natriuretic peptide, is a hormone secreted by cardiomyocytes in the heart ventricles in response to stretching caused by increased ventricular blood volume. It only is sometimes called “brain” natriuretic peptide because it was first discovered in brain tissue. The term will be modified for MedDRA capitalization conventions and added as an LLT B-type natriuretic peptide increase to PT Brain natriuretic peptide increased.

CR Number: 2023165009	Implementation Date: 03-Jul-23	Related CR: 2023165009	MedDRA Code #
Change Requested	Final Disposition	Final Placement	
Proposed Term <i>Mixed ventilatory defects</i>	Approved Not as Requested	Proposed PT <i>Mixed obstructive and restrictive lung disease</i>	10089961
		HLT primary <i>Parenchymal lung disorders NEC</i>	10033979
		SOC primary <i>Respiratory, thoracic and mediastinal disorders</i>	10038738

MSSO Comment: The proposal to add a new term Mixed ventilatory defects is approved but not as requested. Respiratory disorders are commonly classified as demonstrating obstructive or restrictive physiology, however a smaller, third category, called mixed lung disease, has characteristics of obstructive and restrictive lung diseases. For clarity, the proposed term will be modified and added as PT Mixed obstructive and restrictive lung disease under HLT Parenchymal lung disorders NEC.

CR Number: 2023165010	Implementation Date: 03-Jul-23	Related CR: 2023165010	MedDRA Code #
Change Requested	Final Disposition	Final Placement	
Proposed Term <i>Gastrostomy tube migration</i>	Approved as Requested	Proposed LLT <i>Gastrostomy tube migration</i>	10089962 Current
		To PT <i>Device dislocation</i>	10064684

MSSO Comment: The proposal to add a new term Gastrostomy tube migration is approved as requested. The gastrostomy tube is widely used as the method of choice for providing long-term enteral nutrition to patients who are unable to tolerate oral intake. Gastric outlet obstruction is a rare complication of gastrostomy tube placement caused by migration of the tube into pyloric channel or duodenal bulb. The proposed term will be added as a sub concept LLT to PT Device dislocation.

Supplemental Update Report

CR Number: 2023166001 **Implementation Date:** 04-Jul-23 **Related CR:** 2023166001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Occipital nerve stimulation implantation</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>Vagal nerve stimulator implantation</i>		<i>Occipital nerve stimulator implantation</i>	10089991 Current
			To PT	
			<i>Neuroprosthesis implantation</i>	10081968

MSSO Comment: The proposal to add a new LLT Occipital nerve stimulation implantation to PT Vagal nerve stimulator implantation is approved but not as requested. Occipital nerve stimulation is a surgical procedure that may be useful in the treatment of chronic and severe headache disorders that do not respond well to other therapies. The proposed term will modified and placed as LLT Occipital nerve stimulator implantation to PT Neuroprosthesis implantation.

CR Number: 2023166002 **Implementation Date:** 04-Jul-23 **Related CR:** 2023166002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Occipital nerve stimulation removal</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>Vagal nerve stimulator removal</i>		<i>Occipital nerve stimulator removal</i>	10089993 Current
			To PT	
			<i>Neurostimulator removal</i>	10069206

MSSO Comment: The proposal to add a new LLT Occipital nerve stimulation removal to PT Vagal nerve stimulator removal is approved but not as requested. Occipital nerve stimulation is a surgical procedure that may be useful in the treatment of chronic and severe headache disorders that do not respond well to other therapies. The proposed term will be modified and placed as LLT Occipital nerve stimulator removal under PT Neurostimulator removal. In a related change, the HLT for PT Neurostimulator removal will be changed from HLT Therapeutic procedures NEC to HLT Nervous system therapeutic procedures NEC.

CR Number: 2023185018 **Implementation Date:** 04-Jul-23 **Related CR:** 2023166002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Neurostimulator removal</i>	Approved as Requested	Proposed PT	
From HLT	<i>Therapeutic procedures NEC</i>		<i>Neurostimulator removal</i>	10069206
To HLT	<i>Nervous system therapeutic procedures NEC</i>		From HLT	
			<i>Therapeutic procedures NEC</i>	10027700
			To HLT	
			<i>Nervous system therapeutic procedures NEC</i>	10052731

MSSO Comment:

Supplemental Update Report

CR Number: 2023166003 **Implementation Date:** 04-Jul-23 **Related CR:** 2023166003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Occipital nerve stimulation	Approved Not as Requested	Proposed LLT	
HLT primary	Autonomic nerve therapeutic procedures		Occipital nerve stimulation	10089992 Current
SOC primary	Surgical and medical procedures		To PT	
			Peripheral nerve neurostimulation	10034587

MSSO Comment: The proposal to add a new PT Occipital nerve stimulation to primary HLT Autonomic nerve therapeutic procedures in SOC Surgical and medical procedures is approved but not as requested. Occipital nerve stimulation is a surgical procedure that may be useful in the treatment of chronic and severe headache disorders that do not respond well to other therapies. Occipital nerve stimulation will be placed as an LLT under PT Peripheral nerve neurostimulation.

CR Number: 2023166004 **Implementation Date:** 03-Jul-23 **Related CR:** 2023166004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Interval debulking surgery	Approved as Requested	Proposed LLT	
			Interval debulking surgery	10089963 Current
			To PT	
			Cytoreductive surgery	10057647

MSSO Comment: The proposal to add a new LLT Interval debulking surgery is approved as requested. Debulking surgery has been advocated for various types of advanced malignant tumors, including gynecological cancers, urological cancers, gastrointestinal cancers, breast cancers and other malignancies, with or without adjuvant therapy. The proposed term will be added as a sub concept LLT to PT Cytoreductive surgery.

CR Number: 2023166005 **Implementation Date:** 03-Jul-23 **Related CR:** 2023166005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Muscle invasive urothelial carcinoma	Approved Not as Requested	Proposed LLT	
			Muscle invasive urothelial carcinoma	10089964 Current
			To PT	
			Bladder transitional cell carcinoma	10005084

MSSO Comment: The proposal to add a new PT Muscle invasive urothelial carcinoma is approved but not as requested. Muscle invasive bladder cancer has spread into or through the muscle layer of the bladder. Muscle-invasive urothelial (transitional cell) carcinoma is a potentially lethal condition for which an attempt at curative surgery is required. Clinical staging does not allow for accurate determination of eventual pathologic status. Muscle invasive urothelial carcinoma will be added as LLT to PT Bladder transitional cell carcinoma.

Supplemental Update Report

CR Number: 2023166006 Implementation Date: 05-Jul-23 Related CR: 2023166006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Recurrent squamous cell carcinoma head and neck	Approved Not as Requested	Proposed LLT Squamous cell carcinoma of head and neck recurrent	10090001 Current
			To PT Squamous cell carcinoma of head and neck	10060121

MSSO Comment: The proposal to add a new PT Recurrent squamous cell carcinoma head and neck is approved but not as requested. The proposed term will be rephrased to meet MedDRA naming conventions and will be added as an LLT Squamous cell carcinoma of head and neck recurrent under PT Squamous cell carcinoma of head and neck.

CR Number: 2023166007 Implementation Date: 05-Jul-23 Related CR: 2023166007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Metastatic urothelial carcinoma	Approved Not as Requested	Proposed LLT Urothelial carcinoma metastatic	10090000 Current
			To PT Transitional cell carcinoma metastatic	10071080

MSSO Comment: The proposal to add a new PT Metastatic urothelial carcinoma is approved but not as requested. The proposed term will be rephrased to meet MedDRA naming conventions and will be added as a synonym LLT Urothelial carcinoma metastatic under PT Transitional cell carcinoma metastatic.

CR Number: 2023167002 Implementation Date: 05-Jul-23 Related CR: 2023167002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	CSF listeria identified	Approved Not as Requested	Proposed LLT CSF listeria test positive	10090003 Current
			To PT Listeria test positive	10070094

MSSO Comment: The proposal to add a new PT CSF listeria identified is approved but not as requested. The proposed term will be rephrased to meet MedDRA naming conventions and will be added as an LLT CSF listeria test positive under PT Listeria test positive

Supplemental Update Report

CR Number: 2023167003 Implementation Date: 05-Jul-23 Related CR: 2023167003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Central nervous system listeria infection	Approved as Requested	Proposed PT Central nervous system listeria infection	10090002
			HLT primary Listeria infections	10024639
			SOC primary Infections and infestations	10021881
			HLT secondary Nervous system infections NEC	10021888
			SOC secondary Nervous system disorders	10029205

MSSO Comment: The proposal to add a new PT Central nervous system listeria infection is approved as requested. Central nervous system listeria infection will be added as a PT to primary HLT Listeria infections and to secondary HLT Nervous system infections NEC.

CR Number: 2023170018 Implementation Date: 03-Jul-23 Related CR: 2023170018

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Buccal mucosa infection	Approved as Requested	Proposed LLT Buccal mucosa infection	10089965 Current
			To PT Oral infection	10048685

MSSO Comment: The proposal to add a new term Buccal mucosa infection is approved as requested. Buccal mucosa infection will be added as a sub-concept LLT to PT Oral infection.

Supplemental Update Report

CR Number: 2023171001 **Implementation Date:** 04-Jul-23 **Related CR:** 2023171001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Knee Cartilage Transplant</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>Cartilage graft</i>		<i>Knee cartilage transplant</i>	10089994 Current
			To PT	
			<i>Cartilage graft</i>	10064112

MSSO Comment: The proposal to add a new LLT Knee Cartilage Transplant to PT Cartilage graft is approved but not as requested. A cartilage transplant, or cartilage cell or chondrocyte transplant, is a new surgical procedure in which cartilage damage is repaired using cartilage cells from the patient's own body, except when the damaged area is expense for an autograft, and an allograft is needed using cadaver donor cartilage through open surgery. The requested term will be modified in accordance with MedDRA capitalization conventions and will be added as LLT Knee cartilage transplant to PT Cartilage graft.

CR Number: 2023171002 **Implementation Date:** 04-Jul-23 **Related CR:** 2023171002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Effort echocardiography</i>	Approved as Requested	Proposed LLT	
			<i>Effort echocardiography</i>	10089996 Current
			To PT	
			<i>Stress echocardiogram</i>	10050241

MSSO Comment: The proposal to add a new term Effort echocardiography is approved as requested. Effort echocardiography will be added as a synonym LLT to PT Stress echocardiogram.

CR Number: 2023171003 **Implementation Date:** 04-Jul-23 **Related CR:** 2023171003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Endobronchial ablation</i>	Approved as Requested	Proposed LLT	
			<i>Endobronchial ablation</i>	10089995 Current
			To PT	
			<i>Pulmonary ablation</i>	10087559

MSSO Comment: The proposal to add a new term Endobronchial ablation is approved as requested. Endobronchial ablative therapies are standard of care in therapeutic bronchoscopy for management of malignant and non-malignant central airway obstruction and of endobronchial bleeding. In malignant and non-malignant central airway obstruction with endoluminal involvement, a multi-modality bronchoscopic approach combining endobronchial ablative therapies, mechanical debulking, airway dilation, and airway stent placement is often first line treatment. Endobronchial ablation will be added as an LLT to PT Pulmonary ablation.

Supplemental Update Report

CR Number: 2023171004

Implementation Date: 04-Jul-23

Related CR: 2023171004

[Change Requested](#)

Add a New Term

[Final Disposition](#)

[Final Placement](#)

[MedDRA
Code #](#)

Proposed Term *Aspergillosis excision*

Rejected

MSSO Comment: The proposal to add a new term Aspergillosis excision is not approved. The requested term represents a combination of a procedure and underlying causality. This can be represented by choosing more than one LLT, such as LLT Pulmonary resection and LLT Pulmonary aspergillosis or LLT Aspergilloma or LLT Invasive bronchopulmonary aspergillosis.

CR Number: 2023171005

Implementation Date: 05-Jul-23

Related CR: 2023171005

[Change Requested](#)

Add a New PT

[Final Disposition](#)

[Final Placement](#)

[MedDRA
Code #](#)

Proposed PT *Anticoagulation therapy complication*

Rejected

HLT primary *Coagulopathies*

SOC primary *Blood and lymphatic system disorders*

MSSO Comment: The proposal to add a new PT Anticoagulation therapy complication to primary HLT Coagulopathies in SOC Blood and lymphatic system disorders is not approved. It is not feasible to add such vague terms into MedDRA as the complication leading to death as reported could refer to either hyper- or hypocoagulation.

Supplemental Update Report

CR Number: 2023171006 Implementation Date: 05-Jul-23 Related CR: 2023171006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT	Approved Not as Requested	Proposed LLT	
HLT primary	Arteriovenous graft (site) complication		Arteriovenous graft site complication	10055125
SOC primary	Cardiac and vascular procedural complications		From PT	
	Injury, poisoning and procedural complications		Vascular graft complication	10064252
			HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Non-site specific vascular disorders NEC	10047067
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT Arteriovenous graft (site) complication to primary HLT Cardiac and vascular procedural complications in SOC Injury, poisoning and procedural complications and secondary HLT Non-site specific embolism and thrombosis in SOC Vascular disorders is approved but not as requested. LLT Arteriovenous graft site complication will be promoted from under PT Vascular graft complication to a PT level and placed under primary HLT Cardiac and vascular procedural complications and to secondary HLT Non-site specific vascular disorders NEC. In a related change, the following LLTs will be moved from PT Vascular graft complication to the new PT Arteriovenous graft site complication for better alignment: LLT Arteriovenous graft leakage, LLT Arteriovenous graft site edema, LLT Arteriovenous graft site erythema, LLT Arteriovenous graft site inflammation, LLT Arteriovenous graft site oedema, LLT Arteriovenous graft site pain, LLT Arteriovenous graft site pruritus, LLT Arteriovenous graft site rash, LLT Arteriovenous graft site urticaria, LLT Discharge from arteriovenous graft, LLT Drainage from arteriovenous graft.

CR Number: 2023186003 Implementation Date: 05-Jul-23 Related CR: 2023171006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Link (move) an LLT to another PT	Approved as Requested	Proposed LLT	
From PT	Arteriovenous graft leakage		Arteriovenous graft leakage	10073161 Current
To PT	Vascular graft complication		From PT	
	Arteriovenous graft site complication		Vascular graft complication	10064252
			To PT	
			Arteriovenous graft site complication	10055125

MSSO Comment:

Supplemental Update Report

CR Number: 2023186004 Implementation Date: 05-Jul-23 Related CR: 2023171006

<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Arteriovenous graft site edema</i>	Approved as Requested	Proposed LLT	
From PT	<i>Vascular graft complication</i>		<i>Arteriovenous graft site edema</i>	10070080 Current
To PT	<i>Arteriovenous graft site complication</i>		From PT	
			<i>Vascular graft complication</i>	10064252
			To PT	
			<i>Arteriovenous graft site complication</i>	10055125

MSSO
Comment:

CR Number: 2023186005 Implementation Date: 05-Jul-23 Related CR: 2023171006

<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Arteriovenous graft site erythema</i>	Approved as Requested	Proposed LLT	
From PT	<i>Vascular graft complication</i>		<i>Arteriovenous graft site erythema</i>	10055141 Current
To PT	<i>Arteriovenous graft site complication</i>		From PT	
			<i>Vascular graft complication</i>	10064252
			To PT	
			<i>Arteriovenous graft site complication</i>	10055125

MSSO
Comment:

CR Number: 2023186006 Implementation Date: 05-Jul-23 Related CR: 2023171006

<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Arteriovenous graft site inflammation</i>	Approved as Requested	Proposed LLT	
From PT	<i>Vascular graft complication</i>		<i>Arteriovenous graft site inflammation</i>	10055143 Current
To PT	<i>Arteriovenous graft site complication</i>		From PT	
			<i>Vascular graft complication</i>	10064252
			To PT	
			<i>Arteriovenous graft site complication</i>	10055125

MSSO
Comment:

Supplemental Update Report

CR Number: 2023186007 Implementation Date: 05-Jul-23 Related CR: 2023171006

<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Arteriovenous graft site oedema	Approved as Requested	Proposed LLT	
From PT	Vascular graft complication		Arteriovenous graft site oedema	10070081 Current
To PT	Arteriovenous graft site complication		From PT	
			Vascular graft complication	10064252
			To PT	
			Arteriovenous graft site complication	10055125

MSSO
Comment:

CR Number: 2023186008 Implementation Date: 05-Jul-23 Related CR: 2023171006

<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Arteriovenous graft site pain	Approved as Requested	Proposed LLT	
From PT	Vascular graft complication		Arteriovenous graft site pain	10055144 Current
To PT	Arteriovenous graft site complication		From PT	
			Vascular graft complication	10064252
			To PT	
			Arteriovenous graft site complication	10055125

MSSO
Comment:

CR Number: 2023186009 Implementation Date: 05-Jul-23 Related CR: 2023171006

<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Arteriovenous graft site pruritus	Approved as Requested	Proposed LLT	
From PT	Vascular graft complication		Arteriovenous graft site pruritus	10055145 Current
To PT	Arteriovenous graft site complication		From PT	
			Vascular graft complication	10064252
			To PT	
			Arteriovenous graft site complication	10055125

MSSO
Comment:

Supplemental Update Report

CR Number: 2023186010 Implementation Date: 05-Jul-23 Related CR: 2023171006

<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Arteriovenous graft site rash</i>	Approved as Requested	Proposed LLT	
From PT	<i>Vascular graft complication</i>		<i>Arteriovenous graft site rash</i>	10055146 Current
To PT	<i>Arteriovenous graft site complication</i>		From PT	
			<i>Vascular graft complication</i>	10064252
			To PT	
			<i>Arteriovenous graft site complication</i>	10055125

MSSO
Comment:

CR Number: 2023186011 Implementation Date: 05-Jul-23 Related CR: 2023171006

<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Arteriovenous graft site urticaria</i>	Approved as Requested	Proposed LLT	
From PT	<i>Vascular graft complication</i>		<i>Arteriovenous graft site urticaria</i>	10055148 Current
To PT	<i>Arteriovenous graft site complication</i>		From PT	
			<i>Vascular graft complication</i>	10064252
			To PT	
			<i>Arteriovenous graft site complication</i>	10055125

MSSO
Comment:

CR Number: 2023186012 Implementation Date: 05-Jul-23 Related CR: 2023171006

<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Discharge from arteriovenous graft</i>	Approved as Requested	Proposed LLT	
From PT	<i>Vascular graft complication</i>		<i>Discharge from arteriovenous graft</i>	10077111 Current
To PT	<i>Arteriovenous graft site complication</i>		From PT	
			<i>Vascular graft complication</i>	10064252
			To PT	
			<i>Arteriovenous graft site complication</i>	10055125

MSSO
Comment:

Supplemental Update Report

CR Number: 2023186013 Implementation Date: 05-Jul-23 Related CR: 2023171006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Link (move) an LLT to another PT <i>Drainage from arteriovenous graft</i>	Approved as Requested	Proposed LLT <i>Drainage from arteriovenous graft</i>	10055149 Non-Current
From PT	<i>Vascular graft complication</i>		From PT <i>Vascular graft complication</i>	10064252
To PT	<i>Arteriovenous graft site complication</i>		To PT <i>Arteriovenous graft site complication</i>	10055125

MSSO
Comment:

CR Number: 2023171019 Implementation Date: 03-Jul-23 Related CR: 2023171019

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Herpes zoster facial</i>	Approved Not as Requested	Proposed LLT <i>Facial herpes zoster</i>	10089966 Current
			To PT <i>Herpes zoster</i>	10019974

MSSO
Comment: The proposal to add a new LLT Herpes zoster facial is approved but not as requested. The second most common rash site of herpes zoster is the face. It can spread from the ear to the nose and forehead. It can also spread around one eye, which can cause redness and swelling of the eye and surrounding area. The requested term will be added in the natural word order as LLT Facial herpes zoster to PT Herpes zoster.

CR Number: 2023171022 Implementation Date: 03-Jul-23 Related CR: 2023171022

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Infusion rate not according to label</i>	Rejected		
To PT	<i>Off label use</i>			

MSSO
Comment: The proposal to add a new LLT Infusion rate not according to label to PT Off label use is not approved. The requested term can be represented by LLT Incorrect drug administration rate, or by the combination of the existing LLTs Incorrect drug administration rate and LLT Off label dosing, if off label use has been explicitly reported.

Supplemental Update Report

CR Number: 2023172001		Implementation Date: 30-Jun-23	Related CR: 2023172001	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Cold cramps</i>	Approved as Requested	Proposed LLT <i>Cold cramps</i>	10089908 Current
			To PT <i>Muscle spasms</i>	10028334

MSSO Comment: The proposal to add a new term Cold cramps is approved as requested. Cold cramps are sudden and involuntary contractions of one or more muscles brought on by exposure to cold temperatures. Cold cramps will be added as LLT to PT Muscle spasms. In a related change, PT Heat cramps will be demoted under PT Muscle spasms.

CR Number: 2023181004		Implementation Date: 30-Jun-23	Related CR: 2023172001	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	Demote a PT <i>Heat cramps</i>	Approved as Requested	PT to merge <i>Heat cramps</i>	10019330 Current
To PT	<i>Muscle spasms</i>		To PT <i>Muscle spasms</i>	10028334

MSSO Comment:

CR Number: 2023172002		Implementation Date: 30-Jun-23	Related CR: 2023172002	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Implantable Cardioverter-Defibrillator Shock</i>	Approved Not as Requested	Proposed LLT <i>Inappropriate implantable cardioverter defibrillator shock</i>	10089909 Current
			To PT <i>Device inappropriate shock delivery</i>	10075322

MSSO Comment: The proposal to add a new term Implantable Cardioverter-Defibrillator Shock is approved but not as requested. The proposed term may represent the experience of an implantable cardioverter defibrillator shock (or discharge) which may be discomforting and distressing. An implantable cardioverter defibrillator may deliver the so called "inappropriate shock", which is defined as a shock delivered for a non-life-threatening arrhythmia or because of oversensing. The proposed term will be renamed for clarity to Inappropriate implantable cardioverter defibrillator shock and will be added as an LLT to the broader PT Device inappropriate shock delivery.

Supplemental Update Report

CR Number: 2023173001	Implementation Date: 03-Jul-23	Related CR: 2023173001	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Eosinophilic hepatitis</i>	Approved as Requested	Proposed LLT <i>Eosinophilic hepatitis</i> 10089967 To PT <i>Hepatic infiltration eosinophilic</i> 10064668 Current

MSSO Comment: The proposal to add a new term Eosinophilic hepatitis is approved as requested. Eosinophilic hepatitis is associated with a variety of disorders such as parasitic infestations, allergic conditions, internal malignancies, drug hypersensitivity, and hypereosinophilic syndrome. Eosinophilic hepatitis will be added as LLT to PT Hepatic infiltration eosinophilic. In a related change, LLT Eosinophilic hepatitis will be swapped with PT Hepatic infiltration eosinophilic to have the prevalent term at PT level.

CR Number: 2023184060	Implementation Date: 03-Jul-23	Related CR: 2023173001	
<u>Change Requested</u>	Swap a PT with an LLT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed PT	<i>Hepatic infiltration eosinophilic</i>	Approved as Requested	Proposed PT <i>Hepatic infiltration eosinophilic</i> 10064668 Current With LLT <i>Eosinophilic hepatitis</i> 10089967

MSSO Comment:

CR Number: 2023173002	Implementation Date: 05-Jul-23	Related CR: 2023173002	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Ultraviolet associated petechiae</i>	Rejected	

MSSO Comment: The proposal to add a new term Ultraviolet associated petechiae 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.

Supplemental Update Report

CR Number: 2023173003 Implementation Date: 05-Jul-23 Related CR: 2023173003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Postoperative pulmonary torsion</i>	Approved Not as Requested	Proposed PT <i>Pulmonary torsion</i>	10090004
HLT primary	<i>Respiratory tract and thoracic cavity procedural complications</i>		HLT primary <i>Respiratory tract disorders NEC</i>	10057184
SOC primary	<i>Injury, poisoning and procedural complications</i>		SOC primary <i>Respiratory, thoracic and mediastinal disorders</i>	10038738
			HLT secondary <i>Respiratory tract and thoracic cavity procedural complications</i>	10052823
			SOC secondary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new PT Postoperative pulmonary torsion to primary HLT Respiratory tract and thoracic cavity procedural complications in SOC Injury, poisoning and procedural complications is approved but not as requested. Pulmonary torsion is a rare pathology that is classically seen when there is a disruption in the thoracic cavity. Disruptions can include thoracotomy, lung transplantation, and trauma. Lung torsion is a life-threatening disease that requires a timely diagnosis because lung rotation can cause vascular compromise and airway obstruction, which can result in necrosis of the lung tissue. The MSSO generally refrains from adding any new post procedural/postoperative, procedural and intraoperative terms. Please consider section 3.5.4 When to “split” into more than one MedDRA term in the Term Selection Points to consider document. However, the requested term will be modified and will be added as PT Pulmonary torsion to primary HLT Respiratory tract disorders NEC to secondary HLT Respiratory tract and thoracic cavity procedural complications.

CR Number: 2023174001 Implementation Date: 05-Jul-23 Related CR: 2023174001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Cancer of rectum, secondary</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Cancer of rectum, secondary is not approved. The term secondary cancer may refer to either metastasis from primary cancer, or second cancer unrelated to the original cancer. If the report of Cancer of rectum, secondary refers to a metastasis then LLT Metastases to rectum is available. If the report refers to the latter situation, then LLT/PT Second primary malignancy is available.

Supplemental Update Report

<u>Change Requested</u>	<u>Implementation Date:</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Collapse disc</i>	05-Jul-23	Approved Not as Requested	Proposed LLT <i>Collapsed disc</i> To PT <i>Intervertebral disc degeneration</i>	10090007 Current 10061246

MSSO Comment: The proposal to add a new term Collapse disc is approved but not as requested. One unique presentation of spinal disc deterioration is called a collapsed disc. In the case of a collapsed disc, the annulus is the primary affected component. Incurion of the nucleus into the area of the annulus could occur, but wear and tear, along with normal aging, can cause the annulus to decrease in strength even without interference from the nucleus. Proposed term will be modified for better alignment and added as sub-concept LLT Collapsed disc under PT Intervertebral disc degeneration.

<u>Change Requested</u>	<u>Implementation Date:</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Aortic dissection repair</i>	05-Jul-23	Approved as Requested	Proposed PT <i>Aortic dissection repair</i> HLT primary <i>Aortic therapeutic procedures</i> SOC primary <i>Surgical and medical procedures</i>	10090005 10002903 10042613

MSSO Comment: The proposal to add a new term Aortic dissection repair is approved as requested. For aortic dissections, especially of the ascending aorta or aortic arch, surgery will very often be the only viable option. The risk of death approaches 100% after a week without operating on a dissection of the ascending aorta. Aortic dissection repair will be added as a new PT under HLT Aortic therapeutic procedures.

<u>Change Requested</u>	<u>Implementation Date:</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Nephro-Uretero-Cystectomy</i>	05-Jul-23	Approved Not as Requested	Proposed PT <i>Nephroureterocystectomy</i> HLT primary <i>Renal therapeutic procedures</i> SOC primary <i>Surgical and medical procedures</i>	10090006 10023431 10042613

MSSO Comment: The proposal to add a new term Nephro-Uretero-Cystectomy is approved but not as requested. Nephroureterocystectomy is the excision of the kidney, ureter, and part or all of the bladder. This may be indicated when patients have been diagnosed with a mass or tumor within the lining of the kidney and/or ureter. Proposed term will be modified for MedDRA capitalization conventions and added as new PT Nephroureterocystectomy under HLT Renal therapeutic procedures.

Supplemental Update Report

CR Number: 2023177004	Implementation Date: 05-Jul-23	Related CR: 2023177004		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Hyperspermia</i>	Approved as Requested	Proposed PT <i>Hyperspermia</i>	10090008
			HLT primary <i>Spermatogenesis and semen disorders</i>	10013358
			SOC primary <i>Reproductive system and breast disorders</i>	10038604

MSSO Comment: The proposal to add a new term Hyperspermia is approved as requested. Hyperspermia is a condition in which a male has an abnormally large amount of semen or ejaculate volume and is generally defined when the ejaculate is above 5.5 mL. Hyperspermia alone does not appear to influence sperm health. However, large volumes of ejaculate may have lower relative volumes of sperm, leading to low fertility. Hyperspermia will be added as a new PT under HLT Spermatogenesis and semen disorders.

CR Number: 2023177005	Implementation Date: 30-Jun-23	Related CR: 2023177005		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Epithelitis</i>	Approved Not as Requested	Proposed PT <i>Epithelitis</i>	10089937
			HLT primary <i>Inflammations</i>	10021950
			SOC primary <i>General disorders and administration site conditions</i>	10018065

MSSO Comment: The proposal to add a new LLT Epithelitis is approved but not as requested. epithelial cells play a critical role in the pathogenesis of chronic inflammatory processes, e.g. in many excretory glands, intestinal or airway epithelial cells as there are multiple complex interactions between inflammatory cytokines and epithelial cells. Epithelitis will be added as a PT to HLT Inflammations.

CR Number: 2023178001	Implementation Date: 03-Jul-23	Related CR: 2023178001		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Postherpetic nervous system involvement</i>	Rejected		

MSSO Comment: The proposal to add a new term Postherpetic nervous system involvement is not approved. The proposed term is a grouping concept and does not represent a single medical concept as it may refer to many nervous system complications after herpes zoster infection such as cranial nerve palsies, meningitis, contralateral hemiparesis, acute or chronic encephalitis.

Supplemental Update Report

CR Number: 2023178002	Implementation Date: 03-Jul-23	Related CR: 2023178002	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New Term			<u>MedDRA Code #</u>
Proposed Term <i>Lymphoepithelioma-like carcinoma</i>	Approved as Requested	Proposed LLT <i>Lymphoepithelioma-like carcinoma</i>	10089969 Current
		To PT <i>Squamous cell carcinoma</i>	10041823

MSSO Comment: The proposal to add a new term Lymphoepithelioma-like carcinoma is approved as requested. Lymphoepithelioma-like carcinoma (LELC) is a medical term referring to a histological variant of malignant tumor arising from the uncontrolled mitosis of transformed cells originating in epithelial tissue (or in cells that display epithelial characteristics) that bear microscopic resemblance to lymphoepithelioma (nasopharyngeal carcinoma). It is perhaps most commonly considered a subtype of squamous cell carcinoma. LLT Lymphoepithelioma-like carcinoma will be added to PT Squamous cell carcinoma.

CR Number: 2023179001	Implementation Date: 03-Jul-23	Related CR: 2023179001	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New LLT			<u>MedDRA Code #</u>
Proposed LLT <i>Acquired Brachycephaly</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Acquired Brachycephaly is not approved. The requested term can be represented by the recently added PT Postural brachycephaly, available for v26.1.

CR Number: 2023179002	Implementation Date: 04-Jul-23	Related CR: 2023179002	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New LLT			<u>MedDRA Code #</u>
Proposed LLT <i>Periradicular therapy</i>	Approved Not as Requested	Proposed PT <i>Periradicular therapy</i>	10089997
		HLT primary <i>Spine and spinal cord therapeutic procedures</i>	10041590
		SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new LLT Periradicular therapy is approved but not as requested. Periradicular therapy is a treatment procedure for back pain disorders which involves injecting medication through a needle into the nerve roots that branch off the spinal cord in the area of the spine. Periradicular therapy will be added as a PT under HLT Spine and spinal cord therapeutic procedures. In a related change, PT Dorsal root ganglion block will be demoted under PT Periradicular therapy.

Supplemental Update Report

CR Number: 2023185019	Implementation Date: 04-Jul-23	Related CR: 2023179002	
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>
PT to merge	<i>Dorsal root ganglion block</i>	Approved as Requested	PT to merge
To PT	<i>Periradicular therapy</i>		<i>Dorsal root ganglion block</i>
			10082966 Current
			To PT
			<i>Periradicular therapy</i>
			10089997

MSSO
Comment:

CR Number: 2023179003	Implementation Date: 04-Jul-23	Related CR: 2023179003	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Empyemectomy</i>	Approved as Requested	Proposed LLT
			<i>Empyemectomy</i>
			10089998 Current
			To PT
			<i>Pleural decortication</i>
			10066322

MSSO Comment: The proposal to add a new LLT Empyemectomy is approved as requested. Pleural decortication is a surgical procedure that removes a restrictive layer of fibrous pleural tissue overlying the lung, chest wall, and diaphragm. The primary indication for decortication in a patient with fibrothorax is presence of symptoms due to lung restriction. Empyemectomy is a synonym of the existing PT Pleural decortication and will be placed as its LLT.

CR Number: 2023179004	Implementation Date: 04-Jul-23	Related CR: 2023179004	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Hypotensive shock</i>	Approved as Requested	Proposed LLT
			<i>Hypotensive shock</i>
			10089999 Current
			To PT
			<i>Shock</i>
			10040560

MSSO Comment: The proposal to add a new term Hypotensive shock is approved as requested. Hypertension is the final common pathway of different types of shocks, such as in vasodilatation during a septic shock or the lowering of pressure during an hypovolemic shock. Since it is more a common pathogenic condition than a full diagnostic one, it will be considered as a a sub-element of the general PT Shock and placed as its LLT. Hypotensive shock will be added as an LLT to PT Shock.

Supplemental Update Report

CR Number: 2023179007 **Implementation Date:** 03-Jul-23 **Related CR:** 2023179007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Meningoencephalitis</i>	Rejected		
From PT	<i>Encephalitis</i>			
To PT	<i>Meningitis</i>			

MSSO Comment: The proposal to move the LLT Meningoencephalitis from PT Encephalitis to PT Meningitis is not approved. The combination term Meningoencephalitis is best placed as an LLT under PT Encephalitis as Encephalitis is the broader pathophysiological concept. Furthermore, in reference to the subscriber's justification, please note that based on MedDRA term placement rules, LLTs can only be linked to one PT and PTs can only follow one hierarchical way within a particular SOC.

CR Number: 2023179008 **Implementation Date:** 03-Jul-23 **Related CR:** 2023179008

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Granulomatous interstitial nephritis</i>	Approved Not as Requested	Proposed LLT <i>Granulomatous interstitial nephritis</i>	10089968 Current
			To PT <i>Tubulointerstitial nephritis</i>	10048302

MSSO Comment: The proposal to add a new PT Granulomatous interstitial nephritis is approved but not as requested. Granulomatous interstitial nephritis is a type of tubulointerstitial nephritis characterised by tubulointerstitial infiltration of mononuclear cells and eosinophils. It accounts for about 6% of all tubulointerstitial nephritis and is detected in ~0.5%–0.9% of all renal biopsies. Granulomatous interstitial nephritis will be added as LLT to PT Tubulointerstitial nephritis.

CR Number: 2023179009 **Implementation Date:** 05-Jul-23 **Related CR:** 2023179009

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Habit-tic nail deformity</i>	Approved as Requested	Proposed LLT <i>Habit-tic nail deformity</i>	10090009 Current
			To PT <i>Nail picking</i>	10066779

MSSO Comment: The proposal to add a new LLT Habit-tic nail deformity is approved as requested. Habit-tic nail deformity is a form of onychotillomania, which refers to compulsive or habitual self-imposed external trauma involving the fingernails or toenails. Habit-tic nail deformity will be added as LLT to PT Nail picking aligned with LLT Onychotillomania.

Supplemental Update Report

CR Number: 2023180001	Implementation Date: 05-Jul-23	Related CR: 2023180001	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Prepuce pruritus</i>	Approved as Requested	Proposed LLT <i>Prepuce pruritus</i> 10090010 Current
			To PT <i>Pruritus genital</i> 10037093

MSSO Comment: The proposal to add a new term Prepuce pruritus is approved as requested. There are various causes of prepuce pruritus with or without rash such as yeast or chlamydial infection, genital herpes, gonorrhoea, allergy to latex etc. Prepuce pruritus will be added as LLT to PT Pruritus genital.

CR Number: 2023180002	Implementation Date: 10-Jul-23	Related CR: 2023180002	
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
PT to merge	<i>Bifascicular block</i>	Rejected	
To PT	<i>Bundle branch block bilateral</i>		

MSSO Comment: The proposal to demote the PT Bifascicular block under PT Bundle branch block bilateral is not approved. The most common bifascicular block is a right bundle branch block and left anterior fascicular block, followed by right bundle branch block and left posterior fascicular block and complete left bundle branch block (blockages in left anterior and posterior fascicles, but not in right bundle branch). That means that bifascicular does not mean always bilateral (right and left bundle branch affected).

CR Number: 2023180003	Implementation Date: 10-Jul-23	Related CR: 2023180003	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed LLT	<i>Prone position ventilation</i>	Approved as Requested	Proposed LLT <i>Prone position ventilation</i> 10090042 Current
To PT	<i>Mechanical ventilation</i>		To PT <i>Mechanical ventilation</i> 10067221

MSSO Comment: The proposal to add a new LLT Prone position ventilation to PT Mechanical ventilation is approved as requested. Prone position ventilation refers to the delivery of mechanical ventilation with the patient lying in the prone position, face-down. It improves oxygenation in most patients with acute respiratory distress syndrome and reduces mortality.

Supplemental Update Report

CR Number: 2023181003 Implementation Date: 05-Jul-23 Related CR: 2023181003

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New LLT Proposed LLT <i>Glucagon stimulation test</i>	Approved Not as Requested	Proposed PT <i>Glucagon stimulation test</i>	10090011
		HLT primary <i>Pituitary analyses anterior</i>	10035089
		SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new LLT Glucagon stimulation test is approved but not as requested. The insulin tolerance test (ITT) is considered the test of choice for the diagnosis of Growth hormone deficiency (GHD). However, in patients with contraindications to ITT, alternative provocative tests must be used with appropriate cut-offs. The glucagon stimulation test has proved to be a safe, low-cost and effective means of stimulating GH secretion, and therefore can be considered as a suitable alternative to the ITT. The requested term will be added with corrected spelling as PT Glucagon stimulation test to HLT Pituitary analyses anterior.

CR Number: 2023181009 Implementation Date: 10-Jul-23 Related CR: 2023181009

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New LLT Proposed LLT <i>Foot ray amputation</i>	Approved as Requested	Proposed LLT <i>Foot ray amputation</i>	10090017 Current
		To PT <i>Metatarsal excision</i>	10027486

MSSO Comment: The proposal to add a new LLT Foot ray amputation is approved as requested. Ray amputation involves the excision of the toe and part of the metatarsal and it is indicated in wet or dry gangrene of a toe, osteomyelitis of the metatarsal head and/or proximal phalanx, septic arthritis of the metatarsophalangeal joint and gross infection of the toe. Foot ray amputation will be added as LLT to PT Metatarsal excision.

CR Number: 2023181010 Implementation Date: 10-Jul-23 Related CR: 2023181010

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New LLT Proposed LLT <i>Tympanostomy</i>	Approved as Requested	Proposed LLT <i>Tympanostomy</i>	10090016 Current
		To PT <i>Myringotomy</i>	10028662

MSSO Comment: The proposal to add a new LLT Tympanostomy is approved as requested. Although tympanotomy usually involves the insertion of a ventilation tube, which is necessary to help drain the middle ear and provide adequate ventilation after the open incision in the tympanic membrane, the stand-alone Tympanostomy will be added as synonym LLT to PT Myringotomy.

Supplemental Update Report

CR Number: 2023181011 **Implementation Date:** 10-Jul-23 **Related CR:** 2023181011

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term <i>HHV6 viremia</i>	Approved Not as Requested	Proposed LLT <i>Human herpesvirus 6 viremia</i>	10090019 Current
			To PT <i>Human herpesvirus 6 viraemia</i>	10090018

MSSO Comment: The proposal to add a new term HHV6 viremia is approved but not as requested. Human herpesvirus 6 has been increasingly recognized as an opportunistic and potentially life-threatening pathogen after hematopoietic cell transplantation (HCT). In post-HCT patients, human herpesvirus 6 viremia has been reported in association with varying organ dysfunction and clinical syndromes including: delayed/impaired platelet recovery, myelosuppression, encephalitis, fever, rash, hepatitis, pneumonitis, gastroenteritis, CMV reactivation, and graft-versus-host disease. The proposed term will be spelled out as are other existing MedDRA terms for this virus, and added as LLT Human herpesvirus 6 viremia to a new PT representing its British spelling, named Human herpesvirus 6 viraemia, which will be added, in a related change, to HLT Herpes viral infections.

CR Number: 2023191007 **Implementation Date:** 10-Jul-23 **Related CR:** 2023181011

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Add a New PT <i>Human herpesvirus 6 viraemia</i>	Approved as Requested	Proposed PT <i>Human herpesvirus 6 viraemia</i>	10090018
HLT primary	<i>Herpes viral infections</i>		HLT primary <i>Herpes viral infections</i>	10019972
SOC primary	<i>Infections and infestations</i>		SOC primary <i>Infections and infestations</i>	10021881

MSSO Comment:

CR Number: 2023184002 **Implementation Date:** 12-Sep-23 **Related CR:** 2023184002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Add a New PT <i>Suspected illegal product</i>	Rejected After Suspension		
HLT primary	<i>Counterfeit, falsified and substandard products</i>			
SOC primary	<i>Product issues</i>			

MSSO Comment: The proposal to add a new PT Suspected illegal product to primary HLT Counterfeit, falsified and substandard products in SOC Product issues is not approved after suspension. Illegal is too broad a term which can refer to falsified products as well as other products that are illegal such as recreational drugs. Also, what is illegal in one country may not be in another country. MedDRA generally refrains from adding concepts with ambiguity.

Supplemental Update Report

CR Number: 2023184003 Implementation Date: 05-Jul-23 Related CR: 2023184003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>High sensitivity troponin I increased</i>	Approved as Requested	Proposed LLT <i>High sensitivity troponin I increased</i>	10090012 Current
			To PT <i>Troponin I increased</i>	10058268

MSSO Comment: The proposal to add a new term High sensitivity troponin I increased is approved as requested. High levels of high-sensitivity cardiac troponin I are associated with more severe coronary artery disease and its accelerated angiographic progression. In patients with coronary artery disease, high-sensitivity cardiac troponin I levels can be used to risk stratify and predict future cardiovascular outcomes. High sensitivity troponin I increased will be added as subconcept LLT under PT Troponin I increased.

CR Number: 2023184051 Implementation Date: 05-Jul-23 Related CR: 2023184051

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>CT ear</i>	Approved Not as Requested	Proposed LLT <i>Ear CT</i>	10090015 Current
			To PT <i>Computerised tomogram ear</i>	10090013

MSSO Comment: The proposal to add a new term CT ear is approved but not as requested. A computed tomography scan (CT or CAT) of the internal auditory canal, also called cross-sectional imaging, allows the radiologist to look at different levels, or slices, of the skull bones leading from the ear using a rotating X-ray beam. The proposed term will be modified into natural language word order and added as LLT Ear CT under new PT Computerised tomogram ear, which will be added, in a related change, to HLT Auditory and vestibular diagnostic procedures. Furthermore, the American spelled counterpart LLT Computerized tomogram ear will also be added to new PT Computerised tomogram ear.

CR Number: 2023186014 Implementation Date: 05-Jul-23 Related CR: 2023184051

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Computerised tomogram ear</i>	Approved as Requested	Proposed PT <i>Computerised tomogram ear</i>	10090013
HLT primary	<i>Auditory and vestibular diagnostic procedures</i>		HLT primary <i>Auditory and vestibular diagnostic procedures</i>	10085261
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2023186015 Implementation Date: 05-Jul-23 Related CR: 2023184051

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Computerized tomogram ear</i>	Approved as Requested	Proposed LLT <i>Computerized tomogram ear</i>	10090014 Current
To PT	<i>Computerised tomogram ear</i>		To PT <i>Computerised tomogram ear</i>	10090013

MSSO
Comment:

CR Number: 2023184062 Implementation Date: 10-Jul-23 Related CR: 2023184062

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Genital peeling</i>	Rejected		
To PT	<i>Genital exfoliation</i>			

MSSO Comment: The proposal to add a new LLT Genital peeling to PT Genital exfoliation is not approved. Genital peeling is an ambiguous expression as it may refer to either a condition such as skin exfoliation in the genital area or to a cosmetic procedure.

CR Number: 2023184063 Implementation Date: 10-Jul-23 Related CR: 2023184063

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Red papule</i>	Approved as Requested	Proposed LLT <i>Red papule</i>	10090021 Current
To PT	<i>Papule</i>		To PT <i>Papule</i>	10033733

MSSO Comment: The proposal to add a new LLT Red papule to PT Papule is approved as requested. A papule is a small, well-defined bump in the skin. It can be soft or firm and its surface may be rough or smooth, and some have crusts or scales. A papule can be flesh colored, yellow, white, brown, red, blue or purplish.

Supplemental Update Report

CR Number: 2023184064	Implementation Date: 10-Jul-23	Related CR: 2023184064	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Genital dryness</i>	Approved as Requested	Proposed PT <i>Genital dryness</i> 10090020 HLT primary <i>Reproductive tract signs and symptoms NEC</i> 10040674 SOC primary <i>Reproductive system and breast disorders</i> 10038604

MSSO Comment: The proposal to add a new term Genital dryness is approved as requested. Genital dryness will be added as a PT to HLT Reproductive tract signs and symptoms NEC.

CR Number: 2023184065	Implementation Date: 10-Jul-23	Related CR: 2023184065	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Genital sensitivity</i>	Rejected	

MSSO Comment: The proposal to add a new term Genital sensitivity is not approved. Genital sensitivity is a very broad term and may refer to many existing concepts such as LLT Genital hyperaesthesia, LLT Genital discomfort, LLT Genital burning sensation, LLT Genital burning or LLT Genital pain.

Supplemental Update Report

CR Number: 2023184066 Implementation Date: 10-Jul-23 Related CR: 2023184066

<u>Change Requested</u>	<u>Add a New Term</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Autoimmune oophoritis</i>	Approved as Requested	Proposed PT <i>Autoimmune oophoritis</i>	10090023
			HLT primary <i>Fallopian tube and ovary infections and inflammations</i>	10021884
			SOC primary <i>Reproductive system and breast disorders</i>	10038604
			HLT secondary <i>Autoimmune disorders NEC</i>	10027657
			SOC secondary <i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new term Autoimmune oophoritis is approved as requested. Autoimmune oophoritis is a pathological destruction of the ovaries caused by exposure to antiovarial antibodies. It is manifested by disorders of menstrual function (oligomenorrhea, amenorrhea), primary and secondary infertility. Autoimmune oophoritis will be added as PT to primary HLT Fallopian tube and ovary infections and inflammations and secondary HLT Autoimmune disorders NEC.

CR Number: 2023184067 Implementation Date: 10-Jul-23 Related CR: 2023184067

<u>Change Requested</u>	<u>Add a New Term</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Ord's thyroiditis</i>	Approved as Requested	Proposed LLT <i>Ord's thyroiditis</i>	10090024 Current
			To PT <i>Autoimmune thyroiditis</i>	10049046

MSSO Comment: The proposal to add a new term Ord's thyroiditis is approved as requested. Also known as Ord's disease, this autoimmune condition is characterized by atrophy of the thyroid gland and hypothyroidism. Ord's thyroiditis usually results in hypothyroidism. Transient hyperthyroid states in the acute phase, (a common observation in Hashimoto's thyroiditis), are rare in Ord's disease. Ord's thyroiditis will be added as sub-concept LLT to PT Autoimmune thyroiditis.

Supplemental Update Report

CR Number: 2023184068 Implementation Date: 10-Jul-23 Related CR: 2023184068

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Autoimmune hypoparathyroidism</i>	Approved as Requested	Proposed PT <i>Autoimmune hypoparathyroidism</i>	10090022
			HLT primary <i>Hypoparathyroid disorders</i>	10021040
			SOC primary <i>Endocrine disorders</i>	10014698
			HLT secondary <i>Endocrine autoimmune disorders</i>	10003818
			SOC secondary <i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new term Autoimmune hypoparathyroidism is approved as requested. Isolated and acquired hypoparathyroidism occurs as an autoimmune disorder either alone or in association with other autoimmune diseases. Reduced PTH (parathyroid hormone) secretion due to disorder of Ca-sensing regulation in parathyroid gland is most commonly caused by activating mutations of the CaSR (Ca-sensing receptor) gene. Autoimmune hypoparathyroidism will be added as PT to primary HLT Hypoparathyroid disorders, to secondary HLT Endocrine autoimmune disorders and to secondary HLT Calcium metabolism disorders.

CR Number: 2023191008 Implementation Date: 10-Jul-23 Related CR: 2023184068

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Autoimmune hypoparathyroidism</i>	Approved as Requested	Proposed PT <i>Autoimmune hypoparathyroidism</i>	10090022
To HLT	<i>Calcium metabolism disorders</i>		To HLT <i>Calcium metabolism disorders</i>	10006975

MSSO Comment:

Supplemental Update Report

CR Number: 2023184069	Implementation Date: 10-Jul-23	Related CR: 2023184069	MedDRA Code #
Change Requested Add a New Term	Final Disposition	Final Placement	
Proposed Term <i>Autoimmune orchitis</i>	Approved as Requested	Proposed LLT <i>Autoimmune orchitis</i>	10090025 Current
		To PT <i>Testicular autoimmunity</i>	10071574

MSSO Comment: The proposal to add a new term Autoimmune orchitis is approved as requested. Autoimmune orchitis is characterized by testis inflammation and the presence of specific antisperm antibodies (ASA). It is classified as either primary or secondary autoimmune orchitis. The pathogenesis of primary as well as secondary autoimmune orchitis is still unknown. Although the etiology is likely to be multifactorial, testicular inflammation, infection or trauma may induce T cell response with pro-inflammatory cytokine production with a consequent blood-testis-barrier permeability alteration, ASA production and apoptosis of spermatocytes and spermatids. Autoimmune orchitis will be added as LLT to PT Testicular autoimmunity.

CR Number: 2023185001	Implementation Date: 10-Jul-23	Related CR: 2023185001	MedDRA Code #
Change Requested Add a New Term	Final Disposition	Final Placement	
Proposed Term <i>Horizontal Diplopia</i>	Approved Not as Requested	Proposed LLT <i>Horizontal diplopia</i>	10090030 Current
		To PT <i>Diplopia</i>	10013036

MSSO Comment: The proposal to add a new term Horizontal Diplopia is approved but not as requested. Binocular horizontal diplopia (images displaced horizontally) is usually due to disease of the medial or lateral rectus muscle, the neuromuscular junction, or the nerves supplying these muscles (e.g., cranial nerves III or VI). The requested term will be modified according to MedDRA capitalisation conventions and added as LLT Horizontal diplopia to PT Diplopia.

CR Number: 2023185002	Implementation Date: 10-Jul-23	Related CR: 2023185002	MedDRA Code #
Change Requested Add a New Term	Final Disposition	Final Placement	
Proposed Term <i>Parapyelic cyst</i>	Rejected		

MSSO Comment: The proposal to add a new term Parapyelic cyst is not approved. The requested term is represented by LLT Parapyelitic cyst.

Supplemental Update Report

CR Number: 2023185003 Implementation Date: 10-Jul-23 Related CR: 2023185003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Reticular veins</i>	Approved as Requested	Proposed PT	
			<i>Reticular veins</i>	10090027
			HLT primary	
			<i>Varicose veins NEC</i>	10077550
			SOC primary	
			<i>Vascular disorders</i>	10047065
			HLT secondary	
			<i>Telangiectasia and related conditions</i>	10043190
			SOC secondary	
			<i>Skin and subcutaneous tissue disorders</i>	10040785

MSSO Comment: The proposal to add a new term Reticular veins is approved as requested. Telangiectasias, or spider veins, are dilated venules or arterioles measuring less than 1.0 mm in diameter and occurring predominantly in the lower extremities. Reticular veins have a diameter less than 3 mm and are often tortuous and located in the subdermal or subcutaneous tissue. Reticular veins are also called feeder veins because they feed into spider veins. Consequently, treating reticular veins eliminates spider veins at the same time. Reticular veins will be added as PT to primary HLT Varicose veins NEC and to secondary HLT Telangiectasia and related conditions.

CR Number: 2023185004 Implementation Date: 10-Jul-23 Related CR: 2023185004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Suspensionplasty</i>	Approved as Requested	Proposed LLT	
			<i>Suspensionplasty</i>	10090029 Current
			To PT	
			<i>Joint arthroplasty</i>	10057681

MSSO Comment: The proposal to add a new term Suspensionplasty is approved as requested. Suspensionplasty typically involves cleaning out and reconstructing the arthritic joint. A small incision is made at the base of the thumb and some or all of the trapezium bone, which forms the base of the CMC joint, is removed. A tendon graft is often taken from the wrist and then used to help reconstruct and stabilise the joint. The remaining tendon is then rolled up and placed in the space where the trapezium used to sit to help suspend the thumb. Suspensionplasty will be added as LLT to PT Joint arthroplasty.

Supplemental Update Report

CR Number: 2023185005 Implementation Date: 10-Jul-23 Related CR: 2023185005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Pes Anserine Bursitis</i>	Approved Not as Requested	Proposed PT <i>Pes anserinus syndrome</i>	10090028
			HLT primary <i>Bursal disorders</i>	10013297
			SOC primary <i>Musculoskeletal and connective tissue disorders</i>	10028395
			HLT secondary <i>Bone and joint injuries NEC</i>	10074485
			SOC secondary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new term Pes Anserine Bursitis is approved but not as requested. Pes anserine bursitis symptoms typically involve pain. Pes anserine bursa is located superficial to the medial collateral ligament of the knee. After modification in accordance with MedDRA capitalization conventions, and to the more prevalent expression Pes anserinus syndrome as a PT to primary HLT Bursal disorders and to secondary HLT Bone and joint injuries NEC. In a related change, LLT Tibial collateral ligament bursitis will be moved from PT Bursitis to the new PT Pes anserinus syndrome. Furthermore, LLT Pes anserinus tendinitis or bursitis and LLT Pes anserinus tendinitis will both be moved from PT Tendonitis to the new PT Pes anserinus syndrome for better alignment.

CR Number: 2023191011 Implementation Date: 10-Jul-23 Related CR: 2023185005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Tibial collateral ligament bursitis</i>	Approved as Requested	Proposed LLT <i>Tibial collateral ligament bursitis</i>	10043830 Current
From PT	<i>Bursitis</i>		From PT <i>Bursitis</i>	10006811
To PT	<i>Pes anserinus syndrome</i>		To PT <i>Pes anserinus syndrome</i>	10090028

MSSO Comment:

Supplemental Update Report

CR Number: 2023191012		Implementation Date: 10-Jul-23	Related CR: 2023185005	
<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Pes anserinus tendinitis or bursitis</i>	Approved as Requested	Proposed LLT	
From PT	<i>Tendonitis</i>		<i>Pes anserinus tendinitis or bursitis</i>	10034742 Non-Current
To PT	<i>Pes anserinus syndrome</i>		From PT	
			<i>Tendonitis</i>	10043255
			To PT	
			<i>Pes anserinus syndrome</i>	10090028

MSSO
Comment:

CR Number: 2023191013		Implementation Date: 10-Jul-23	Related CR: 2023185005	
<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Pes anserinus tendinitis</i>	Approved as Requested	Proposed LLT	
From PT	<i>Tendonitis</i>		<i>Pes anserinus tendinitis</i>	10075608 Current
To PT	<i>Pes anserinus syndrome</i>		From PT	
			<i>Tendonitis</i>	10043255
			To PT	
			<i>Pes anserinus syndrome</i>	10090028

MSSO
Comment:

CR Number: 2023185006		Implementation Date: 10-Jul-23	Related CR: 2023185006	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Silent reflux</i>	Approved as Requested	Proposed LLT	
			<i>Silent reflux</i>	10090034 Current
			To PT	
			<i>Reflux laryngitis</i>	10067869

MSSO
Comment: The proposal to add a new term Silent reflux is approved as requested. Laryngopharyngeal reflux typically results from the effects of reflux on the glottis and vocal cords. Patients may present with a multitude of symptoms ranging from hoarseness, globus sensation, and chronic throat clearing to heartburn and regurgitation. However, since it often doesn't cause any symptoms it is also called silent reflux. Silent reflux is a synonym of LLT Laryngopharyngeal reflux and will be added as LLT to PT Reflux laryngitis.

Supplemental Update Report

CR Number: 2023185007 **Implementation Date:** 10-Jul-23 **Related CR:** 2023185007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Transvesical prostatic adenomectomy</i>	Approved as Requested	Proposed LLT <i>Transvesical prostatic adenomectomy</i>	10090031 Current
			To PT <i>Trans-vesical prostatectomy</i>	10044342

MSSO Comment: The proposal to add a new term Transvesical prostatic adenomectomy is approved as requested. Endoscopic transvesical adenomectomy is a new minimally invasive technique possible to treat large volume (>80 ml) benign prostatic hyperplasia which involves a cystotomy to remove prostatic tissue. Transvesical prostatic adenomectomy will be added as an LLT to the newly PT Trans-vesical prostatectomy which will be promoted, in a related change, from under PT Suprapubic prostatectomy to a PT level, and linked to HLT Prostatic therapeutic procedures.

CR Number: 2023191010 **Implementation Date:** 10-Jul-23 **Related CR:** 2023185007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Trans-vesical prostatectomy</i>	Approved as Requested	Proposed LLT <i>Trans-vesical prostatectomy</i>	10044342
From PT	<i>Suprapubic prostatectomy</i>		From PT <i>Suprapubic prostatectomy</i>	10042594
HLT primary	<i>Prostatic therapeutic procedures</i>		HLT primary <i>Prostatic therapeutic procedures</i>	10036967
			SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment:

CR Number: 2023185008 **Implementation Date:** 10-Jul-23 **Related CR:** 2023185008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Blunt eye trauma</i>	Approved as Requested	Proposed LLT <i>Blunt eye trauma</i>	10090032 Current
			To PT <i>Eye injury</i>	10061128

MSSO Comment: The proposal to add a new term Blunt eye trauma is approved as requested. Blunt trauma can result in open and closed globe injuries. The closed globe injuries are further classified as contusion and lamellar lacerations, while open globe injuries can be due to penetrating, perforation, or injury due to an intraocular foreign body. Blunt eye trauma will be added as an LLT to PT Eye injury.

Supplemental Update Report

CR Number: 2023185009	Implementation Date: 10-Jul-23	Related CR: 2023185009	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Breast prosthesis revision</i>	Approved Not as Requested	Proposed LLT <i>Breast implant revision</i> To PT <i>Mammoplasty</i>
			10090036 Current 10068647
MSSO Comment:	The proposal to add a new term Breast prosthesis revision is approved but not as requested. The goal of breast implant revision surgery is to replace old breast implants with new implants. Often the goal is also to change or improve the appearance of the breasts while updating the implant material. The requested term will be modified and will be added as an LLT Breast implant revision to PT Mammoplasty.		

CR Number: 2023185010	Implementation Date: 10-Jul-23	Related CR: 2023185010	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Ceruminous Adenoma</i>	Approved Not as Requested	Proposed PT <i>Ceruminous adenoma</i> HLT primary <i>Aural neoplasms benign</i> SOC primary <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i> HLT secondary <i>Ear disorders NEC</i> SOC secondary <i>Ear and labyrinth disorders</i>
			10090026 10003792 10029104 10027666 10013993
MSSO Comment:	The proposal to add a new term Ceruminous Adenoma is approved but not as requested. Ceruminous adenomas are circumscribed, usually unencapsulated and lacking invasion. Surface pagetoid-type extension, ulceration, and pseudoepitheliomatous hyperplasia may be seen. They are predominantly glandular, often with cystic change, and extending into the surrounding stroma. Symptoms include an outer EAC mass with intact tympanic membrane, conductive hearing loss, otorrhea or discharge and otalgia. Proposed term will be modified in accordance with MedDRA capitalization conventions and added as new PT Ceruminous adenoma under primary HLT Aural neoplasms benign and secondary HLT Ear disorders NEC.		

Supplemental Update Report

CR Number: 2023185011 **Implementation Date:** 10-Jul-23 **Related CR:** 2023185011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Graham Little-Piccardi-Lassueur syndrome</i>	Approved as Requested	Proposed LLT <i>Graham Little-Piccardi-Lassueur syndrome</i>	10090035 Current
			To PT <i>Lichen planopilaris</i>	10081142

MSSO Comment: The proposal to add a new term Graham Little-Piccardi-Lassueur syndrome is approved as requested. Graham Little-Piccardi-Lassueur syndrome is a type of lichen planopilaris (follicular lichen planus) characterized by the triad of patchy cicatricial alopecia of the scalp, noncicatricial alopecia of the axilla and groin, and a follicular spinous papule on the body, scalp, or both. Graham Little-Piccardi-Lassueur syndrome will be added as LLT under PT Lichen planopilaris. In a related change synonym LLT Follicular lichen planus will be added under PT Lichen planopilaris.

CR Number: 2023191009 **Implementation Date:** 10-Jul-23 **Related CR:** 2023185011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Follicular lichen planus</i>	Approved as Requested	Proposed LLT <i>Follicular lichen planus</i>	10090037 Current
To PT	<i>Lichen planopilaris</i>		To PT <i>Lichen planopilaris</i>	10081142

MSSO Comment:

CR Number: 2023185012 **Implementation Date:** 10-Jul-23 **Related CR:** 2023185012

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Menopausal acne</i>	Approved as Requested	Proposed LLT <i>Menopausal acne</i>	10090033 Current
			To PT <i>Acne</i>	10000496

MSSO Comment: The proposal to add a new term Menopausal acne is approved as requested. The etiology of menopausal acne is multifactorial. In menopause, the hormonal imbalance between estrogen and androgen further increases due to decrease in sex hormone-binding globulin (SHBG) levels and is called postmenopausal hyperandrogenism which can lead to menopausal acne. Menopausal acne will be added as subconcept LLT under PT Acne.

Supplemental Update Report

CR Number: 2023185021 Implementation Date: 10-Jul-23 Related CR: 2023185021

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Fluoroscopy-Guided Endoscopic Removal of Foreign Bodies	Rejected		
To PT	Removal of foreign body			

MSSO Comment: The proposal to add a new LLT Fluoroscopy-Guided Endoscopic Removal of Foreign Bodies to PT Removal of foreign body is not approved. Fluoroscopy is used in a wide variety of examinations and procedures to diagnose or treat patients. It is not feasible for MedDRA to add such combination concepts between the technique and a particular procedure and the purpose.

CR Number: 2023185022 Implementation Date: 10-Jul-23 Related CR: 2023185022

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Paracentesis ascites	Rejected		

MSSO Comment: The proposal to add a new term Paracentesis ascites is not approved. The requested the term can be represented by LLT Ascites drainage or LLT Paracentesis abdominal, both LLTs are under PT Abdominal cavity drainage.

CR Number: 2023185023 Implementation Date: 10-Jul-23 Related CR: 2023185023

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Inactive viral hepatitis B carrier	Approved Not as Requested	Proposed LLT HBeAg-negative chronic infection	10090038 Current
			To PT Chronic hepatitis B	10008910

MSSO Comment: The proposal to add a new term Inactive viral hepatitis B carrier is approved but not as requested. The inactive HBsAg carrier state is diagnosed by absence of HBeAg and presence of anti-HBe, undetectable or low levels of HBV DNA in PCR-based assays, repeatedly normal ALT levels, and minimal or no necroinflammation, slight fibrosis, or even normal histology on biopsy. Inactive cirrhosis may be present in patients who had active liver disease during the replicative phase of infection. The prognosis of the inactive HBsAg carrier state is usually benign. Inactive viral hepatitis B carrier is a historical term and will be replaced by the updated concept HBeAg-negative chronic infection which will be added as an LLT to PT Chronic hepatitis B.

Supplemental Update Report

CR Number: 2023186001 Implementation Date: 10-Jul-23 Related CR: 2023186001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Venous restenosis</i>	Approved as Requested	Proposed PT <i>Venous restenosis</i>	10090039
HLT primary	<i>Cardiac and vascular procedural complications</i>		HLT primary <i>Cardiac and vascular procedural complications</i>	10007602
SOC primary	<i>Injury, poisoning and procedural complications</i>		SOC primary <i>Injury, poisoning and procedural complications</i>	10022117
			HLT secondary <i>Non-site specific necrosis and vascular insufficiency NEC</i>	10029558
			SOC secondary <i>Vascular disorders</i>	10047065

MSSO Comment: The proposal to add a new PT Venous restenosis to primary HLT Cardiac and vascular procedural complications in SOC Injury, poisoning and procedural complications is approved as requested. Venous restenosis refers to the re-occurrence of narrowing of the vein after treatment e.g. with balloon angioplasty or stenting. PT Venous restenosis will also be linked to secondary HLT Non-site specific necrosis and vascular insufficiency NEC and secondary HLT Vascular complications associated with device.

CR Number: 2023191014 Implementation Date: 10-Jul-23 Related CR: 2023186001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Venous restenosis</i>	Approved as Requested	Proposed PT <i>Venous restenosis</i>	10090039
To HLT	<i>Vascular complications associated with device</i>		To HLT <i>Vascular complications associated with device</i>	10069789

MSSO Comment:

Supplemental Update Report

CR Number: 2023186002	Implementation Date: 10-Jul-23	Related CR: 2023186002	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Low phenylalanine</i>	Approved Not as Requested	Proposed LLT <i>Phenylalanine decreased</i>
			10090040 Current
			To PT <i>Amino acid level decreased</i>
			10063260

MSSO Comment: The proposal to add a new term Low phenylalanine is approved but not as requested. Phenyl (Phe) is an essential amino acid that cannot be produced inside the body but must be ingested as dietary protein. Low plasma Phe levels are reported to be associated e.g. with listlessness, eczematous eruptions and failure to gain weight, most often in infants in their first year of life. The requested term will be modified for consistency with other qualified test terms and added as LLT Phenylalanine decreased to PT Amino acid level decreased.

CR Number: 2023187001	Implementation Date: 10-Jul-23	Related CR: 2023187001	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Resectable non-small cell lung cancer</i>	Approved as Requested	Proposed LLT <i>Resectable non-small cell lung cancer</i>
			10090041 Current
			To PT <i>Non-small cell lung cancer</i>
			10061873

MSSO Comment: The proposal to add a new LLT Resectable non-small cell lung cancer is approved as requested. The landscape of resectable non-small cell lung cancer has changed dramatically in recent years, with the advent of neoadjuvant chemotherapy and evaluation of immunotherapy and targeted therapy in adjuvant and neoadjuvant settings. Resectable non-small cell lung cancer will be added as LLT to PT Non-small cell lung cancer.

CR Number: 2023187002	Implementation Date: 13-Jul-23	Related CR: 2023187002	
<u>Change Requested</u>	Rename PT/LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Term to modify	<i>IDH-mutant astrocytoma with homozygous CDK2NA/B deletion</i>	Approved Not as Requested	Term to modify <i>IDH-mutant astrocytoma with homozygous CDK2NA/B deletion</i>
			10089837
Replacement term	<i>IDH-mutant astrocytoma with homozygous CDKN2AB deletion</i>		Replacement term <i>IDH-mutant astrocytoma with homozygous CDKN2A/B deletion</i>
			10089837 Current

MSSO Comment: The proposal to rename PT/LLT IDH-mutant astrocytoma with homozygous CDK2NA/B deletion to IDH-mutant astrocytoma with homozygous CDKN2AB deletion is approved but not as requested. This request is proposed to correct the spelling of "CDK2NA/B" to "CDKN2A/B".

Supplemental Update Report

CR Number: 2023187003 Implementation Date: 13-Jul-23 Related CR: 2023187003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Term to modify	Rename PT/LLT <i>IDH-mutant diffuse glioma with homozygous CDK2NA/B deletion</i>	Approved Not as Requested	Term to modify <i>IDH-mutant diffuse glioma with homozygous CDK2NA/B deletion</i>	10089833
Replacement term	<i>IDH-mutant diffuse glioma with homozygous CDKN2AB deletion</i>		Replacement term <i>IDH-mutant diffuse glioma with homozygous CDKN2A/B deletion</i>	10089833 Current

MSSO Comment: The proposal to rename PT/LLT IDH-mutant diffuse glioma with homozygous CDK2NA/B deletion to IDH-mutant diffuse glioma with homozygous CDKN2AB deletion is approved but not as requested. This request is proposed to correct the spelling of "CDK2NA/B" to "CDKN2A/B".

CR Number: 2023187004 Implementation Date: 13-Jul-23 Related CR: 2023187004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term <i>Aldosterone/renin ratio</i>	Approved as Requested	Proposed PT <i>Aldosterone/renin ratio</i>	10090044
			HLT primary <i>Adrenal cortex tests</i>	10001339
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new term Aldosterone/renin ratio is approved as requested. Aldosterone/renin ratio is the most reliable screening method for primary aldosteronism and its differentiation from secondary aldosteronism. Aldosterone/renin ratio will be added as a new PT to HLT Adrenal cortex tests.

CR Number: 2023187005 Implementation Date: 13-Jul-23 Related CR: 2023187005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Biclonal gammopathy</i>	Approved as Requested	Proposed LLT <i>Biclonal gammopathy</i>	10090045 Current
			To PT <i>Oligoclonal gammopathy</i>	10075625

MSSO Comment: The proposal to add a new LLT Biclonal gammopathy is approved as requested. Monoclonal gammopathy is a group of B-cell disorders which result in the production of a specific and unique monoclonal immunoglobulin (M-component). Biclonal gammopathy is characterized by the simultaneous appearance of two different M-components. The incidence is about 1% of all monoclonal gammopathy. Oligoclonality (incl. biclonal, triclinal) could develop at any time after the diagnosis of monoclonal gammopathy, but it happens more frequently during the first 30 months, with advanced myeloma being the most prevalent underlying disorder. Biclonal gammopathy will be added as sub-concept LLT to PT Oligoclonal gammopathy which was promoted, in a related change, from under PT Hypergammaglobulinaemia and linked to HLT Plasma cell neoplasms NEC (bi-axial at HLG level to primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and to secondary SOC Blood and lymphatic system disorders).

Supplemental Update Report

CR Number: 2023194004 Implementation Date: 13-Jul-23 Related CR: 2023187005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Oligoclonal gammopathy</i>	Approved as Requested	Proposed LLT	
From PT	<i>Hypergammaglobulinaemia</i>		<i>Oligoclonal gammopathy</i>	10075625
HLT primary	<i>Plasma cell neoplasms NEC</i>		From PT	
			<i>Hypergammaglobulinaemia</i>	10020630
			HLT primary	
			<i>Plasma cell neoplasms NEC</i>	10035228
			SOC primary	
			<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary	
			<i>Plasma cell neoplasms NEC</i>	10035228
			SOC secondary	
			<i>Blood and lymphatic system disorders</i>	10005329

MSSO
Comment:

CR Number: 2023187007 Implementation Date: 13-Jul-23 Related CR: 2023187007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Acute isthmus of fauces inflammation</i>	Approved Not as Requested	Proposed LLT	
			<i>Oropharyngeal isthmus inflammation</i>	10090046 Current
			To PT	
			<i>Pharyngeal inflammation</i>	10065716

MSSO
Comment: The proposal to add a new LLT Acute isthmus of fauces inflammation is approved but not as requested. The isthmus of the fauces or the oropharyngeal isthmus is a part of the oropharynx directly behind the mouth cavity, bounded superiorly by the soft palate, laterally by the palatoglossal arches, and inferiorly by the tongue. The requested term will be modified to the more globally prevalent term and added as LLT Oropharyngeal isthmus inflammation to PT Pharyngeal inflammation.

Supplemental Update Report

CR Number: 2023188001 Implementation Date: 13-Jul-23 Related CR: 2023188001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Magnetic resonance imaging prostatic	Rejected		

MSSO Comment: The proposal to add a new term Magnetic resonance imaging prostatic is not approved. The proposed concept is already represented in PT/LLT Magnetic resonance imaging prostate, which was added recently in change request 2023129005, and will be available next September in version 26.1.

CR Number: 2023191002 Implementation Date: 13-Jul-23 Related CR: 2023191002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Meningoencephalitis	Rejected		
From PT	Encephalitis			
HLT primary	Central nervous system and spinal infections			

MSSO Comment: The proposal to promote the LLT Meningoencephalitis from PT Encephalitis to primary HLT Central nervous system and spinal infections in SOC Infections and infestations and secondary HLT Encephalitis NEC in SOC Nervous system disorders is not approved. As Encephalitis is a broad term and means inflammation of the brain, the term Meningoencephalitis is a more specific term meaning the brain including the meninges. Therefore, the LLT Meningoencephalitis is appropriately placed under broad term concept of PT Encephalitis. However, in a related change, the following actions will be taken. The secondary HLT for PT Meningoencephalitis bacterial will be changed from HLT Meningeal bacterial infections to HLT Encephalitis nonviral infectious. In a second step, PT Meningoencephalitis bacterial will be swapped with LLT Encephalitis bacterial. Furthermore, PT Meningoencephalitis herpetic will be swapped with LLT Encephalitis herpes. Those changes are done to have the more severe concepts of encephalitis represented at the PT level for cases where both meningoencephalitis and encephalitis terms are available.

CR Number: 2023194005 Implementation Date: 13-Jul-23 Related CR: 2023191002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Meningoencephalitis bacterial	Approved as Requested	Proposed PT	
With LLT	Encephalitis bacterial		Meningoencephalitis bacterial	10051256 Current
			With LLT	
			Encephalitis bacterial	10065185

MSSO Comment:

Supplemental Update Report

CR Number: 2023194006	Implementation Date: 13-Jul-23	Related CR: 2023191002		
<u>Change Requested</u>	Link (move) a PT to another HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Meningoencephalitis bacterial</i>	Approved as Requested	Proposed PT	
From HLT	<i>Meningeal bacterial infections</i>		<i>Meningoencephalitis bacterial</i>	10051256 Current
To HLT	<i>Encephalitis nonviral infectious</i>		From HLT	
			<i>Meningeal bacterial infections</i>	10027203
			To HLT	
			<i>Encephalitis nonviral infectious</i>	10014600

MSSO
Comment:

CR Number: 2023194007	Implementation Date: 13-Jul-23	Related CR: 2023191002		
<u>Change Requested</u>	Swap a PT with an LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Meningoencephalitis herpetic</i>	Approved as Requested	Proposed PT	
With LLT	<i>Encephalitis herpes</i>		<i>Meningoencephalitis herpetic</i>	10027285 Current
			With LLT	
			<i>Encephalitis herpes</i>	10014590

MSSO
Comment:

CR Number: 2023191003	Implementation Date: 13-Jul-23	Related CR: 2023191003		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Surgical wound oozing</i>	Rejected		

MSSO
Comment: The proposal to add a new term Surgical wound oozing is not approved. Proposed term surgical wound oozing may be represented by LLT Wound oozing and/or other most appropriate LLT term code to represent the concept as a post-operative complication or revision surgery term. Please reference section 3.5.4 When to "split" into more than one MedDRA term in the MedDRA Term selection Points To Consider document.

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CR Number: 2023191004	Implementation Date: 13-Jul-23	Related CR: 2023191004	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>Neuropsychomotor developmental delay</i>		Approved as Requested	Proposed LLT <i>Neuropsychomotor developmental delay</i> 10090047 Current
			To PT <i>Neurodevelopmental delay</i> 10088444

MSSO Comment: The proposal to add a new term Neuropsychomotor developmental delay is approved as requested. There are no standard uniform definitions for Neuropsychomotor developmental delay. The tests for assessing neuropsychomotor developmental delay aim to investigate passive muscle tone (shoulders, limbs, and trunk), standing and synkinesia, static and dynamic balance, tonic laterality (extensibility and dangling of hands and feet to identify the tonic dominant side), laterality of use, fine-digit movements, digital tactile gnosis, and body spatial integration (knowing left from right: for oneself and that of others, and with regard to objects). Neuropsychomotor developmental delay will be added as sub-concept LLT under PT Neurodevelopmental delay.

CR Number: 2023191005	Implementation Date: 13-Jul-23	Related CR: 2023191005	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT <i>Tuberculosis pleural effusion</i>		Approved Not as Requested	Proposed LLT <i>Tuberculosis pleural effusion</i> 10090048 Current
To PT <i>Tuberculous pleurisy</i>			To PT <i>Tuberculous pleurisy</i> 10045104

MSSO Comment: The proposal to add a new LLT Tuberculosis pleural effusion to PT Tuberculous pleurisy is approved but not as requested. Development of tuberculous pleural effusion may occur as a result of delayed hypersensitivity reaction to mycobacteria or mycobacterial antigens in the pleural space in sensitized individuals or by rupture of a subpleural focus of pulmonary disease into the pleural space. Proposed term will be modified for better wording and added as synonym LLT Tuberculous pleural effusion under PT Tuberculous pleurisy.

CR Number: 2023192001	Implementation Date: 13-Jul-23	Related CR: 2023192001	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>Myocardial infarction with non-obstructive coronary arteries</i>		Rejected	

MSSO Comment: The proposal to add a new term Myocardial infarction with non-obstructive coronary arteries is not approved. The requested term can be represented by LLT Myocardial infarction with nonobstructive coronary arteries.

Supplemental Update Report

CR Number: 2023193001 **Implementation Date:** 13-Jul-23 **Related CR:** 2023193001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Abdominal pain of unknown origin</i>	Approved as Requested	Proposed LLT	
To PT	<i>Abdominal pain</i>		<i>Abdominal pain of unknown origin</i>	10090049 Current
			To PT	
			<i>Abdominal pain</i>	10000081

MSSO Comment: The proposal to add a new LLT Abdominal pain of unknown origin to PT Abdominal pain is approved as requested. For abdominal pain it may be an important additional clinical information if the origin is unknown, especially pediatric population.

CR Number: 2023193002 **Implementation Date:** 20-Jul-23 **Related CR:** 2023193002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Atypical nevus</i>	Approved as Requested	Proposed LLT	
To PT	<i>Dysplastic naevus</i>		<i>Atypical nevus</i>	10090050 Current
			To PT	
			<i>Dysplastic naevus</i>	10062805

MSSO Comment: The proposal to add a new LLT Atypical nevus to PT Dysplastic naevus is approved as requested. An atypical nevus, also called a dysplastic nevus or Clark's nevus, is a benign melanocytic skin lesion that may share some of the clinical or microscopic features with malignant melanoma, but is not a melanoma or any form of cancer. In a related change, the British spelled LLT Atypical naevus will also be added to PT Dysplastic naevus. Synonym LLT Clark's nevus will also be added, together with British English counterpart LLT Clark's naevus, to PT Dysplastic naevus.

CR Number: 2023201020 **Implementation Date:** 20-Jul-23 **Related CR:** 2023193002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Atypical naevus</i>	Approved as Requested	Proposed LLT	
To PT	<i>Dysplastic naevus</i>		<i>Atypical naevus</i>	10090052 Current
			To PT	
			<i>Dysplastic naevus</i>	10062805

MSSO Comment:

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CR Number: 2023201021		Implementation Date: 20-Jul-23	Related CR: 2023193002	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Clark's naevus</i>	Approved as Requested	Proposed LLT <i>Clark's naevus</i>	10090053 Current
To PT	<i>Dysplastic naevus</i>		To PT <i>Dysplastic naevus</i>	10062805

MSSO
Comment:

CR Number: 2023201022		Implementation Date: 20-Jul-23	Related CR: 2023193002	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Clark's nevus</i>	Approved as Requested	Proposed LLT <i>Clark's nevus</i>	10090051 Current
To PT	<i>Dysplastic naevus</i>		To PT <i>Dysplastic naevus</i>	10062805

MSSO
Comment:

CR Number: 2023194001		Implementation Date: 20-Jul-23	Related CR: 2023194001	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>TRISECTIONECTOMY</i>	Approved Not as Requested	Proposed LLT <i>Trisectionectomy</i>	10090054 Current
			To PT <i>Hepatectomy</i>	10061997

MSSO Comment: The proposal to add a new LLT TRISECTIONECTOMY is approved but not as requested. Trisectionectomy is a kind of partial hepatectomy which is an option to treat extensive liver malignancy, including colorectal liver metastases and remains one of the most challenging major hepatectomies to perform. Left hepatic trisectionectomy is defined as excision of Couinaud liver segments 2, 3, 4, 5 and 8, with or without segment 1; whereas right hepatic trisectionectomy requires excision of segments 4, 5, 6, 7 and 8, with or without segment 1. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as LLT Trisectionectomy to the PT Hepatectomy.

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CR Number: 2023194002	Implementation Date: 20-Jul-23	Related CR: 2023194002	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New Term			
Proposed Term <i>Vaping</i>		Rejected	

MSSO Comment: The proposal to add a new term Vaping is not approved. Proposed concept may be represented by existing LLT Vapor cigarette smoker.

CR Number: 2023194003	Implementation Date: 20-Jul-23	Related CR: 2023194003	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New LLT			
Proposed LLT <i>Rectal packing</i>		Approved Not as Requested	Proposed PT <i>Rectal tamponade</i> 10090055 HLT primary <i>Anorectal therapeutic procedures</i> 10002580 SOC primary <i>Surgical and medical procedures</i> 10042613

MSSO Comment: The proposal to add a new LLT Rectal packing is approved but not as requested. Rectal packing or tamponade is often indicated after certain surgical procedures and should provide for hemostasis, but it should also indicate persistent bleeding. Rectal packing has been a useful adjunct in many postoperative rectal procedures, especially after hemorrhoidectomy. The proposed term will be renamed for clarity to PT Rectal tamponade and added to HLT Anorectal therapeutic procedures.

CR Number: 2023194008	Implementation Date: 12-Sep-23	Related CR: 2023194008	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New LLT			
Proposed LLT <i>Medical aid in dying</i>		Approved Not as Requested After Suspension	Proposed PT <i>Medical aid in dying</i> 10090248 HLT primary <i>Therapeutic procedures NEC</i> 10027700 SOC primary <i>Surgical and medical procedures</i> 10042613

MSSO Comment: The proposal to add a new LLT Medical aid in dying is approved but not as requested after suspension. Medical aid in dying is available only to terminally ill patients who will soon die. Medical aid in dying will be added as a PT to HLT Therapeutic procedures NEC.

Supplemental Update Report

CR Number: 2023198001 Implementation Date: 20-Jul-23 Related CR: 2023198001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Adynamia</i>	Rejected		
From PT	<i>Asthenia</i>			

MSSO Comment: The proposal to promote the LLT *Adynamia* from PT *Asthenia* is not approved. *Adynamia* is best placed as LLT to PT *Asthenia* aligned with e.g. LLT Feeling of total lack of energy. However, in a related change, PT *Asthenia* will be linked to secondary HLT Mood disorders NEC.

CR Number: 2023201023 Implementation Date: 20-Jul-23 Related CR: 2023198001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Asthenia</i>	Approved as Requested	Proposed PT	
To HLT	<i>Mood disorders NEC</i>		<i>Asthenia</i>	10003549
			To HLT	
			<i>Mood disorders NEC</i>	10027948

MSSO Comment:

CR Number: 2023198002 Implementation Date: 20-Jul-23 Related CR: 2023198002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Malignant ossifying fibromyxoid tumor</i>	Approved as Requested	Proposed LLT	
			<i>Malignant ossifying fibromyxoid tumor</i>	10090057 Current
			To PT	
			<i>Malignant ossifying fibromyxoid tumour</i>	10090056

MSSO Comment: The proposal to add a new LLT *Malignant ossifying fibromyxoid tumor* is approved as requested. *Ossifying fibromyxoid tumors* are rare, soft tissue neoplasms that develop in the subcutaneous layer of the skin. *Ossifying fibromyxoid tumors* are a unique mesenchymal tumor that can mimic other dermatological disorders and go undiagnosed in many patients. According to the Folpe and Weiss classification model, there are typical, atypical and malignant *ossifying fibromyxoid tumors*. *Malignant ossifying fibromyxoid tumor* will be added as LLT under PT *Malignant ossifying fibromyxoid tumour*, which will be added, in a related change, to primary HLT *Soft tissue neoplasms malignant and unspecified NEC (excl sarcomas)* and to secondary HLT *Malignant musculoskeletal and connective tissue neoplasms*.

Supplemental Update Report

CR Number: 2023201024 Implementation Date: 20-Jul-23 Related CR: 2023198002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT	Approved as Requested	Proposed PT	
HLT primary	<i>Malignant ossifying fibromyxoid tumour</i>		<i>Malignant ossifying fibromyxoid tumour</i>	10090056
SOC primary	<i>Soft tissue neoplasms malignant and unspecified NEC (excl sarcomas)</i>		HLT primary	
	<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>		<i>Soft tissue neoplasms malignant and unspecified NEC (excl sarcomas)</i>	10041293
			SOC primary	
			<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary	
			<i>Malignant musculoskeletal and connective tissue neoplasms</i>	10025681
			SOC secondary	
			<i>Musculoskeletal and connective tissue disorders</i>	10028395

MSSO
Comment:

CR Number: 2023198003 Implementation Date: 20-Jul-23 Related CR: 2023198003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT	Approved as Requested	Proposed LLT	
To PT	<i>Oropharyngeal chlamydia infection</i>		<i>Oropharyngeal chlamydia infection</i>	10090058 Current
	<i>Pharyngeal chlamydia infection</i>		To PT	
			<i>Pharyngeal chlamydia infection</i>	10034820

MSSO The proposal to add a new LLT Oropharyngeal chlamydia infection to PT Pharyngeal chlamydia infection is approved as requested as subconcept LLT.
Comment:

Supplemental Update Report

CR Number: 2023198004	Implementation Date: 20-Jul-23	Related CR: 2023198004	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New Term			
Proposed Term <i>Refractory sprue</i>		Approved as Requested	Proposed LLT <i>Refractory sprue</i> 10090059 Current
			To PT <i>Sprue-like enteropathy</i> 10079622

MSSO Comment: The proposal to add a new term Refractory sprue is approved as requested. A minority of patients with celiac-like enteropathy are resistant to gluten-free diet, so-called refractory sprue, or unclassified sprue. Refractory sprue is a diagnosis of exclusion; all other causes of a celiac-like enteropathy must be eliminated before a diagnosis of refractory sprue can be made. Refractory sprue will be added as an LLT to PT Sprue-like enteropathy. In a related change, PT Sprue-like enteropathy will be linked to secondary HLT Autoimmune disorders NEC.

CR Number: 2023201025	Implementation Date: 20-Jul-23	Related CR: 2023198004	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Link a PT to a HLT			
Proposed PT <i>Sprue-like enteropathy</i>		Approved as Requested	Proposed PT <i>Sprue-like enteropathy</i> 10079622
To HLT <i>Autoimmune disorders NEC</i>			To HLT <i>Autoimmune disorders NEC</i> 10027657

MSSO Comment:

CR Number: 2023198005	Implementation Date: 20-Jul-23	Related CR: 2023198005	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New PT			
Proposed PT <i>Tumor related chest pain</i>		Rejected	
HLT primary <i>Pain and discomfort NEC</i>			
SOC primary <i>General disorders and administration site conditions</i>			

MSSO Comment: The proposal to add a new PT Tumor related chest pain to primary HLT Pain and discomfort NEC in SOC General disorders and administration site conditions and secondary HLT Oncologic complications and emergencies in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is not approved. MedDRA cannot provide combination terms for all possible cancer related/associated regional pain. Please consider representing this type of report using more than one LLT - e.g. LLT Chest pain, LLT Musculoskeletal chest pain, LLT Non-cardiac chest pain and/or LLT Tumor pain and the underlying cause - such as LLT Lung cancer. 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: 2023199001 Implementation Date: 20-Jul-23 Related CR: 2023199001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Hashitoxicosis</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Immune system disorders</i>		<i>Hashitoxicosis</i>	10067873
New Primary SOC	<i>Endocrine disorders</i>		Old Primary SOC	
			<i>Immune system disorders</i>	10021428
			New Primary SOC	
			<i>Endocrine disorders</i>	10014698

MSSO Comment: The proposal to reassign the primary SOC of PT Hashitoxicosis from current SOC Immune system disorders to SOC Endocrine disorders is approved as requested as organ specificity prevails over etiology for concepts. For the same reason primary SOC will be swapped from SOC Immune system disorders to SOC Endocrine disorders for PT Atrophic thyroiditis. Furthermore, PT Insulin autoimmune syndrome will be moved from HLT Diabetes mellitus (incl subtypes) and to HLT Hypoglycaemic conditions NEC. Then the primary SOC for PT Insulin autoimmune syndrome will be re-assigned from SOC Immune system disorders to SOC Metabolism and nutrition disorders.

CR Number: 2023201016 Implementation Date: 20-Jul-23 Related CR: 2023199001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Atrophic thyroiditis</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Immune system disorders</i>		<i>Atrophic thyroiditis</i>	10077172
New Primary SOC	<i>Endocrine disorders</i>		Old Primary SOC	
			<i>Immune system disorders</i>	10021428
			New Primary SOC	
			<i>Endocrine disorders</i>	10014698

MSSO Comment:

Supplemental Update Report

CR Number: 2023201017		Implementation Date: 20-Jul-23	Related CR: 2023199001	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Reassign Primary SOC <i>Insulin autoimmune syndrome</i>	Approved as Requested	Proposed PT <i>Insulin autoimmune syndrome</i>	10022472
Old Primary SOC	<i>Immune system disorders</i>		Old Primary SOC	
New Primary SOC	<i>Metabolism and nutrition disorders</i>		New Primary SOC <i>Metabolism and nutrition disorders</i>	10021428 10027433

MSSO
Comment:

CR Number: 2023201018		Implementation Date: 20-Jul-23	Related CR: 2023199001	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Insulin autoimmune syndrome</i>	Approved as Requested	Proposed PT <i>Insulin autoimmune syndrome</i>	10022472
From HLT	<i>Diabetes mellitus (incl subtypes)</i>		From HLT	
To HLT	<i>Hypoglycaemic conditions NEC</i>		To HLT <i>Hypoglycaemic conditions NEC</i>	10012602 10021001

MSSO
Comment:

CR Number: 2023200007		Implementation Date: 26-Jul-23	Related CR: 2023200007	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Oxygen therapy glasses</i>	Approved Not as Requested	Proposed LLT <i>Oxygen therapy glasses application</i>	10090060 Current
			To PT <i>Oxygen therapy</i>	10078798

MSSO
Comment: The proposal to add a new LLT Oxygen therapy glasses is approved but not as requested. Oxygen therapy glasses are listed as a Class 1 medical device designed for people who use oxygen to support and facilitate their breathing. The requested term will be modified to clarify as an procedural term within the scope of MedDRA and added as LLT Oxygen therapy glasses application to PT Oxygen therapy.

Supplemental Update Report

CR Number: 2023200008 Implementation Date: 26-Jul-23 Related CR: 2023200008

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Add a New PT <i>Cerebellar toxicity</i>	Approved as Requested	Proposed LLT <i>Cerebellar toxicity</i>	10090061 Current
			To PT <i>Neurotoxicity</i>	10029350

MSSO Comment: The proposal to add a new PT Cerebellar toxicity is approved as requested. Cerebellar toxicity is a known potential adverse effect of high-dose of some chemotherapy drugs or toxic substances. Cerebellar toxicity will be added as a sub-concept LLT to PT Neurotoxicity.

CR Number: 2023200009 Implementation Date: 26-Jul-23 Related CR: 2023200009

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term <i>Pleural fluid lymphocytosis</i>	Approved Not as Requested	Proposed LLT <i>Pleural fluid lymphocytes increased</i>	10090062 Current
			To PT <i>White blood cell count increased</i>	10047943

MSSO Comment: The proposal to add a new term Pleural fluid lymphocytosis is approved but not as requested. The proposed term will be modified to an investigation term as LLT Pleural fluid lymphocytes increased and will be added to PT White blood cell count increased, aligned with existing LLT Pleural fluid leukocyte count increased.

CR Number: 2023200010 Implementation Date: 26-Jul-23 Related CR: 2023200010

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term <i>Acute exacerbation of fibrosing hypersensitivity pneumonitis</i>	Approved Not as Requested	Proposed LLT <i>Fibrotic hypersensitivity pneumonitis</i>	10090063 Current
			To PT <i>Hypersensitivity pneumonitis</i>	10081988

MSSO Comment: The proposal to add a new term Acute exacerbation of fibrosing hypersensitivity pneumonitis is approved but not as requested. Fibrotic hypersensitivity pneumonitis is a chronic, often progressive fibrosing form of hypersensitivity pneumonitis and is also often categorized as a form of interstitial lung disease. Proposed term will be modified to form referenced in literature and added as LLT Fibrotic hypersensitivity pneumonitis under PT Hypersensitivity pneumonitis. The exacerbation of the condition may be represented by the LLT Exacerbation of disease.

Supplemental Update Report

CR Number: 2023200011 Implementation Date: 12-Sep-23 Related CR: 2023200011

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT <i>Prosthetic cardiac valve obstruction</i>	Approved Not as Requested After Suspension	Proposed PT <i>Prosthetic cardiac valve obstruction</i>	10090249
		HLT primary <i>Cardiac complications associated with device</i>	10069784
		SOC primary <i>General disorders and administration site conditions</i>	10018065
		HLT secondary <i>Device issues NEC</i>	10069794
		SOC secondary <i>Product issues</i>	10077536

MSSO Comment: The proposal to add a new LLT Prosthetic cardiac valve obstruction is approved but not as requested after suspension. Prosthetic valve obstruction is a condition associated with significant morbidity and mortality. The most common causes of obstruction include valve thrombosis or pannus formation. Prosthetic cardiac valve obstruction will be added as new PT under primary HLT Cardiac complications associated with device and secondary HLT Device issues NEC.

CR Number: 2023201001 Implementation Date: 26-Jul-23 Related CR: 2023201001

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>SPONDYLECTOMY</i>	Approved Not as Requested	Proposed PT <i>Spondylectomy</i>	10090067
		HLT primary <i>Spine and spinal cord therapeutic procedures</i>	10041590
		SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new term SPONDYLECTOMY is approved but not as requested. En bloc spondylectomy is a surgical procedure that enables the complete resection of a vertebra for the total removal of a vertebral malignant lesion. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as PT Spondylectomy to the HLT Spine and spinal cord therapeutic procedures. In a related change, the PT Spinal corpectomy, which is a kind of partial spondylectomy removing the body of the vertebra, will be demoted under the new PT Spondylectomy. Additionally, a new LLT Total en bloc spondylectomy will also be added to this new PT Spondylectomy.

Supplemental Update Report

CR Number: 2023207339	Implementation Date: 26-Jul-23	Related CR: 2023201001	
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>
PT to merge	<i>Spinal corpectomy</i>	Approved as Requested	PT to merge
To PT	<i>Spondylectomy</i>		<i>Spinal corpectomy</i>
			10063841 Current
			To PT
			<i>Spondylectomy</i>
			10090067

MSSO
Comment:

CR Number: 2023207340	Implementation Date: 26-Jul-23	Related CR: 2023201001	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Total en bloc spondylectomy</i>	Approved as Requested	Proposed LLT
To PT	<i>Spondylectomy</i>		<i>Total en bloc spondylectomy</i>
			10090071 Current
			To PT
			<i>Spondylectomy</i>
			10090067

MSSO
Comment:

CR Number: 2023201002	Implementation Date: 26-Jul-23	Related CR: 2023201002	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Embryonic stem cell test</i>	Approved Not as Requested	Proposed PT
			<i>Embryotoxicity test</i>
			10090068
			HLT primary
			<i>Toxicology laboratory analyses</i>
			10044261
			SOC primary
			<i>Investigations</i>
			10022891

MSSO
Comment: The proposal to add a new term Embryonic stem cell test is approved but not as requested. Embryonic stem cell test is a novel in vitro method to predict human developmental toxicity. Human-induced pluripotent stem cells obtained by conversion of adult somatic cells can differentiate into most cell types of the body, and be used in different toxicity models - such the evaluation of the appearance of contractions on cells differentiated into cardiomyocytes - after the exposure to different agents, thus helping to detect very early possible toxicity of the human embryo. The requested term will be modified and added as Embryotoxicity test which will be added as a PT to the HLT Toxicology laboratory analyses.

Supplemental Update Report

CR Number: 2023201003	Implementation Date: 26-Jul-23	Related CR: 2023201003		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Sialoendoscopy</i>	Approved as Requested	Proposed LLT <i>Sialoendoscopy</i> To PT <i>Sialendoscopy</i>	10090079 Current 10089291
MSSO Comment:	The proposal to add a new term Sialoendoscopy is approved as requested. Sialoendoscopy will be added as synonym LLT to PT Sialendoscopy which will be available in MedDRA version 26.1.			

CR Number: 2023201004	Implementation Date: 26-Jul-23	Related CR: 2023201004		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Trypophobia</i>	Approved as Requested	Proposed PT <i>Trypophobia</i> HLT primary <i>Fear symptoms and phobic disorders (incl social phobia)</i> SOC primary <i>Psychiatric disorders</i>	10090069 10068299 10037175
MSSO Comment:	The proposal to add a new term Trypophobia is approved as requested. Trypophobia usually involves an intense and disproportionate fear towards holes, repetitive patterns, protrusions and, in general, images that present high-contrast energy at low and midrange spatial frequencies. Trypophobia will be added as a PT with a primary link to the HLT Fear symptoms and phobic disorders (incl social phobia).			

CR Number: 2023201005	Implementation Date: 26-Jul-23	Related CR: 2023201005		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Septomeatoplasty</i>	Approved as Requested	Proposed LLT <i>Septomeatoplasty</i> To PT <i>Nasal septal operation</i>	10090075 Current 10028760
MSSO Comment:	The proposal to add a new term Septomeatoplasty is approved as requested. Septomeatoplasty is an intervention which combines a Deviated septum repair with a Sinus antrostomy (both existing MedDRA terms). Septomeatoplasty will be added as LLT under PT Nasal septal operation, in line with the existing anatomically-combined LLT Septoturbinoplasty.			

Supplemental Update Report

CR Number: 2023201006 Implementation Date: 26-Jul-23 Related CR: 2023201006

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Dursun syndrome</i>	Approved as Requested	Proposed PT <i>Dursun syndrome</i>	10090065
		HLT primary <i>Gene mutations and other alterations NEC</i>	10083625
		SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
		HLT secondary <i>Myocardial disorders NEC</i>	10028590
		SOC secondary <i>Cardiac disorders</i>	10007541

MSSO Comment: The proposal to add a new term Dursun syndrome is approved as requested. Dursun syndrome (DS) is a rare congenital disorder caused by mutations of the G6PC3 gene. The clinical hallmarks of DS are atrial septal defect, pulmonary arterial hypertension, and leukopenia. Dursun syndrome will be added as PT to primary HLT Gene mutations and other alterations NEC and secondary HLT Myocardial disorders NEC and secondary HLT Neutropenias.

CR Number: 2023207341 Implementation Date: 26-Jul-23 Related CR: 2023201006

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT <i>Dursun syndrome</i>	Approved as Requested	Proposed PT <i>Dursun syndrome</i>	10090065
To HLT <i>Neutropenias</i>		To HLT <i>Neutropenias</i>	10029355

MSSO Comment:

CR Number: 2023201007 Implementation Date: 26-Jul-23 Related CR: 2023201007

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Corticotroph adenomas</i>	Approved Not as Requested	Proposed LLT <i>Corticotroph adenoma</i>	10090077 Current
		To PT <i>ACTH-producing pituitary tumour</i>	10000613

MSSO Comment: The proposal to add a new term Corticotroph adenomas is approved but not as requested. Pituitary tumors that make adrenocorticotrophic hormone are called corticotroph adenomas. The requested term will be added in singular form as LLT Corticotroph adenoma to PT ACTH-producing pituitary tumour.

Supplemental Update Report

CR Number: 2023201008 Implementation Date: 26-Jul-23 Related CR: 2023201008

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Chung-Jansen syndrome</i>	Approved as Requested	Proposed PT <i>Chung-Jansen syndrome</i>	10090066
			HLT primary <i>Gene mutations and other alterations NEC</i>	10083625
			SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Intellectual disabilities</i>	10077548
			SOC secondary <i>Nervous system disorders</i>	10029205

MSSO Comment: The proposal to add a new term Chung-Jansen syndrome is approved as requested. Chung-Jansen syndrome, also called PHIP-related disorder is caused by a heterozygous mutation along the PHIP gene (6q14.1). Individuals with this disorder typically have developmental delay, impaired intellectual development or learning difficulties, behavioral abnormalities, dysmorphic features, and obesity. The severity of the phenotype and additional features are variable. Chung-Jansen syndrome will be added as PT to primary HLT Gene mutations and other alterations NEC and to secondary HLT Intellectual disabilities.

CR Number: 2023201009 Implementation Date: 26-Jul-23 Related CR: 2023201009

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Incarcerated bowel</i>	Approved as Requested	Proposed LLT <i>Incarcerated bowel</i>	10090076 Current
			To PT <i>Incarcerated hernia</i>	10021610

MSSO Comment: The proposal to add a new term Incarcerated bowel is approved as requested. The loops of bowel are in the abdominal and pelvic cavity. They are surrounded by abdominal wall and pelvic floor where they can freely move. If there is any defect in the abdominal wall or pelvic floor (abdominal wall hernia or pelvic floor hernia) or any abnormal opening/hole inside the abdominal cavity created by scar secondary to previous surgery or infection (internal hernia) then a loop of intestine could potentially get stuck in that defect which is called incarcerated bowel. Incarcerated bowel will be added as synonym LLT to PT Incarcerated hernia.

Supplemental Update Report

CR Number: 2023201010 Implementation Date: 26-Jul-23 Related CR: 2023201010

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New Term Proposed Term <i>Ovarian papilloma</i>	Approved as Requested	Proposed PT <i>Ovarian papilloma</i>	10090070
		HLT primary <i>Ovarian neoplasms benign</i>	10033273
		SOC primary <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
		HLT secondary <i>Ovarian and fallopian tube cysts and neoplasms</i>	10033121
		SOC secondary <i>Reproductive system and breast disorders</i>	10038604

MSSO Comment: The proposal to add a new term Ovarian papilloma is approved as requested. Superficial papilloma of the ovary is a rare benign ovarian finding with similar appearance to borderline and malignant papillary ovarian tumors. Ovarian papilloma will be added as PT to primary HLT Ovarian neoplasms benign, to secondary HLT Ovarian and fallopian tube cysts and neoplasms and to secondary HLT Papilloma viral infections.

CR Number: 2023207342 Implementation Date: 26-Jul-23 Related CR: 2023201010

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Link a PT to a HLT Proposed PT <i>Ovarian papilloma</i>	Approved as Requested	Proposed PT <i>Ovarian papilloma</i>	10090070
To HLT <i>Papilloma viral infections</i>		To HLT <i>Papilloma viral infections</i>	10033724

MSSO Comment:

Supplemental Update Report

CR Number: 2023201011 Implementation Date: 26-Jul-23 Related CR: 2023201011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Mural Thrombi	Approved Not as Requested	Proposed LLT	
To PT	Intracardiac thrombus		Mural thrombus	10090073 Current
			To PT	
			Cardiac ventricular thrombosis	10053994

MSSO Comment: The proposal to add a new LLT Mural Thrombi to PT Intracardiac thrombus is approved but not as requested. Mural thrombus are thrombus attached to the wall of the heart adjacent to an area of diseased endocardium, or to the aortic wall overlying an intimal lesion. Proposed term will be modified for MedDRA capitalization conventions and into singular form for better alignment and added as LLT Mural thrombus under PT Cardiac ventricular thrombosis. In a related change, PT Intracardiac thrombus will be demoted under PT Cardiac ventricular thrombosis for better alignment of concepts.

CR Number: 2023207343 Implementation Date: 26-Jul-23 Related CR: 2023201011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	Intracardiac thrombus	Approved as Requested	PT to merge	
To PT	Cardiac ventricular thrombosis		Intracardiac thrombus	10048620 Current
			To PT	
			Cardiac ventricular thrombosis	10053994

MSSO Comment:

CR Number: 2023201012 Implementation Date: 26-Jul-23 Related CR: 2023201012

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Mixed angina pectoris	Approved as Requested	Proposed LLT	
			Mixed angina pectoris	10090074 Current
			To PT	
			Angina pectoris	10002383

MSSO Comment: The proposal to add a new term Mixed angina pectoris is approved as requested. Mixed angina pectoris patients can experience angina both as a result of an excessive increase in myocardial demand with exertion, and at rest as a result of the transient impairment of coronary blood flow supply, without a clear predominance of either occurrence. Mixed angina pectoris will be added as subconcept LLT under PT Angina pectoris.

Supplemental Update Report

CR Number: 2023201013	Implementation Date: 26-Jul-23	Related CR: 2023201013	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New Term			
Proposed Term <i>BICHECTOMY</i>		Approved Not as Requested	Proposed LLT <i>Bichectomy</i> 10090078 Current
			To PT <i>Plastic surgery to the face</i> 10035509

MSSO Comment: The proposal to add a new term BICHECTOMY is approved but not as requested. A bichectomy is a straightforward plastic surgery designed to narrow out the mid to lower part of the face. In the procedure there is removal of the buccal fat of the cheeks, resulting in prominent cheekbones, a better-defined jaw, and an overall slimmer, more sculpted look. Proposed term will be modified for MedDRA capitalization conventions and added as LLT Bichectomy under PT Plastic surgery to the face.

CR Number: 2023201014	Implementation Date: 26-Jul-23	Related CR: 2023201014	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New Term			
Proposed Term <i>Pelvic venous embolism</i>		Approved Not as Requested	Proposed PT <i>Pelvic vein embolisation</i> 10090064
			HLT primary <i>Venous therapeutic procedures</i> 10047231
			SOC primary <i>Surgical and medical procedures</i> 10042613

MSSO Comment: The proposal to add a new term Pelvic venous embolism is approved but not as requested. Pelvic vein embolization is performed as an outpatient procedure using xray or fluoroscopic guidance. It is a incision-less procedure where a catheter is threaded through the groin into the veins that are not working correctly into the pelvis, around the ovaries. Proposed term will be modified into a procedural term as referenced in justification and added as PT Pelvic vein embolisation under HLT Venous therapeutic procedures. In a related change, the American English counterpart LLT Pelvic vein embolization will also be added under the new PT Pelvic vein embolisation.

CR Number: 2023207344	Implementation Date: 26-Jul-23	Related CR: 2023201014	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New LLT			
Proposed LLT <i>Pelvic vein embolization</i>		Approved as Requested	Proposed LLT <i>Pelvic vein embolization</i> 10090072 Current
To PT <i>Pelvic vein embolisation</i>			To PT <i>Pelvic vein embolisation</i> 10090064

MSSO Comment:

Supplemental Update Report

CR Number: 2023201015 **Implementation Date:** 26-Jul-23 **Related CR:** 2023201015

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Cytokine release reaction	Rejected		

MSSO Comment: The proposal to add a new LLT Cytokine release reaction is not approved. The proposed is represented by LLT Cytokine release syndrome.

CR Number: 2023201019 **Implementation Date:** 26-Jul-23 **Related CR:** 2023201019

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Renal stone passed naturally	Approved Not as Requested	Proposed LLT Spontaneous passage of renal stone To PT Nephrolithiasis	10090080 Current 10029148

MSSO Comment: The proposal to add a new term Renal stone passed naturally is approved but not as requested. Some small stones pass through the kidney and urinary tract with little discomfort, while larger ones can block the flow of urine and impair kidney function. The requested term will be modified and added as LLT Spontaneous passage of renal stone under PT Nephrolithiasis.

CR Number: 2023201026 **Implementation Date:** 26-Jul-23 **Related CR:** 2023201026

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Serous surface infection	Rejected		

MSSO Comment: The proposal to add a new PT Serous surface infection is not approved. Proposed term is ambiguous and may refer to multiple site/organ locations without context.

Supplemental Update Report

CR Number: 2023201027 Implementation Date: 26-Jul-23 Related CR: 2023201027

[Change Requested](#) Link (move) a PT to another HLT [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed PT Scar excision Rejected

From HLT Skin lesion excisions

To HLT Therapeutic procedures NEC

MSSO Comment: The proposal to move the PT Scar excision from HLT Skin lesion excisions to HLT Therapeutic procedures NEC is not approved. The placement of LLT/PT Scar excision is appropriately placed as for purposes of MedDRA, scar is associated with skin (as seen in linkage of PT Scar under primary HLT Skin injuries NEC).

CR Number: 2023201028 Implementation Date: 26-Jul-23 Related CR: 2023201028

[Change Requested](#) Add a New LLT [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed LLT Fungemia Candidiasis Rejected

MSSO Comment: The proposal to add a new LLT Fungemia Candidiasis is not approved. The requested term is represented by LLT Candidaemia.

CR Number: 2023202001 Implementation Date: 26-Jul-23 Related CR: 2023202001

[Change Requested](#) Add a New LLT [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed LLT Multiplex PCR test Approved as Requested Proposed LLT Multiplex PCR test 10090081 Current
To PT Multipathogen PCR test 10077018

MSSO Comment: The proposal to add a new LLT Multiplex PCR test is approved as requested. Multiplex PCR is a type of polymerase chain reaction which makes possible to rapidly identify, genotype and quantify multiple DNA targets simultaneously in a single reaction. Multiplex PCR test will be added as a synonym LLT to PT Multipathogen PCR test.

Supplemental Update Report

CR Number: 2023202003 **Implementation Date:** 26-Jul-23 **Related CR:** 2023202003

[Change Requested](#) Add a New PT [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed PT *Overdose and underdose symptoms fluctuating* Rejected

HLT primary *General signs and symptoms NEC*

SOC primary *General disorders and administration site conditions*

MSSO Comment: The proposal to add a new PT Overdose and underdose symptoms fluctuating to primary HLT General signs and symptoms NEC in SOC General disorders and administration site conditions is not approved. Proposed term represents multiple concepts and does not describe specific signs or symptoms, and is too vague for inclusion in MedDRA. Instead, it is suggested to code the reported symptoms and the corresponding "overdose" and/or "underdose" concept if criteria are met. Depending upon the scenario reported, you may also consider LLT Drug level fluctuating and/or LLT Therapeutic product effect variable as an option.

CR Number: 2023202004 **Implementation Date:** 26-Jul-23 **Related CR:** 2023202004

[Change Requested](#) Add a New LLT [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed LLT *Resectoscope procedure* Rejected

MSSO Comment: The proposal to add a new LLT Resectoscope procedure is not approved. Resectoscope can be used for Transurethral resection of the prostate in male or e.g. endometrial ablation or myomectomy in females. Without anatomical location the concept is too broad.

CR Number: 2023203001 **Implementation Date:** 26-Jul-23 **Related CR:** 2023203001

[Change Requested](#) Add a New LLT [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed LLT *Drug-induced sarcoidosis- like reaction* Rejected

MSSO Comment: The proposal to add a new LLT Drug-induced sarcoidosis- like reaction 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. However, please see LLT/PT Sarcoid-like reaction to represent the concept.

Supplemental Update Report

CR Number: 2023205001 Implementation Date: 26-Jul-23 Related CR: 2023205001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Music therapy	Approved as Requested	Proposed LLT Music therapy	10090082 Current
			To PT Psychotherapy	10037247

MSSO Comment: The proposal to add a new term Music therapy is approved as requested. Music therapy is the use of music and/or elements of music (like sound, rhythm and harmony) in psychotherapy or to accomplish goals, like reducing stress or improving quality of life. It should be provided by a qualified professional who has completed an approved music therapy program. Music therapy will be added as LLT under PT Psychotherapy, aligned with existing LLT Art therapy.

CR Number: 2023205002 Implementation Date: 26-Jul-23 Related CR: 2023205002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Interleukin gene expression	Approved as Requested	Proposed PT Interleukin gene expression	10090085
			HLT primary Cell marker analyses	10072981
			SOC primary Investigations	10022891

MSSO Comment: The proposal to add a new term Interleukin gene expression is approved as requested. Interleukins have a critical role in cancer development, progression and control. Interleukins can nurture an environment enabling and favouring cancer growth while simultaneously being essential for a productive tumour-directed immune response. Interleukin gene expression will be added as new PT under HLT Cell marker analyses.

CR Number: 2023205003 Implementation Date: 26-Jul-23 Related CR: 2023205003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Interleukin gene expression positive	Approved as Requested	Proposed PT Interleukin gene expression positive	10090086
			HLT primary Cell marker analyses	10072981
			SOC primary Investigations	10022891

MSSO Comment: The proposal to add a new term Interleukin gene expression positive is approved as requested. Interleukins have a critical role in cancer development, progression and control. Interleukins can nurture an environment enabling and favouring cancer growth while simultaneously being essential for a productive tumour-directed immune response. Interleukin gene expression positive will be added as new PT under HLT Cell marker analyses.

Supplemental Update Report

CR Number: 2023205004	Implementation Date: 26-Jul-23	Related CR: 2023205004		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Interleukin gene expression negative</i>	Approved as Requested	Proposed PT <i>Interleukin gene expression negative</i>	10090083
			HLT primary <i>Cell marker analyses</i>	10072981
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new term Interleukin gene expression negative is approved as requested. Interleukins have a critical role in cancer development, progression and control. Interleukins can nurture an environment enabling and favouring cancer growth while simultaneously being essential for a productive tumour-directed immune response. Interleukin gene expression negative will be added as new PT under HLT Cell marker analyses.

CR Number: 2023205005	Implementation Date: 26-Jul-23	Related CR: 2023205005		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Interleukin gene positive cancer</i>	Approved as Requested	Proposed PT <i>Interleukin gene positive cancer</i>	10090084
			HLT primary <i>Neoplasms malignant site unspecified NEC</i>	10029105
			SOC primary <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104

MSSO Comment: The proposal to add a new term Interleukin gene positive cancer is approved as requested. Among cytokines, several interleukins are particularly relevant in the development and progression of cancer. Along these lines, interleukin action can be cell specific and spans cancer initiation, tumour progression and tumour control. Interleukin gene positive cancer will be added as new PT under HLT Neoplasms malignant site unspecified NEC.

CR Number: 2023205006	Implementation Date: 26-Jul-23	Related CR: 2023205006		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Procedural hemothorax</i>	Rejected		

MSSO Comment: The proposal to add a new term Procedural hemothorax is not approved. It is not possible to have all procedure related type concept term in MedDRA. Please consider the combination of LLT Haemothorax and LLT Procedural complication.

Supplemental Update Report

CR Number: 2023206003	Implementation Date: 01-Aug-23	Related CR: 2023206003	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Artery Cannulation</i>	Approved Not as Requested	Proposed LLT <i>Arterial cannulation</i>
			To PT <i>Arterial catheterisation</i>
			10090099 Current
			10003148

MSSO Comment: The proposal to add a new term Artery Cannulation is approved but not as requested. Arterial cannulation is a procedure frequently performed in acute and critical care settings. It serves as an invasive means to more accurately measure blood pressure and mean arterial pressure than non-invasive means. The requested term will be modified to meet MedDRA capitalization standards and added as LLT Arterial cannulation to PT Arterial catheterisation.

CR Number: 2023206004	Implementation Date: 01-Aug-23	Related CR: 2023206004	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Acromioclavicular joint Excision</i>	Approved Not as Requested	Proposed LLT <i>Acromioclavicular joint excision</i>
			To PT <i>Distal clavicle excision</i>
			10090098 Current
			10089332

MSSO Comment: The proposal to add a new term Acromioclavicular joint Excision is approved but not as requested. Excision arthroplasty of the acromioclavicular joint is a well-tried and tested procedure for degenerative change at this joint. The outer centimeter of the clavicle is removed, and any osteophytes on the acromial side are also trimmed. The requested term will be modified according to MedDRA capitalisation conventions to Acromioclavicular joint excision and added as LLT to the recently added, for version 27.0, PT Distal clavicle excision.

CR Number: 2023206005	Implementation Date: 01-Aug-23	Related CR: 2023206005	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Polyethylene exchange</i>	Approved Not as Requested	Proposed LLT <i>Polyethylene liner exchange procedure</i>
			To PT <i>Joint arthroplasty</i>
			10090100 Current
			10057681

MSSO Comment: The proposal to add a new LLT Polyethylene exchange is approved but not as requested. Isolated polyethylene liner exchanges are becoming a more common procedure in total hip and knee arthroplasty for problems such as impending wear-through of the polyethylene liner, wear with progressive osteolysis, wear with symptoms related to the hip and knee joint, and mechanical failure of the polyethylene. Proposed term will be modified for greater clarity and added as new LLT Polyethylene liner exchange procedure to PT Joint arthroplasty.

Supplemental Update Report

CR Number: 2023206006	Implementation Date: 01-Aug-23	Related CR: 2023206006		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Sartorius transposition</i>	Approved Not as Requested	Proposed PT <i>Sartorius transposition</i>	10090101
			HLT primary <i>Muscle therapeutic procedures</i>	10028321
			SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new LLT Sartorius transposition is approved but not as requested. Transposition of the sartorius muscle is indicated to cover exposed femoral vessels after inguinal lymph node dissection. This technique has been used as a definitive or prophylactic treatment in groin infections after surgical reconstruction of the femoral vessels. The requested term Sartorius transposition will be added as a PT under HLT Muscle therapeutic procedures.

CR Number: 2023206007	Implementation Date: 01-Aug-23	Related CR: 2023206007		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Bacterial bursitis</i>	Approved as Requested	Proposed PT <i>Bacterial bursitis</i>	10090102
			HLT primary <i>Bacterial infections NEC</i>	10004047
			SOC primary <i>Infections and infestations</i>	10021881
			HLT secondary <i>Bone and joint infections (excl arthritis)</i>	10005941
			SOC secondary <i>Musculoskeletal and connective tissue disorders</i>	10028395

MSSO Comment: The proposal to add a new term Bacterial bursitis is approved as requested. Bursitis is the painful inflammation of the bursae around joints. Bursitis can also be caused by an infection, usually a bacterial infection. Bacterial bursitis will be added as PT to primary HLT Bacterial infections NEC and secondary HLT Bone and joint infections (excl arthritis).

Supplemental Update Report

CR Number: 2023207001 Implementation Date: 01-Aug-23 Related CR: 2023207001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Implanon insertion</i>	Approved Not as Requested	Proposed LLT <i>Hormonal contraceptive implant insertion</i>	10090103 Current
			To PT <i>Contraceptive implant</i>	10072571

MSSO Comment: The proposal to add a new term Implanon insertion is approved but not as requested. Etonogestrel is a medication which is used as a means of birth control for women. It is available as an implant placed under the skin of the upper arm under the brand names Nexplanon and Implanon. Implanon is a trade name for an implant contraceptive containing etonogestrel. Trade/Trademark names are beyond the scope of MedDRA and not included in the terminology. The trademark concept will be represented as LLT Hormonal contraceptive implant insertion to PT Contraceptive implant.

CR Number: 2023207002 Implementation Date: 04-Aug-23 Related CR: 2023207002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Cornell assessment of pediatric delirium score</i>	Approved as Requested	PT to merge <i>Cornell assessment of pediatric delirium score</i>	10089641 Current
To PT	<i>Cornell assessment of paediatric delirium score</i>		To PT <i>Cornell assessment of paediatric delirium score</i>	10090117

MSSO Comment: The proposal to demote the PT Cornell assessment of pediatric delirium score under PT Cornell assessment of paediatric delirium score is approved as requested. The US spelling of "Cornell assessment of pediatric delirium score" was incorrectly added as a PT in change request number 2023110016. This U.S. spelled term will be demoted under the British English PT Cornell assessment of paediatric delirium score, newly added in CR 2023207002.

CR Number: 2023207003 Implementation Date: 04-Aug-23 Related CR: 2023207003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Cornell assessment of paediatric delirium score</i>	Approved as Requested	Proposed PT <i>Cornell assessment of paediatric delirium score</i>	10090117
HLT primary	<i>Neurologic diagnostic procedures</i>		HLT primary <i>Neurologic diagnostic procedures</i>	10029285
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Cornell assessment of paediatric delirium score to primary HLT Neurologic diagnostic procedures in SOC Investigations is approved as requested. The US spelling of "Cornell assessment of pediatric delirium score" was added as a PT in change request number 2023110016. This request is for a replacement PT with the British English spelling to comply with MedDRA conventions.

Supplemental Update Report

CR Number: 2023208001 Implementation Date: 01-Aug-23 Related CR: 2023208001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>18F FLUORO-DOPA POSITRON EMISSION TOMOGRAPHY</i>	Approved Not as Requested	Proposed LLT <i>18F fluoro-DOPA positron emission tomography</i>	10090091 Current
To PT	<i>Positron emission tomogram</i>		To PT <i>Positron emission tomogram</i>	10036220

MSSO Comment: The proposal to add a new LLT 18F FLUORO-DOPA POSITRON EMISSION TOMOGRAPHY to PT Positron emission tomogram is approved but not as requested. 18F-DOPA is a radiotracer analog of L-DOPA, which enters cells via the amino acid transporter system. 18F-DOPA offers distinct advantage over fluorodeoxyglucose for the detection of carcinoids especially, since many of these tumors are indolent with low proliferation activity and good differentiation. The proposed term will be modified according to MedDRA capitalization conventions and added as the LLT 18F fluoro-DOPA positron emission tomography under PT Positron emission tomogram. In a related change, LLT 18F-DOPA-PET will also be added to PT Positron emission tomogram.

CR Number: 2023213240 Implementation Date: 01-Aug-23 Related CR: 2023208001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>18F-DOPA-PET</i>	Approved as Requested	Proposed LLT <i>18F-DOPA-PET</i>	10090097 Current
To PT	<i>Positron emission tomogram</i>		To PT <i>Positron emission tomogram</i>	10036220

MSSO Comment:

CR Number: 2023208002 Implementation Date: 01-Aug-23 Related CR: 2023208002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Lacunar ischemic stroke</i>	Approved as Requested	Proposed LLT <i>Lacunar ischemic stroke</i>	10090092 Current
To PT	<i>Lacunar stroke</i>		To PT <i>Lacunar stroke</i>	10076994

MSSO Comment: The proposal to add a new LLT Lacunar ischemic stroke to PT Lacunar stroke is approved as requested. A quarter of all ischaemic strokes (a fifth of all strokes) are lacunar type. Lacunar infarcts are small infarcts (2–20 mm in diameter) in the deep cerebral white matter, basal ganglia, or pons, presumed to result from the occlusion of a single small perforating artery supplying the subcortical areas of the brain. In related changes, the British English counterpart LLT Lacunar ischaemic stroke will also be added to PT Lacunar stroke.

Supplemental Update Report

CR Number: 2023213237	Implementation Date: 01-Aug-23	Related CR: 2023208002	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Lacunar ischaemic stroke</i>	Approved as Requested	Proposed LLT
To PT	<i>Lacunar stroke</i>		<i>Lacunar ischaemic stroke</i>
			10090096 Current
			To PT
			<i>Lacunar stroke</i>
			10076994

MSSO
Comment:

CR Number: 2023208003	Implementation Date: 01-Aug-23	Related CR: 2023208003	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Pancreatobiliar carcinoma</i>	Approved Not as Requested	Proposed PT
			<i>Pancreaticobiliary carcinoma</i>
			10090088
			HLT primary
			<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>
			10033633
			SOC primary
			<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>
			10029104
			HLT secondary
			<i>Pancreatic neoplasms</i>
			10033632
			SOC secondary
			<i>Gastrointestinal disorders</i>
			10017947

MSSO
Comment: The proposal to add a new term Pancreatobiliar carcinoma is approved but not as requested. Pancreaticobiliary cancers are a group of malignancies affecting the pancreas and biliary tract and are often associated with poor prognosis. Existing treatment strategies for these malignancies are limited. However, with the development of more advanced genomic analysis techniques, several mutations have been identified that may be targeted for the development of novel treatments. The requested term will be modified to PT Pancreaticobiliary carcinoma and added to primary HLT Pancreatic neoplasms malignant (excl islet cell and carcinoid) and to secondary HLT Pancreatic neoplasms.

Supplemental Update Report

CR Number: 2023208004		Implementation Date: 01-Aug-23	Related CR: 2023208004	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>High-grade appendical mucinosis neoplasia</i>	Approved Not as Requested	Proposed LLT <i>High-grade appendiceal mucinous neoplasm</i> To PT <i>Appendiceal mucinous neoplasm</i>	10090093 Current 10090090

MSSO Comment: The proposal to add a new term High-grade appendical mucinosis neoplasia is approved but not as requested. High-grade appendiceal mucinous neoplasm is a type of mucinous neoplasm of the appendix with features similar to those of Low-grade appendiceal mucinous neoplasm, but with the addition of micropapillary features, cribriforming and piling up of epithelial cells with high-grade features (i.e. enlarged, hyperchromatic, and pleomorphic nuclei; numerous atypical mitotic figures...). The proposed term will be modified to its more prevalent denomination in literature and added as the LLT High-grade appendiceal mucinous neoplasm to a new PT Appendiceal mucinous neoplasm. In a related change, a new PT Appendiceal mucinous neoplasm will be added to primary HLT Upper gastrointestinal neoplasms benign and to secondary HLT Benign neoplasms gastrointestinal (excl oral cavity) to represent an appendiceal neoplasm characterized by mucinous epithelial proliferation with extracellular mucin and pushing tumour margins.

CR Number: 2023213238		Implementation Date: 01-Aug-23	Related CR: 2023208004	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Appendiceal mucinous neoplasm</i>	Approved as Requested	Proposed PT <i>Appendiceal mucinous neoplasm</i>	10090090
HLT primary	<i>Upper gastrointestinal neoplasms benign</i>		HLT primary <i>Upper gastrointestinal neoplasms benign</i>	10046275
SOC primary	<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>		SOC primary <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary <i>Benign neoplasms gastrointestinal (excl oral cavity)</i>	10017988
			SOC secondary <i>Gastrointestinal disorders</i>	10017947

MSSO Comment:

Supplemental Update Report

CR Number: 2023208005	Implementation Date: 01-Aug-23	Related CR: 2023208005	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>Low-grade appendical mucinosis neoplasia</i>		Approved Not as Requested	Proposed LLT <i>Low-grade appendiceal mucinous neoplasm</i> 10090094 Current To PT <i>Appendiceal mucinous neoplasm</i> 10090090

MSSO Comment: The proposal to add a new term Low-grade appendical mucinosis neoplasia is approved but not as requested. Low-grade appendiceal mucinous neoplasm is a filiform or villous mucinous epithelium with tall cytoplasmic mucin vacuoles and compressed bland nuclei or epithelial undulations/scalloping with columnar cells with nuclear pseudostratification, fibrosis, hyalinization, and calcification of the appendiceal wall. The proposed term will be modified to its more prevalent denomination in literature and added as the LLT Low-grade appendiceal mucinous neoplasm to a new PT Appendiceal mucinous neoplasm, which was added as an associated change in change request 2023208004.

CR Number: 2023208006	Implementation Date: 01-Aug-23	Related CR: 2023208006	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed PT <i>Entomophagy</i>	Add a New PT	Approved as Requested	Proposed PT <i>Entomophagy</i> 10090089
HLT primary <i>Dietary and nutritional issues</i>			HLT primary <i>Dietary and nutritional issues</i> 10012776
SOC primary <i>Social circumstances</i>			SOC primary <i>Social circumstances</i> 10041244

MSSO Comment: The proposal to add a new PT Entomophagy to primary HLT Dietary and nutritional issues in SOC Social circumstances is approved as requested. Entomophagy, the practice of eating insects, is considered a potent dietary practice to replace animal protein due to its highly nutritious, protein-rich, and environmentally sustainable nature.

CR Number: 2023208007	Implementation Date: 01-Aug-23	Related CR: 2023208007	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>Handl syndrome</i>	Add a New Term	Approved Not as Requested	Proposed PT <i>HaNDL syndrome</i> 10090087 HLT primary <i>Headaches NEC</i> 10019233 SOC primary <i>Nervous system disorders</i> 10029205

MSSO Comment: The proposal to add a new term Handl syndrome is approved but not as requested. Syndrome of transient headache and neurological deficits with cerebrospinal fluid lymphocytosis (usually abbreviated as HaNDL syndrome) is defined as a migraine-like headache episodes (typically one to twelve) accompanied by neurological deficits including hemiparaesthesia, hemiparesis and/or dysphasia, but positive visual symptoms only uncommonly, lasting several hours. The requested term will be modified and added as PT HaNDL syndrome to HLT Headaches NEC. In a related change, LLT Syndrome of transient headache and neurological deficits with cerebrospinal fluid lymphocytosis will be added to PT HaNDL syndrome.

Supplemental Update Report

CR Number: 2023213239 Implementation Date: 01-Aug-23 Related CR: 2023208007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Syndrome of transient headache and neurological deficits with cerebrospinal fluid lymphocytosis</i>	Approved as Requested	Proposed LLT <i>Syndrome of transient headache and neurological deficits with cerebrospinal fluid lymphocytosis</i>	10090095 Current
To PT	<i>HaNDL syndrome</i>		To PT <i>HaNDL syndrome</i>	10090087

MSSO
Comment:

CR Number: 2023209001 Implementation Date: 01-Aug-23 Related CR: 2023209001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term <i>Watchman implant</i>	Rejected		

MSSO Comment: The proposal to add a new term Watchman implant is not approved. Watchman is the brand name of a device and so out of MedDRA scope. However the requested concept can be represented by LLT/PT Left atrial appendage closure implant.

CR Number: 2023209002 Implementation Date: 01-Aug-23 Related CR: 2023209002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Rheumatic fever related Arthritis</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Rheumatic fever related Arthritis is not approved. The requested term can be represented by LLT/PT Rheumatic fever or LLT Polyarthritis rheumatica acuta because one of the leading symptoms is painful and tender joints, most often the ankles, knees, elbows or wrists. Please also note that the primary HLT for PT Rheumatic fever is HLT Arthropathies NEC reflecting the association between the diagnosis and its principal symptoms.

Supplemental Update Report

CR Number: 2023209004 Implementation Date: 01-Aug-23 Related CR: 2023209004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Anaemia of beta thalassemia	Rejected		

MSSO Comment: The proposal to add a new PT Anaemia of beta thalassemia 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. The concept can be represented by LLT Anaemia- Hypochromic microcytic picture and the underlying cause by LLT Thalassemia beta, if needed and not covered by medical history.

CR Number: 2023209005 Implementation Date: 01-Aug-23 Related CR: 2023209005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Anaemia of myelodysplastic syndrome	Rejected		

MSSO Comment: The proposal to add a new PT Anaemia of myelodysplastic syndrome 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. Myelodysplastic syndromes (MDS) are a constellation of different diseases sharing anemia in the great majority of cases, and this cytopenia defines these pathologies and their most dramatic clinical manifestations. The concept can be represented by the combination of LLT Myelodysplastic syndrome and e.g. LLT Macrocytic anaemia.

CR Number: 2023212001 Implementation Date: 04-Aug-23 Related CR: 2023212001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	De Quervain's release	Approved Not as Requested	Proposed LLT	
To PT	Tenolysis		De Quervain's tendon release	10090104 Current
			To PT	
			Tenolysis	10065570

MSSO Comment: The proposal to add a new LLT De Quervain's release to PT Tenolysis is approved but not as requested. De Quervain's tendon release is surgery to reduce pressure on a tendon that runs along the side of the wrist near the thumb. The surgical procedure involves opening or cutting the inflamed part of the tendon sheath to relieve the pressure on the tendon and allow free movement of the wrist. The requested term will be modified for clarity and added as LLT De Quervain's tendon release to PT Tenolysis. In a related change, PT Tendon sheath incision will be demoted under PT Tenolysis as a sub-concept LLT.

Supplemental Update Report

CR Number: 2023216001	Implementation Date: 04-Aug-23	Related CR: 2023212001		
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Tendon sheath incision</i>	Approved as Requested	PT to merge	
To PT	<i>Tenolysis</i>		<i>Tendon sheath incision</i>	10043250 Current
			To PT	
			<i>Tenolysis</i>	10065570

MSSO
Comment:

CR Number: 2023212002	Implementation Date: 04-Aug-23	Related CR: 2023212002		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Tendon release</i>	Rejected		
To PT	<i>Tenolysis</i>			

MSSO Comment: The proposal to add a new LLT Tendon release to PT Tenolysis is not approved. The requested term is not specific enough. The word is used for both cutting tissue around the tendon (tenolysis, tendon sheath incision), the tendon itself (tenotomy) or even as tendon release therapy as a form of physiotherapy. A non-specific PT Tendon operation exists and can be used for coding if the concept is unclear from context and cannot be assigned to the more specific PTs.

CR Number: 2023212003	Implementation Date: 04-Aug-23	Related CR: 2023212003		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Ghost vision</i>	Approved as Requested	Proposed LLT	
To PT	<i>Diplopia</i>		<i>Ghost vision</i>	10090105 Current
			To PT	
			<i>Diplopia</i>	10013036

MSSO Comment: The proposal to add a new LLT Ghost vision to PT Diplopia is approved as requested. Ghost image is a frequent synonym expression often used to refer to the false or diplopic image in diplopia.

Supplemental Update Report

CR Number: 2023212021 **Implementation Date:** 04-Aug-23 **Related CR:** 2023212021

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Non-cardiac death</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Non-cardiac death is not approved. Non-cardiac death may refer to a vast number of causes and is non-specific.

CR Number: 2023212024 **Implementation Date:** 04-Aug-23 **Related CR:** 2023212024

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>COVID-19 pneumopathy</i>	Rejected		

MSSO Comment: The proposal to add a new LLT COVID-19 pneumopathy is not approved. MedDRA cannot provide combination terms for all events associated with COVID-19. Please consider split coding with PT COVID-19 and PT Pneumopathy.

CR Number: 2023212025 **Implementation Date:** 04-Aug-23 **Related CR:** 2023212025

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term <i>Prostatic urothelial carcinoma</i>	Approved as Requested	Proposed PT <i>Prostatic urothelial carcinoma</i>	10090106
			HLT primary <i>Prostatic neoplasms malignant</i>	10036908
			SOC primary <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary <i>Prostatic neoplasms and hypertrophy</i>	10036966
			SOC secondary <i>Reproductive system and breast disorders</i>	10038604

MSSO Comment: The proposal to add a new term Prostatic urothelial carcinoma is approved as requested. Prostatic urothelial carcinoma is a very rare disease with high aggressiveness and poor prognosis. The gold standard to diagnose prostatic urothelial carcinoma is grounded in histologic and immunohistochemical analysis. Prostatic urothelial carcinoma will be added as PT under primary HLT Prostatic neoplasms malignant and secondary HLT Prostatic neoplasms and hypertrophy.

Supplemental Update Report

CR Number: 2023212026	Implementation Date: 04-Aug-23	Related CR: 2023212026	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Intraparenchymal hemorrhage</i>	Approved Not as Requested	Proposed LLT <i>Intraparenchymal cerebral hemorrhage</i>
			To PT <i>Cerebral haemorrhage</i>
			10090107 Current
			10008111

MSSO Comment: The proposal to add a new term Intraparenchymal hemorrhage is approved but not as requested. Intraparenchymal hemorrhage is most often used to indicate bleeding into the brain parenchyma proper. The requested term will be modified for organ specificity, and will be added as LLT Intraparenchymal cerebral hemorrhage to PT Cerebral haemorrhage. In a related change, the British English counterpart LLT Intraparenchymal cerebral haemorrhage will also be added to PT Cerebral haemorrhage.

CR Number: 2023216002	Implementation Date: 04-Aug-23	Related CR: 2023212026	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Intraparenchymal cerebral haemorrhage</i>	Approved as Requested	Proposed LLT <i>Intraparenchymal cerebral haemorrhage</i>
To PT	<i>Cerebral haemorrhage</i>		To PT <i>Cerebral haemorrhage</i>
			10090108 Current
			10008111

MSSO Comment:

CR Number: 2023213001	Implementation Date: 04-Aug-23	Related CR: 2023213001	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Hamstring syndrome</i>	Approved as Requested	Proposed LLT <i>Hamstring syndrome</i>
			To PT <i>Tight hamstring syndrome</i>
			10090109 Current
			10086324

MSSO Comment: The proposal to add a new term Hamstring syndrome is approved as requested. Hamstring syndrome is defined as pain felt over the area of the ischial tuberosity and radiating down the back of the thigh. Their symptoms were caused by the tight, tendinous structures of the lateral insertion area of the hamstring muscles to the ischial tuberosity. Hamstring syndrome will be added as synonym LLT to PT Tight hamstring syndrome. In a related change, PT Tight hamstring syndrome will be linked to HLT Mononeuropathies.

Supplemental Update Report

CR Number: 2023216003	Implementation Date: 04-Aug-23	Related CR: 2023213001		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Tight hamstring syndrome</i>	Approved as Requested	Proposed PT	
To HLT	<i>Mononeuropathies</i>		<i>Tight hamstring syndrome</i>	10086324
			To HLT	
			<i>Mononeuropathies</i>	10027917

MSSO
Comment:

CR Number: 2023213002	Implementation Date: 04-Aug-23	Related CR: 2023213002		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Computed Radiography</i>	Approved Not as Requested	Proposed LLT	
			<i>Computed radiography</i>	10090110 Current
			To PT	
			<i>Digital radiogram</i>	10087730

MSSO Comment: The proposal to add a new LLT Computed Radiography is approved but not as requested. Computed radiography is the use of a phosphor imaging plate to create a digital image. The requested term will be modified according to MedDRA capitalisation conventions and added as LLT Computed radiography to PT Digital radiogram.

CR Number: 2023213003	Implementation Date: 04-Aug-23	Related CR: 2023213003		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Drumstick finger</i>	Approved Not as Requested	Proposed LLT	
			<i>Drumstick fingers</i>	10090112 Current
			To PT	
			<i>Clubbing</i>	10009691

MSSO Comment: The proposal to add a new LLT Drumstick finger is approved but not as requested. Finger clubbing, also called "drumstick fingers" or Hippocratic fingers, is a common clinical sign mainly seen in patients with heart or lung disease. The term is used to describe an enlargement of the distal phalanges of the fingers, giving them a drumstick or club-like appearance. The requested term will be added in the plural form as LLT Drumstick fingers to PT Clubbing.

Supplemental Update Report

CR Number: 2023213004	Implementation Date: 04-Aug-23	Related CR: 2023213004	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New LLT			
Proposed LLT <i>Hippocratic finger</i>		Approved Not as Requested	Proposed LLT <i>Hippocratic fingers</i> 10090111 Current
			To PT <i>Clubbing</i> 10009691

MSSO Comment: The proposal to add a new LLT Hippocratic finger is approved but not as requested. Finger clubbing, also called "drumstick fingers" or Hippocratic fingers, is a common clinical sign mainly seen in patients with heart or lung disease. The term is used to describe an enlargement of the distal phalanges of the fingers, giving them a drumstick or club-like appearance. The requested term will be added in the plural form as LLT Hippocratic fingers to PT Clubbing.

CR Number: 2023213005	Implementation Date: 04-Aug-23	Related CR: 2023213005	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New LLT			
Proposed LLT <i>Watch glass nail</i>		Approved Not as Requested	Proposed LLT <i>Watch glass nails</i> 10090113 Current
			To PT <i>Clubbing</i> 10009691

MSSO Comment: The proposal to add a new LLT Watch glass nail is approved but not as requested. Clubbed fingers are also referred to as hypertrophic osteoarthropathy (HOA), digital clubbing, watch-glass nails, drumstick fingers, Hippocratic fingers, and Hippocratic nails. Proposed term will be modified to the plural form and added as LLT Watch glass nails under PT Clubbing aligned with synonym LLT Clubbing of nails.

CR Number: 2023213006	Implementation Date: 09-Aug-23	Related CR: 2023213006	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Link (move) an LLT to another PT			
Proposed LLT <i>Self injurious behaviour</i>		Approved as Requested	Proposed LLT <i>Self injurious behaviour</i> 10063495 Current
From PT <i>Intentional self-injury</i>			From PT <i>Intentional self-injury</i> 10022524
To PT <i>Self-destructive behaviour</i>			To PT <i>Self-destructive behaviour</i> 10085233

MSSO Comment: The proposal to move the LLT Self injurious behaviour from PT Intentional self-injury to PT Self-destructive behaviour is approved as requested to make a clear distinction between a self-injury and a behaviour which could lead to injury.

Supplemental Update Report

CR Number: 2023213007 Implementation Date: 09-Aug-23 Related CR: 2023213007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Link (move) an LLT to another PT <i>Self injurious behaviour without suicidal intent</i>	Approved as Requested	Proposed LLT <i>Self injurious behaviour without suicidal intent</i>	10071770 Current
From PT	<i>Intentional self-injury</i>		From PT <i>Intentional self-injury</i>	10022524
To PT	<i>Self-destructive behaviour</i>		To PT <i>Self-destructive behaviour</i>	10085233

MSSO Comment: The proposal to move the LLT Self injurious behaviour without suicidal intent from PT Intentional self-injury to PT Self-destructive behaviour is approved as requested to make a clear distinction between a self-injury and a behaviour which could lead to injury.

CR Number: 2023213008 Implementation Date: 09-Aug-23 Related CR: 2023213008

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Link (move) an LLT to another PT <i>Self injurious behavior without suicidal intent</i>	Approved as Requested	Proposed LLT <i>Self injurious behavior without suicidal intent</i>	10071771 Current
From PT	<i>Intentional self-injury</i>		From PT <i>Intentional self-injury</i>	10022524
To PT	<i>Self-destructive behaviour</i>		To PT <i>Self-destructive behaviour</i>	10085233

MSSO Comment: The proposal to move the LLT Self injurious behavior without suicidal intent from PT Intentional self-injury to PT Self-destructive behaviour is approved as requested to make a clear distinction between a self-injury and a behaviour which could lead to injury.

CR Number: 2023213009 Implementation Date: 09-Aug-23 Related CR: 2023213009

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Link (move) an LLT to another PT <i>Self injurious behavior</i>	Approved as Requested	Proposed LLT <i>Self injurious behavior</i>	10052303 Current
From PT	<i>Intentional self-injury</i>		From PT <i>Intentional self-injury</i>	10022524
To PT	<i>Self-destructive behaviour</i>		To PT <i>Self-destructive behaviour</i>	10085233

MSSO Comment: The proposal to move the LLT Self injurious behavior from PT Intentional self-injury to PT Self-destructive behaviour is approved as requested to make a clear distinction between a self-injury and a behaviour which could lead to injury.

Supplemental Update Report

CR Number: 2023214001 Implementation Date: 04-Aug-23 Related CR: 2023214001

<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Malignant pleural effusion</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>		<i>Malignant pleural effusion</i>	10026673
New Primary SOC	<i>Respiratory, thoracic and mediastinal disorders</i>		Old Primary SOC	
			<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			New Primary SOC	
			<i>Respiratory, thoracic and mediastinal disorders</i>	10038738

MSSO Comment: The proposal to reassign the primary SOC of PT Malignant pleural effusion from current SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) to SOC Respiratory, thoracic and mediastinal disorders is approved as requested. This change request is based on the proactivity proposal to harmonise primary SOC assignment for PTs in the HLT Oncologic complications and emergencies, which have a site of manifestation and in context of already processed change request 2022203006 and as stated in the MedDRA Introductory Guide. These concepts 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). In a related change, for the same reason the primary SOC for PT Pulmonary tumour thrombotic microangiopathy will be changed from SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) to SOC Respiratory, thoracic and mediastinal disorders.

CR Number: 2023216004 Implementation Date: 04-Aug-23 Related CR: 2023214001

<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Pulmonary tumour thrombotic microangiopathy</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>		<i>Pulmonary tumour thrombotic microangiopathy</i>	10079988
New Primary SOC	<i>Respiratory, thoracic and mediastinal disorders</i>		Old Primary SOC	
			<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			New Primary SOC	
			<i>Respiratory, thoracic and mediastinal disorders</i>	10038738

MSSO Comment:

Supplemental Update Report

CR Number: 2023214002 Implementation Date: 04-Aug-23 Related CR: 2023214002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Reassign Primary SOC <i>Pericardial effusion malignant</i>	Approved as Requested	Proposed PT <i>Pericardial effusion malignant</i>	10048630
Old Primary SOC	<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>		Old Primary SOC	
New Primary SOC	<i>Cardiac disorders</i>		<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			New Primary SOC <i>Cardiac disorders</i>	10007541

MSSO Comment: The proposal to reassign the primary SOC of PT Pericardial effusion malignant from current SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) to SOC Cardiac disorders is approved as requested. This change request is based on the proactivity proposal to harmonise primary SOC assignment for PTs in the HLT Oncologic complications and emergencies, which have a site of manifestation and in context of already processed change request 2022203006. These concepts 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: 2023214003 Implementation Date: 04-Aug-23 Related CR: 2023214003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Reassign Primary SOC <i>Intracranial tumour haemorrhage</i>	Approved as Requested	Proposed PT <i>Intracranial tumour haemorrhage</i>	10022775
Old Primary SOC	<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>		Old Primary SOC	
New Primary SOC	<i>Nervous system disorders</i>		<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			New Primary SOC <i>Nervous system disorders</i>	10029205

MSSO Comment: The proposal to reassign the primary SOC of PT Intracranial tumour haemorrhage from current SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) to SOC Nervous system disorders is approved as requested. This change request is based on the proactivity proposal to harmonise primary SOC assignment for PTs in the HLT Oncologic complications and emergencies, which have a site of manifestation and in context of already processed change request 2022203006. These concepts 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: 2023214004 Implementation Date: 04-Aug-23 Related CR: 2023214004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Reassign Primary SOC <i>Metastatic pulmonary embolism</i>	Approved as Requested	Proposed PT <i>Metastatic pulmonary embolism</i>	10069909
Old Primary SOC	<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>		Old Primary SOC	
New Primary SOC	<i>Respiratory, thoracic and mediastinal disorders</i>		New Primary SOC <i>Respiratory, thoracic and mediastinal disorders</i>	10029104 10038738

MSSO Comment: The proposal to reassign the primary SOC of PT Metastatic pulmonary embolism from current SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) to SOC Respiratory, thoracic and mediastinal disorders is approved as requested. This change request is based on the proactivity proposal to harmonise primary SOC assignment for PTs in the HLT Oncologic complications and emergencies, which have a site of manifestation and in context of already processed change request 2022203006. These concepts 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: 2023214005 Implementation Date: 09-Aug-23 Related CR: 2023214005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Anti-DNAJB9 antibody</i>	Approved Not as Requested	Proposed PT <i>Anti-DNAJB9 antibody</i>	10090118
			HLT primary <i>Autoimmunity analyses</i>	10003828
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new LLT Anti-DNAJB9 antibody is approved but not as requested. A recently discovered novel proteomic tissue biomarker for fibrillary glomerulonephritis, namely, DNAJB9 has been discovered. Immuno-Electron Microscopy for DNAJB9 can be performed using an anti-DNAJB9 rabbit polyclonal antibody and a gold-conjugated IgG as a secondary antibody. Anti-DNAJB9 antibody will be added as new PT under HLT Autoimmunity analyses.

CR Number: 2023214006 Implementation Date: 04-Aug-23 Related CR: 2023214006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Add a New PT <i>Lupus anticoagulant syndrome</i>	Rejected		

MSSO Comment: The proposal to add a new PT Lupus anticoagulant syndrome is not approved. Lupus anticoagulant syndrome is generally used synonymously with antiphospholipid syndrome in scientific medical literature.

Supplemental Update Report

CR Number: 2023214007 Implementation Date: 04-Aug-23 Related CR: 2023214007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Watermelon stomach syndrome	Approved as Requested	Proposed LLT	
To PT	Gastric antral vascular ectasia		Watermelon stomach syndrome	10090114 Current
			To PT	
			Gastric antral vascular ectasia	10051585

MSSO Comment: The proposal to add a new LLT Watermelon stomach syndrome to PT Gastric antral vascular ectasia is approved as requested. Gastric antral vascular ectasia (GAVE) syndrome, also known as watermelon stomach is a significant cause of acute or chronic gastrointestinal blood loss in the elderly is characterized endoscopically by "watermelon stripes."

CR Number: 2023215001 Implementation Date: 04-Aug-23 Related CR: 2023215001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Lichenoid interface dermatitis	Approved as Requested	Proposed LLT	
			Lichenoid interface dermatitis	10090115 Current
			To PT	
			Lichenoid keratosis	10064000

MSSO Comment: The proposal to add a new term Lichenoid interface dermatitis is approved as requested. Interface dermatitis includes diseases in which the primary pathology involves the dermo-epidermal junction. The salient histological findings include basal cell vacuolization, apoptotic keratinocytes, and obscuring of the dermo-epidermal junction by inflammatory cells. The requested term describes the dermatological feature of a lichenoid reaction and best will be added as LLT Lichenoid interface dermatitis to PT Lichenoid keratosis.

CR Number: 2023215002 Implementation Date: 04-Aug-23 Related CR: 2023215002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Gnathitis	Approved as Requested	Proposed LLT	
			Gnathitis	10090116 Current
			To PT	
			Osteitis	10031149

MSSO Comment: The proposal to add a new term Gnathitis is approved as requested. Gnathitis will be added as LLT to PT Osteitis aligned with the synonym LLT Jaw inflammation.

Supplemental Update Report

CR Number: 2023215003 Implementation Date: 09-Aug-23 Related CR: 2023215003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Supersensitivity psychosis</i>	Approved Not as Requested	Proposed PT <i>Dopamine supersensitivity psychosis</i>	10090119
			HLT primary <i>Psychotic disorder NEC</i>	10037252
			SOC primary <i>Psychiatric disorders</i>	10037175
			HLT secondary <i>Therapeutic and nontherapeutic responses</i>	10043409
			SOC secondary <i>General disorders and administration site conditions</i>	10018065

MSSO Comment: The proposal to add a new LLT Supersensitivity psychosis is approved but not as requested. Dopamine supersensitivity psychosis may be caused by the dopamine receptor D2 antagonizing effect of antipsychotics, causing a compensatory increase in D2 receptors within the brain that sensitizes neurons to endogenous release of the neurotransmitter dopamine. The activity of dopamine in the presence of supersensitivity may paradoxically give rise to worsening psychotic symptoms despite antipsychotic treatment at a given dose. Proposed term will be modified for clarity and added as PT Dopamine supersensitivity psychosis under primary HLT Psychotic disorder NEC and secondary HLT Therapeutic and nontherapeutic responses.

CR Number: 2023215004 Implementation Date: 09-Aug-23 Related CR: 2023215004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Malakoplakia</i>	Approved as Requested	Proposed LLT <i>Malakoplakia</i>	10090120 Current
			To PT <i>Malacoplakia</i>	10080344

MSSO Comment: The proposal to add a new LLT Malakoplakia is approved as requested. Malakoplakia is an extremely rare chronic infectious granulomatous lesion. It can occur in all organs and tissues of the body, with the urinary system being the most common. Malakoplakia will be added as a synonym LLT to PT Malacoplakia.

Supplemental Update Report

CR Number: 2023215005	Implementation Date: 09-Aug-23	Related CR: 2023215005	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed PT	Add a New PT <i>Cerebellar toxicity</i>	Rejected	

MSSO Comment: The proposal to add a new PT Cerebellar toxicity is not approved. The concept LLT Cerebellar toxicity is appropriately placed under PT Neurotoxicity as a subconcept. The mode of diagnosis as well as treatment may differ for subconcepts. Neurotoxicity is the anatomically broader representation of exposure to natural or manmade toxic substances (neurotoxicants) which alters the normal activity of the nervous system. In a related change, PT Toxic leukoencephalopathy will be moved from HLT Encephalopathies NEC to HLT Encephalopathies toxic and metabolic, for better alignment for similar terms such as PT Toxic encephalopathy.

CR Number: 2023221001	Implementation Date: 09-Aug-23	Related CR: 2023215005	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed PT	Link (move) a PT to another HLT <i>Toxic leukoencephalopathy</i>	Approved as Requested	Proposed PT
From HLT	<i>Encephalopathies NEC</i>		<i>Toxic leukoencephalopathy</i> 10075528
To HLT	<i>Encephalopathies toxic and metabolic</i>		From HLT <i>Encephalopathies NEC</i> 10014632
			To HLT <i>Encephalopathies toxic and metabolic</i> 10014624

MSSO Comment:

CR Number: 2023219001	Implementation Date: 16-Aug-23	Related CR: 2023219001	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	Add a New Term <i>Saber-sheath trachea</i>	Approved as Requested	Proposed PT <i>Saber-sheath trachea</i> 10090125
			HLT primary <i>Tracheal disorders (excl infections and neoplasms)</i> 10044288
			SOC primary <i>Respiratory, thoracic and mediastinal disorders</i> 10038738

MSSO Comment: The proposal to add a new term Saber-sheath trachea is approved as requested. Narrowing of the intrathoracic trachea in the coronal plane with anteroposterior lengthening is characteristic of the "saber-sheath" trachea deformity. This structural disorder is strongly associated with chronic obstructive pulmonary disease and may be related to chronic bronchitis. Saber-sheath trachea will be added as PT to HLT Tracheal disorders (excl infections and neoplasms).

Supplemental Update Report

CR Number: 2023219002	Implementation Date: 16-Aug-23	Related CR: 2023219002	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>Binocular Visual Dysfunction</i>		Approved Not as Requested	Proposed PT <i>Binocular visual dysfunction</i> 10090124
			HLT primary <i>Visual disorders NEC</i> 10047541
			SOC primary <i>Eye disorders</i> 10015919

MSSO Comment: The proposal to add a new term Binocular Visual Dysfunction is approved but not as requested. Binocular Vision Dysfunction is a condition where the eyes are misaligned, causing each eye to send a different image to the brain. This can lead to a variety of symptoms such as dizziness, headache, light sensitivity, motion sickness, and anxiety in large spaces with tall ceilings. Requested term Binocular Visual Dysfunction will be modified to comply with MedDRA capitalization rules to Binocular visual dysfunction and added as PT under HLT Visual disorders NEC. In a related change, existing LLT Binocular vision disorder, unspecified, will be moved to new PT Binocular visual dysfunction.

CR Number: 2023228006	Implementation Date: 16-Aug-23	Related CR: 2023219002	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT <i>Binocular vision disorder, unspecified</i>	Link (move) an LLT to another PT	Approved as Requested	Proposed LLT <i>Binocular vision disorder, unspecified</i> 10004718 Current
From PT <i>Visual impairment</i>			From PT <i>Visual impairment</i> 10047571
To PT <i>Binocular visual dysfunction</i>			To PT <i>Binocular visual dysfunction</i> 10090124

MSSO Comment:

CR Number: 2023219003	Implementation Date: 16-Aug-23	Related CR: 2023219003	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>Benign Inverted papilloma</i>	Add a New Term	Rejected	

MSSO Comment: The proposal to add a new term Benign Inverted papilloma is not approved. Inverted papillomas may occur in the nose and/or sinuses or in the urinary tract (bladder, renal pelvis, ureter, urethra). As per requester justification the site of manifestation of the unspecific term Benign Inverted papilloma is supposed to be in the sinonasal region. LLT Inverting papilloma of the nasal cavity and LLT Inverting papilloma of the paranasal sinus exist. The benign nature is captured through the medical concept (papillomas defined as benign tumours) as well as placement in HLT Nasal and paranasal sinus neoplasms benign.

Supplemental Update Report

CR Number: 2023219004	Implementation Date: 16-Aug-23	Related CR: 2023219004	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed LLT	<i>White coat syndrome</i>	Approved as Requested	Proposed LLT <i>White coat syndrome</i> 10090134 Current To PT <i>White coat hypertension</i> 10051581

MSSO Comment: The proposal to add a new LLT White coat syndrome is approved as requested. White coat syndrome is defined as a change in BP levels due to the presence of a physician or other health professional. When the difference between office and self-measurement is relevant and confirmed by 24-hour ambulatory blood pressure monitoring, it reveals the clinical conditions defined as "white coat syndrome". White coat syndrome will be added as a synonym LLT to PT White coat hypertension.

CR Number: 2023219005	Implementation Date: 16-Aug-23	Related CR: 2023219005	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Pigment epithelial detachment</i>	Rejected	

MSSO Comment: The proposal to add a new term Pigment epithelial detachment is not approved. The requested term is represented by existing LLT Detachment of retinal pigment epithelium.

CR Number: 2023219006	Implementation Date: 16-Aug-23	Related CR: 2023219006	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Functional voice disorder</i>	Approved Not as Requested	Proposed LLT <i>Functional dysphonia</i> 10090139 Current To PT <i>Dysphonia</i> 10013952

MSSO Comment: The proposal to add a new term Functional voice disorder is approved but not as requested. Functional dysphonia is poor voice quality without any obvious anatomical, neurological or other organic difficulties affecting the larynx or voice box. The proposed term will be modified for greater specificity and added as LLT Functional dysphonia to PT Dysphonia.

Supplemental Update Report

CR Number: 2023219007 Implementation Date: 16-Aug-23 Related CR: 2023219007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Ineffective coping</i>	Rejected		

MSSO Comment: The proposal to add a new term Ineffective coping is not approved. The proposed term can be interpreted in multiple different ways which makes it difficult to classify in MedDRA. For reconsideration, please provide more information around the context how this term was reported.

CR Number: 2023219008 Implementation Date: 16-Aug-23 Related CR: 2023219008

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Pseudocoarctation of aorta</i>	Approved as Requested	Proposed PT <i>Pseudocoarctation of aorta</i>	10090126
			HLT primary <i>Great vessel disorders congenital</i>	10018717
			SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Vascular malformations and acquired anomalies</i>	10047091
			SOC secondary <i>Vascular disorders</i>	10047065

MSSO Comment: The proposal to add a new term Pseudocoarctation of aorta is approved as requested. Pseudocoarctation is a very rare anomaly of kinking, or buckling, of the aorta without a pressure gradient across the lesion. It is thought to be of congenital origin, and characterized by elongation and kinking of the aorta at the level of the ligamentum arteriosum. The requested term will be added as PT Pseudocoarctation of aorta under primary HLT Great vessel disorders congenital with a secondary link to HLT Vascular malformations and acquired anomalies.

CR Number: 2023219009 Implementation Date: 16-Aug-23 Related CR: 2023219009

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Peroneal split syndrome</i>	Approved as Requested	Proposed LLT <i>Peroneal split syndrome</i>	10090140 Current
			To PT <i>Tendon rupture</i>	10043248

MSSO Comment: The proposal to add a new term Peroneal split syndrome is approved as requested. Peroneal split syndrome refers to longitudinal tearing of the peroneus brevis tendon at the level of the retrofibular groove. Peroneal split syndrome will be added as LLT to PT Tendon rupture.

Supplemental Update Report

CR Number: 2023219010	Implementation Date: 16-Aug-23	Related CR: 2023219010	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Phlebectasia</i>	Approved as Requested	Proposed PT <i>Phlebectasia</i> 10090127 HLT primary <i>Vascular malformations and acquired anomalies</i> 10047091 SOC primary <i>Vascular disorders</i> 10047065

MSSO Comment: The proposal to add a new term Phlebectasia is approved as requested. Diffuse, uniform dilatation of a vein or venous complex, which may be round or cylindrical, tortuous or tendril-shaped or even star-shaped (spider veins). Phlebectasia will be added as PT to primary HLT Vascular malformations and acquired anomalies.

CR Number: 2023219011	Implementation Date: 16-Aug-23	Related CR: 2023219011	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Bertolotti syndrome</i>	Rejected	

MSSO Comment: The proposal to add a new term Bertolotti syndrome is not approved. The proposed term was added as PT Bertolotti's syndrome for version 26.1. In a related change, PT Bertolotti's syndrome will be demoted to an LLT under PT Transitional vertebrae for better alignment.

CR Number: 2023228008	Implementation Date: 16-Aug-23	Related CR: 2023219011	
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
PT to merge	<i>Bertolotti's syndrome</i>	Approved as Requested	PT to merge <i>Bertolotti's syndrome</i> 10089233 Current
To PT	<i>Transitional vertebrae</i>		To PT <i>Transitional vertebrae</i> 10074306

MSSO Comment:

Supplemental Update Report

CR Number: 2023219012	Implementation Date: 16-Aug-23	Related CR: 2023219012	
Change Requested	Add a New Term	Final Disposition	MedDRA Code #
Proposed Term	<i>Metroptosis</i>	Approved as Requested	Proposed LLT <i>Metroptosis</i> 10090136 Current To PT <i>Uterine prolapse</i> 10046814
MSSO Comment:	The proposal to add a new term Metroptosis is approved as requested. Metroptosis, a rare synonym for Uterine prolapse, will be added as LLT to PT Uterine prolapse, aligned with LLT Hysteroptosis.		

CR Number: 2023219013	Implementation Date: 16-Aug-23	Related CR: 2023219013	
Change Requested	Add a New Term	Final Disposition	MedDRA Code #
Proposed Term	<i>Encephalatrophy</i>	Approved as Requested	Proposed LLT <i>Encephalatrophy</i> 10090141 Current To PT <i>Cerebral atrophy</i> 10008096
MSSO Comment:	The proposal to add a new term Encephalatrophy is approved as requested. Encephalatrophy is a (rare) synonym of brain atrophy and will be added as sub-concept LLT to PT Cerebral atrophy.		

CR Number: 2023219014	Implementation Date: 16-Aug-23	Related CR: 2023219014	
Change Requested	Add a New Term	Final Disposition	MedDRA Code #
Proposed Term	<i>Serum procollagen type II N-terminal propeptide decreased</i>	Approved as Requested	Proposed LLT <i>Serum procollagen type II N-terminal propeptide decreased</i> 10090145 Current To PT <i>Procollagen type II N-terminal propeptide decreased</i> 10090131
MSSO Comment:	The proposal to add a new term Serum procollagen type II N-terminal propeptide decreased is approved as requested. Procollagen type II N-terminal propeptide has been shown to be a marker for bone and mineral metabolism. Procollagen II N-Terminal Propeptide (PIINP) concentrations can be measured in serum, plasma, tissue homogenates and other biological fluids. Serum procollagen type II N-terminal propeptide decreased will be added as LLT to a new PT Procollagen type II N-terminal propeptide decreased which will be added, in a related change, to HLT Protein analyses NEC.		

Supplemental Update Report

CR Number: 2023228009 Implementation Date: 16-Aug-23 Related CR: 2023219014

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Procollagen type II N-terminal propeptide decreased</i>	Approved as Requested	Proposed PT <i>Procollagen type II N-terminal propeptide decreased</i>	10090131
HLT primary	<i>Protein analyses NEC</i>		HLT primary <i>Protein analyses NEC</i>	10036998
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO
Comment:

CR Number: 2023219015 Implementation Date: 16-Aug-23 Related CR: 2023219015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Serum procollagen type II N-terminal propeptide increased</i>	Approved as Requested	Proposed LLT <i>Serum procollagen type II N-terminal propeptide increased</i>	10090146 Current
			To PT <i>Procollagen type II N-terminal propeptide increased</i>	10090130

MSSO
Comment: The proposal to add a new term Serum procollagen type II N-terminal propeptide increased is approved as requested. Procollagen type II N-terminal propeptide has been shown to be a marker for bone and mineral metabolism. Procollagen II N-Terminal Propeptide (PIINP) concentrations can be measured in serum, plasma, tissue homogenates and other biological fluids. Procollagen II N-Terminal Propeptide (PIINP) concentrations can be measured in serum, plasma, tissue homogenates and other biological fluids. Serum procollagen type II N-terminal propeptide increased will be added as LLT to a new PT Procollagen type II N-terminal propeptide increased which will be added, in a related change, to HLT Protein analyses NEC.

Supplemental Update Report

CR Number: 2023228010	Implementation Date: 16-Aug-23	Related CR: 2023219015		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Procollagen type II N-terminal propeptide increased</i>	Approved as Requested	Proposed PT <i>Procollagen type II N-terminal propeptide increased</i>	10090130
HLT primary	<i>Protein analyses NEC</i>		HLT primary <i>Protein analyses NEC</i>	10036998
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO
Comment:

CR Number: 2023219016	Implementation Date: 16-Aug-23	Related CR: 2023219016		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Pharmacodermia</i>	Approved Not as Requested	Proposed LLT <i>Pharmacoderma</i>	10090135 Current
			To PT <i>Drug eruption</i>	10013687

MSSO
Comment: The proposal to add a new term Pharmacodermia is approved but not as requested. Pharmacoderma is a set of skin and body reactions, caused by the use of drugs, which can manifest in various ways, such as red spots on the skin, lumps, rashes or even skin detachment, which can be very serious. The requested term will be modified to the more prevalent term in medical English literature and added as LLT Pharmacoderma to PT Drug eruption.

CR Number: 2023219017	Implementation Date: 16-Aug-23	Related CR: 2023219017		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Diabetic vitreous haemorrhage</i>	Rejected		

MSSO
Comment: The proposal to add a new term Diabetic vitreous haemorrhage is not approved. Vitreous hemorrhage is secondary to proliferative diabetic retinopathy is a cause of severe vision loss in diabetic patients. The proposed term may be represented by existing LLT Proliferative diabetic retinopathy and/or LLT Vitreous haemorrhage. Please refer to the MedDRA Points to Consider document, section 3.5.4 When to "split" into more than one MedDRA term.

Supplemental Update Report

CR Number: 2023219018	Implementation Date: 16-Aug-23	Related CR: 2023219018	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New Term			
Proposed Term <i>Metrectomy</i>		Approved as Requested	Proposed LLT <i>Metrectomy</i> 10090142 Current
			To PT <i>Hysterectomy</i> 10021151

MSSO Comment: The proposal to add a new term Metrectomy is approved as requested. Metrectomy is a rarely used synonym and will be added as an LLT to PT Hysterectomy.

CR Number: 2023219019	Implementation Date: 16-Aug-23	Related CR: 2023219019	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New Term			
Proposed Term <i>Progenia</i>		Approved Not as Requested	Proposed LLT <i>Progenism</i> 10090143 Current
			To PT <i>Prognathism</i> 10051481

MSSO Comment: The proposal to add a new term Progenia is approved but not as requested. Progenism is a congenital bone defect involving excessive growth of the lower jaw in the anterior direction. It is associated both with a cosmetic defect as well as with other dental and laryngological problems. The proposed term will be modified to the most commonly found term in literature and added as a synonym LLT Progenism under PT Prognathism. In a related change, PT Prognathism will be moved from HLT Musculoskeletal and connective tissue deformities of skull, face and buccal cavity to HLT Musculoskeletal and connective tissue disorders of face, neck and jaw congenital. In addition, the primary SOC for PT Prognathism will be changed from SOC Musculoskeletal and connective tissue disorders to SOC Congenital, familial and genetic disorders, in accordance with other PTs like Macrognathia, Micrognathia, Microgenia.

CR Number: 2023228013	Implementation Date: 16-Aug-23	Related CR: 2023219019	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Reassign Primary SOC			
Proposed PT <i>Prognathism</i>		Approved as Requested	Proposed PT <i>Prognathism</i> 10051481
Old Primary SOC <i>Musculoskeletal and connective tissue disorders</i>			Old Primary SOC
New Primary SOC <i>Congenital, familial and genetic disorders</i>			<i>Musculoskeletal and connective tissue disorders</i> 10028395
			New Primary SOC <i>Congenital, familial and genetic disorders</i> 10010331

MSSO Comment:

Supplemental Update Report

CR Number: 2023228016

Implementation Date: 16-Aug-23

Related CR: 2023219019

Change Requested

Link (move) a PT to another HLT

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT	<i>Prognathism</i>	Approved as Requested	Proposed PT	
From HLT	<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		<i>Prognathism</i>	10051481
To HLT	<i>Musculoskeletal and connective tissue disorders of face, neck and jaw congenital</i>		From HLT	
			<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>	10028378
			To HLT	
			<i>Musculoskeletal and connective tissue disorders of face, neck and jaw congenital</i>	10028380

MSSO

Comment:

CR Number: 2023219020

Implementation Date: 16-Aug-23

Related CR: 2023219020

Change Requested

Add a New Term

Final Disposition

Final Placement

MedDRA
Code #

Proposed Term	<i>Reentry arrhythmia</i>	Approved as Requested	Proposed LLT	
			<i>Reentry arrhythmia</i>	10090137 Current
			To PT	
			<i>Tachyarrhythmia</i>	10049447

MSSO

Comment: The proposal to add a new term Reentry arrhythmia is approved as requested. A reentry arrhythmia is a self-sustaining cardiac tachyarrhythmia in which the action potential propagates in a manner analogous to a closed-loop circuit. It is a disorder of impulse conduction and is discrete from disorders of impulse generation such as automaticity or triggered activity. Reentry arrhythmia will be added as sub-concept LLT under PT Tachyarrhythmia.

Supplemental Update Report

CR Number: 2023219021 Implementation Date: 16-Aug-23 Related CR: 2023219021

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Agenesis hepatic lobe</i>	Approved Not as Requested	Proposed PT <i>Hepatic lobe agenesis</i>	10090128
		HLT primary <i>Hepatobiliary abnormalities congenital</i>	10019803
		SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
		HLT secondary <i>Hepatic and hepatobiliary disorders NEC</i>	10027681
		SOC secondary <i>Hepatobiliary disorders</i>	10019805

MSSO Comment: The proposal to add a new term Agenesis hepatic lobe is approved but not as requested. Agenesis of a lobe of the liver is a rare finding and is defined as the absence of liver tissue, with preservation of the middle hepatic vein, without previous disease or surgery. Anomalies of hepatic morphology are rare and correspond to developmental defects during embryogenesis and are generally diagnosed incidentally based on imaging. Proposed term will be modified into natural language word order and for greater clarity and added as new PT Hepatic lobe agenesis under primary HLT Hepatobiliary abnormalities congenital and secondary HLT Hepatic and hepatobiliary disorders NEC.

CR Number: 2023219022 Implementation Date: 16-Aug-23 Related CR: 2023219022

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Bifurcation of middle cerebral artery</i>	Rejected		

MSSO Comment: The proposal to add a new term Bifurcation of middle cerebral artery is not approved. The middle cerebral artery usually bifurcates into a superior or frontal and inferior or temporal branch. However, it may have various branching pattern, and there may be additional arteries from the anterior circulation supplying its territory. Proposed term is a natural phenomenon, and unless anomalous, a normal finding.

Supplemental Update Report

CR Number: 2023219023	Implementation Date: 16-Aug-23	Related CR: 2023219023	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Intracapt procedure</i>	Approved Not as Requested	Proposed LLT <i>Basivertebral nerve ablation</i> 10090138 Current
			To PT <i>Therapeutic nerve ablation</i> 10070755

MSSO Comment: The proposal to add a new term Intracapt procedure is approved but not as requested. The Intracapt procedure is an ultra-minimally invasive outpatient procedure developed to help patients with chronic low back pain due to vertebrogenic pain. This procedure targets the basivertebral nerve located within the vertebral body, which, once ablated, has been shown to provide long-term pain relief and improve physical function. Proposed term is a trademark name and not within the scope of MedDRA and therefore will be modified and added as a medical procedure concept as LLT Basivertebral nerve ablation under PT Therapeutic nerve ablation.

CR Number: 2023219024	Implementation Date: 16-Aug-23	Related CR: 2023219024	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Cholecystokinin Increased</i>	Approved Not as Requested	Proposed PT <i>Cholecystokinin increased</i> 10090129
			HLT primary <i>Digestive enzymes</i> 10012981
			SOC primary <i>Investigations</i> 10022891

MSSO Comment: The proposal to add a new term Cholecystokinin Increased is approved but not as requested. Accurate cholecystokinin measurements require radioimmunoassay technology based on high-affinity antibodies. Cholecystokinin is released by the small intestine during the digestive process. Proposed term will be modified to comply with MedDRA capitalization conventions and added as new PT Cholecystokinin increased under HLT Digestive enzymes.

CR Number: 2023219025	Implementation Date: 16-Aug-23	Related CR: 2023219025	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Metabolic inflammation</i>	Approved as Requested	Proposed LLT <i>Metabolic inflammation</i> 10090147 Current
			To PT <i>Metabolic syndrome</i> 10052066

MSSO Comment: The proposal to add a new term Metabolic inflammation is approved as requested. The characteristics of obesity-associated chronic inflammation differ from other general inflammatory paradigms in that it involves tonic activation of the innate immune system, which has an impact on metabolic homeostasis, generally for a lifetime, and affects multiple organs, such as adipose tissue, the pancreas, liver, muscle, and brain. This led to the establishment of the concept of 'Metaflammation' also known as para-inflammation or metabolic inflammation. Metabolic inflammation will be added as an LLT to PT Metabolic syndrome.

Supplemental Update Report

CR Number: 2023219026	Implementation Date: 16-Aug-23	Related CR: 2023219026		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Nonobstructive coronary artery disease</i>	Approved as Requested	Proposed LLT <i>Nonobstructive coronary artery disease</i>	10090144 Current
			To PT <i>Coronary artery disease</i>	10011078

MSSO Comment: The proposal to add a new term Nonobstructive coronary artery disease is approved as requested. Nonobstructive coronary artery disease displays less than 50% atherosclerotic plaque blockage. Damaged endothelial lining (endothelial dysfunction), coronary spasms, and microvascular dysfunction are often seen in people with nonobstructive coronary heart disease. Nonobstructive coronary artery disease will be added as sub-concept LLT under PT Coronary artery disease.

CR Number: 2023219027	Implementation Date: 16-Aug-23	Related CR: 2023219027		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Obstructive sleep apnea</i>	Approved as Requested	Proposed LLT <i>Obstructive sleep apnea</i>	10090133 Current
			To PT <i>Obstructive sleep apnoea syndrome</i>	10029983

MSSO Comment: The proposal to add a new term Obstructive sleep apnea is approved as requested. Obstructive sleep apnea is a condition in which there is repetitive partial or complete collapse of the pharynx during sleep. Obstructive sleep apnea associated with excessive daytime sleepiness is commonly called obstructive sleep apnea syndrome. Obstructive sleep apnea will be added as subconcept LLT under PT Obstructive sleep apnoea syndrome. In a related change, the British English spelled counterpart, LLT Obstructive sleep apnoea will also be added under PT Obstructive sleep apnoea syndrome.

CR Number: 2023228007	Implementation Date: 16-Aug-23	Related CR: 2023219027		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Obstructive sleep apnoea</i>	Approved as Requested	Proposed LLT <i>Obstructive sleep apnoea</i>	10090132 Current
To PT	<i>Obstructive sleep apnoea syndrome</i>		To PT <i>Obstructive sleep apnoea syndrome</i>	10029983

MSSO Comment:

Supplemental Update Report

CR Number: 2023219028	Implementation Date: 09-Aug-23	Related CR: 2023219028		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>BIOTRONIK Monitoring</i>	Approved Not as Requested	Proposed PT <i>Remote cardiac monitoring</i>	10090121
			HLT primary <i>Cardiac function diagnostic procedures</i>	10007566
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new LLT BIOTRONIK Monitoring is approved but not as requested. Remote cardiac monitoring collects daily data from the patient's device allowing physicians to review cardiac function as well as device status. Trade names are outside the scope of MedDRA and therefore the proposed term will be modified to represent the concept as PT Remote cardiac monitoring to HLT Cardiac function diagnostic procedures.

CR Number: 2023219029	Implementation Date: 09-Aug-23	Related CR: 2023219029		
<u>Change Requested</u>	Rename PT/LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Term to modify	<i>Paracetamol</i>	Rejected		
Replacement term	<i>Paracetamol level</i>			

MSSO Comment: The proposal to rename PT/LLT Paracetamol to Paracetamol level is not approved. Paracetamol is a legacy term since version 2.1 (1998) and any changes would impact legacy data. Any confusion of the LLT term can be clarified by referencing the PT Analgesic drug level. In general, the MSSO does not add stand alone drug names, since it is out of MedDRA scope.

CR Number: 2023219030	Implementation Date: 09-Aug-23	Related CR: 2023219030		
<u>Change Requested</u>	Rename PT/LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Term to modify	<i>Acetaminophen</i>	Rejected		
Replacement term	<i>Acetaminophen level</i>			

MSSO Comment: The proposal to rename PT/LLT Acetaminophen to Acetaminophen level is not approved. Acetaminophen is a legacy term since version 2.1 (1998) and any changes would impact legacy data. Any confusion of the LLT term can be clarified by referencing the PT Analgesic drug level. In general, the MSSO does not add stand alone drug names, since it is out of MedDRA scope.

Supplemental Update Report

CR Number: 2023219031 **Implementation Date:** 09-Aug-23 **Related CR:** 2023219031

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Term to modify	Salicylate	Rejected		
Replacement term	Salicylate level			

MSSO Comment: The proposal to rename PT/LLT Salicylate to Salicylate level is not approved. Salicylate is a legacy term since version 2.1 (1998) and any changes would impact legacy data. Any confusion of the LLT term can be clarified by referencing the PT Analgesic drug level. In general, the MSSO does not add stand alone drug names, since it is out of MedDRA scope.

CR Number: 2023220001 **Implementation Date:** 17-Aug-23 **Related CR:** 2023220001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Respiratory Polygraphy	Approved Not as Requested	Proposed LLT Respiratory polygraphy	10090148 Current
			To PT Sleep study	10053319

MSSO Comment: The proposal to add a new term Respiratory Polygraphy is approved but not as requested. Respiratory polygraphy allows the evaluation of a large number of physiological signals associated with respiratory disorders during sleep. The requested term will be modified according to the MedDRA capitalization conventions to Respiratory polygraphy and added as LTT under PT Sleep study.

CR Number: 2023220002 **Implementation Date:** 17-Aug-23 **Related CR:** 2023220002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Langenskiöld procedure	Rejected		

MSSO Comment: The proposal to add a new term Langenskiöld procedure is not approved. The Langenskiöld procedure is a complex surgical intervention with varying surgical extent. There are existing LLTs which can be used to coding unspecifically as e.g. LLT Limb operation or Bone operation as well as specific terms including e.g. LLTs Bone prosthesis insertion or Limb reconstructive surgery.

Supplemental Update Report

CR Number: 2023220003	Implementation Date: 17-Aug-23	Related CR: 2023220003	
Change Requested	Add a New Term	Final Disposition	Final Placement
			MedDRA Code #
Proposed Term	<i>Lipotransfer</i>	Approved as Requested	Proposed LLT <i>Lipotransfer</i>
			10090150 Current
			To PT <i>Lipoinjection</i>
			10072153

MSSO Comment: The proposal to add a new term Lipotransfer is approved as requested. Lipotransfer is a surgical procedure used to transfer fat from one part of the body to another. Lipotransfer is commonly used for both cosmetic and reconstructive purposes. Lipotransfer will be added as a synonym LLT to PT Lipoinjection.

CR Number: 2023220004	Implementation Date: 17-Aug-23	Related CR: 2023220004	
Change Requested	Add a New Term	Final Disposition	Final Placement
			MedDRA Code #
Proposed Term	<i>Acupoint catgut embedding</i>	Approved as Requested	Proposed LLT <i>Acupoint catgut embedding</i>
			10090149 Current
			To PT <i>Acupuncture</i>
			10000646

MSSO Comment: The proposal to add a new term Acupoint catgut embedding is approved as requested. Acupoint catgut embedding is an innovative acupuncture method combined with traditional theory and modern materials, which embeds absorbed catgut into the acupoints, where the catgut will undergo softening, liquefaction, and absorption, thereby stimulating the acupoints for a long time. LLT Acupoint catgut embedding will be added under PT Acupuncture aligned with the synonym LLT Needle embedding therapy.

CR Number: 2023220005	Implementation Date: 31-Aug-23	Related CR: 2023220005	
Change Requested	Add a New Term	Final Disposition	Final Placement
			MedDRA Code #
Proposed Term	<i>Thyroid incidentaloma</i>	Approved After Suspension	Proposed LLT <i>Thyroid incidentaloma</i>
			10090207 Current
			To PT <i>Thyroid neoplasm</i>
			10043744

MSSO Comment: The proposal to add a new term Thyroid incidentaloma is approved as requested after suspension. A thyroid incidentaloma is an unexpected, asymptomatic thyroid tumor fortuitously discovered during the investigation of an unrelated condition. LLT Thyroid incidentaloma will be added under PT Thyroid neoplasm.

Supplemental Update Report

CR Number: 2023220007 **Implementation Date:** 17-Aug-23 **Related CR:** 2023220007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Gynaecological trichomonas infection</i>	Rejected		
HLT primary	<i>Trichomonas infections</i>			
SOC primary	<i>Infections and infestations</i>			

MSSO Comment: The proposal to add a new PT Gynaecological trichomonas infection to primary HLT Trichomonas infections in SOC Infections and infestations and secondary HLT Pelvic and site unspecified infections and inflammations in SOC Reproductive system and breast disorders is not approved. The proposed term can be represented by split coding with LLT Genital infection female and/or LLT Trichomoniasis.

CR Number: 2023221002 **Implementation Date:** 17-Aug-23 **Related CR:** 2023221002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Chronic gastritis with hemorrhage</i>	Rejected		

MSSO Comment: The proposal to add a new term Chronic gastritis with hemorrhage is not approved. Concept may be represented by existing MedDRA LLTs Chronic gastritis and Gastritis haemorrhagic. The LLT Atrophic gastritis, with hemorrhage can also be used depending on the context. Please refer to the MedDRA Points to Consider section 3.5.4, "When to 'split' into more than one MedDRA term."

CR Number: 2023221003 **Implementation Date:** 17-Aug-23 **Related CR:** 2023221003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Naso-intestinal tube placement</i>	Approved as Requested	Proposed LLT <i>Naso-intestinal tube placement</i>	10090151 Current
			To PT <i>Gastrointestinal tube insertion</i>	10053050

MSSO Comment: The proposal to add a new LLT Naso-intestinal tube placement is approved as requested. Patients unsuitable for enteral nutrition by nasogastric tube, need to be provided with post-pyloric feeding. Enteral nutrition through nasointestinal tube (NIT) is the preferred choice, as it can effectively avoid aspiration caused by reflux, and enhance feeding tolerance. Naso-intestinal tube placement will be added as sub-concept LLT under PT Gastrointestinal tube insertion aligned with LLT Nasogastric tube insertion.

Supplemental Update Report

CR Number: 2023221004 Implementation Date: 31-Aug-23 Related CR: 2023221004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>RRNP</i>	Rejected After Suspension		

MSSO Comment: The proposal to add a new LLT RRNP is not approved after suspension. The proposed term is vague. Please consider if LLT Ribonucleoprotein antibody fulfills your coding needs.

CR Number: 2023222001 Implementation Date: 16-Aug-23 Related CR: 2023222001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Ashy dermatosis</i>	Approved as Requested	Proposed LLT <i>Ashy dermatosis</i>	10090123 Current
To PT	<i>Erythema dyschromicum perstans</i>		To PT <i>Erythema dyschromicum perstans</i>	10055035

MSSO Comment: The proposal to add a new LLT Ashy dermatosis to PT Erythema dyschromicum perstans is approved as requested. Erythema dyschromicum perstans, also called ashly dermatosis (of Ramirez), is a form of acquired dermal macular hyperpigmentation characterised by well-circumscribed round to oval or irregular patches on the face, neck and trunk that are grey in colour.

CR Number: 2023222002 Implementation Date: 16-Aug-23 Related CR: 2023222002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Add a New PT <i>Granulocytapheresis</i>	Approved as Requested	Proposed PT <i>Granulocytapheresis</i>	10090122
HLT primary	<i>Blood and blood product treatment</i>		HLT primary <i>Blood and blood product treatment</i>	10019028
SOC primary	<i>Surgical and medical procedures</i>		SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new PT Granulocytapheresis to primary HLT Blood and blood product treatment in SOC Surgical and medical procedures is approved as requested. Granulocytapheresis (GCAP) is a new technique that removes a significant amount of circulating granulocytes, reducing their migration into the intestinal mucosa. Granulocytapheresis may be an alternative treatment in a variety of inflammatory conditions: It can be used in cases of granulocytosis, inflammatory bowel disease (IBD), rheumatoid arthritis, and certain leukemias with high granulocyte counts.

Supplemental Update Report

CR Number: 2023222003 Implementation Date: 17-Aug-23 Related CR: 2023222003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Cone beam computed tomography (CBCT)</i>	Approved Not as Requested	Proposed LLT <i>Cone beam computerised tomography</i>	10090152 Current
			To PT <i>Computerised tomogram</i>	10010234

MSSO Comment: The proposal to add a new LLT Cone beam computed tomography (CBCT) is approved but not as requested. Cone-beam CT is a specialized medical imaging technique used primarily in the fields of dentistry, oral, maxillofacial and extremity imaging. It differs from conventional CT in that it uses a cone-shaped x-ray beam and two dimensional detectors instead of a fan-shaped x-ray beam. The requested term will be modified to LLT Cone beam computerised tomography for consistency reasons and removal of acronym added to PT Computerised tomogram. In a related change, the LLT Cone beam computerized tomography will be added as the American English counterpart to PT Computerised tomogram. Furthermore, the acronym LLT CBCT will be added to PT Computerised tomogram.

CR Number: 2023229004 Implementation Date: 17-Aug-23 Related CR: 2023222003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Cone beam computerized tomography</i>	Approved as Requested	Proposed LLT <i>Cone beam computerized tomography</i>	10090154 Current
To PT	<i>Computerised tomogram</i>		To PT <i>Computerised tomogram</i>	10010234

MSSO Comment:

CR Number: 2023229005 Implementation Date: 17-Aug-23 Related CR: 2023222003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>CBCT</i>	Approved as Requested	Proposed LLT <i>CBCT</i>	10090153 Current
To PT	<i>Computerised tomogram</i>		To PT <i>Computerised tomogram</i>	10010234

MSSO Comment:

Supplemental Update Report

CR Number: 2023223001		Implementation Date: 17-Aug-23	Related CR: 2023223001	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Anti-liver cytosol antibody type 1 negative</i>	Approved Not as Requested	Proposed PT <i>Anti-liver cytosol antibody type 1 negative</i>	10090155
			HLT primary <i>Autoimmunity analyses</i>	10003828
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new LLT Anti-liver cytosol antibody type 1 negative is approved but not as requested. Anti-liver cytosol antibody type 1 negative indicates absence of autoantibodies (immunoglobulins) in the serum that react against a 60-kd peptide contained in the liver cytosolic fraction. Anti-liver cytosol antibody type 1 negative will be added as PT to HLT Autoimmunity analyses as counterpart to existing PT Anti-liver cytosol antibody type 1 positive.

CR Number: 2023223002		Implementation Date: 17-Aug-23	Related CR: 2023223002	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Anti-liver cytosol antibody type 1</i>	Approved Not as Requested	Proposed PT <i>Anti-liver cytosol antibody type 1</i>	10090156
			HLT primary <i>Autoimmunity analyses</i>	10003828
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new LLT Anti-liver cytosol antibody type 1 is approved but not as requested. Anti-liver cytosol antibody type 1 is an investigation for autoantibodies (immunoglobulins) in the serum that react against a 60-kd peptide contained in the liver cytosolic fraction. Anti-liver cytosol antibody type 1 will be added as a PT to HLT Autoimmunity analyses as the unqualified counterpart to existing LLT/PT Anti-liver cytosol antibody type 1 positive and LLT/PT Anti-liver cytosol antibody type 1 negative.

CR Number: 2023223003		Implementation Date: 17-Aug-23	Related CR: 2023223003	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Pre-osteoporosis</i>	Rejected		
To PT	<i>Osteopenia</i>			

MSSO Comment: The proposal to add a new LLT Pre-osteoporosis to PT Osteopenia is not approved. Although the term does exist in some literature references, there is no clear medical definition for pre-osteoporosis.

Supplemental Update Report

CR Number: 2023223004 Implementation Date: 17-Aug-23 Related CR: 2023223004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Dengue reinfection	Rejected		
To PT	Dengue fever			

MSSO Comment: The proposal to add a new LLT Dengue reinfection to PT Dengue fever is not approved. The requested concept exists in LLT Dengue fever virus reinfection and LLT Dengue virus reinfection.

CR Number: 2023223005 Implementation Date: 17-Aug-23 Related CR: 2023223005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Inappropriate interval between two different vaccine administrations	Approved Not as Requested	Proposed LLT Inappropriate administration interval between different vaccines	10090157 Current
To PT	Inappropriate schedule of product administration		To PT Inappropriate schedule of product administration	10081572

MSSO Comment: The proposal to add a new LLT Inappropriate interval between two different vaccine administrations to PT Inappropriate schedule of product administration is approved but not as requested. Drugs often require specific intervals between administration when taken alongside other medications. The same applies for vaccines, especially live virus vaccines. The requested term Inappropriate interval between two different vaccine administrations will be modified for clarity to LLT Inappropriate administration interval between different vaccines to PT Inappropriate schedule of product administration.

CR Number: 2023226001 Implementation Date: 17-Aug-23 Related CR: 2023226001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Bacterial nail infection	Approved Not as Requested	Proposed LLT Bacterial nail infection	10090158
To PT	Paronychia		To PT Nail bed infection bacterial	10065244 Current

MSSO Comment: The proposal to add a new LLT Bacterial nail infection to PT Paronychia is approved but not as requested. Bacterial nail infection is a general term to represent cases not specified as paronychia or nail bed infections. Bacterial nail infection will be added as an LLT under PT Nail bed infection bacterial. In a related change, PT Nail bed infection bacterial will be swapped with LLT Bacterial nail infection to represent the broader concept at PT level.

Supplemental Update Report

CR Number: 2023229006	Implementation Date: 17-Aug-23	Related CR: 2023226001		
<u>Change Requested</u>	Swap a PT with an LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Nail bed infection bacterial</i>	Approved as Requested	Proposed PT	
With LLT	<i>Bacterial nail infection</i>		<i>Nail bed infection bacterial</i>	10065244 Current
			With LLT	
			<i>Bacterial nail infection</i>	10090158

MSSO
Comment:

CR Number: 2023226002	Implementation Date: 17-Aug-23	Related CR: 2023226002		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Peritoneal thickening</i>	Approved Not as Requested	Proposed PT	
			<i>Peritoneal thickening</i>	10090159
			HLT primary	
			<i>Peritoneal and retroperitoneal disorders</i>	10034653
			SOC primary	
			<i>Gastrointestinal disorders</i>	10017947

MSSO
Comment: The proposal to add a new LLT Peritoneal thickening is approved but not as requested. Peritoneal thickening is a descriptive term given to describe any form of thickening of the peritoneum. It can occur with both benign and malignant peritoneal disease. It can be classified into various sub-types based on its morphology: smooth, irregular or nodular peritoneal thickening. Peritoneal thickening will be added as new PT under HLT Peritoneal and retroperitoneal disorders.

CR Number: 2023226003	Implementation Date: 25-Aug-23	Related CR: 2023226003		
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Aortic dissection repair</i>	Rejected		
To SMQ	<i>Haemorrhage terms (excl laboratory terms) (SMQ)</i>			
Term scope	<i>Narrow</i>			

MSSO
Comment: The proposal to add PT Aortic dissection repair to Haemorrhage terms (excl laboratory terms) (SMQ) as a narrow term is not approved. Aortic dissection can lead to internal bleeding however, the intent of the repair is to prevent the bleeding from happening rather than to treat a ruptured vessel. Additionally, PT Aortic dissection is not included in the SMQ.

Supplemental Update Report

CR Number: 2023226004 Implementation Date: 25-Aug-23 Related CR: 2023226004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Hypophenylalaninaemia</i>	Rejected		
To SMQ	<i>Depression (excl suicide and self injury) (SMQ)</i>			
Term scope	<i>Broad</i>			

MSSO Comment: The proposal to add PT Hypophenylalaninaemia to Depression (excl suicide and self injury) (SMQ) as a broad term is not approved. Although newer studies suggest that low levels of phenylalanine could be linked to major depressive disorder, it is not yet fully established. Other neurotransmitter related terms such as PT Serotonin deficiency are not included in the SMQ.

CR Number: 2023226006 Implementation Date: 25-Aug-23 Related CR: 2023226006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Chung-Jansen syndrome</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Congenital, familial and genetic disorders (SMQ)</i>		<i>Chung-Jansen syndrome</i>	10090066
Term scope	<i>Narrow</i>		To SMQ	
			<i>Congenital, familial and genetic disorders (SMQ)</i>	20000077
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Chung-Jansen 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: 2023226007

Implementation Date: 25-Aug-23

Related CR: 2023226007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Dursun syndrome</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Congenital, familial and genetic disorders (SMQ)</i>		<i>Dursun syndrome</i>	10090065
Term scope	<i>Narrow</i>		To SMQ	
			<i>Congenital, familial and genetic disorders (SMQ)</i>	20000077
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Dursun 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: 2023226008

Implementation Date: 25-Aug-23

Related CR: 2023226008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Nerve oedema</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Peripheral neuropathy (SMQ)</i>		<i>Nerve oedema</i>	10089959
Term scope	<i>Broad</i>		To SMQ	
			<i>Peripheral neuropathy (SMQ)</i>	20000034
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Nerve oedema to Peripheral neuropathy (SMQ) as a Broad term is approved as requested. Nerve edema is a common response to the nerve injury seen in many peripheral neuropathies and is an important component of Wallerian degeneration. Because a finding of nerve swelling is not limited to peripheral neuropathies, this term will be added to the broad search terms of this SMQ.

Supplemental Update Report

CR Number: 2023226009

Implementation Date: 25-Aug-23

Related CR: 2023226009

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT *Painful legs-moving toes syndrome*

Approved as Requested

Proposed PT

To SMQ *Peripheral neuropathy (SMQ)*

Painful legs-moving toes syndrome

10089938

Term scope *Broad*

To SMQ

Peripheral neuropathy (SMQ)

20000034

Term scope

Broad

Term_category

A

Term_weight

0

MSSO Comment: The proposal to add PT Painful legs-moving toes syndrome to Peripheral neuropathy (SMQ) as a Broad term is approved as requested. The syndrome of painful legs-moving toes (PLMT) is a rare, adult-onset disorder characterized by pain, typically of a neuropathic quality, in the feet or legs, associated with writhing movements of one or more toes. The syndrome may be unilateral or bilateral. The pathophysiology of PLMT is not known, but most reports suggest an association with a peripheral lesion, usually at the level of the root or nerve. This term will be included as a broad search term in this SMQ.

CR Number: 2023226010

Implementation Date: 25-Aug-23

Related CR: 2023226010

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT *Subcortical stroke*

Approved as Requested

Proposed PT

To SMQ *Haemorrhagic central nervous system vascular conditions (SMQ)*

Subcortical stroke

10089974

Term scope *Narrow*

To SMQ

Haemorrhagic central nervous system vascular conditions (SMQ)

20000064

Term scope

Narrow

Term_category

A

Term_weight

0

MSSO Comment: The proposal to add PT Subcortical stroke to Haemorrhagic central nervous system vascular conditions (SMQ) as a Narrow term is approved as requested. A stroke may affect subcortical structures including the internal capsule, thalamus, basal ganglia, brainstem and cerebellum. These strokes may be either ischemic or hemorrhagic in nature. Depending upon the locations, patients may experience symptoms include motor weakness, sensory loss, imbalance, visual impairment and autonomic findings. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2023226011 Implementation Date: 25-Aug-23 Related CR: 2023226011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add term to SMQ <i>Subcortical stroke</i>	Approved as Requested	Proposed PT <i>Subcortical stroke</i>	10089974
To SMQ	<i>Ischaemic central nervous system vascular conditions (SMQ)</i>		To SMQ <i>Ischaemic central nervous system vascular conditions (SMQ)</i>	20000063
Term scope	<i>Narrow</i>		Term scope <i>Narrow</i>	
			Term_category A	
			Term_weight 0	

MSSO Comment: The proposal to add PT Subcortical stroke to Ischaemic central nervous system vascular conditions (SMQ) as a Narrow term is approved as requested. A stroke may affect subcortical structures including the internal capsule, thalamus, basal ganglia, brainstem and cerebellum. These strokes may be either ischemic or hemorrhagic in nature. Depending upon the locations, patients may experience symptoms include motor weakness, sensory loss, imbalance, visual impairment and autonomic findings. All terms in this SMQ are narrow in scope.

CR Number: 2023226012 Implementation Date: 25-Aug-23 Related CR: 2023226012

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add term to SMQ <i>Cardiac ventricular thrombosis</i>	Approved as Requested	Proposed PT <i>Cardiac ventricular thrombosis</i>	10053994
To SMQ	<i>Noninfectious myocarditis/pericarditis (SMQ)</i>		To SMQ <i>Noninfectious myocarditis/pericarditis (SMQ)</i>	20000239
Term scope	<i>Broad</i>		Term scope <i>Broad</i>	
			Term_category A	
			Term_weight 0	

MSSO Comment: The proposal to add PT Cardiac ventricular thrombosis to Noninfectious myocarditis/pericarditis (SMQ) as a Broad term is approved as requested. An intraventricular thrombus may develop as a consequence of myocarditis due to associated ventricular and systolic dysfunction. PT Intracardiac thrombus was previously included under the broad search terms of this SMQ, but this term has now been demoted under PT Cardiac ventricular thrombosis. Because cardiac ventricular thrombus formation can occur in disorders besides myocarditis, this PT will be added to the broad search terms of this SMQ.

Supplemental Update Report

CR Number: 2023226013

Implementation Date: 25-Aug-23

Related CR: 2023226013

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add term to SMQ <i>Opsoclonus</i>	Approved as Requested	Proposed PT <i>Opsoclonus</i>	10090043
To SMQ	<i>Ocular motility disorders (SMQ)</i>		To SMQ <i>Ocular motility disorders (SMQ)</i>	20000184
Term scope	<i>Narrow</i>		Term scope <i>Narrow</i>	
			Term_category A	
			Term_weight 0	

MSSO Comment: The proposal to add PT Opsoclonus to Ocular motility disorders (SMQ) as a Narrow term is approved as requested. New term for v27.0 which fits inclusion criteria as a narrow term, see related PT Opsoclonus myoclonus. Opsoclonus is an oculomotor dyskinesia characterized by rapid, repetitive conjugate eye movements that are involuntary, arrhythmic, chaotic, and multidirectional (horizontal, vertical, and torsional components) without intersaccadic intervals. It is most pronounced when the patient is awake and attempting fixation, often causing visual blur and oscillopsia because of the high frequency of the oscillations.

CR Number: 2023226014

Implementation Date: 25-Aug-23

Related CR: 2023226014

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add term to SMQ <i>Proliferating pilar tumour</i>	Approved as Requested	Proposed PT <i>Proliferating pilar tumour</i>	10089977
To SMQ	<i>Non-haematological tumours of unspecified malignancy (SMQ)</i>		To SMQ <i>Non-haematological tumours of unspecified malignancy (SMQ)</i>	20000230
Term scope	<i>Narrow</i>		Term scope <i>Narrow</i>	
			Term_category A	
			Term_weight 0	

MSSO Comment: The proposal to add PT Proliferating pilar tumour to Non-haematological tumours of unspecified malignancy (SMQ) as a Narrow term is approved as requested. New term for v27.0 which fits inclusion - all term are narrow in sope. A proliferating pilar tumor is a rare skin neoplasm that arises from the outer root sheath of a hair follicle. Presentation varies widely, as the tumor can be benign or malignant and has a high probability of recurring after excision.

Supplemental Update Report

CR Number: 2023226015

Implementation Date: 25-Aug-23

Related CR: 2023226015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Interleukin gene expression positive</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Tumour markers (SMQ)</i>		<i>Interleukin gene expression positive</i>	10090086
Term scope	<i>Narrow</i>		To SMQ	
			<i>Tumour markers (SMQ)</i>	20000094
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Interleukin gene expression positive to Tumour markers (SMQ) as a Narrow term is approved as requested. New term for v27.0 which fits inclusion criterion as a tumor marker. Interleukins have a critical role in cancer development, progression and control. Interleukins can nurture an environment enabling and favouring cancer growth while simultaneously being essential for a productive tumour-directed immune response.

CR Number: 2023226016

Implementation Date: 25-Aug-23

Related CR: 2023226016

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Interleukin gene expression</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Tumour markers (SMQ)</i>		<i>Interleukin gene expression</i>	10090085
Term scope	<i>Narrow</i>		To SMQ	
			<i>Tumour markers (SMQ)</i>	20000094
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Interleukin gene expression to Tumour markers (SMQ) as a Narrow term is approved as requested. New term which fits inclusion as a tumor marker. Interleukins and associated cytokines serve as the means of communication for innate and adaptive immune cells as well as non-immune cells and tissues. Thus, interleukins have a critical role in cancer development, progression and control. Interleukins can nurture an environment enabling and favouring cancer growth while simultaneously being essential for a productive tumour-directed immune response.

Supplemental Update Report

CR Number: 2023226017

Implementation Date: 25-Aug-23

Related CR: 2023226017

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Lactate dehydrogenase pleural fluid increased</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>		<i>Lactate dehydrogenase pleural fluid increased</i>	10089926
Term scope	<i>Narrow</i>		To SMQ	
			<i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>	20000093
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Lactate dehydrogenase pleural fluid increased to Malignancy related therapeutic and diagnostic procedures (SMQ) as a Narrow term is approved as requested. New term for v27.0 Elevated levels of LDH in pleural effusion may be an indicator for some cancers.

CR Number: 2023226018

Implementation Date: 25-Aug-23

Related CR: 2023226018

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Matrix metalloproteinase inhibitor-1 increased</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>		<i>Matrix metalloproteinase inhibitor-1 increased</i>	10089941
Term scope	<i>Narrow</i>		To SMQ	
			<i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>	20000093
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Matrix metalloproteinase inhibitor-1 increased to Malignancy related therapeutic and diagnostic procedures (SMQ) as a Narrow term is approved as requested. New term for v27.0 which fit inclusion criterion for this SMQ. Matrix metalloproteinases and their inhibitors play a major role in the maintenance of extracellular matrix homeostasis. Alterations of MMP and TIMP expressions have been found in several malignant tumour entities.

Supplemental Update Report

CR Number: 2023226019 Implementation Date: 25-Aug-23 Related CR: 2023226019

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add term to SMQ <i>Interleukin gene positive cancer</i>	Approved as Requested	Proposed PT <i>Interleukin gene positive cancer</i>	10090084
To SMQ	<i>Non-haematological malignant tumours (SMQ)</i>		To SMQ <i>Non-haematological malignant tumours (SMQ)</i>	20000228
Term scope	<i>Narrow</i>		Term scope <i>Narrow</i>	
			Term_category A	
			Term_weight 0	

MSSO Comment: The proposal to add PT Interleukin gene positive cancer to Non-haematological malignant tumours (SMQ) as a Narrow term is approved as requested. New term for v27.0 which fits inclusion criterion. Interleukin signaling in cancer cells can become a pathological mechanism of tumour growth, metastatic spread and cancer progression.

CR Number: 2023226020 Implementation Date: 25-Aug-23 Related CR: 2023226020

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add term to SMQ <i>Malignant ossifying fibromyxoid tumour</i>	Approved as Requested	Proposed PT <i>Malignant ossifying fibromyxoid tumour</i>	10090056
To SMQ	<i>Non-haematological malignant tumours (SMQ)</i>		To SMQ <i>Non-haematological malignant tumours (SMQ)</i>	20000228
Term scope	<i>Narrow</i>		Term scope <i>Narrow</i>	
			Term_category A	
			Term_weight 0	

MSSO Comment: The proposal to add PT Malignant ossifying fibromyxoid tumour to Non-haematological malignant tumours (SMQ) as a Narrow term is approved as requested. New term for v27.0 which fit inclusion criterion for this SMQ. Ossifying fibromyxoid tumors are rare, soft tissue neoplasms that develop in the subcutaneous layer of the skin. Ossifying fibromyxoid tumors are a unique mesenchymal tumor that can mimic other dermatological disorders and go undiagnosed in many patients.

Supplemental Update Report

CR Number: 2023226021 Implementation Date: 25-Aug-23 Related CR: 2023226021

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Proliferating pilar tumour</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Skin tumours of unspecified malignancy (SMQ)</i>		<i>Proliferating pilar tumour</i>	10089977
Term scope	<i>Narrow</i>		To SMQ	
			<i>Skin tumours of unspecified malignancy (SMQ)</i>	20000205
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Proliferating pilar tumour to Skin tumours of unspecified malignancy (SMQ) as a Narrow term is approved as requested. New term for v27.0 which fit inclusion criterion as narrow in scope. A proliferating pilar tumor is a rare skin neoplasm that arises from the outer root sheath of a hair follicle. Presentation varies widely, as the tumor can be benign or malignant and has a high probability of recurring after excision.

CR Number: 2023226022 Implementation Date: 25-Aug-23 Related CR: 2023226022

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Bile duct tumour margin resection</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>		<i>Bile duct tumour margin resection</i>	10089924
Term scope	<i>Narrow</i>		To SMQ	
			<i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>	20000093
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Bile duct tumour margin resection to Malignancy related therapeutic and diagnostic procedures (SMQ) as a Narrow term is approved as requested. New term which fits inclusion criterion for this SMQ. Resection margin of extra-hepatic cholangiocarcinomas is of utmost importance, because both high-grade dysplasia and carcinoma in situ of the biliary duct tumor margin are negative prognostic factors, especially between patients with early stages of extra-hepatic cholangiocarcinoma.

Supplemental Update Report

CR Number: 2023226023

Implementation Date: 25-Aug-23

Related CR: 2023226023

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add term to SMQ <i>Nephroureterocystectomy</i>	Approved as Requested	Proposed PT <i>Nephroureterocystectomy</i>	10090006
To SMQ	<i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>		To SMQ <i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>	20000093
Term scope	<i>Narrow</i>		Term scope <i>Narrow</i>	
			Term_category A	
			Term_weight 0	

MSSO Comment: The proposal to add PT Nephroureterocystectomy to Malignancy related therapeutic and diagnostic procedures (SMQ) as a Narrow term is approved as requested. New term for v27.0 which fits inclusion criterion for this SMQ. Nephroureterocystectomy is the excision of the kidney, ureter, and part or all of the bladder. This may be indicated when patients have been diagnosed with a mass or tumor within the lining of the kidney and/or ureter most often malignancies.

CR Number: 2023226024

Implementation Date: 25-Aug-23

Related CR: 2023226024

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add term to SMQ <i>Spondylectomy</i>	Approved as Requested	Proposed PT <i>Spondylectomy</i>	10090067
To SMQ	<i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>		To SMQ <i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>	20000093
Term scope	<i>Narrow</i>		Term scope <i>Narrow</i>	
			Term_category A	
			Term_weight 0	

MSSO Comment: The proposal to add PT Spondylectomy to Malignancy related therapeutic and diagnostic procedures (SMQ) as a Narrow term is approved as requested. New term which fits inclusion criterion of this SMQ: En bloc spondylectomy is a surgical procedure that enables the complete resection of a vertebra for the total removal of a vertebral malignant lesion.

Supplemental Update Report

CR Number: 2023226025

Implementation Date: 25-Aug-23

Related CR: 2023226025

Change Requested

Add term to SMQ

Final Disposition

Approved as Requested

Final Placement

MedDRA
Code #

Proposed PT *Oligoclonal gammopathy*

To SMQ *Malignancy related conditions (SMQ)*

Term scope *Narrow*

Proposed PT

Oligoclonal gammopathy

To SMQ

Malignancy related conditions (SMQ)

Term scope

Narrow

Term_category

A

Term_weight

0

10075625

20000092

MSSO The proposal to add PT Oligoclonal gammopathy to Malignancy related conditions (SMQ) as a Narrow term is approved as requested. This term was promoted for v27.0 from under PT
Comment: Hypergammaglobulinaemia and now is reassigned to primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps). Oligoclonal gammopathy often is related to malignancies and therefore fits inclusion criterion for this SMQ. Related PT Monoclonal gammopathy is included as well. Oligoclonality could develop at any time after the diagnosis of monoclonal gammopathy as seen in hematological malignancies such as multiple myeloma.

CR Number: 2023226026

Implementation Date: 25-Aug-23

Related CR: 2023226026

Change Requested

Add term to SMQ

Final Disposition

Approved as Requested

Final Placement

MedDRA
Code #

Proposed PT *Renal forniceal rupture*

To SMQ *Malignancy related conditions (SMQ)*

Term scope *Narrow*

Proposed PT

Renal forniceal rupture

To SMQ

Malignancy related conditions (SMQ)

Term scope

Narrow

Term_category

A

Term_weight

0

10089973

20000092

MSSO The proposal to add PT Renal forniceal rupture to Malignancy related conditions (SMQ) as a Narrow term is approved as requested. Renal forniceal rupture is a common finding in patients with ureteral obstruction. It is thought to be due to increased renal pelvis pressure from backup of urine, causing one or more renal fornices to leak urine. The most common aetiology of renal forniceal rupture is obstruction caused by distal ureteric stones followed by malignant extrinsic ureteric compression.

Supplemental Update Report

CR Number: 2023226027

Implementation Date: 25-Aug-23

Related CR: 2023226027

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Eosinophilic hepatitis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Hepatitis, non-infectious (SMQ)</i>		<i>Eosinophilic hepatitis</i>	10089967
Term scope	<i>Narrow</i>		To SMQ	
			<i>Hepatitis, non-infectious (SMQ)</i>	20000010
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Eosinophilic hepatitis to Hepatitis, non-infectious (SMQ) as a Narrow term is approved as requested. Eosinophilic hepatitis is associated with a variety of disorders such as parasitic infestations, allergic conditions, internal malignancies, drug hypersensitivity, and hypereosinophilic syndrome. Like other non-directly-infective hepatitis, this term will be added to the narrow scope of this SMQ.

CR Number: 2023226028

Implementation Date: 25-Aug-23

Related CR: 2023226028

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Rectal tamponade</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Gastrointestinal haemorrhage (SMQ)</i>		<i>Rectal tamponade</i>	10090055
Term scope	<i>Narrow</i>		To SMQ	
			<i>Gastrointestinal haemorrhage (SMQ)</i>	20000108
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Rectal tamponade to Gastrointestinal haemorrhage (SMQ) as a Narrow term is approved as requested. The application of a balloon tamponade device or procedure is an important treatment option to be considered in the management of acute lower gastrointestinal bleed.

Supplemental Update Report

CR Number: 2023226029

Implementation Date: 25-Aug-23

Related CR: 2023226029

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT	<i>Autoimmune hypoparathyroidism</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Immune-mediated/autoimmune disorders (SMQ)</i>		<i>Autoimmune hypoparathyroidism</i>	10090022
Term scope	<i>Narrow</i>		To SMQ	
			<i>Immune-mediated/autoimmune disorders (SMQ)</i>	20000236
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Autoimmune hypoparathyroidism to Immune-mediated/autoimmune disorders (SMQ) as a Narrow term is approved as requested. Isolated and acquired hypoparathyroidism occurs as an autoimmune disorder either alone or in association with other autoimmune diseases. Like other terms referring to immune-mediated and autoimmune disorders, this term will be added to the narrow scope of this SMQ.

CR Number: 2023226030

Implementation Date: 25-Aug-23

Related CR: 2023226030

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT	<i>Autoimmune oophoritis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Immune-mediated/autoimmune disorders (SMQ)</i>		<i>Autoimmune oophoritis</i>	10090023
Term scope	<i>Narrow</i>		To SMQ	
			<i>Immune-mediated/autoimmune disorders (SMQ)</i>	20000236
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Autoimmune oophoritis to Immune-mediated/autoimmune disorders (SMQ) as a Narrow term is approved as requested. Autoimmune oophoritis is a pathological destruction of the ovaries caused by exposure to antiovarial antibodies. Like other terms referring to immune-mediated and autoimmune disorders, this term will be added to the narrow scope of this SMQ.

Supplemental Update Report

CR Number: 2023226031

Implementation Date: 25-Aug-23

Related CR: 2023226031

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Central nervous system listeria infection	Approved as Requested	Proposed PT	
To SMQ	Opportunistic infections (SMQ)		Central nervous system listeria infection	10090002
Term scope	Narrow		To SMQ	
			Opportunistic infections (SMQ)	20000235
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Central nervous system listeria infection to Opportunistic infections (SMQ) as a Narrow term is approved as requested. CNS infections is due to listeria occur mainly in neonates, adults \geq age 60, pregnant women, and immunocompromised patients. Like PTs Listeria encephalitis and Meningitis listeria, this new term will be added to the narrow scope of this SMQ.

CR Number: 2023226032

Implementation Date: 25-Aug-23

Related CR: 2023226032

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Dermatolymphangiadenitis	Approved as Requested	Proposed PT	
To SMQ	Opportunistic infections (SMQ)		Dermatolymphangiadenitis	10089930
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 Dermatolymphangiadenitis to Opportunistic infections (SMQ) as a Broad term is approved as requested. Dermatolymphangiadenitis (also known as infectious cellulitis) is a common and serious bacterial infection of the deeper layers of the skin, due to obstructive peripheral lymphedema. The presentation is a combination of lymphangitis, lymphadenitis, cellulitis and abscess formation which in more frequent in the immunocompromised host. Similarly to PTs PT Cellulitis streptococcal and PT Cellulitis staphylococcal, this new term will be added to the broad scope.

Supplemental Update Report

CR Number: 2023226033

Implementation Date: 25-Aug-23

Related CR: 2023226033

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Human herpesvirus 6 viraemia</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Opportunistic infections (SMQ)</i>		<i>Human herpesvirus 6 viraemia</i>	10090018
Term scope	<i>Narrow</i>		To SMQ	
			<i>Opportunistic infections (SMQ)</i>	20000235
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Human herpesvirus 6 viraemia to Opportunistic infections (SMQ) as a Narrow term is approved as requested. Human herpesvirus 6 has been increasingly recognized as an opportunistic and potentially life-threatening pathogen after hematopoietic cell transplantation and other immunocompromised states. Like PT Human herpesvirus 6 infection reactivation, it will be added to the narrow scope of the SMQ.

CR Number: 2023226034

Implementation Date: 25-Aug-23

Related CR: 2023226034

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Genital dryness</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Sexual dysfunction (SMQ)</i>		<i>Genital dryness</i>	10090020
Term scope	<i>Narrow</i>		To SMQ	
			<i>Sexual dysfunction (SMQ)</i>	20000238
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Genital dryness to Sexual dysfunction (SMQ) as a Narrow term is approved as requested. Genital dryness is frequently associated to discomfort. Like PT Inadequate lubrication and other already included PTs related to genital discomfort and dysesthesia leading to diminished or altered genital sensation, this PT will be added to the narrow scope of the SMQ.

Supplemental Update Report

CR Number: 2023226035

Implementation Date: 25-Aug-23

Related CR: 2023226035

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT

Gastrointestinal angiodysplasia

Approved as Requested

Proposed PT

Gastrointestinal angiodysplasia

10017928

To SMQ

Gastrointestinal haemorrhage (SMQ)

Term scope

Narrow

To SMQ

Gastrointestinal haemorrhage (SMQ)

20000108

Term scope

Narrow

Term_category

A

Term_weight

0

MSSO Comment: The proposal to add PT Gastrointestinal angiodysplasia to Gastrointestinal haemorrhage (SMQ) as a Narrow term is approved as requested. Gastrointestinal angiodysplasias are dilated arteriovenous malformations with tortuous vessels that typically develop in the cecum and ascending colon. They occur mainly in people > age 60 and are the most common cause of lower gastrointestinal bleeding in that age group. Similarly, to other vascular malformations with high hemorrhage proclivity already included the SMQ (such as PTs Duodenal vascular ectasia, Gastric antral vascular ectasia, Gastroduodenal artery aneurysm or Gastrointestinal vascular malformation haemorrhagic), PT Gastrointestinal angiodysplasia, to which PT Gastrointestinal angiectasia was demoted, will be added to this SMQ.

CR Number: 2023226036

Implementation Date: 25-Aug-23

Related CR: 2023226036

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT

Rectal tamponade

Approved as Requested

Proposed PT

Rectal tamponade

10090055

To SMQ

Ischaemic colitis (SMQ)

Term scope

Broad

To SMQ

Ischaemic colitis (SMQ)

20000144

Term scope

Broad

Term_category

A

Term_weight

0

MSSO Comment: The proposal to add PT Rectal tamponade to Ischaemic colitis (SMQ) as a Broad term is approved as requested. Ischemic colitis is a frequent cause of acute lower intestinal hemorrhage, a circumstance in which rectal tamponade can be an effective treatment approach. Since rectal tamponade can be also used in other causes of acute lower intestinal hemorrhage, this PT will be added to the broad scope of this SMQ.

Supplemental Update Report

CR Number: 2023226037

Implementation Date: 25-Aug-23

Related CR: 2023226037

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Pes anserinus syndrome</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Tendinopathies and ligament disorders (SMQ)</i>		<i>Pes anserinus syndrome</i>	10090028
Term scope	<i>Narrow</i>		To SMQ	
			<i>Tendinopathies and ligament disorders (SMQ)</i>	20000223
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT *Pes anserinus syndrome* to *Tendinopathies and ligament disorders (SMQ)* as a *Narrow* term is approved as requested. This term fits the inclusion criteria for this SMQ for a narrow scope term. A related PT *Tendonitis* is already included as a narrow scope term.

CR Number: 2023226038

Implementation Date: 25-Aug-23

Related CR: 2023226038

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Hyperspermia</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Fertility disorders (SMQ)</i>		<i>Hyperspermia</i>	10090008
Term scope	<i>Narrow</i>		To SMQ	
			<i>Fertility disorders (SMQ)</i>	20000210
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT *Hyperspermia* to *Fertility disorders (SMQ)* as a *Narrow* term is approved as requested. This term fits the inclusion criteria for this SMQ which includes terms for low fertility. Large volumes of ejaculate may have lower relative volumes of sperm, leading to low fertility. Similar term such as PT *Hypospermia* is already included as a narrow scope term.

Supplemental Update Report

CR Number: 2023226039

Implementation Date: 25-Aug-23

Related CR: 2023226039

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Eosinophilic hepatitis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)</i>		<i>Eosinophilic hepatitis</i>	10089967
Term scope	<i>Broad</i>		To SMQ	
			<i>Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)</i>	20000225
			Term scope	
			<i>Broad</i>	
			Term_category	
			<i>B</i>	
			Term_weight	
			<i>0</i>	

MSSO Comment: The proposal to add PT Eosinophilic hepatitis 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 Eosinophilic gastritis and PT Allergic hepatitis are already included as broad scope terms.

CR Number: 2023226040

Implementation Date: 25-Aug-23

Related CR: 2023226040

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Epithelitis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)</i>		<i>Epithelitis</i>	10089937
Term scope	<i>Broad</i>		To SMQ	
			<i>Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)</i>	20000225
			Term scope	
			<i>Broad</i>	
			Term_category	
			<i>B</i>	
			Term_weight	
			<i>0</i>	

MSSO Comment: The proposal to add PT Epithelitis 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 which includes relevant terms related to mucocutaneous involvement commonly seen in DRESS cases. Similar term such as PT Dermatitis is already included as a broad scope term.

Supplemental Update Report

CR Number: 2023226041

Implementation Date: 25-Aug-23

Related CR: 2023226041

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT	<i>Nerve oedema</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Haemodynamic oedema, effusions and fluid overload (SMQ)</i>		<i>Nerve oedema</i>	10089959
Term scope	<i>Narrow</i>		To SMQ	
			<i>Haemodynamic oedema, effusions and fluid overload (SMQ)</i>	20000145
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Nerve 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 Bone marrow oedema and PT Brain oedema are already included as narrow scope terms.

CR Number: 2023226042

Implementation Date: 25-Aug-23

Related CR: 2023226042

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT	<i>Autoimmune hypoparathyroidism</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)</i>		<i>Autoimmune hypoparathyroidism</i>	10090022
Term scope	<i>Broad</i>		To SMQ	
			<i>Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)</i>	20000225
			Term scope	
			<i>Broad</i>	
			Term_category	
			B	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Autoimmune hypoparathyroidism 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 Autoimmune thyroiditis and PT Autoimmune myocarditis are already included as broad scope terms.

Supplemental Update Report

CR Number: 2023226043

Implementation Date: 25-Aug-23

Related CR: 2023226043

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT *Hyperspermia*
To SMQ *Fertility disorders (SMQ)*
Term scope *Narrow*

Rejected

Proposed PT
Hyperspermia 10090008
To SMQ
Fertility disorders (SMQ) 20000210
Term scope
Narrow
Term_category
A
Term_weight
0

MSSO Comment: The proposal to add PT Hyperspermia to Fertility disorders (SMQ) as a narrow term is not approved. This change request is a duplicate of CR 2033226038.

CR Number: 2023226044

Implementation Date: 25-Aug-23

Related CR: 2023226044

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT *Schistosomiasis pulmonary*
To SMQ *Infective pneumonia (SMQ)*
Term scope *Narrow*

Approved as Requested

Proposed PT
Schistosomiasis pulmonary 10089957
To SMQ
Infective pneumonia (SMQ) 20000231
Term scope
Narrow
Term_category
A
Term_weight
0

MSSO Comment: The proposal to add PT Schistosomiasis pulmonary to Infective pneumonia (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ for a narrow scope term. A similar PT Pulmonary echinococcosis is already included as a narrow scope term.

Supplemental Update Report

CR Number: 2023226045

Implementation Date: 25-Aug-23

Related CR: 2023226045

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add term to SMQ <i>Subcortical stroke</i>	Approved as Requested	Proposed PT <i>Subcortical stroke</i>	10089974
To SMQ	<i>Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ)</i>		To SMQ <i>Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ)</i>	20000083
Term scope	<i>Narrow</i>		Term scope <i>Narrow</i>	
			Term_category A	
			Term_weight 0	

MSSO Comment: The proposal to add PT Subcortical stroke 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 stroke related events. Similar terms, such as PT Basal ganglia stroke and PT Brain stem stroke are already included in this SMQ. All terms are narrow scope.

CR Number: 2023226046

Implementation Date: 25-Aug-23

Related CR: 2023226046

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add term to SMQ <i>Mixed obstructive and restrictive lung disease</i>	Approved as Requested	Proposed PT <i>Mixed obstructive and restrictive lung disease</i>	10089961
To SMQ	<i>Interstitial lung disease (SMQ)</i>		To SMQ <i>Interstitial lung disease (SMQ)</i>	20000042
Term scope	<i>Broad</i>		Term scope <i>Broad</i>	
			Term_category A	
			Term_weight 0	

MSSO Comment: The proposal to add PT Mixed obstructive and restrictive lung disease to Interstitial lung disease (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ for the terms referring to interstitial pulmonary disease for a broad scope term. A similar PT Sarcoidosis is already included as a broad scope term.

Supplemental Update Report

CR Number: 2023226047

Implementation Date: 25-Aug-23

Related CR: 2023226047

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT *Renal forniceal rupture*
To SMQ *Retroperitoneal fibrosis (SMQ)*
Term scope *Broad*

Approved as Requested

Proposed PT
Renal forniceal rupture 10089973
To SMQ
Retroperitoneal fibrosis (SMQ) 20000065
Term scope
Broad
Term_category
A
Term_weight
0

MSSO Comment: The proposal to add PT Renal forniceal rupture to Retroperitoneal fibrosis (SMQ) as a Broad term is approved as requested. The PT Renal forniceal rupture was added in v27.0. Renal forniceal rupture is a common finding in patients with ureteral obstruction. It is thought to be due to increased renal pelvis pressure from backup of urine, causing one or more renal fornices to leak urine. PT Renal forniceal rupture is included in this SMQ as broad scope term representing associated conditions that develop as a consequence.

CR Number: 2023226048

Implementation Date: 25-Aug-23

Related CR: 2023226048

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT *Mixed obstructive and restrictive lung disease*
To SMQ *Asthma/bronchospasm (SMQ)*
Term scope *Broad*

Approved as Requested

Proposed PT
Mixed obstructive and restrictive lung disease 10089961
To SMQ
Asthma/bronchospasm (SMQ) 20000025
Term scope
Broad
Term_category
A
Term_weight
0

MSSO Comment: The proposal to add PT Mixed obstructive and restrictive lung disease to Asthma/bronchospasm (SMQ) as a Broad term is approved as requested. The PT Mixed obstructive and restrictive lung disease was added in v27.0. Respiratory disorders are commonly classified as demonstrating obstructive or restrictive physiology, however a smaller, third category, called mixed lung disease, has characteristics of obstructive and restrictive lung diseases. The PT Mixed obstructive and restrictive lung disease is included in this SMQ as broad scope term in line with PT Obstructive airways disorder.

Supplemental Update Report

CR Number: 2023226049	Implementation Date: 25-Aug-23	Related CR: 2023226049		
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Autoimmune oophoritis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Fertility disorders (SMQ)</i>		<i>Autoimmune oophoritis</i>	10090023
Term scope	<i>Narrow</i>		To SMQ	
			<i>Fertility disorders (SMQ)</i>	20000210
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Autoimmune oophoritis to Fertility disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar term such as PT Ovarian failure is already included as narrow scope term.

CR Number: 2023226051	Implementation Date: 23-Aug-23	Related CR: 2023226051		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Patellar ligament rupture</i>	Approved Not as Requested	Proposed LLT	
			<i>Patellar tendon rupture</i>	10090160 Current
			To PT	
			<i>Tendon rupture</i>	10043248

MSSO Comment: The proposal to add a new term Patellar ligament rupture is approved but not as requested. The patella is a bone fragment inserted into the tendon of the quadriceps muscle for better transmission of forces. A patellar tendon rupture is a severe injury in which the patellar tendon, which connects the patella to the tibia, becomes completely torn or ruptured. Patellar ligament and tendon are used interchangeably, although ligaments are defined as connecting bone to bone and tendons as connecting muscle to bone. The requested term will be modified to LLT Patellar tendon rupture to align the concept with the existing LLT Non-traumatic rupture of patellar tendon and added under PT Tendon rupture.

CR Number: 2023227001	Implementation Date: 23-Aug-23	Related CR: 2023227001		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Frog in throat</i>	Rejected		
To PT	<i>Sensation of foreign body</i>			

MSSO Comment: The proposal to add a new LLT Frog in throat to PT Sensation of foreign body is not approved. The proposed term is too colloquial and can be interpreted to mean many different things.

Supplemental Update Report

CR Number: 2023228001	Implementation Date: 23-Aug-23	Related CR: 2023228001	MedDRA Code #
Change Requested	Add a New Term	Final Disposition	Final Placement
Proposed Term	<i>Diastema closure</i>	Approved as Requested	Proposed PT <i>Diastema closure</i> 10090161 HLT primary <i>Dental and gingival therapeutic procedures</i> 10012317 SOC primary <i>Surgical and medical procedures</i> 10042613

MSSO Comment: The proposal to add a new term Diastema closure is approved as requested. Diastema closure is correction of maxillary anterior spacing. Diastema closure will be placed as a PT to HLT Dental and gingival therapeutic procedures.

CR Number: 2023228002	Implementation Date: 23-Aug-23	Related CR: 2023228002	MedDRA Code #
Change Requested	Add a New Term	Final Disposition	Final Placement
Proposed Term	<i>Orthodontic tooth movement</i>	Rejected	

MSSO Comment: The proposal to add a new term Orthodontic tooth movement is not approved. Orthodontic tooth movement is an inherent feature of orthodontic procedures, which are always intended to align teeth through moving them. In a related change, PT Orthodontic traction will be demoted under PT Orthodontic procedure. Orthodontic procedures apply a combination of forces to the teeth to push or pull them into the desired place.

CR Number: 2023235002	Implementation Date: 23-Aug-23	Related CR: 2023228002	MedDRA Code #
Change Requested	Demote a PT	Final Disposition	Final Placement
PT to merge	<i>Orthodontic traction</i>	Approved as Requested	PT to merge <i>Orthodontic traction</i> 10080402 Current
To PT	<i>Orthodontic procedure</i>		To PT <i>Orthodontic procedure</i> 10031121

MSSO Comment:

Supplemental Update Report

CR Number: 2023228003	Implementation Date: 23-Aug-23	Related CR: 2023228003	MedDRA Code #
Change Requested		Final Disposition	Final Placement
Proposed Term <i>Maxillary osteotomy</i>		Approved as Requested	Proposed PT <i>Maxillary osteotomy</i> 10090162
			HLT primary <i>Facial therapeutic procedures</i> 10016058
			SOC primary <i>Surgical and medical procedures</i> 10042613

MSSO Comment: The proposal to add a new term Maxillary osteotomy is approved as requested. Maxillary osteotomy is a routine procedure for the correction of dentofacial deformities, and can be performed in one or multiple bone segments. Maxillary osteotomy will be added as a PT to HLT Facial therapeutic procedures, aligned with the closely related PT Orthognathic surgery. In a related change, LLT Le Fort osteotomy will be moved from PT Maxillofacial operation to new PT Maxillary osteotomy for better alignment.

CR Number: 2023235003	Implementation Date: 23-Aug-23	Related CR: 2023228003	MedDRA Code #
Change Requested		Final Disposition	Final Placement
Proposed LLT <i>Le Fort osteotomy</i>	Link (move) an LLT to another PT	Approved as Requested	Proposed LLT <i>Le Fort osteotomy</i> 10077382 Current
From PT <i>Maxillofacial operation</i>			From PT <i>Maxillofacial operation</i> 10054806
To PT <i>Maxillary osteotomy</i>			To PT <i>Maxillary osteotomy</i> 10090162

MSSO Comment:

CR Number: 2023228004	Implementation Date: 23-Aug-23	Related CR: 2023228004	MedDRA Code #
Change Requested		Final Disposition	Final Placement
Proposed Term <i>Pulmonary inflammatory granuloma</i>	Add a New Term	Rejected	

MSSO Comment: The proposal to add a new term Pulmonary inflammatory granuloma is not approved. The proposed term is a characteristic inherent to granulomas since they all have an inflammatory component.

Supplemental Update Report

CR Number: 2023228005 Implementation Date: 23-Aug-23 Related CR: 2023228005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Gamma-aminobutyrate aminotransferase increased</i>	Approved as Requested	Proposed PT <i>Gamma-aminobutyrate aminotransferase increased</i>	10090163
			HLT primary <i>Tissue enzyme analyses NEC</i>	10043891
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new term Gamma-aminobutyrate aminotransferase increased is approved as requested. It has been found that raising Gamma-aminobutyric acid (GABA) levels can antagonize the rapid elevation and release of dopamine in the nucleus accumbens, which is responsible for the reward response in addiction. Therefore, the design of new inhibitors of GABA-AT, which increases brain GABA levels, is an important approach to new treatments for epilepsy and addiction. Gamma-aminobutyrate aminotransferase increased will be added as new PT under HLT Tissue enzyme analyses NEC.

CR Number: 2023228017 Implementation Date: 23-Aug-23 Related CR: 2023228017

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Planning target volume</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Planning target volume is not approved. The planning target volume (PTV) is determined by adding margin to the clinical target volume to account for internal target volume and patient motion, and the field margins are set to conform to the PTV with allowance for the radiotherapy beam penumbra and dose build-up effect. This is a term beyond the scope of MedDRA as it deals with technical aspects of radiation oncology.

CR Number: 2023228018 Implementation Date: 23-Aug-23 Related CR: 2023228018

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Secondary haemophagocytic lymphohistiocytosis</i>	Rejected		
From PT	<i>Haemophagocytic lymphohistiocytosis</i>			

MSSO Comment: The proposal to promote the LLT Secondary haemophagocytic lymphohistiocytosis from PT Haemophagocytic lymphohistiocytosis is not approved. The non qualified PT Haemophagocytic lymphohistiocytosis already represents the secondary form of the hematologic disorder, since it is the more frequent form. The primary (or familial) hematophagic lymphohistiocytosis is represented independently by PT Familial haemophagocytic lymphohistiocytosis and all its "primary qualified" LLTs.

Supplemental Update Report

CR Number: 2023229001	Implementation Date: 23-Aug-23	Related CR: 2023229001	MedDRA Code #
Change Requested	Add a New Term	Final Disposition	Final Placement
Proposed Term	<i>Disseminated herpes simplex</i>	Approved as Requested	Proposed PT <i>Disseminated herpes simplex</i> 10090164 HLT primary <i>Herpes viral infections</i> 10019972 SOC primary <i>Infections and infestations</i> 10021881

MSSO Comment: The proposal to add a new term Disseminated herpes simplex is approved as requested. Disseminated herpes simplex is a severe and widespread form of HSV infection that occurs when the virus spreads beyond the initial site of infection. This condition is more common in individuals with compromised immune systems. It can lead to serious symptoms and complications and can be life-threatening if not treated promptly. Disseminated herpes simplex will be added as a PT under the HLT Herpes viral infections.

CR Number: 2023229002	Implementation Date: 31-Aug-23	Related CR: 2023229002	MedDRA Code #
Change Requested	Add a New LLT	Final Disposition	Final Placement
Proposed LLT	<i>Robotic salvage lymph node dissection</i>	Approved After Suspension	Proposed LLT <i>Robotic salvage lymph node dissection</i> 10090208 Current To PT <i>Lymphadenectomy</i> 10048956

MSSO Comment: The proposal to add a new LLT Robotic salvage lymph node dissection is approved as requested after suspension. Salvage lymph node dissection is a rescue treatment for patients with nodal or biochemical recurrence. Robotic salvage lymph node dissection is a feasible approach with low perioperative morbidity and delays further systemic therapy in most patients. Robotic salvage lymph node dissection will be added as sub-concept LLT under PT Lymphadenectomy.

CR Number: 2023230001	Implementation Date: 23-Aug-23	Related CR: 2023230001	MedDRA Code #
Change Requested	Add a New LLT	Final Disposition	Final Placement
Proposed LLT	<i>Immune-mediated rheumatoid arthritis</i>	Rejected	

MSSO Comment: The proposal to add a new LLT Immune-mediated rheumatoid arthritis is not approved. Rheumatoid arthritis is understood to be an autoimmune and inflammatory disease and thus the very nature of the concept is immune mediated. Furthermore, the link of PT Rheumatoid arthritis is secondary HLT Rheumatoid arthritis and associated conditions which is in SOC Immune system disorders.

Supplemental Update Report

CR Number: 2023230002 **Implementation Date:** 23-Aug-23 **Related CR:** 2023230002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Streptococcus Hominis infection</i>	Rejected		

MSSO Comment: The proposal to add a new term Streptococcus Hominis infection is not approved. Majority of literature references point to Staphylococcus hominis which is normally found on human skin and is usually harmless, but can sometimes cause infections in people with abnormally weak immune systems.

CR Number: 2023230003 **Implementation Date:** 23-Aug-23 **Related CR:** 2023230003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Cheiralgia paraesthetica</i>	Approved as Requested	Proposed LLT	
To PT	<i>Radial nerve compression</i>		<i>Cheiralgia paraesthetica</i>	10090168 Current
			To PT	
			<i>Radial nerve compression</i>	10071930

MSSO Comment: The proposal to add a new LLT Cheiralgia paraesthetica to PT Radial nerve compression is approved as requested. This LLT is the British English spelling for the LLT Cheiralgia paresthetica which was added in v26.1.

CR Number: 2023230004 **Implementation Date:** 23-Aug-23 **Related CR:** 2023230004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Wound tunnelling</i>	Approved as Requested	Proposed LLT	
To PT	<i>Wound complication</i>		<i>Wound tunnelling</i>	10090167 Current
			To PT	
			<i>Wound complication</i>	10053692

MSSO Comment: The proposal to add a new LLT Wound tunnelling to PT Wound complication is approved as requested. This LLT is the British English spelling for the LLT Wound tunneling.

Supplemental Update Report

CR Number: 2023230005 Implementation Date: 23-Aug-23 Related CR: 2023230005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Term to modify	<i>Tunneled haemodialysis</i>	Approved as Requested	Term to modify	
Replacement term	<i>Tunnelled haemodialysis</i>		<i>Tunneled haemodialysis</i>	10086496
			Replacement term	
			<i>Tunnelled haemodialysis</i>	10086496 Current

MSSO Comment: The proposal to rename PT/LLT Tunneled haemodialysis to Tunnelled haemodialysis is approved as requested. LLT Tunneled haemodialysis is a combination of the American English spelling of "Tunneled" and the British English spelling of "haemodialysis". Therefore, the spelling will be changed to Tunnelled haemodialysis, as a British English counterpart for the LLT Tunneled hemodialysis.

CR Number: 2023231001 Implementation Date: 23-Aug-23 Related CR: 2023231001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Speech-language pathology (SLP)</i>	Approved Not as Requested	Proposed LLT	
			<i>Speech-language therapy</i>	10090165
			To PT	
			<i>Speech rehabilitation</i>	10051212 Current

MSSO Comment: The proposal to add a new LLT Speech-language pathology (SLP) is approved but not as requested. Speech-language therapy or speech-language pathology, is a type of therapeutic intervention aimed at assessing and treating individuals with communication disorders or difficulties related to language and speech. The term will be modified to Speech-language therapy for better distinction between a therapy and a disorder, as well as better universal understanding. LLT Speech-language therapy will be added under PT Speech rehabilitation. In a related change, PT Speech rehabilitation will be swapped with LLT Speech-language therapy, to have the broader concept represented at the PT level.

CR Number: 2023235005 Implementation Date: 23-Aug-23 Related CR: 2023231001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Speech rehabilitation</i>	Approved as Requested	Proposed PT	
With LLT	<i>Speech-language therapy</i>		<i>Speech rehabilitation</i>	10051212 Current
			With LLT	
			<i>Speech-language therapy</i>	10090165

MSSO Comment:

Supplemental Update Report

CR Number: 2023233001	Implementation Date: 23-Aug-23	Related CR: 2023233001		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Gastrocolic fistula</i>	Approved Not as Requested	Proposed PT	
To PT	<i>Gastrointestinal fistula</i>		<i>Gastrocolic fistula</i>	10090166
			HLT primary	
			<i>Gastrointestinal fistulae</i>	10017952
			SOC primary	
			<i>Gastrointestinal disorders</i>	10017947

MSSO Comment: The proposal to add a new LLT Gastrocolic fistula to PT Gastrointestinal fistula is approved but not as requested. The fistulous connection in a gastrocolic fistula usually arises between the greater curvature of stomach and the distal half of the transverse colon because of their close anatomical proximity separated only by the gastrocolic omentum. Gastrocolic fistula will be added as a PT to HLT Gastrointestinal fistulae.

CR Number: 2023233002	Implementation Date: 23-Aug-23	Related CR: 2023233002		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Rotator cuff calcific tendinopathy</i>	Rejected		
To PT	<i>Tendon calcification</i>			

MSSO Comment: The proposal to add a new LLT Rotator cuff calcific tendinopathy to PT Tendon calcification is not approved. The proposed term is represented as LLT Calcifying tendinitis of shoulder under PT Rotator cuff syndrome.

CR Number: 2023233004	Implementation Date: 31-Aug-23	Related CR: 2023233004		
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Exposure via father</i>	Rejected After Suspension		
To PT	<i>Paternal exposure timing unspecified</i>			

MSSO Comment: The proposal to demote the PT Exposure via father under PT Paternal exposure timing unspecified is not approved after suspension. Based on your question, the LLT Fetal exposure via father under the PT Exposure via father clarifies that the exposure is to fetus. The second concern of exposure to a child whose father may have been wearing a medicinal patch is addressed in the Points to Consider Term selection guide in section 3.15.2 Accidental exposures, in which the code that would most appropriately capture this scenario is LLT Exposure via skin contact. Please check the term hierarchy for better clarity/context of the concept. For your information The MSSO has been working with the Points To Consider working group to reorganize existing and add new sets of pregnancy exposure terms in order to make them self explanatory. The placement for Exposure via father as a PT was the result of this collaboration.

Supplemental Update Report

CR Number: 2023233005 **Implementation Date:** 31-Aug-23 **Related CR:** 2023233005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
LLT to change	<i>Exposure via father</i>	Rejected After Suspension		
Status	<i>non-current</i>			

MSSO Comment: The proposal to change status of LLT Exposure via father to non-current is not approved after suspension. This is a technical rejection since PT Exposure via father was not demoted in change request 2023233004.

CR Number: 2023234005 **Implementation Date:** 30-Aug-23 **Related CR:** 2023234005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Splenic iron overload</i>	Approved Not as Requested	Proposed PT <i>Splenic iron overload</i>	10090170
			HLT primary <i>Spleen disorders</i>	10041635
			SOC primary <i>Blood and lymphatic system disorders</i>	10005329
			HLT secondary <i>Iron excess</i>	10022979
			SOC secondary <i>Metabolism and nutrition disorders</i>	10027433

MSSO Comment: The proposal to add a new LLT Splenic iron overload is approved but not as requested. Iron overload is characterized by excess iron deposition within the reticuloendothelial cells of the liver, spleen, heart and endocrine organs. Splenic iron overload will be added as PT with a primary link to HLT Spleen disorders, secondary link to HLT Iron excess, and secondary link to HLT Transfusion related complications.

CR Number: 2023242002 **Implementation Date:** 30-Aug-23 **Related CR:** 2023234005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Splenic iron overload</i>	Approved as Requested	Proposed PT <i>Splenic iron overload</i>	10090170
To HLT	<i>Transfusion related complications</i>		To HLT <i>Transfusion related complications</i>	10057191

MSSO Comment:

Supplemental Update Report

CR Number: 2023234006

Implementation Date: 30-Aug-23

Related CR: 2023234006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Hepatic iron overload</i>	Approved Not as Requested	Proposed PT <i>Hepatic iron overload</i>	10090169
			HLT primary <i>Hepatic metabolic disorders</i>	10019689
			SOC primary <i>Hepatobiliary disorders</i>	10019805
			HLT secondary <i>Iron excess</i>	10022979
			SOC secondary <i>Metabolism and nutrition disorders</i>	10027433

MSSO Comment: The proposal to add a new LLT Hepatic iron overload is approved but not as requested. Morbidity resulting from iron overload is mainly due to iron accumulation in the liver, endocrine organs and heart. Hepatic iron overload is characterized by iron accumulation in hepatocytes and bile duct epithelium. Hepatic iron overload will be added as PT with a primary link to HLT Hepatic metabolic disorders, to secondary HLT Iron excess and to secondary HLT Transfusion related complications. In a related change existing PT Hepatic siderosis will be demoted under new PT Hepatic iron overload.

CR Number: 2023242003

Implementation Date: 30-Aug-23

Related CR: 2023234006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Hepatic iron overload</i>	Approved as Requested	Proposed PT <i>Hepatic iron overload</i>	10090169
To HLT	<i>Transfusion related complications</i>		To HLT <i>Transfusion related complications</i>	10057191

MSSO Comment:

Supplemental Update Report

CR Number: 2023242004	Implementation Date: 30-Aug-23	Related CR: 2023234006	
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>
PT to merge	<i>Hepatic siderosis</i>	Approved as Requested	PT to merge
To PT	<i>Hepatic iron overload</i>		<i>Hepatic siderosis</i>
			10051659 Current
			To PT
			<i>Hepatic iron overload</i>
			10090169

MSSO
Comment:

CR Number: 2023234007	Implementation Date: 30-Aug-23	Related CR: 2023234007	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Ischiofemoral impingement syndrome</i>	Approved Not as Requested	Proposed PT
			<i>Ischiofemoral impingement syndrome</i>
			10090171
			HLT primary
			<i>Joint related disorders NEC</i>
			10027685
			SOC primary
			<i>Musculoskeletal and connective tissue disorders</i>
			10028395
			HLT secondary
			<i>Bone and joint injuries NEC</i>
			10074485
			SOC secondary
			<i>Injury, poisoning and procedural complications</i>
			10022117

MSSO
Comment: The proposal to add a new LLT Ischiofemoral impingement syndrome is approved but not as requested. Ischiofemoral impingement syndrome is a neglected cause of posterior hip pain which is derived from narrowing of the space between the lateral aspect of the ischium and the medial aspect of the lesser trochanter, causing edema, fat infiltration or even tearing of the quadratus femoris muscle. Ischiofemoral impingement syndrome will be added as a PT to primary HLT Joint related disorders NEC and to secondary HLT Bone and joint injuries NEC.

Supplemental Update Report

CR Number: 2023235001 Implementation Date: 30-Aug-23 Related CR: 2023235001

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Anogenital granulomatosis</i>	Approved as Requested	Proposed PT <i>Anogenital granulomatosis</i>	10090172
		HLT primary <i>Reproductive tract infections and inflammations NEC</i>	10038613
		SOC primary <i>Reproductive system and breast disorders</i>	10038604
		HLT secondary <i>Immune and associated conditions NEC</i>	10027682
		SOC secondary <i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new term Anogenital granulomatosis is approved as requested. Anogenital granulomatosis is a rare condition that presents with genital lymphoedema, and there is frequently a protracted delay in diagnosis. There is a very strong association with intestinal Crohn's disease. Anogenital granulomatosis will be added as new PT under primary HLT Reproductive tract infections and inflammations NEC, to secondary HLT Immune and associated conditions NEC, to secondary HLT Anal and rectal disorders NEC, to secondary HLT Granulomatous and deep cutaneous inflammatory conditions and to secondary HLT Lymphoedemas.

CR Number: 2023242007 Implementation Date: 30-Aug-23 Related CR: 2023235001

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT <i>Anogenital granulomatosis</i>	Approved as Requested	Proposed PT <i>Anogenital granulomatosis</i>	10090172
To HLT <i>Anal and rectal disorders NEC</i>		To HLT <i>Anal and rectal disorders NEC</i>	10002113

MSSO Comment:

Supplemental Update Report

CR Number: 2023242008	Implementation Date: 30-Aug-23	Related CR: 2023235001		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Anogenital granulomatosis</i>	Approved as Requested	Proposed PT	
To HLT	<i>Granulomatous and deep cutaneous inflammatory conditions</i>		<i>Anogenital granulomatosis</i>	10090172
			To HLT	
			<i>Granulomatous and deep cutaneous inflammatory conditions</i>	10018699

MSSO
Comment:

CR Number: 2023242009	Implementation Date: 30-Aug-23	Related CR: 2023235001		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Anogenital granulomatosis</i>	Approved as Requested	Proposed PT	
To HLT	<i>Lymphoedemas</i>		<i>Anogenital granulomatosis</i>	10090172
			To HLT	
			<i>Lymphoedemas</i>	10052790

MSSO
Comment:

CR Number: 2023235004	Implementation Date: 30-Aug-23	Related CR: 2023235004		
<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Pseudomyxoma peritonei</i>	Rejected		
Old Primary SOC	<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>			
New Primary SOC	<i>Gastrointestinal disorders</i>			

MSSO
Comment: The proposal to reassign the primary SOC of PT Pseudomyxoma peritonei from current SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) to SOC Gastrointestinal disorders is not approved. Although seemingly associated with peritoneal location, this is actually a phenomenon of the tumour itself and thus best placed in primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps).

Supplemental Update Report

CR Number: 2023236003 Implementation Date: 30-Aug-23 Related CR: 2023236003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Shark bite	Rejected		
To PT	Animal bite			

MSSO Comment: The proposal to add a new LLT Shark bite to PT Animal bite is not approved. Shark bites on humans are extremely rare but can have very serious consequences potentially resulting in death. The addition of a new LLT Shark bite is rejected. In order to avoid the overpopulation of terms in MedDRA, the MSSO generally refrains from adding additional terms for animal bites from different species, especially for extremely rare incidences.

CR Number: 2023236004 Implementation Date: 30-Aug-23 Related CR: 2023236004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Radiotherapy treatment planning	Rejected		

MSSO Comment: The proposal to add a new LLT Radiotherapy treatment planning is not approved. The objective of radiotherapy treatment planning is to obtain an optimal balance between delivering a high dose to target volume and a low dose to intervening tissues. This concept is beyond the scope of MedDRA as it deals with technical preparatory aspects of radiation oncology.

CR Number: 2023236005 Implementation Date: 30-Aug-23 Related CR: 2023236005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Rectal wall edema	Approved as Requested	Proposed LLT Rectal wall edema	10090173 Current
			To PT Gastrointestinal oedema	10058061

MSSO Comment: The proposal to add a new LLT Rectal wall edema is approved as requested. Gastrointestinal oedema is a medical condition referring to the build-up of excess fluid in the interstitial spaces of the intestinal wall tissue and may be seen in places such as rectal wall. Rectal wall edema will be added as LLT under PT Gastrointestinal oedema. In a related change, the British English spelled counterpart LLT Rectal wall oedema will also be added under PT Gastrointestinal oedema.

Supplemental Update Report

CR Number: 2023242010	Implementation Date: 30-Aug-23	Related CR: 2023236005		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Rectal wall oedema</i>	Approved as Requested	Proposed LLT	
To PT	<i>Gastrointestinal oedema</i>		<i>Rectal wall oedema</i>	10090175 Current
			To PT	
			<i>Gastrointestinal oedema</i>	10058061

MSSO
Comment:

CR Number: 2023236006	Implementation Date: 30-Aug-23	Related CR: 2023236006		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Streptococcal Salivarius infection</i>	Approved Not as Requested	Proposed LLT	
			<i>Streptococcus salivarius infection</i>	10090174 Current
			To PT	
			<i>Alpha haemolytic streptococcal infection</i>	10054265

MSSO
Comment: The proposal to add a new LLT Streptococcal Salivarius infection is approved but not as requested. Streptococcus salivarius, a nonpathogenic and commensal organism, may cause symptomatic infection in patients with end-stage liver disease. This streptococcal infection may be associated with increased morbidity. The proposed term will be modified to conform with MedDRA capitalization standards and better alignment added as LLT Streptococcus salivarius infection to PT Alpha haemolytic streptococcal infection.

CR Number: 2023236007	Implementation Date: 30-Aug-23	Related CR: 2023236007		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Intraspinal abscess drainage</i>	Approved as Requested	Proposed LLT	
			<i>Intraspinal abscess drainage</i>	10090176 Current
			To PT	
			<i>Abscess drainage</i>	10000279

MSSO
Comment: The proposal to add a new LLT Intraspinal abscess drainage is approved as requested. Intraspinal refers to space within the vertebral column. As such, spinal epidural abscess represents infection of the epidural space, located between the spinal dura mater and the vertebral periosteum. It can present with rapidly deteriorating neurological function due to compression. Intraspinal abscess drainage will be added as sub-concept LLT under PT Abscess drainage.

Supplemental Update Report

CR Number: 2023237001 Implementation Date: 30-Aug-23 Related CR: 2023237001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Capillary hyperplasia	Rejected		

MSSO Comment: The proposal to add a new term Capillary hyperplasia is not approved. Capillary hyperplasia refers to an abnormal increase in the number of capillaries in a particular tissue or organ. Capillary hyperplasia can be a response to various factors or conditions, including tumour growth but also in wound healing or increased demand in exercising muscle. The requester justification refers to reactive cutaneous capillary endothelial proliferation existing as an LLT Reactive cutaneous capillary endothelial proliferation under PT Reactive capillary endothelial proliferation.

CR Number: 2023237004 Implementation Date: 31-Aug-23 Related CR: 2023237004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Post-administration patient monitoring incorrectly performed	Approved as Requested	Proposed LLT Post-administration patient monitoring incorrectly performed	10090188 Current
To PT	Drug monitoring procedure incorrectly performed		To PT Drug monitoring procedure incorrectly performed	10075461

MSSO Comment: The proposal to add a new LLT Post-administration patient monitoring incorrectly performed to PT Drug monitoring procedure incorrectly performed is approved as requested. There are many instances where a patient is administered a drug and not followed long enough as recommended in the label.

CR Number: 2023237005 Implementation Date: 31-Aug-23 Related CR: 2023237005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Drug monitoring procedure performed at incorrect intervals	Approved as Requested	Proposed LLT Drug monitoring procedure performed at incorrect intervals	10090189 Current
To PT	Drug monitoring procedure incorrectly performed		To PT Drug monitoring procedure incorrectly performed	10075461

MSSO Comment: The proposal to add a new LLT Drug monitoring procedure performed at incorrect intervals to PT Drug monitoring procedure incorrectly performed is approved as requested. Often a patient who is on a treatment regimen does not receive proper monitoring at pre-specified intervals as recommended in the label.

Supplemental Update Report

CR Number: 2023237006 **Implementation Date:** 31-Aug-23 **Related CR:** 2023237006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Post-administration patient monitoring not performed</i>	Approved as Requested	Proposed LLT <i>Post-administration patient monitoring not performed</i>	10090194 Current
To PT	<i>Drug monitoring procedure not performed</i>		To PT <i>Drug monitoring procedure not performed</i>	10075462

MSSO Comment: The proposal to add a new LLT Post-administration patient monitoring not performed to PT Drug monitoring procedure not performed is approved as requested. There are many instances where a patient is not monitored at all after receiving treatment which is labeled for post-administration monitoring.

CR Number: 2023237007 **Implementation Date:** 31-Aug-23 **Related CR:** 2023237007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>First-dose observation not performed</i>	Approved as Requested	Proposed LLT <i>First-dose observation not performed</i>	10090195 Current
To PT	<i>Drug monitoring procedure not performed</i>		To PT <i>Drug monitoring procedure not performed</i>	10075462

MSSO Comment: The proposal to add a new LLT First-dose observation not performed to PT Drug monitoring procedure not performed is approved as requested. Often a patient receives a first dose of a medication and is not monitored after the first dose as recommended in the label.

CR Number: 2023237008 **Implementation Date:** 31-Aug-23 **Related CR:** 2023237008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Labeled hepatic function monitoring not performed</i>	Approved as Requested	Proposed LLT <i>Labeled hepatic function monitoring not performed</i>	10090191 Current
To PT	<i>Drug monitoring procedure not performed</i>		To PT <i>Drug monitoring procedure not performed</i>	10075462

MSSO Comment: The proposal to add a new LLT Labeled hepatic function monitoring not performed to PT Drug monitoring procedure not performed is approved as requested. The concept may capture the scenario where a patient was not clinically monitored for hepatic function even though it is labelled for the drug that the patient needs hepatic function monitoring. In a related change, the British spelled counterpart will be added as LLT Labelled hepatic function monitoring not performed to PT Drug monitoring procedure not performed.

Supplemental Update Report

CR Number: 2023243006 Implementation Date: 31-Aug-23 Related CR: 2023237008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT	Approved as Requested	Proposed LLT	
To PT	<i>Labelled hepatic function monitoring not performed</i>		<i>Labelled hepatic function monitoring not performed</i>	10090198 Current
	<i>Drug monitoring procedure not performed</i>		To PT	
			<i>Drug monitoring procedure not performed</i>	10075462

MSSO
Comment:

CR Number: 2023237009 Implementation Date: 31-Aug-23 Related CR: 2023237009

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT	Approved Not as Requested	Proposed LLT	
To PT	<i>Labeled blood test not monitored</i>		<i>Labeled blood monitoring test not performed</i>	10090192 Current
	<i>Drug monitoring procedure not performed</i>		To PT	
			<i>Drug monitoring procedure not performed</i>	10075462

MSSO
Comment: The proposal to add a new LLT Labeled blood test not monitored to PT Drug monitoring procedure not performed is approved but not as requested. Concept will capture the scenario where specific blood tests are not obtained during the use of the drug, which are recommended in the label of product administered. Proposed term will be modified for greater clarity and added as LLT Labeled blood monitoring test not performed under PT Drug monitoring procedure not performed. In a related change, the British spelled counterpart LLT Labelled blood monitoring test not performed will also be added under PT Drug monitoring procedure not performed.

CR Number: 2023243007 Implementation Date: 31-Aug-23 Related CR: 2023237009

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT	Approved as Requested	Proposed LLT	
To PT	<i>Labelled blood monitoring test not performed</i>		<i>Labelled blood monitoring test not performed</i>	10090197 Current
	<i>Drug monitoring procedure not performed</i>		To PT	
			<i>Drug monitoring procedure not performed</i>	10075462

MSSO
Comment:

Supplemental Update Report

CR Number: 2023237010 **Implementation Date:** 31-Aug-23 **Related CR:** 2023237010

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Labeled monitoring of drug effect by a blood test not performed</i>	Approved Not as Requested	Proposed LLT <i>Labeled drug effect monitoring not performed</i>	10090190 Current
To PT	<i>Drug monitoring procedure not performed</i>		To PT <i>Drug monitoring procedure not performed</i>	10075462

MSSO Comment: The proposal to add a new LLT Labeled monitoring of drug effect by a blood test not performed to PT Drug monitoring procedure not performed is approved but not as requested. The requested term will be modified and added as LLT Labeled drug effect monitoring not performed to PT Drug monitoring procedure not performed. In a related change, the British spelled counterpart LLT Labelled drug effect monitoring not performed will also be added to PT Drug monitoring procedure not performed.

CR Number: 2023243008 **Implementation Date:** 31-Aug-23 **Related CR:** 2023237010

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Labelled drug effect monitoring not performed</i>	Approved as Requested	Proposed LLT <i>Labelled drug effect monitoring not performed</i>	10090199 Current
To PT	<i>Drug monitoring procedure not performed</i>		To PT <i>Drug monitoring procedure not performed</i>	10075462

MSSO Comment:

CR Number: 2023237011 **Implementation Date:** 31-Aug-23 **Related CR:** 2023237011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Drug level monitored incorrectly</i>	Approved as Requested	Proposed LLT <i>Drug level monitored incorrectly</i>	10090193 Current
To PT	<i>Therapeutic drug monitoring analysis incorrectly performed</i>		To PT <i>Therapeutic drug monitoring analysis incorrectly performed</i>	10073703

MSSO Comment: The proposal to add a new LLT Drug level monitored incorrectly to PT Therapeutic drug monitoring analysis incorrectly performed is approved as requested as a sub-concept LLT.

Supplemental Update Report

CR Number: 2023237012	Implementation Date: 31-Aug-23	Related CR: 2023237012		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Drug level not monitored as per label</i>	Approved as Requested	Proposed LLT	
To PT	<i>Therapeutic drug monitoring analysis not performed</i>		<i>Drug level not monitored as per label</i>	10090196 Current
			To PT	
			<i>Therapeutic drug monitoring analysis not performed</i>	10073702

MSSO Comment: The proposal to add a new LLT Drug level not monitored as per label to PT Therapeutic drug monitoring analysis not performed is approved as requested as a sub-concept.

CR Number: 2023237013	Implementation Date: 31-Aug-23	Related CR: 2023237013		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Blood therapeutic drug level not monitored as per label</i>	Rejected		
To PT	<i>Therapeutic drug monitoring analysis not performed</i>			

MSSO Comment: The proposal to add a new LLT Blood therapeutic drug level not monitored as per label to PT Therapeutic drug monitoring analysis not performed is not approved. The proposed term can be represented by LLT Drug level not monitored as per label added in change request 2023237012.

CR Number: 2023237014	Implementation Date: 31-Aug-23	Related CR: 2023237014		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Labeled monitoring of drug level by a blood test not performed</i>	Rejected		
To PT	<i>Therapeutic drug monitoring analysis not performed</i>			

MSSO Comment: The proposal to add a new LLT Labeled monitoring of drug level by a blood test not performed to PT Therapeutic drug monitoring analysis not performed is not approved. The proposed term can be represented by LLT Drug level not monitored as per label added in change request 2023237012.

Supplemental Update Report

CR Number: 2023239001	Implementation Date: 30-Aug-23	Related CR: 2023239001	
Change Requested	Add a New Term	Final Disposition	Final Placement MedDRA Code #
Proposed Term	<i>Fimbriectomy</i>	Approved as Requested	Proposed LLT <i>Fimbriectomy</i> 10090183 Current To PT <i>Female sterilisation</i> 10056199

MSSO Comment: The proposal to add a new term Fimbriectomy is approved as requested. Fimbriectomy is performed by removing the fimbrial and infundibular portions of the fallopian tube next to the ovary, leaving behind one tubal segment attached to the uterus. Fimbriectomy will be added as LLT to PT Female sterilisation, aligned with the related LLT Tubal ligation.

CR Number: 2023239002	Implementation Date: 30-Aug-23	Related CR: 2023239002	
Change Requested	Add a New Term	Final Disposition	Final Placement MedDRA Code #
Proposed Term	<i>Unfolded protein response</i>	Rejected	

MSSO Comment: The proposal to add a new term Unfolded protein response is not approved. Unfolded protein response is an intracellular system of proteins synthesis control, which is out of the scope of MedDRA. Measurement or determination of the proteins which triggers the process - such as IRE1 or PERK - could be represented by MedDRA terms, but not the intracellular process itself, despite its relevance in pathogenesis of several metabolic derangements.

CR Number: 2023239003	Implementation Date: 30-Aug-23	Related CR: 2023239003	
Change Requested	Add a New Term	Final Disposition	Final Placement MedDRA Code #
Proposed Term	<i>Colostomy bag user</i>	Approved as Requested	Proposed PT <i>Colostomy bag user</i> 10090177 HLT primary <i>Disability issues</i> 10057171 SOC primary <i>Social circumstances</i> 10041244

MSSO Comment: The proposal to add a new term Colostomy bag user is approved as requested. A colostomy bag user is a person wearing a plastic bag that collects fecal matter from the digestive tract through an opening in the abdominal wall called a stoma, after a colostomy intervention. Colostomy bag user will be added as a PT to the HLT Disability issues.

Supplemental Update Report

CR Number: 2023239004	Implementation Date: 30-Aug-23	Related CR: 2023239004	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	ACETABULAR PROTRUSION	Approved Not as Requested	Proposed LLT Acetabular protrusion
			To PT Joint dislocation
			10090179 Current
			10023204

MSSO Comment: The proposal to add a new term ACETABULAR PROTRUSION is approved but not as requested. Acetabular protrusion, also known as protrusio acetabuli, represents an intrapelvic displacement of the acetabulum and femoral head, so that the femoral head projects medial to the ilioischial line. Acetabular protrusion will be modified according to MedDRA capitalization conventions and added as an LLT to PT Joint dislocation.

CR Number: 2023239005	Implementation Date: 30-Aug-23	Related CR: 2023239005	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	PUERPERAL STERILIZATION	Approved Not as Requested	Proposed LLT Puerperal sterilization
			To PT Female sterilisation
			10090182 Current
			10056199

MSSO Comment: The proposal to add a new term PUERPERAL STERILIZATION is approved but not as requested. When female sterilization is performed at the time of a neonate's birth, either at cesarean delivery or very soon after vaginal birth, such sterilization is called puerperal or postpartum sterilization. The proposed term will be modified according to MedDRA capitalization conventions added as an LLT Puerperal sterilization to PT Female sterilisation. In a related change, the British counterpart of the term will be added as the LLT Puerperal sterilisation placed under the PT Female sterilisation.

CR Number: 2023242011	Implementation Date: 30-Aug-23	Related CR: 2023239005	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	Puerperal sterilisation	Approved as Requested	Proposed LLT Puerperal sterilisation
To PT	Female sterilisation		To PT Female sterilisation
			10090185 Current
			10056199

MSSO Comment:

Supplemental Update Report

CR Number: 2023239006	Implementation Date: 30-Aug-23	Related CR: 2023239006	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>Ingrown eyelash removal</i>		Approved as Requested	Proposed PT <i>Ingrown eyelash removal</i> 10090178
			HLT primary <i>Eyelid therapeutic procedures</i> 10015994
			SOC primary <i>Surgical and medical procedures</i> 10042613

MSSO Comment: The proposal to add a new term Ingrown eyelash removal is approved as requested. Ingrown eyelash removal consists on extracting inward eyelashes using pincers or forceps to grapple them and pull them out. An ingrown eyelash can be removed using electrolysis, cryosurgery or laser with the aim to damage the follicle in order to prevent the hair from re-growing. Ingrown eyelash removal will be added as a PT to HLT Eyelid therapeutic procedures.

CR Number: 2023239007	Implementation Date: 30-Aug-23	Related CR: 2023239007	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>Mullerectomy</i>		Approved as Requested	Proposed LLT <i>Mullerectomy</i> 10090180 Current
			To PT <i>Ptosis repair</i> 10037275

MSSO Comment: The proposal to add a new term Mullerectomy is approved as requested. A Mullerectomy is a surgical procedure in which the Superior tarsal muscle (Muller's muscle) and underlying conjunctiva are resected to treat a mild cases of plepharoptosis. In its standard fashion, it involves resection of Muller's muscle and conjunctiva, followed by suturing of the conjunctiva and Muller's muscle to the tarsus. Mullerectomy will be added as an LLT to PT Ptosis repair.

CR Number: 2023239008	Implementation Date: 30-Aug-23	Related CR: 2023239008	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>Adenomyomectomy</i>		Approved as Requested	Proposed LLT <i>Adenomyomectomy</i> 10090181 Current
			To PT <i>Myomectomy</i> 10028634

MSSO Comment: The proposal to add a new term Adenomyomectomy is approved as requested. An adenomyomectomy is an endometrial reduction that is performed by uterine incision and wedge resection removing a large part of myometrium, either laparoscopically or laparotomically. It is performed by a sagital incision, followed by removal of the endometrial or adenomatous tissue and ending with suturing the uterus without entering the endometrial cavity. Adenomyomectomy will be added as LLT to PT Myomectomy.

Supplemental Update Report

CR Number: 2023239009 **Implementation Date:** 30-Aug-23 **Related CR:** 2023239009

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Cone-beam CT(Cone-beam Computed Tomography)	Rejected		

MSSO Comment: The proposal to add a new term Cone-beam CT(Cone-beam Computed Tomography) is not approved. The proposed concept already exists as LLT Cone beam computerized tomography. It was recently added in change request 2023222003 and it is now a supplemental term that will be available in version 27.0 on March 2024.

CR Number: 2023239010 **Implementation Date:** 30-Aug-23 **Related CR:** 2023239010

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Rezum	Rejected		

MSSO Comment: The proposal to add a new term Rezum is not approved. The proposed term represents a trade name, and can be represented by the generic term LLT Water vapour thermal therapy. MedDRA refrains from adding trade names.

CR Number: 2023239011 **Implementation Date:** 30-Aug-23 **Related CR:** 2023239011

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Tubular breasts	Approved as Requested	Proposed LLT Tubular breasts	10090184 Current
			To PT Breast hypoplasia	10049070

MSSO Comment: The proposal to add a new term Tubular breasts is approved as requested. Tubular breasts is the name of a condition caused by breast tissue not proliferating properly during puberty. The condition is also called tuberous breasts or breast hypoplasia. Tubular breasts will be added as LLT to PT Breast hypoplasia. In a related change, the PT Breast hypoplasia will be linked to the HLT Breast disorders congenital. In a next step, the PT Breast hypoplasia will change its primary link from SOC Reproductive system and breast disorders to SOC Congenital, familial and genetic disorders.

Supplemental Update Report

CR Number: 2023242012	Implementation Date: 30-Aug-23	Related CR: 2023239011		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Breast hypoplasia</i>	Approved as Requested	Proposed PT	
To HLT	<i>Breast disorders congenital</i>		<i>Breast hypoplasia</i>	10049070
			To HLT	
			<i>Breast disorders congenital</i>	10006233

MSSO
Comment:

CR Number: 2023242013	Implementation Date: 30-Aug-23	Related CR: 2023239011		
<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Breast hypoplasia</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Reproductive system and breast disorders</i>		<i>Breast hypoplasia</i>	10049070
New Primary SOC	<i>Congenital, familial and genetic disorders</i>		Old Primary SOC	
			<i>Reproductive system and breast disorders</i>	10038604
			New Primary SOC	
			<i>Congenital, familial and genetic disorders</i>	10010331

MSSO
Comment:

CR Number: 2023239012	Implementation Date: 30-Aug-23	Related CR: 2023239012		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Influenza B virus test negative</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Virus identification and serology</i>		<i>Influenza B virus test negative</i>	10090187
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Virus identification and serology</i>	10047490
			SOC primary	
			<i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Influenza B virus test negative to primary HLT Virus identification and serology in SOC Investigations is approved as requested to compliment the existing positive counterpart.

Supplemental Update Report

CR Number: 2023239013 **Implementation Date:** 30-Aug-23 **Related CR:** 2023239013

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Influenza C virus test negative</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Virus identification and serology</i>		<i>Influenza C virus test negative</i>	10090186
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Virus identification and serology</i>	10047490
			SOC primary	
			<i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Influenza C virus test negative to primary HLT Virus identification and serology in SOC Investigations is approved as requested to compliment the existing positive counterpart.

CR Number: 2023240001 **Implementation Date:** 31-Aug-23 **Related CR:** 2023240001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Type 1 interferonopathy</i>	Approved Not as Requested	Proposed LLT	
HLT primary	<i>Immune system abnormalities congenital</i>		<i>Type 1 interferonopathy</i>	10090202 Current
SOC primary	<i>Congenital, familial and genetic disorders</i>		To PT	
			<i>Interferonopathy</i>	10090200

MSSO Comment: The proposal to add a new PT Type 1 interferonopathy to primary HLT Immune system abnormalities congenital in SOC Congenital, familial and genetic disorders and secondary HLT Autoinflammatory diseases in SOC Immune system disorders is approved but not as requested. Type I interferonopathies comprise a genetically and phenotypically heterogeneous group of auto-inflammatory and autoimmune disorders characterized by constitutive activation of the antiviral type I interferon axis. Type 1 interferonopathy will be added as an LLT to the broader PT Interferonopathy which will be added in change request 2023240002.

Supplemental Update Report

CR Number: 2023240002 Implementation Date: 31-Aug-23 Related CR: 2023240002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT	Approved Not as Requested	Proposed PT	
	<i>Interferonopathy</i>		<i>Interferonopathy</i>	10090200
			HLT primary	
			<i>Immune system abnormalities congenital</i>	10021424
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Autoinflammatory diseases</i>	10073080
			SOC secondary	
			<i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new LLT Interferonopathy is approved but not as requested. Interferonopathy is used interchangeably with the term "Type 1 interferonopathy". Type 1 interferonopathies are a recently identified group of ultra-rare inherited autoinflammatory diseases, characterized by a dysregulation of the interferon pathway. Interferonopathy will be added as a PT to primary HLT Immune system abnormalities congenital and to secondary HLT Autoinflammatory diseases.

CR Number: 2023240003 Implementation Date: 31-Aug-23 Related CR: 2023240003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT	Approved Not as Requested	Proposed PT	
	<i>Familial Chilblain Lupus</i>		<i>Familial chilblain lupus</i>	10090201
HLT primary			HLT primary	
	<i>Connective tissue disorders congenital</i>		<i>Connective tissue disorders congenital</i>	10010763
SOC primary			SOC primary	
	<i>Congenital, familial and genetic disorders</i>		<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Lupus erythematosus and associated conditions</i>	10025136
			SOC secondary	
			<i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new PT Familial Chilblain Lupus to primary HLT Connective tissue disorders congenital in SOC Congenital, familial and genetic disorders and secondary HLT Lupus erythematosus and associated conditions in SOC Immune system disorders is approved but not as requested. Familial chilblain lupus is a rare, autosomal dominant form of lupus erythematosus characterized by cold-induced inflammatory lesions at acral locations presenting in early childhood. Familial chilblain lupus is usually caused by a mutation in TREX1. Proposed term will be modified for MedDRA capitalization conventions and added as PT Familial chilblain lupus under primary HLT Connective tissue disorders congenital, to secondary HLT Lupus erythematosus and associated conditions and to secondary HLT Connective tissue disorders.

Supplemental Update Report

CR Number: 2023243009	Implementation Date: 31-Aug-23	Related CR: 2023240003		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Familial chilblain lupus</i>	Approved as Requested	Proposed PT	
To HLT	<i>Connective tissue disorders</i>		<i>Familial chilblain lupus</i>	10090201
			To HLT	
			<i>Connective tissue disorders</i>	10010760

MSSO
Comment:

CR Number: 2023240004	Implementation Date: 31-Aug-23	Related CR: 2023240004		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Congenital chronic cutaneous lupus erythematosus</i>	Rejected		

MSSO
Comment: The proposal to add a new LLT Congenital chronic cutaneous lupus erythematosus is not approved. The proposed concept is broader than familial chilblain lupus, since it represents several forms of neonatal lupus. Neonatal lupus erythematosus is already represented in MedDRA at PT level. Neonatal lupus erythematosus is a rare autoimmune disease that occurs in infants born to mothers with anti-Ro/SSA and/or anti-La/SSB antibodies. The disease can manifest as a rash resembling subacute cutaneous lupus erythematosus, and in some cases, it can lead to systemic abnormalities such as complete heart block or hepatosplenomegaly.

CR Number: 2023240005	Implementation Date: 31-Aug-23	Related CR: 2023240005		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Abscess ear</i>	Rejected		

MSSO
Comment: The proposal to add a new LLT Abscess ear is not approved. The proposed concept is too broad and may mean abscesses in potentially different anatomical areas of ear and with different clinical implications. However, LLT Abscess of external ear will be promoted to PT level and linked to primary HLT Ear infections, to secondary HLT External ear infections and inflammations and to secondary HLT Skin and subcutaneous tissue infections NEC. Furthermore, PT Abscess of external auditory meatus will be demoted under new PT Abscess of external ear for better alignment.

Supplemental Update Report

CR Number: 2023243010

Implementation Date: 31-Aug-23

Related CR: 2023240005

Change Requested

Link a PT to a HLT

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT

Abscess of external ear

Approved as Requested

Proposed PT

To HLT

Skin and subcutaneous tissue infections NEC

Abscess of external ear

10000296

To HLT

Skin and subcutaneous tissue infections NEC 10040793

MSSO

Comment:

CR Number: 2023243011

Implementation Date: 31-Aug-23

Related CR: 2023240005

Change Requested

Demote a PT

Final Disposition

Final Placement

MedDRA
Code #

PT to merge

Abscess of external auditory meatus

Approved as Requested

PT to merge

To PT

Abscess of external ear

Abscess of external auditory meatus

10000295 Current

To PT

Abscess of external ear

10000296

MSSO

Comment:

Supplemental Update Report

CR Number: 2023243012 Implementation Date: 31-Aug-23 Related CR: 2023240005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Promote an LLT	Approved as Requested	Proposed LLT	
From PT	<i>Abscess of external ear</i>		<i>Abscess of external ear</i>	10000296
HLT primary	<i>Subcutaneous abscess</i>		From PT	
	<i>Ear infections</i>		<i>Subcutaneous abscess</i>	10042343
			HLT primary	
			<i>Ear infections</i>	10014013
			SOC primary	
			<i>Infections and infestations</i>	10021881
			HLT secondary	
			<i>External ear infections and inflammations</i>	10015734
			SOC secondary	
			<i>Ear and labyrinth disorders</i>	10013993

MSSO
Comment:

CR Number: 2023240006 Implementation Date: 31-Aug-23 Related CR: 2023240006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT	Approved Not as Requested	Proposed LLT	
	<i>Sagittal Split Ramal Osteotomy</i>		<i>Sagittal split mandibular ramus osteotomy</i>	10090203 Current
			To PT	
			<i>Orthognathic surgery</i>	10079944

MSSO
Comment: The proposal to add a new LLT Sagittal Split Ramal Osteotomy is approved but not as requested. Sagittal split mandibular ramus osteotomy is one of the most frequently employed surgical procedures in orthognathic surgery, and is used to advance, set-back and rotate the distal (tooth-bearing) segment of the mandible. Proposed term will be modified for clarity and MedDRA capitalization conventions and added as LLT Sagittal split mandibular ramus osteotomy to PT Orthognathic surgery.

Supplemental Update Report

CR Number: 2023240007	Implementation Date: 31-Aug-23	Related CR: 2023240007	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New LLT			
Proposed LLT <i>Goniometry</i>		Approved as Requested	Proposed LLT <i>Goniometry</i> 10090204 Current
			To PT <i>Joint range of motion measurement</i> 10075631

MSSO Comment: The proposal to add a new LLT Goniometry is approved as requested. Goniometry refers to the measurement of angles, which in rehabilitation settings refers to the measurement of angles in each plane at the joints of the body. Goniometry will be added as a synonym LLT to PT Joint range of motion measurement.

CR Number: 2023241001	Implementation Date: 31-Aug-23	Related CR: 2023241001	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New Term			
Proposed Term <i>Infected small intestinal ulcer</i>		Approved as Requested	Proposed LLT <i>Infected small intestinal ulcer</i> 10090206 Current
			To PT <i>Infected intestinal ulcer</i> 10090205

MSSO Comment: The proposal to add a new term Infected small intestinal ulcer is approved as requested. Infected small intestinal ulcer will be added as an LLT to a new broader PT Infected intestinal ulcer which will be added in a related change, to primary HLT Abdominal and gastrointestinal infections and secondary HLT Intestinal ulcers and perforation NEC. Furthermore PT Infected large intestinal ulcer will be demoted to new PT Infected intestinal ulcer as a sub-concept LLT.

CR Number: 2023243013	Implementation Date: 31-Aug-23	Related CR: 2023241001	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New PT			
Proposed PT <i>Infected intestinal ulcer</i>		Approved as Requested	Proposed PT <i>Infected intestinal ulcer</i> 10090205
HLT primary <i>Abdominal and gastrointestinal infections</i>			HLT primary <i>Abdominal and gastrointestinal infections</i> 10017967
SOC primary <i>Infections and infestations</i>			SOC primary <i>Infections and infestations</i> 10021881
			HLT secondary <i>Intestinal ulcers and perforation NEC</i> 10032172
			SOC secondary <i>Gastrointestinal disorders</i> 10017947

MSSO Comment:

Supplemental Update Report

CR Number: 2023243014	Implementation Date: 31-Aug-23	Related CR: 2023241001		
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Infected large intestinal ulcer</i>	Approved as Requested	PT to merge	
To PT	<i>Infected intestinal ulcer</i>		<i>Infected large intestinal ulcer</i>	10085096 Current
			To PT	
			<i>Infected intestinal ulcer</i>	10090205

MSSO
Comment:

CR Number: 2023241002	Implementation Date: 11-Sep-23	Related CR: 2023241002		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Stomal mucocutaneous dehiscence</i>	Approved as Requested	Proposed LLT	
			<i>Stomal mucocutaneous dehiscence</i>	10090209 Current
			To PT	
			<i>Stoma site mucocutaneous separation</i>	10088747

MSSO
Comment: The proposal to add a new LLT Stomal mucocutaneous dehiscence is approved as requested. There are concerns about stomal mucocutaneous dehiscence when using the dynamic abdominal wound closure system in the management of patients with an open abdomen and a stoma. Stomal mucocutaneous dehiscence will be added as LLT under PT Stoma site mucocutaneous separation.

CR Number: 2023241003	Implementation Date: 11-Sep-23	Related CR: 2023241003		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Post chemotherapy aplasia</i>	Rejected		
To PT	<i>Aplasia bone marrow</i>			

MSSO
Comment: The proposal to add a new LLT Post chemotherapy aplasia to PT Aplasia bone marrow is not approved. The MSSO refrains from adding more post chemotherapy/drug induced terms to MedDRA.

Supplemental Update Report

CR Number: 2023241004 Implementation Date: 11-Sep-23 Related CR: 2023241004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Reassign Primary SOC <i>Aplasia</i>	Rejected		
Old Primary SOC	<i>Congenital, familial and genetic disorders</i>			
New Primary SOC	<i>Blood and lymphatic system disorders</i>			

MSSO Comment: The proposal to reassign the primary SOC of PT Aplasia from current SOC Congenital, familial and genetic disorders to SOC Blood and lymphatic system disorders is not approved. The concept of aplasia is understood to be "congenital" in nature and may refer to lack of development of any organ or tissue. However, as the term is often used for reports of bone marrow aplasia, and therefore ambiguous in meaning, PT Aplasia will be demoted as LLT under new PT Congenital aplasia and made non-current, please see change request 2023241005 for these two actions.

CR Number: 2023241005 Implementation Date: 11-Sep-23 Related CR: 2023241005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Congenital aplasia</i>	Approved Not as Requested	Proposed PT <i>Congenital aplasia</i>	10090210
			HLT primary <i>Congenital disorders NEC</i>	10010445
			SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Trophic disorders</i>	10044694
			SOC secondary <i>General disorders and administration site conditions</i>	10018065

MSSO Comment: The proposal to add a new LLT Congenital aplasia is approved but not as requested. Congenital aplasia will be added as a PT to primary HLT Congenital disorders NEC and to secondary HLT Trophic disorders. Furthermore, PT Aplasia will be demoted under the new PT Congenital aplasia as an LLT and then flagged non-current as to avoid confusion with bone marrow aplasia.

Supplemental Update Report

CR Number: 2023254003	Implementation Date: 11-Sep-23	Related CR: 2023241005		
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Aplasia</i>	Approved as Requested	PT to merge	
To PT	<i>Congenital aplasia</i>		<i>Aplasia</i>	10002961 Non-Current
			To PT	
			<i>Congenital aplasia</i>	10090210

MSSO
Comment:

CR Number: 2023254004	Implementation Date: 11-Sep-23	Related CR: 2023241005		
<u>Change Requested</u>	Change Status of LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
LLT to change	<i>Aplasia</i>	Approved as Requested	LLT to change	
Status	<i>Non-current</i>		<i>Aplasia</i>	10002961 Non-Current
			Status	
			<i>Non-current</i>	

MSSO
Comment:

CR Number: 2023241006	Implementation Date: 11-Sep-23	Related CR: 2023241006		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Subcutaneous inflammation</i>	Rejected		

MSSO
Comment: The proposal to add a new LLT Subcutaneous inflammation is not approved. The proposed concept can be represented by existing LLT Skin inflammation or PT/LLT Panniculitis depending on reported scenario.

Supplemental Update Report

CR Number: 2023241007	Implementation Date: 11-Sep-23	Related CR: 2023241007	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed LLT	<i>Postpartum uterine atony</i>	Approved as Requested	Proposed LLT <i>Postpartum uterine atony</i> 10090211 Current To PT <i>Uterine atony</i> 10046763

MSSO Comment: The proposal to add a new LLT Postpartum uterine atony is approved as requested. Postpartum uterine atony refers to the inadequate contraction of the uterus myometrial cells in response to endogenous oxytocin release. Postpartum uterine atony will be added as an LLT to PT Uterine atony. In a related change, PT Uterine atony will be moved from HLT Maternal complications of labour NEC to HLT Postpartum complications NEC for better alignment.

CR Number: 2023254005	Implementation Date: 11-Sep-23	Related CR: 2023241007	
<u>Change Requested</u>	Link (move) a PT to another HLT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed PT	<i>Uterine atony</i>	Approved as Requested	Proposed PT <i>Uterine atony</i> 10046763
From HLT	<i>Maternal complications of labour NEC</i>		From HLT <i>Maternal complications of labour NEC</i> 10026907
To HLT	<i>Postpartum complications NEC</i>		To HLT <i>Postpartum complications NEC</i> 10036416

MSSO Comment:

CR Number: 2023242001	Implementation Date: 11-Sep-23	Related CR: 2023242001	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed LLT	<i>Neurofibroma excision</i>	Rejected	

MSSO Comment: The proposal to add a new LLT Neurofibroma excision is not approved. The treatment for neurofibromas depends on the size, location, and symptoms of the tumor. Consider to reject and refer to split code with the underlying diagnosis and the technique - LLT Benign tumour excision as MedDRA cannot provide a combination term for all possible specific tumors and their removal.

Supplemental Update Report

CR Number: 2023242005 Implementation Date: 11-Sep-23 Related CR: 2023242005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Harvey-Bradshaw index abnormal</i>	Approved Not as Requested	Proposed PT <i>Harvey-Bradshaw index abnormal</i>	10090213
			HLT primary <i>Physical examination procedures and organ system status</i>	10071941
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new LLT Harvey-Bradshaw index abnormal is approved but not as requested. The index was created in 1980 by Harvey and Bradshaw as a simpler alternative to the Crohn's disease activity index (CDAI). It is easier to calculate because it uses data about the patient's general health status that is readily available. By comparison CDAI requires biochemical test results. Harvey-Bradshaw index abnormal will be added as new PT under HLT Physical examination procedures and organ system status.

CR Number: 2023242006 Implementation Date: 11-Sep-23 Related CR: 2023242006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Autoimmune nodopathy</i>	Approved Not as Requested	Proposed PT <i>Autoimmune nodopathy</i>	10090212
			HLT primary <i>Chronic polyneuropathies</i>	10036107
			SOC primary <i>Nervous system disorders</i>	10029205
			HLT secondary <i>Nervous system autoimmune disorders</i>	10074484
			SOC secondary <i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new LLT Autoimmune nodopathy is approved but not as requested. Autoimmune neuropathies are characterized by the presence of antibodies targeting cell adhesion molecules of the node of Ranvier with an association to specific clinicopathological features that are different from classical chronic inflammatory demyelinating polyneuropathy. Autoimmune nodopathy will be added as new PT under primary HLT Chronic polyneuropathies and secondary HLT Nervous system autoimmune disorders.

Supplemental Update Report

CR Number: 2023242014		Implementation Date: 11-Sep-23	Related CR: 2023242014	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Immune effector cell-associated hematotoxicity</i>	Approved as Requested	Proposed LLT <i>Immune effector cell-associated hematotoxicity</i>	10090215 Current
			To PT <i>Immune effector cell-associated haematotoxicity</i>	10090214

MSSO Comment: The proposal to add a new term Immune effector cell-associated hematotoxicity is approved as requested. Hematological toxicity represents the most common adverse event following chimeric antigen receptor (CAR) T-cell therapy. Cytopenias can be profound, long-lasting, and can predispose for severe infectious complications. Haematotoxicity is a common adverse drug reaction induced by a variety of products. Immune effector cell-associated hematotoxicity will be added as an LLT to the British spelled PT Immune effector cell-associated haematotoxicity, which will be added, in a related change to primary HLT Haematological disorders, to secondary HLT Poisoning and toxicity and to secondary HLT Immune and associated conditions NEC.

CR Number: 2023254007		Implementation Date: 11-Sep-23	Related CR: 2023242014	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Immune effector cell-associated haematotoxicity</i>	Approved as Requested	Proposed PT <i>Immune effector cell-associated haematotoxicity</i>	10090214
HLT primary	<i>Haematological disorders</i>		HLT primary <i>Haematological disorders</i>	10018847
SOC primary	<i>Blood and lymphatic system disorders</i>		SOC primary <i>Blood and lymphatic system disorders</i>	10005329
			HLT secondary <i>Poisoning and toxicity</i>	10035777
			SOC secondary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment:

Supplemental Update Report

CR Number: 2023254008	Implementation Date: 11-Sep-23	Related CR: 2023242014		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Immune effector cell-associated haematotoxicity</i>	Approved as Requested	Proposed PT	
To HLT	<i>Immune and associated conditions NEC</i>		<i>Immune effector cell-associated haematotoxicity</i>	10090214
			To HLT	
			<i>Immune and associated conditions NEC</i>	10027682

MSSO
Comment:

CR Number: 2023242015	Implementation Date: 11-Sep-23	Related CR: 2023242015		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Beta thalassemia major</i>	Approved as Requested	Proposed LLT	
			<i>Beta thalassemia major</i>	10090216 Current
			To PT	
			<i>Thalassaemia beta</i>	10043391

MSSO
Comment: The proposal to add a new LLT Beta thalassemia major is approved as requested. Thalassemias are a group of inherited blood disorders characterized by a reduced production of hemoglobin. Beta thalassemia results from mutations in the genes responsible for beta globin chains. Beta thalassemia major is the most severe form and requires lifelong blood transfusions and iron chelation therapy to manage the condition. Beta thalassemia major and its British English counterpart Beta thalassaemia major will both be added as LLTs under PT Thalassaemia beta.

CR Number: 2023254009	Implementation Date: 11-Sep-23	Related CR: 2023242015		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Beta thalassaemia major</i>	Approved as Requested	Proposed LLT	
To PT	<i>Thalassaemia beta</i>		<i>Beta thalassaemia major</i>	10090217 Current
			To PT	
			<i>Thalassaemia beta</i>	10043391

MSSO
Comment:

Supplemental Update Report

CR Number: 2023243001 Implementation Date: 11-Sep-23 Related CR: 2023243001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Intellectual and developmental disabilities	Rejected		

MSSO Comment: The proposal to add a new LLT Intellectual and developmental disabilities is not approved. Intellectual and developmental disabilities is a grouping concept and may be captured with LLT/PT Intellectual disability and based on the specific clinical scenario, possibly LLT/PT Neurodevelopmental delay, Developmental delay, Motor developmental delay, etc. Please refer to the MedDRA Term Selection: Points to Consider document, Section 3.5.

CR Number: 2023243002 Implementation Date: 11-Sep-23 Related CR: 2023243002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Post transfusion iron overload	Approved as Requested	Proposed LLT Post transfusion iron overload	10090218 Current
			To PT Iron overload	10065973

MSSO Comment: The proposal to add a new LLT Post transfusion iron overload is approved as requested. Transfusion iron overload is a major concern in the management of patients with severe anemic syndromes like thalassemia. Because of the close monitoring of iron homeostasis, excess iron from multiple blood transfusions deposits in different organs of the body and causes organ damage. Post transfusion iron overload will be added as LLT under PT Iron overload.

CR Number: 2023243003 Implementation Date: 11-Sep-23 Related CR: 2023243003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Harvey-Bradshaw index	Approved Not as Requested	Proposed PT Harvey-Bradshaw index	10090219
			HLT primary Physical examination procedures and organ system status	10071941
			SOC primary Investigations	10022891

MSSO Comment: The proposal to add a new LLT Harvey-Bradshaw index is approved but not as requested. The index was created in 1980 by Harvey and Bradshaw as a simpler alternative to the Crohn's disease activity index (CDAI). It is easier to calculate because it uses data about the patients general health status that is readily available. By comparison CDAI requires biochemical test results. Harvey-Bradshaw index will be added as new PT under HLT Physical examination procedures and organ system status.

Supplemental Update Report

CR Number: 2023243004	Implementation Date: 11-Sep-23	Related CR: 2023243004	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Oropharyngeal perforation</i>	Approved as Requested	Proposed LLT <i>Oropharyngeal perforation</i> 10090220 Current To PT <i>Pharyngeal perforation</i> 10081767

MSSO Comment: The proposal to add a new term Oropharyngeal perforation is approved as requested. Oropharyngeal perforation is a condition deriving from barotrauma, iatrogenic injury, or rarely infection. Although reported in the literature, spontaneous perforation is rarely described and association with underlying localised malignancy and treatment is not described. Oropharyngeal perforation will be added as an LLT to PT Pharyngeal perforation.

CR Number: 2023243005	Implementation Date: 11-Sep-23	Related CR: 2023243005	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Community acquired malnutrition</i>	Rejected	

MSSO Comment: The proposal to add a new term Community acquired malnutrition is not approved. The proposed concept can be captured by existing PT/LLT Malnutrition. Malnutrition may be multifactorial, and all the etiologies cannot be added to MedDRA.

CR Number: 2023244001	Implementation Date: 11-Sep-23	Related CR: 2023244001	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Herlyn-Werner-Wunderlich syndrome</i>	Approved as Requested	Proposed LLT <i>Herlyn-Werner-Wunderlich syndrome</i> 10090222 Current To PT <i>OHVIRA syndrome</i> 10083351

MSSO Comment: The proposal to add a new term Herlyn-Werner-Wunderlich syndrome is approved as requested. Herlyn-Werner-Wunderlich syndrome, also known as OHVIRA syndrome, is a rare congenital disorder that affects the female reproductive system. It is characterized by a combination of three primary features Obstructed Hemivagina and Ipsilateral Renal Anomaly (OHVIRA) and Uterus Didelphys. Herlyn-Werner-Wunderlich syndrome will be added as synonym LLT to PT OHVIRA syndrome.

Supplemental Update Report

CR Number: 2023244002	Implementation Date: 11-Sep-23	Related CR: 2023244002	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>Exercise-induced vasculitis</i>		Approved as Requested	Proposed LLT <i>Exercise-induced vasculitis</i> 10090221 Current
			To PT <i>Cutaneous vasculitis</i> 10011686

MSSO Comment: The proposal to add a new term Exercise-induced vasculitis is approved as requested. Exercise-induced vasculitis is a harmless form of cutaneous small vessel vasculitis affecting the lower legs that occurs after strenuous sports activity. It is also called golfer's vasculitis. It is also known as exercise-induced urticaria or exercise-induced angioedema. Exercise-induced vasculitis will be added as a sub-concept LLT to PT Cutaneous vasculitis.

CR Number: 2023244003	Implementation Date: 11-Sep-23	Related CR: 2023244003	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>Golfer's vasculitis</i>		Approved as Requested	Proposed LLT <i>Golfer's vasculitis</i> 10090223 Current
			To PT <i>Cutaneous vasculitis</i> 10011686

MSSO Comment: The proposal to add a new term Golfer's vasculitis is approved as requested. Golfer's vasculitis is a specific form of exercise-induced vasculitis, also known as exercise-induced urticaria or exercise-induced angioedema. Exercise-induced vasculitis is a small-vessel vasculitis affecting the lower legs that occurs after strenuous sports activity. Golfer's vasculitis will be added as a sub-concept LLT to PT Cutaneous vasculitis.

CR Number: 2023244004	Implementation Date: 11-Sep-23	Related CR: 2023244004	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed PT <i>Anti-reflux device placement</i>		Approved as Requested	Proposed PT <i>Anti-reflux device placement</i> 10090224
HLT primary <i>Gastric therapeutic procedures</i>			HLT primary <i>Gastric therapeutic procedures</i> 10017813
SOC primary <i>Surgical and medical procedures</i>			SOC primary <i>Surgical and medical procedures</i> 10042613

MSSO Comment: The proposal to add a new PT Anti-reflux device placement to primary HLT Gastric therapeutic procedures in SOC Surgical and medical procedures is approved as requested. The "Anti-reflux device placement" procedure is designed to correct the cause of acid reflux issues, by placing a device around the lower esophageal sphincter. To account for different devices and distinguish from other types of reflux surgeries, the general term Anti-reflux device placement will be added.

Supplemental Update Report

CR Number: 2023244005	Implementation Date: 11-Sep-23	Related CR: 2023244005	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>Factor XII activity decreased</i>		Approved as Requested	Proposed PT <i>Factor XII activity decreased</i> 10090225
			HLT primary <i>Coagulation and bleeding analyses</i> 10009728
			SOC primary <i>Investigations</i> 10022891

MSSO Comment: The proposal to add a new term Factor XII activity decreased is approved as requested. Factor XII is one of the clotting factors in the blood that plays a role in the coagulation cascade. Factor XII (FXII) primarily exists in its inactive form in the bloodstream, and its activity is initiated when it comes into contact with certain surfaces. Therefore, decreased Factor XII activity is typically based on its reduced ability to become activated rather than variations in its baseline levels in the bloodstream. Factor XII activity decreased will be added as a PT to HLT Coagulation and bleeding analyses.

CR Number: 2023244006	Implementation Date: 11-Sep-23	Related CR: 2023244006	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT <i>Intra-abdominal infection bacterial</i>		Rejected	

MSSO Comment: The proposal to add a new LLT Intra-abdominal infection bacterial is not approved. The proposed term can be represented LLT/PT Bacterial abdominal infection.

CR Number: 2023247001	Implementation Date: 12-Sep-23	Related CR: 2023247001	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>Stapled hemorrhoidectomy</i>		Approved as Requested	Proposed LLT <i>Stapled hemorrhoidectomy</i> 10090233 Current
			To PT <i>Haemorrhoid operation</i> 10059624

MSSO Comment: The proposal to add a new term Stapled hemorrhoidectomy is approved as requested. Stapled hemorrhoidectomy and the British English spelled counterpart Stapled haemorrhoidectomy will both be added as LLTs to PT Haemorrhoid operation, as synonym of existing LLT Stapled hemorrhoidopexy.

Supplemental Update Report

CR Number: 2023255002	Implementation Date: 12-Sep-23	Related CR: 2023247001		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Stapled haemorrhoidectomy</i>	Approved as Requested	Proposed LLT	
To PT	<i>Haemorrhoid operation</i>		<i>Stapled haemorrhoidectomy</i>	10090244 Current
			To PT	
			<i>Haemorrhoid operation</i>	10059624

MSSO
Comment:

CR Number: 2023247002	Implementation Date: 12-Sep-23	Related CR: 2023247002		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Procedure for prolapse and hemorrhoids</i>	Rejected		

MSSO Comment: The proposal to add a new term Procedure for prolapse and hemorrhoids is not approved. The requested term can be represented by the broader PT Haemorrhoid operation or any other LLTs based on the specific information provided.

CR Number: 2023247003	Implementation Date: 12-Sep-23	Related CR: 2023247003		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Iatrogenic hypothyroidism</i>	Rejected		

MSSO Comment: The proposal to add a new term Iatrogenic hypothyroidism is not approved. The requested term can be represented by existing terms, depending on the scenario e.g., LLT Drug-induced hypothyroidism, LLT Post procedural hypothyroidism, and LLT Radiation hypothyroidism.

Supplemental Update Report

CR Number: 2023247004	Implementation Date: 12-Sep-23	Related CR: 2023247004	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Ureterolithotripsy</i>	Approved as Requested	Proposed LLT <i>Ureterolithotripsy</i> 10090234 Current To PT <i>Ureteric calculus removal</i> 10046391

MSSO Comment: The proposal to add a new term Ureterolithotripsy is approved as requested. Ureterolithotripsy is an procedure to fragment and remove ureteral stones with the use of a telescopic camera or percutaneous via ultrasound. Ureterolithotripsy will be added as subconcept LLT to PT Ureteric calculus removal. In a related change, PT Ureterolithotomy will be demoted under PT Ureteric calculus removal to reduce overgranularity at PT level for specific techniques.

CR Number: 2023255003	Implementation Date: 12-Sep-23	Related CR: 2023247004	
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
PT to merge	<i>Ureterolithotomy</i>	Approved as Requested	PT to merge <i>Ureterolithotomy</i> 10046412 Current To PT <i>Ureteric calculus removal</i> 10046391

MSSO Comment:

CR Number: 2023247005	Implementation Date: 12-Sep-23	Related CR: 2023247005	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Lymphocytic vasculitis</i>	Approved as Requested	Proposed LLT <i>Lymphocytic vasculitis</i> 10090241 Current To PT <i>Cutaneous vasculitis</i> 10011686

MSSO Comment: The proposal to add a new term Lymphocytic vasculitis is approved as requested. Lymphocytic vasculitis is one of several skin conditions which are collectively referred to as cutaneous vasculitis. In Lymphocytic vasculitis, white blood cells (lymphocytes) cause damage to blood vessels in the skin. Lymphocytic vasculitis will be added as sub-concept LLT to PT Cutaneous vasculitis.

Supplemental Update Report

CR Number: 2023247006		Implementation Date: 12-Sep-23	Related CR: 2023247006	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Agatston score</i>	Approved as Requested	Proposed PT <i>Agatston score</i>	10090229
			HLT primary <i>Cardiac imaging procedures</i>	10007574
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new term Agatston score is approved as requested. Agatston score is a semi-automated tool to calculate a score based on the extent of coronary artery calcification detected by an unenhanced low-dose CT scan, which is routinely performed in patients undergoing cardiac CT. Agatston score will be added as PT to HLT Cardiac imaging procedures.

CR Number: 2023247007		Implementation Date: 12-Sep-23	Related CR: 2023247007	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Basal pneumonia/Lower lobe pneumonia</i>	Approved Not as Requested	Proposed LLT <i>Lower lobe pneumonia</i>	10090235 Current
			To PT <i>Pneumonia</i>	10035664

MSSO Comment: The proposal to add a new term Basal pneumonia/Lower lobe pneumonia is approved but not as requested. X-rays play an important role in distinguishing between anatomical locations of pneumonias: the term lobar pneumonia is used if an entire lung lobe is visibly inflamed. Depending on which lung lobe is affected, the pneumonia is referred to as upper, middle or lower lobe pneumonia. The requested term will be modified and added as LLT Lower lobe pneumonia under PT Pneumonia.

CR Number: 2023247008		Implementation Date: 12-Sep-23	Related CR: 2023247008	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Posterior colporrhaphy</i>	Approved as Requested	Proposed LLT <i>Posterior colporrhaphy</i>	10090242 Current
			To PT <i>Colporrhaphy</i>	10061780

MSSO Comment: The proposal to add a new term Posterior colporrhaphy is approved as requested. Posterior colporrhaphy, also known as posterior repair or rectocele repair, is a surgical procedure performed to correct a rectocele, which is a bulging of the rectum into the vagina due to weakened pelvic floor muscles and supporting tissues. Posterior colporrhaphy will be added as LLT to PT Colporrhaphy. In a related change, PT Rectocele repair will be demoted under PT Colporrhaphy as well.

Supplemental Update Report

CR Number: 2023255004	Implementation Date: 12-Sep-23	Related CR: 2023247008		
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Rectocele repair</i>	Approved as Requested	PT to merge	
To PT	<i>Colporrhaphy</i>		<i>Rectocele repair</i>	10064044 Current
			To PT	
			<i>Colporrhaphy</i>	10061780

MSSO
Comment:

CR Number: 2023247009	Implementation Date: 12-Sep-23	Related CR: 2023247009		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Diverticulosis of large intestine</i>	Rejected		

MSSO The proposal to add a new term Diverticulosis of large intestine is not approved. The requestd term can be represented by LLT Colonic diverticulosis.
Comment:

CR Number: 2023247010	Implementation Date: 12-Sep-23	Related CR: 2023247010		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Lumbar decompression surgery</i>	Rejected		

MSSO The proposal to add a new term Lumbar decompression surgery is not approved. The requested term can be represented by LLT Lumbar nerve decompression.
Comment:

Supplemental Update Report

CR Number: 2023247011	Implementation Date: 12-Sep-23	Related CR: 2023247011		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Honeydew allergy</i>	Rejected		

MSSO Comment: The proposal to add a new term Honeydew allergy is not approved. The requested term can be represented by LLT Fruit allergy. MedDRA cannot provide a term for all possible types of fruit allergies.

CR Number: 2023247012	Implementation Date: 12-Sep-23	Related CR: 2023247012		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Cantaloupe allergy</i>	Rejected		

MSSO Comment: The proposal to add a new term Cantaloupe allergy is not approved. The requested term can be represented by LLT Fruit allergy. MedDRA cannot provide a term for all possible types of fruit allergies.

CR Number: 2023247013	Implementation Date: 12-Sep-23	Related CR: 2023247013		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Esophageal leiomyoma</i>	Approved as Requested	Proposed LLT <i>Esophageal leiomyoma</i> To PT <i>Oesophageal leiomyoma</i>	10090239 Current 10090232

MSSO Comment: The proposal to add a new term Esophageal leiomyoma is approved as requested. Esophageal leiomyomas are the most common benign tumors of the esophagus. They are rare lesions that constitute less than 1% of esophageal neoplasms. Esophageal leiomyoma will be added as an LLT to a new PT Oesophageal leiomyoma representing its British spelling, which will be added, in a related change, to primary HLT Upper gastrointestinal neoplasms benign and to secondary HLT Benign neoplasms gastrointestinal (excl oral cavity).

Supplemental Update Report

CR Number: 2023255005 Implementation Date: 12-Sep-23 Related CR: 2023247013

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Oesophageal leiomyoma</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Upper gastrointestinal neoplasms benign</i>		<i>Oesophageal leiomyoma</i>	10090232
SOC primary	<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>		HLT primary	
			<i>Upper gastrointestinal neoplasms benign</i>	10046275
			SOC primary	
			<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary	
			<i>Benign neoplasms gastrointestinal (excl oral cavity)</i>	10017988
			SOC secondary	
			<i>Gastrointestinal disorders</i>	10017947

MSSO
Comment:

CR Number: 2023247014 Implementation Date: 12-Sep-23 Related CR: 2023247014

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Esophageal myoma</i>	Rejected		

MSSO
Comment: The proposal to add a new term Esophageal myoma is not approved. The concept can be represented with LLT Esophageal leiomyoma, added in change request number 2023247013.

Supplemental Update Report

CR Number: 2023247015	Implementation Date: 12-Sep-23	Related CR: 2023247015		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Solar melanosis</i>	Approved as Requested	Proposed LLT <i>Solar melanosis</i> To PT <i>Solar lentigo</i>	10090243 Current 10064127

MSSO Comment: The proposal to add a new term Solar melanosis is approved as requested. Brown spots on the skin, which are produced by an excess of the pigment called melanin, are called melanosis. These spots frequently appear due to the sun and are called solar lentiginos. Solar melanosis will be added as an synonym LLT to PT Solar lentigo.

CR Number: 2023247016	Implementation Date: 12-Sep-23	Related CR: 2023247016		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Vaginal polypectomy</i>	Rejected		

MSSO Comment: The proposal to add a new term Vaginal polypectomy is not approved. MedDRA cannot provide for all possible neoplasms or lesions a corresponding removal term. Please consider split coding with LLT Vaginal polyp and LLT Polypectomy.

CR Number: 2023247017	Implementation Date: 12-Sep-23	Related CR: 2023247017		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Pharmacodermia</i>	Rejected		

MSSO Comment: The proposal to add a new term Pharmacodermia is not approved. Please note that LLT Pharmacoderma has been recently added in change request 2023219016 and will be available for version 27.0.

Supplemental Update Report

CR Number: 2023247018 **Implementation Date:** 12-Sep-23 **Related CR:** 2023247018

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Female pattern hair loss (FPHL)	Rejected		

MSSO Comment: The proposal to add a new term Female pattern hair loss (FPHL) is not approved. The requested concept is already represented in LLT Female pattern baldness.

CR Number: 2023247019 **Implementation Date:** 09-Oct-23 **Related CR:** 2023247019

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Parenchymal liver disease	Rejected After Suspension		

MSSO Comment: The proposal to add a new term Parenchymal liver disease is not approved after suspension. Parenchymal liver disease may be interpreted in multiple ways as many liver diseases may manifest in the parenchyma. As such, the term is ambiguous.

CR Number: 2023247020 **Implementation Date:** 12-Sep-23 **Related CR:** 2023247020

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Left main coronary artery stenosis	Approved as Requested	Proposed LLT Left main coronary artery stenosis	10090240 Current
			To PT Coronary artery stenosis	10011089

MSSO Comment: The proposal to add a new term Left main coronary artery stenosis is approved as requested. The significant stenosis of the left main coronary artery is associated with poor outcomes and is considered a strong indication for revascularization. Left main coronary artery stenosis will be added as LLT to PT Coronary artery stenosis.

Supplemental Update Report

CR Number: 2023247021 **Implementation Date:** 12-Sep-23 **Related CR:** 2023247021

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Hypovitaminosis B12</i>	Rejected		

MSSO Comment: The proposal to add a new term Hypovitaminosis B12 is not approved. The requested term can be represented by the LLT/PT Vitamin B12 deficiency.

CR Number: 2023247022 **Implementation Date:** 12-Sep-23 **Related CR:** 2023247022

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Mood disturbnce</i>	Rejected		

MSSO Comment: The proposal to add a new term Mood disturbnce is not approved. The proposed term is ambiguous and may be represented by existing LLT/PT Mood disorder, LLT/PT Mood altered, LLT/PT Mood swings, etc.

CR Number: 2023247023 **Implementation Date:** 12-Sep-23 **Related CR:** 2023247023

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>MMP1 increased</i>	Approved as Requested	Proposed LLT <i>MMP1 increased</i> To PT <i>Matrix metalloproteinase-1 increased</i>	10090237 Current 10090231

MSSO Comment: The proposal to add a new term MMP1 increased is approved as requested. Excess matrix metalloproteinases activity following infection may lead to immunopathology that causes host morbidity or mortality and favours pathogen dissemination or persistence. MMP1 increased will be added as the acronym LLT for new PT Matrix metalloproteinase-1 increased. In a related change, new PT Matrix metalloproteinase-1 increased will be added under HLT Tissue enzyme analyses NEC.

Supplemental Update Report

CR Number: 2023255006	Implementation Date: 12-Sep-23	Related CR: 2023247023		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Matrix metalloproteinase-1 increased</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Tissue enzyme analyses NEC</i>		<i>Matrix metalloproteinase-1 increased</i>	10090231
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Tissue enzyme analyses NEC</i>	10043891
			SOC primary	
			<i>Investigations</i>	10022891

MSSO
Comment:

CR Number: 2023247024	Implementation Date: 12-Sep-23	Related CR: 2023247024		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Upper crossed syndrome</i>	Approved as Requested	Proposed PT	
			<i>Upper crossed syndrome</i>	10090226
			HLT primary	
			<i>Musculoskeletal and connective tissue pain and discomfort</i>	10068757
			SOC primary	
			<i>Musculoskeletal and connective tissue disorders</i>	10028395

MSSO
Comment: The proposal to add a new term Upper crossed syndrome is approved as requested. Upper crossed syndrome is caused by weakness in one group of muscles and tightness in other group of muscles. This syndrome mainly arises as a result of muscular imbalance that usually develops between weak and tonic muscles. Upper crossed syndrome will be added as new PT under HLT Musculoskeletal and connective tissue pain and discomfort.

CR Number: 2023247025	Implementation Date: 12-Sep-23	Related CR: 2023247025		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Supernumerary kidney</i>	Rejected		

MSSO
Comment: The proposal to add a new term Supernumerary kidney is not approved. The requested term is represented by existing term PT Accessory kidney.

Supplemental Update Report

CR Number: 2023247026 **Implementation Date:** 12-Sep-23 **Related CR:** 2023247026

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Medically induced menopause	Rejected		

MSSO Comment: The proposal to add a new term Medically induced menopause is not approved. The MSSO generally refrains from adding concepts that assign causality such as secondary to/induced by in order to avoid overpopulation of the terminology by combined concepts. The proposed concept may be represented by LLT/PT Artificial menopause.

CR Number: 2023247027 **Implementation Date:** 12-Sep-23 **Related CR:** 2023247027

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Hemicrania continua	Approved as Requested	Proposed PT Hemicrania continua	10090227
			HLT primary Headaches NEC	10019233
			SOC primary Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Hemicrania continua is approved as requested. Hemicrania continua is a chronic and persistent form of headache marked by continuous pain that varies in severity and always occurs on the same side of the face and head. Hemicrania continua has been proposed as a category of chronic daily headache based on its eventually continuous pattern. Hemicrania continua will be added as a PT to HLT Headaches NEC.

CR Number: 2023247028 **Implementation Date:** 12-Sep-23 **Related CR:** 2023247028

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Space occupying lesion kidney	Rejected		

MSSO Comment: The proposal to add a new term Space occupying lesion kidney is not approved. The MSSO considers "lesion" terms as imprecise and generally refrains from adding new lesion terms. Please reference section 5.1 of the MedDRA Introductory Guide Version 26.0 under the topic of lesion.

Supplemental Update Report

CR Number: 2023247029	Implementation Date: 12-Sep-23	Related CR: 2023247029	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Subleukemic leukemia</i>	Approved as Requested	Proposed LLT <i>Subleukemic leukemia</i> 10090236 Current To PT <i>Aleukaemic leukaemia</i> 10001660

MSSO Comment: The proposal to add a new term Subleukemic leukemia is approved as requested. Subleukemic leukemia is a type of leukemia that is characterized by the presence of abnormal white blood cells located in peripheral blood, but in which the total number of white blood cells is normal. It can also refer to the infiltration of the skin and subcutaneous tissue by leukemic cells without evidence of leukemia in the bone marrow and peripheral blood. Subleukemic leukemia and the British English counterpart Subleukaemic leukaemia will both be added as synonym LLTs to PT Aleukaemic leukaemia.

CR Number: 2023255007	Implementation Date: 12-Sep-23	Related CR: 2023247029	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed LLT	<i>Subleukaemic leukaemia</i>	Approved as Requested	Proposed LLT <i>Subleukaemic leukaemia</i> 10090245 Current To PT <i>Aleukaemic leukaemia</i> 10001660

MSSO Comment:

CR Number: 2023247030	Implementation Date: 12-Sep-23	Related CR: 2023247030	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed Term	<i>Hypoleukemia</i>	Rejected	

MSSO Comment: The proposal to add a new term Hypoleukemia is not approved. Hypoleukemia is rarely used in medical literature and may be represented by synonym LLT Subleukaemic leukaemia, added in change request 2023247029.

Supplemental Update Report

CR Number: 2023247031	Implementation Date: 12-Sep-23	Related CR: 2023247031	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>Factor XIII V34L mutation</i>		Approved as Requested	Proposed LLT <i>Factor XIII V34L mutation</i> 10090238 Current
			To PT <i>Factor XIII mutation</i> 10090230

MSSO Comment: The proposal to add a new term Factor XIII V34L mutation is approved as requested. Factor XIII, or fibrin-stabilizing factor, is responsible for stabilizing blood clots once they have formed. The Factor XIII V34L mutation affects Factor XIII activity. This mutation can lead to a bleeding disorder known as congenital Factor XIII deficiency, where individuals have a higher risk of bleeding due to unstable blood clots. Factor XIII V34L mutation will be added as an LLT to a new PT Factor XIII mutation. In a related change, PT Factor XIII mutation will be added to primary HLT Coagulation disorders congenital and to secondary HLT Coagulation factor deficiencies.

CR Number: 2023255008	Implementation Date: 12-Sep-23	Related CR: 2023247031	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed PT <i>Factor XIII mutation</i>		Approved as Requested	Proposed PT <i>Factor XIII mutation</i> 10090230
HLT primary <i>Coagulation disorders congenital</i>			HLT primary <i>Coagulation disorders congenital</i> 10009735
SOC primary <i>Congenital, familial and genetic disorders</i>			SOC primary <i>Congenital, familial and genetic disorders</i> 10010331
			HLT secondary <i>Coagulation factor deficiencies</i> 10009737
			SOC secondary <i>Blood and lymphatic system disorders</i> 10005329

MSSO Comment:

CR Number: 2023247032	Implementation Date: 12-Sep-23	Related CR: 2023247032	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term <i>PAI-1 4G/5G mutation</i>		Rejected	

MSSO Comment: The proposal to add a new term PAI-1 4G/5G mutation is not approved. The provided justification describes the common 4G/5G polymorphism in the promoter of the PAI-1 gene. This polymorphism is suggested to be a risk factor for some of the thrombotic disorders, its significance in the development of thrombosis still being controversial. The proposed term can be represented by LLT PAI-1 4G/5G polymorphism.

Supplemental Update Report

CR Number: 2023247033 Implementation Date: 12-Sep-23 Related CR: 2023247033

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Beta-fibrinogen-455G A Mutation</i>	Approved Not as Requested	Proposed PT <i>Beta-fibrinogen-455G A mutation</i>	10090228
			HLT primary <i>Gene mutations and other alterations NEC</i>	10083625
			SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Coagulopathies</i>	10053567
			SOC secondary <i>Blood and lymphatic system disorders</i>	10005329

MSSO Comment: The proposal to add a new term Beta-fibrinogen-455G A Mutation is approved but not as requested. A polymorphism (-455G>A) in the beta-fibrinogen gene is associated with an increased risk of cerebral infarction. The fibrinogen-raising -455G/A beta-fibrinogen gene polymorphism may enhance the physiological increase in fibrinogen levels during pregnancy and thereby predispose to obstetric complications. The proposed term will be modified for MedDRA capitalization standards and added as LLT Beta-fibrinogen-455G A mutation to primary HLT Gene mutations and other alterations NEC and to secondary HLT Coagulopathies.

CR Number: 2023247034 Implementation Date: 11-Sep-23 Related CR: 2023247034

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Sacroiliac joint blockage</i>	Rejected		
To PT	<i>Sacroiliac joint dysfunction</i>			

MSSO Comment: The proposal to add a new LLT Sacroiliac joint blockage to PT Sacroiliac joint dysfunction is not approved. Sacroiliac joint blockage is an ambiguous term representing both a semi-colloquial synonym of joint dysfunction and treatment through a sacroiliac joint injection - also called a sacroiliac joint block - primarily used to treat low back pain and/or sciatica.

CR Number: 2023247035 Implementation Date: 11-Sep-23 Related CR: 2023247035

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Thoracic spine blockage</i>	Rejected		
To PT	<i>Spinal segmental dysfunction</i>			

MSSO Comment: The proposal to add a new LLT Thoracic spine blockage to PT Spinal segmental dysfunction is not approved. The proposed term is an imprecise expression used for different spinal pathologies, such as spinal stenosis, thoracic radiculopathy or thoracic back pain as well for thoracic steroid injections for the treatment of radiculopathy.

Supplemental Update Report

CR Number: 2023248001

Implementation Date: 26-Oct-23

Related CR: 2023248001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Drug-induced liver injury	Approved as Requested	Proposed PT	
To SMQ	Hepatitis, non-infectious (SMQ)		Drug-induced liver injury	10072268
Term scope	Narrow		To SMQ	
			Hepatitis, non-infectious (SMQ)	20000010
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Drug-induced liver injury to Hepatitis, non-infectious (SMQ) as a narrow term is approved as requested. Drug induced liver injury can manifest phenotypically with different forms of non-infectious hepatitis, both acute and chronic as well as hepatocellular, cholestatic or mixed. In a related change, PT Suspected drug-induced liver injury will also be added to Hepatitis, non-infectious (SMQ) as a Narrow scope term for similiar reasons as PT Drug-induced liver injury.

CR Number: 2023296003

Implementation Date: 26-Oct-23

Related CR: 2023248001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Suspected drug-induced liver injury	Approved as Requested	Proposed PT	
To SMQ	Hepatitis, non-infectious (SMQ)		Suspected drug-induced liver injury	10088572
Term scope	Narrow		To SMQ	
			Hepatitis, non-infectious (SMQ)	20000010
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment:

Supplemental Update Report

CR Number: 2023248002 **Implementation Date:** 12-Sep-23 **Related CR:** 2023248002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Functional convergence spasm</i>	Approved as Requested	Proposed LLT <i>Functional convergence spasm</i> To PT <i>Psychogenic visual disorder</i>	10090246 Current 10076241

MSSO Comment: The proposal to add a new term Functional convergence spasm is approved as requested. Most convergence spasm cases are caused by a functional disorder, such as hysteria or neurosis. If an emotional etiology is suspected, psychological counseling is in order. Emotional instability may result in a variety of ocular manifestations besides convergence spasms, such as blurred vision, monocular diplopia, tunnel vision, blepharospasm, and nystagmus. Functional convergence spasm will be added as an LLT to PT Psychogenic visual disorder.

CR Number: 2023248003 **Implementation Date:** 12-Sep-23 **Related CR:** 2023248003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Non-cicatricial alopecia</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Non-cicatricial alopecia is not approved. The proposed term may be represented by existing LLT/PT Non-scarring alopecia.

CR Number: 2023248004 **Implementation Date:** 12-Sep-23 **Related CR:** 2023248004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Somnipathy</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Somnipathy is not approved. Somnipathy is a general term that refers to any disorder or abnormality related to sleep. This broad general term can be appropriately coded to existing unspecific terms, eg. LLT Sleep disorder.

Supplemental Update Report

CR Number: 2023250001 Implementation Date: 12-Sep-23 Related CR: 2023250001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Factor VII activity decreased</i>	Approved as Requested	Proposed PT <i>Factor VII activity decreased</i>	10090247
			HLT primary <i>Coagulation and bleeding analyses</i>	10009728
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new term Factor VII activity decreased is approved as requested. Factor VII protein is part of the cascade of clotting factors that form the chain leading to a protective blood clot. patients with less than 1% Factor VII activity experience similar symptoms to hemophilia. Factor VII activity decreased will be added as PT to HLT Coagulation and bleeding analyses.

CR Number: 2023254001 Implementation Date: 19-Sep-23 Related CR: 2023254001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>SHORT syndrome</i>	Approved as Requested	Proposed PT <i>SHORT syndrome</i>	10090250
			HLT primary <i>Musculoskeletal disorders congenital NEC</i>	10029513
			SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Congenital anterior segment disorders</i>	10010366
			SOC secondary <i>Eye disorders</i>	10015919

MSSO Comment: The proposal to add a new PT SHORT syndrome is approved as requested. A rare disorder characterized by multiple congenital anomalies. The common features observed in SHORT syndrome include; short stature, hyperextensibility of joints, ocular depression, Rieger anomaly and teething delay. SHORT syndrome will be added as PT under primary HLT Musculoskeletal disorders congenital NEC and secondary HLT Congenital anterior segment disorders and secondary HLT Dental developmental disorders and anomalies.

Supplemental Update Report

CR Number: 2023262005	Implementation Date: 19-Sep-23	Related CR: 2023254001	
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed PT	<i>SHORT syndrome</i>	Approved as Requested	Proposed PT
To HLT	<i>Dental developmental disorders and anomalies</i>		<i>SHORT syndrome</i>
			To HLT
			<i>Dental developmental disorders and anomalies</i>
			10090250
			10012321

MSSO
Comment:

CR Number: 2023254002	Implementation Date: 19-Sep-23	Related CR: 2023254002	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Autoimmune myelitis</i>	Approved as Requested	Proposed PT
			<i>Autoimmune myelitis</i>
			HLT primary
			<i>Nervous system autoimmune disorders</i>
			10090251
			10074484
			SOC primary
			<i>Immune system disorders</i>
			10021428
			HLT secondary
			<i>Myelitis (incl infective)</i>
			10028525
			SOC secondary
			<i>Nervous system disorders</i>
			10029205

MSSO
Comment: The proposal to add a new term Autoimmune myelitis is approved as requested. Myelitis is sometimes caused by an autoimmune reaction in which the immune system mistakes the body's own tissue as dangerous and attacks it. This causes swelling that results in damage to the myelin sheath. Autoimmune myelitis will be added as new PT under primary HLT Nervous system autoimmune disorders and secondary HLT Myelitis (incl infective).

Supplemental Update Report

CR Number: 2023254006	Implementation Date: 19-Sep-23	Related CR: 2023254006	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Cryoprecipitate transfusion</i>	Approved as Requested	Proposed LLT <i>Cryoprecipitate transfusion</i>
			To PT <i>Clotting factor transfusion</i>
			10090252 Current
			10009678

MSSO Comment: The proposal to add a new term Cryoprecipitate transfusion is approved as requested. Cryoprecipitate is made from fresh frozen plasma which is frozen and repeatedly thawed in a laboratory to produce a source of concentrated clotting factors including Factor VIII, von Willebrand factor and fibrinogen. Cryoprecipitate transfusion will be added as an LLT to PT Clotting factor transfusion.

CR Number: 2023255001	Implementation Date: 19-Sep-23	Related CR: 2023255001	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Complement Factor 5 increased</i>	Approved Not as Requested	Proposed PT <i>Complement factor C5 increased</i>
			HLT primary <i>Immune response protein analyses NEC</i>
			SOC primary <i>Investigations</i>
			10090253
			10021421
			10022891

MSSO Comment: The proposal to add a new LLT Complement Factor 5 increased is approved but not as requested. Under normal circumstances, the level of C5 in the bloodstream is tightly regulated to maintain immune balance. However, in certain situations or medical conditions, C5 levels can increase. The requested term will be adapted according to MedDRA's capitalization conventions and for further clarity and will be added as a new PT Complement factor C5 increased under HLT Immune response protein analyses NEC.

CR Number: 2023256001	Implementation Date: 19-Sep-23	Related CR: 2023256001	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Breakthrough cancer pain</i>	Rejected	
From PT	<i>Breakthrough pain</i>		
HLT primary	<i>Oncologic complications and emergencies</i>		

MSSO Comment: The proposal to promote the LLT Breakthrough cancer pain from PT Breakthrough pain to primary HLT Oncologic complications and emergencies in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is not approved. Breakthrough cancer pain (BTP) is a term used to describe a sudden and intense flare-up of pain that occurs in cancer patients who are already receiving treatment for their underlying cancer-related pain. The promotion of LLT Breakthrough cancer pain would create two closely related and overlapping concepts at PT level which may result in signal dilution, since the non-qualified Breakthrough pain is often used in relation with cancer pain, as well as it can also be used in the context of other non-cancer conditions. Furthermore, PT Breakthrough pain is linked to secondary HLT Oncologic complications and emergencies.

Supplemental Update Report

CR Number: 2023258001 Implementation Date: 19-Sep-23 Related CR: 2023258001

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New PT			
Proposed PT <i>Ulegyria</i>	Approved as Requested	Proposed PT <i>Ulegyria</i>	10090254
HLT primary <i>Cerebral disorders congenital</i>		HLT primary <i>Cerebral disorders congenital</i>	10052634
SOC primary <i>Congenital, familial and genetic disorders</i>		SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
		HLT secondary <i>Congenital and peripartum cerebral disorders</i>	10010334
		SOC secondary <i>Nervous system disorders</i>	10029205

MSSO Comment: The proposal to add a new PT Ulegyria to primary HLT Cerebral disorders congenital in SOC Congenital, familial and genetic disorders and secondary HLT Congenital and peripartum cerebral disorders in SOC Nervous system disorders is approved as requested. Ulegyria is a parenchymal sequel of hypoxic ischemic encephalopathy causing mushroom-like appearance in gyri accompanied by gliosis and atrophy in subcortical white matter. This condition is most often caused by hypoxic-ischemic brain injury in the perinatal period. The effects of ulegyria can range in severity, although it is most commonly associated with cerebral palsy, mental retardation and epilepsy.

CR Number: 2023258002 Implementation Date: 19-Sep-23 Related CR: 2023258002

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New PT			
Proposed PT <i>Vaccine viraemia</i>	Approved as Requested	Proposed PT <i>Vaccine viraemia</i>	10090256
HLT primary <i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		HLT primary <i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>	10040054
SOC primary <i>Infections and infestations</i>		SOC primary <i>Infections and infestations</i>	10021881
		HLT secondary <i>Vaccination related complications</i>	10068755
		SOC secondary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new PT Vaccine viraemia to primary HLT Sepsis, bacteraemia, viraemia and fungaemia NEC in SOC Infections and infestations is approved as requested. Vaccine viraemia refers to the presence of viral particles in the bloodstream following the administration of vaccines, primarily live attenuated vaccines or viral vector vaccines. PT Vaccine viraemia will also be linked to secondary HLT Vaccination related complications. In a related change, the American English counterpart will be added as LLT Vaccine viraemia to new PT Vaccine viraemia.

Supplemental Update Report

CR Number: 2023262006 Implementation Date: 19-Sep-23 Related CR: 2023258002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Vaccine viremia</i>	Approved as Requested	Proposed LLT	10090258 Current
To PT	<i>Vaccine viraemia</i>		To PT	
			<i>Vaccine viraemia</i>	10090256

MSSO
Comment:

CR Number: 2023258003 Implementation Date: 19-Sep-23 Related CR: 2023258003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Dengue viraemia</i>	Approved as Requested	Proposed PT	10090255
HLT primary	<i>Flaviviral infections</i>		HLT primary	
SOC primary	<i>Infections and infestations</i>		SOC primary	
			<i>Infections and infestations</i>	10021881

MSSO
Comment: The proposal to add a new PT Dengue viraemia to primary HLT Flaviviral infections in SOC Infections and infestations is approved as requested. Dengue viraemia refers to the presence of the dengue virus in the bloodstream of an infected individual. Dengue is a viral infection caused by the dengue virus, which is a member of the Flaviviridae family. It is transmitted primarily through the bites of infected Aedes mosquitoes, particularly Aedes aegypti and Aedes albopictus. In a related change, the American English counterpart Dengue viremia will be added as LLT to the new PT Dengue viraemia.

CR Number: 2023262007 Implementation Date: 19-Sep-23 Related CR: 2023258003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Dengue viremia</i>	Approved as Requested	Proposed LLT	10090257 Current
To PT	<i>Dengue viraemia</i>		To PT	
			<i>Dengue viraemia</i>	10090255

MSSO
Comment:

Supplemental Update Report

CR Number: 2023261001	Implementation Date: 25-Sep-23	Related CR: 2023261001	MedDRA Code #
Change Requested	Add a New Term	Final Disposition	Final Placement
Proposed Term	<i>Pretreatment of cellular and tissue-based products</i>	Rejected	

MSSO Comment: The proposal to add a new term Pretreatment of cellular and tissue-based products is not approved. MedDRA includes concepts related to manufacturing issues. The use and preservation of these natural biomaterials have typically required pre-treatment aimed at reducing the antigenicity of the materials, enhancing the resistance of the materials to enzymatic degradation, and stabilizing the structure of the tissues and maintaining their mechanical properties. Physical and chemical methods for the pre-treatment are out of scope.

CR Number: 2023262003	Implementation Date: 25-Sep-23	Related CR: 2023262003	MedDRA Code #
Change Requested	Add a New PT	Final Disposition	Final Placement
Proposed PT	<i>Maternal immunisation</i>	Approved as Requested	Proposed PT
HLT primary	<i>Immunisations</i>		<i>Maternal immunisation</i> 10090260
SOC primary	<i>Surgical and medical procedures</i>		HLT primary <i>Immunisations</i> 10021431
			SOC primary <i>Surgical and medical procedures</i> 10042613

MSSO Comment: The proposal to add a new PT Maternal immunisation to primary HLT Immunisations in SOC Surgical and medical procedures is approved as requested. Maternal vaccination is an effective means of protecting pregnant women, their fetuses, and infants from vaccine-preventable infections. In a related change, the American English counterpart Maternal immunization will be added as an LLT to the new PT Maternal immunisation.

CR Number: 2023268004	Implementation Date: 25-Sep-23	Related CR: 2023262003	MedDRA Code #
Change Requested	Add a New LLT	Final Disposition	Final Placement
Proposed LLT	<i>Maternal immunization</i>	Approved as Requested	Proposed LLT
To PT	<i>Maternal immunisation</i>		<i>Maternal immunization</i> 10090261 Current
			To PT <i>Maternal immunisation</i> 10090260

MSSO Comment:

Supplemental Update Report

CR Number: 2023262004 **Implementation Date:** 25-Sep-23 **Related CR:** 2023262004

Change Requested Add a New PT Final Disposition Final Placement MedDRA Code #

Proposed PT *Testicular hypotrophy* Rejected

HLT primary *Testicular and epididymal disorders NEC*

SOC primary *Reproductive system and breast disorders*

MSSO Comment: The proposal to add a new PT Testicular hypotrophy to primary HLT Testicular and epididymal disorders NEC in SOC Reproductive system and breast disorders is not approved. In context of testis, the two terms, hypotrophy and atrophy are used interchangeably and existing concept PT Testicular atrophy may be used. The additional proposed terms by subscriber, Testicular size decreased, Smaller testicles, Decreased testicular volume and Softer testes will not be added to MedDRA as they are ambiguous depending on context of both congenital and acquired testicular pathology.

CR Number: 2023262008 **Implementation Date:** 25-Sep-23 **Related CR:** 2023262008

Change Requested Add a New LLT Final Disposition Final Placement MedDRA Code #

Proposed LLT *Anhelation* Rejected

To PT *Dyspnoea*

MSSO Comment: The proposal to add a new LLT Anhelation to PT Dyspnoea is not approved. The proposed term is rarely used in medical literature and is not uniformly translated.

CR Number: 2023262009 **Implementation Date:** 25-Sep-23 **Related CR:** 2023262009

Change Requested Add a New Term Final Disposition Final Placement MedDRA Code #

Proposed Term *Septolobular panniculitis* Approved as Requested Proposed LLT
Septolobular panniculitis 10090259 Current
To PT
Panniculitis 10033675

MSSO Comment: The proposal to add a new term Septolobular panniculitis is approved as requested. The inflammation involving subcutaneous fat can be represented in septa (septal panniculitis) or in lobules (lobular panniculitis) or be equally distributed in both (mixed panniculitis). Septolobular panniculitis will be added as a sub-concept LLT to PT Panniculitis. In a related change, PT Panniculitis lobular and PT Septal panniculitis will be demoted under PT Panniculitis as LLTs, to avoid anatomical overgranularity at PT Level.

Supplemental Update Report

CR Number: 2023268002	Implementation Date: 25-Sep-23	Related CR: 2023262009		
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Panniculitis lobular</i>	Approved as Requested	PT to merge	
To PT	<i>Panniculitis</i>		<i>Panniculitis lobular</i>	10033678 Current
			To PT	
			<i>Panniculitis</i>	10033675

MSSO
Comment:

CR Number: 2023268003	Implementation Date: 25-Sep-23	Related CR: 2023262009		
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Septal panniculitis</i>	Approved as Requested	PT to merge	
To PT	<i>Panniculitis</i>		<i>Septal panniculitis</i>	10056876 Current
			To PT	
			<i>Panniculitis</i>	10033675

MSSO
Comment:

CR Number: 2023262010	Implementation Date: 25-Sep-23	Related CR: 2023262010		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Bone marrow fibrosis</i>	Approved as Requested	Proposed LLT	
			<i>Bone marrow fibrosis</i>	10090264 Current
			To PT	
			<i>Myelofibrosis</i>	10028537

MSSO
Comment: The proposal to add a new LLT Bone marrow fibrosis is approved as requested. Bone marrow fibrosis will be added as an synonym LLT to PT Myelofibrosis. In a related change, PT Bone marrow reticulin fibrosis will be demoted under PT Myelofibrosis as a sub-concept LLT.

Supplemental Update Report

CR Number: 2023268005	Implementation Date: 25-Sep-23	Related CR: 2023262010		
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Bone marrow reticulin fibrosis</i>	Approved as Requested	PT to merge	
To PT	<i>Myelofibrosis</i>		<i>Bone marrow reticulin fibrosis</i>	10069678 Current
			To PT	
			<i>Myelofibrosis</i>	10028537

MSSO
Comment:

CR Number: 2023263001	Implementation Date: 25-Sep-23	Related CR: 2023263001		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Arginine</i>	Approved Not as Requested	Proposed LLT	
			<i>Arginine level</i>	10090263 Current
			To PT	
			<i>Amino acid level</i>	10063258

MSSO
Comment: The proposal to add a new term Arginine is approved but not as requested. Elevated arginine levels (which can rise 4-fold) and ammonia levels are suggestive of the presence of a arginase deficiency, which can later on be confirmed by a subsequent arginase enzyme analysis on red blood cells. The proposed term will be modified to Arginine level and added as an LLT to PT Amino acid level.

CR Number: 2023263002	Implementation Date: 25-Sep-23	Related CR: 2023263002		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Glutamine</i>	Approved Not as Requested	Proposed LLT	
			<i>Glutamine level</i>	10090262 Current
			To PT	
			<i>Amino acid level</i>	10063258

MSSO
Comment: The proposal to add a new term Glutamine is approved but not as requested. Glutamine, as an ammonia buffer, reflects the direction of control of the hyperammonemia and, therefore, it is a useful marker for monitoring of ammonia status. The proposed term will be modified to Glutamine level and added as an LLT to PT Amino acid level.

Supplemental Update Report

CR Number: 2023263003	Implementation Date: 25-Sep-23	Related CR: 2023263003		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Ketotic hyperglycemia</i>	Rejected		

MSSO Comment: The proposal to add a new term Ketotic hyperglycemia is not approved. The proposed term can be represented by existing PT Diabetic ketoacidosis.

CR Number: 2023263004	Implementation Date: 25-Sep-23	Related CR: 2023263004		
Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Quality of life scale</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Investigations NEC</i>		<i>Quality of life scale</i>	10090273
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Investigations NEC</i>	10022892
			SOC primary	
			<i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Quality of life scale to primary HLT Investigations NEC in SOC Investigations is approved as requested. The Quality of Life Scale has been adapted for use in chronic illness groups, and frequently used in clinical trials as well as postmarketing studies and registries. The content validity analysis indicates that the instrument measures domains that diverse patient groups with chronic illness define as quality of life.

CR Number: 2023263005	Implementation Date: 25-Sep-23	Related CR: 2023263005		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Thumb arthritis</i>	Rejected		
To PT	<i>Arthritis</i>			

MSSO Comment: The proposal to add a new LLT Thumb arthritis to PT Arthritis is not approved. Although there are several types of arthritis, the one that most often affects the basal joint of thumb is osteoarthritis. Please consider existing LLT Rhizarthrosis which refers to degenerative arthritis of the trapeziometacarpal joint of the thumb.

Supplemental Update Report

CR Number: 2023263006	Implementation Date: 25-Sep-23	Related CR: 2023263006	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed PT	<i>Circulating tumor DNA test negative</i>	Approved Not as Requested	Proposed LLT <i>Circulating tumor DNA test negative</i> 10090271 Current To PT <i>Circulating tumour DNA test negative</i> 10090267

MSSO Comment: The proposal to add a new PT Circulating tumor DNA test negative is approved but not as requested. Circulating tumor DNA (ctDNA) is tumor-derived fragmented DNA in the bloodstream that is not associated with cells and a promising blood-based biomarker for monitoring disease status of patients with advanced cancers. Circulating tumor DNA test negative will be added as LLT to the British spelled PT Circulating tumour DNA test negative, which will be added in a related change to HLT Cell marker analyses.

CR Number: 2023268006	Implementation Date: 25-Sep-23	Related CR: 2023263006	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed PT	<i>Circulating tumour DNA test negative</i>	Approved as Requested	Proposed PT <i>Circulating tumour DNA test negative</i> 10090267
HLT primary	<i>Cell marker analyses</i>		HLT primary <i>Cell marker analyses</i> 10072981
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i> 10022891

MSSO Comment:

CR Number: 2023263007	Implementation Date: 25-Sep-23	Related CR: 2023263007	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed PT	<i>Circulating tumor DNA test positive</i>	Approved Not as Requested	Proposed LLT <i>Circulating tumor DNA test positive</i> 10090270 Current To PT <i>Circulating tumour DNA test positive</i> 10090265

MSSO Comment: The proposal to add a new PT Circulating tumor DNA test positive is approved but not as requested. Circulating tumor DNA (ctDNA) is tumor-derived fragmented DNA in the bloodstream that is not associated with cells and a promising blood-based biomarker for monitoring disease status of patients with advanced cancers. Circulating tumor DNA test positive will be added as LLT to the British English PT Circulating tumour DNA test positive which will be added in a related change to HLT Cell marker analyses.

Supplemental Update Report

CR Number: 2023268007 Implementation Date: 25-Sep-23 Related CR: 2023263007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Circulating tumour DNA test positive</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Cell marker analyses</i>		<i>Circulating tumour DNA test positive</i>	10090265
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Cell marker analyses</i>	10072981
			SOC primary	
			<i>Investigations</i>	10022891

MSSO
Comment:

CR Number: 2023263008 Implementation Date: 25-Sep-23 Related CR: 2023263008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Circulating tumor DNA test</i>	Approved Not as Requested	Proposed LLT	
			<i>Circulating tumor DNA test</i>	10090269 Current
			To PT	
			<i>Circulating tumour DNA test</i>	10090266

MSSO
Comment: The proposal to add a new PT Circulating tumor DNA test is approved but not as requested. Circulating tumor DNA (ctDNA) is tumor-derived fragmented DNA in the bloodstream that is not associated with cells and a promising blood-based biomarker for monitoring disease status of patients with advanced cancers. Circulating tumor DNA test will be added as LLT to the British English PT Circulating tumour DNA test which will be added in a related change to HLT Cell marker analyses

CR Number: 2023268008 Implementation Date: 25-Sep-23 Related CR: 2023263008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Circulating tumour DNA test</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Cell marker analyses</i>		<i>Circulating tumour DNA test</i>	10090266
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Cell marker analyses</i>	10072981
			SOC primary	
			<i>Investigations</i>	10022891

MSSO
Comment:

Supplemental Update Report

CR Number: 2023263009	Implementation Date: 25-Sep-23	Related CR: 2023263009		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Cell-free circulating tumor DNA test</i>	Approved Not as Requested	Proposed LLT <i>Cell-free circulating tumor DNA test</i>	10090272 Current
			To PT <i>Circulating tumour DNA test</i>	10090266

MSSO Comment: The proposal to add a new PT Cell-free circulating tumor DNA test is approved but not as requested. Cell-free DNA refers to small fragments of DNA found in the bloodstream that originate from various cells in the body, including healthy and normal cells. These fragments can come from cell turnover, apoptosis, and other physiological processes. Cell-free circulating tumor DNA test and the its British English spelled counterpart Cell-free circulating tumour DNA test will both be added as LLTs to PT Circulating tumour DNA test added in change request 2023263008.

CR Number: 2023268009	Implementation Date: 25-Sep-23	Related CR: 2023263009		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Cell-free circulating tumour DNA test</i>	Approved as Requested	Proposed LLT <i>Cell-free circulating tumour DNA test</i>	10090268 Current
To PT	<i>Circulating tumour DNA test</i>		To PT <i>Circulating tumour DNA test</i>	10090266

MSSO Comment:

CR Number: 2023264001	Implementation Date: 25-Sep-23	Related CR: 2023264001		
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Obstructive sleep apnoea syndrome</i>	Rejected		
To PT	<i>Obstructive sleep apnoea</i>			

MSSO Comment: The proposal to demote the PT Obstructive sleep apnoea syndrome under PT Obstructive sleep apnoea is not approved. Despite the academic differentiation mentioned in justification there is a continuum between the two concepts involved and modifications, i.e. swapping PT Obstructive sleep apnoea syndrome with PT Obstructive sleep apnoea, may have a huge impact on legacy data.

Supplemental Update Report

CR Number: 2023265001 Implementation Date: 03-Oct-23 Related CR: 2023265001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Intraductal papillary mucinous neoplasm benign</i>	Rejected		

MSSO Comment: The proposal to add a new PT Intraductal papillary mucinous neoplasm benign is not approved. Adding the proposed term will cause confusion because of its overlap with existing PT Intraductal papillary mucinous neoplasm. Intraductal papillary mucinous neoplasm is a dysplastic lesion and therefore should "theoretically" be understood as a benign risk factor. However, the high-grade types are most times indistinguishable of in-situ carcinomas of such a severe malignancy as pancreatic cancer represents. For this reason it seems preferable to keep the HLT Gastrointestinal neoplasms malignancy unspecified NEC as primary link. However, and in order warrant a more specific representation in terms of anatomical location, the secondary link of the PT Intraductal papillary mucinous neoplasm will be changed from HLT Gastrointestinal neoplasms NEC to HLT Pancreatic neoplasms, which additionally is an HLT that does not take a stand on the malignant behavior of the lesions grouped underneath.

CR Number: 2023276004 Implementation Date: 03-Oct-23 Related CR: 2023265001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Intraductal papillary mucinous neoplasm</i>	Approved as Requested	Proposed PT	
From HLT	<i>Gastrointestinal neoplasms NEC</i>		<i>Intraductal papillary mucinous neoplasm</i>	10070999
To HLT	<i>Pancreatic neoplasms</i>		From HLT	
			<i>Gastrointestinal neoplasms NEC</i>	10017993
			To HLT	
			<i>Pancreatic neoplasms</i>	10033632

MSSO Comment:

CR Number: 2023267007 Implementation Date: 03-Oct-23 Related CR: 2023267007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Sclerosing glomerulonephritis</i>	Approved as Requested	Proposed LLT	
			<i>Sclerosing glomerulonephritis</i>	10090284 Current
			To PT	
			<i>Glomerulonephritis</i>	10018364

MSSO Comment: The proposal to add a new term Sclerosing glomerulonephritis is approved as requested. Sclerosing glomerulonephritis is a specific type of glomerular disease characterized by inflammation and scarring of the glomeruli. The term expresses the specific pattern of injury seen in biopsies. Sclerosing glomerulonephritis will be added as an LLT to PT Glomerulonephritis.

Supplemental Update Report

CR Number: 2023268001	Implementation Date: 03-Oct-23	Related CR: 2023268001	MedDRA Code #
Change Requested		Final Disposition	Final Placement
Proposed Term <i>Sleepiness postvaccinal</i>		Rejected	

MSSO Comment: The proposal to add a new term Sleepiness postvaccinal is not approved. MedDRA cannot provide for all possible systemic side effects observed after vaccination such as headache, nausea, fatigue, body ache etc. with a single combination term. Please consider selection of two LLTs in combination to represent the requested term.

CR Number: 2023268010	Implementation Date: 03-Oct-23	Related CR: 2023268010	MedDRA Code #
Change Requested		Final Disposition	Final Placement
Proposed LLT <i>Secondary hypersplenism</i>		Approved as Requested	
			Proposed LLT <i>Secondary hypersplenism</i> 10090276 Current
			To PT <i>Hypersplenism</i> 10020769

MSSO Comment: The proposal to add a new LLT Secondary hypersplenism is approved as requested. Except for cases originating in the spleen itself, such as primary splenic hyperplasia or idiopathic splenomegaly, hypersplenism is a secondary process that can arise from multiple causes usually associated to the presence of splenomegaly, which increases the spleen's mechanical filtering and destruction of red blood cells and often of white blood cells and platelets. Secondary hypersplenism will be added as LLT to PT Hypersplenism.

CR Number: 2023268011	Implementation Date: 03-Oct-23	Related CR: 2023268011	MedDRA Code #
Change Requested		Final Disposition	Final Placement
Proposed LLT <i>Primary normocalcemic hyperparathyroidism</i>		Approved Not as Requested	
			Proposed LLT <i>Normocalcemic primary hyperparathyroidism</i> 10090278 Current
			To PT <i>Hyperparathyroidism primary</i> 10020707

MSSO Comment: The proposal to add a new LLT Primary normocalcemic hyperparathyroidism is approved but not as requested. Normocalcemic primary hyperparathyroidism is a disorder where elevated parathyroid hormone levels are the result of autonomous hypersecretion of one or more parathyroid glands and serum calcium is consistently within the normal range as measured at least twice over a six month period. The requested term will be added in alternate word order as LLT Normocalcemic primary hyperparathyroidism to PT Hyperparathyroidism primary. In a related change, the British English spelled counterpart LLT Normocalcaemic primary hyperparathyroidism will also be added to PT Hyperparathyroidism primary.

Supplemental Update Report

CR Number: 2023276001 Implementation Date: 03-Oct-23 Related CR: 2023268011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Normocalcaemic primary hyperparathyroidism	Approved as Requested	Proposed LLT	
To PT	Hyperparathyroidism primary		Normocalcaemic primary hyperparathyroidism	10090279 Current
			To PT	
			Hyperparathyroidism primary	10020707

MSSO
Comment:

CR Number: 2023268012 Implementation Date: 03-Oct-23 Related CR: 2023268012

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Secondary normocalcemic hyperparathyroidism	Approved Not as Requested	Proposed LLT	
			Normocalcemic secondary hyperparathyroidism	10090274 Current
			To PT	
			Hyperparathyroidism secondary	10020708

MSSO
Comment: The proposal to add a new LLT Secondary normocalcemic hyperparathyroidism is approved but not as requested. In normocalcemic secondary hyperparathyroidism, the parathyroid hormone elevation is a reaction to a low calcium stimulus from various causes. The parathyroid hormone remains elevated as long as the low calcium stimulus persists and returns to normal as soon as it is removed. Patients with secondary hyperparathyroidism typically develop hyperplasia of all four parathyroid glands. The requested term will be added in the alternate word order as LLT Normocalcemic secondary hyperparathyroidism to PT Hyperparathyroidism secondary. In a related change, the British counterpart of the term will be added as the LLT Normocalcaemic secondary hyperparathyroidism under PT Hyperparathyroidism secondary.

CR Number: 2023276002 Implementation Date: 03-Oct-23 Related CR: 2023268012

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Normocalcaemic secondary hyperparathyroidism	Approved as Requested	Proposed LLT	
To PT	Hyperparathyroidism secondary		Normocalcaemic secondary hyperparathyroidism	10090280 Current
			To PT	
			Hyperparathyroidism secondary	10020708

MSSO
Comment:

Supplemental Update Report

CR Number: 2023268013	Implementation Date: 03-Oct-23	Related CR: 2023268013		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Ureteroscopic Lithotripsy</i>	Approved Not as Requested	Proposed LLT <i>Ureteroscopic lithotripsy</i>	10090277 Current
			To PT <i>Ureteric calculus removal</i>	10046391

MSSO Comment: The proposal to add a new LLT Ureteroscopic Lithotripsy is approved but not as requested. Ureteroscopic lithotripsy is a minimally invasive surgical procedure used to locate and treat kidney stones in the ureter and kidneys. The procedure, which is also known as ureteroscopy with laser lithotripsy, is required when the kidney stones are untreatable by medicines or other non-surgical options. The proposed term will be modified according to MedDRA capitalization conventions and added as LLT Ureteroscopic lithotripsy to the PT Ureteric calculus removal.

CR Number: 2023268014	Implementation Date: 03-Oct-23	Related CR: 2023268014		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Triplex ultrasound</i>	Approved as Requested	Proposed LLT <i>Triplex ultrasound</i>	10090275 Current
			To PT <i>Ultrasound Doppler</i>	10045412

MSSO Comment: The proposal to add a new LLT Triplex ultrasound is approved as requested. Triplex ultrasound (also called color-flow imaging) is an enhanced form of Doppler ultrasound technology. In a procedure similar to duplex ultrasound, it uses color to highlight the direction and intensity of blood flow. Triplex ultrasound will be added as LLT to PT Ultrasound Doppler aligned with LLT Duplex ultrasound.

CR Number: 2023268015	Implementation Date: 03-Oct-23	Related CR: 2023268015		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Femoral vein thrombosis</i>	Rejected		
To PT	<i>Peripheral vein thrombosis</i>			

MSSO Comment: The proposal to add a new LLT Femoral vein thrombosis to PT Peripheral vein thrombosis is not approved. Femoral vein thrombosis is a type of deep vein thrombosis. The MSSO refrains from adding all possible synonyms to existing concepts. The proposed term can be captured by existing LLT Deep venous thrombosis femoral.

Supplemental Update Report

CR Number: 2023268016 Implementation Date: 03-Oct-23 Related CR: 2023268016

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Cystic renal lesion</i>	Rejected		

MSSO Comment: The proposal to add a new term Cystic renal lesion is not approved. A cystic renal lesion refers to an abnormal fluid-filled sac or cavity that forms within the kidneys. These cysts can vary in size and may be simple or complex. Generally, the MSSO refrains from adding broad "lesion" terms, as they only add an additional imprecise term to existing "disorder" concepts. The proposed term can be captured by e.g. existing LLT Renal cyst.

CR Number: 2023269001 Implementation Date: 03-Oct-23 Related CR: 2023269001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Gastrointestinal basidiobolomycosis</i>	Approved as Requested	Proposed PT <i>Gastrointestinal basidiobolomycosis</i>	10090285
			HLT primary <i>Fungal infections NEC</i>	10017536
			SOC primary <i>Infections and infestations</i>	10021881
			HLT secondary <i>Gastrointestinal infections, site unspecified</i>	10017968
			SOC secondary <i>Gastrointestinal disorders</i>	10017947

MSSO Comment: The proposal to add a new term Gastrointestinal basidiobolomycosis is approved as requested. Gastrointestinal basidiobolomycosis is a rare fungal infection that primarily affects the gastrointestinal tract. It is caused by the fungus *Basidiobolus ranarum*, which belongs to the class Zygomycetes. This infection is extremely rare and occurs predominantly in tropical and subtropical regions, such as parts of Africa, Asia, and the Middle East. Gastrointestinal basidiobolomycosis will be added as PT with a primary link to HLT Fungal infections NEC and a secondary link to HLT Gastrointestinal infections, site unspecified.

Supplemental Update Report

CR Number: 2023269002 Implementation Date: 03-Oct-23 Related CR: 2023269002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	5-hydroxyindolacetic acid in urine increased	Approved as Requested	PT to merge	
To PT	5-hydroxyindolacetic acid increased		5-hydroxyindolacetic acid in urine increased	10051183 Current
			To PT	
			5-hydroxyindolacetic acid increased	10058611

MSSO Comment: The proposal to demote the PT 5-hydroxyindolacetic acid in urine increased under PT 5-hydroxyindolacetic acid increased is approved as requested. During the review of SMQ Tumour markers, PT placement for 5-hydroxyindolacetic acid in urine increased was noted to be noncompliant with MedDRA placement rules. 5-hydroxyindolacetic acid (5-HIAA) is usually measured in 24-h urine. Plasma 5-HIAA measurement in certain patient populations with difficulty in collecting 24-h urine is possible, although the assay has to be further validated in large clinical series.

CR Number: 2023269003 Implementation Date: 03-Oct-23 Related CR: 2023269003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	5-hydroxyindolacetic acid in urine decreased	Approved as Requested	PT to merge	
To PT	5-hydroxyindolacetic acid decreased		5-hydroxyindolacetic acid in urine decreased	10058615 Current
			To PT	
			5-hydroxyindolacetic acid decreased	10058616

MSSO Comment: The proposal to demote the PT 5-hydroxyindolacetic acid in urine decreased under PT 5-hydroxyindolacetic acid decreased is approved as requested. During the review of SMQ Tumour markers, PT placement for 5-hydroxyindolacetic acid in urine decreased was noted to be noncompliant with MedDRA placement rules. 5-hydroxyindolacetic acid (5-HIAA) is usually measured in 24-h urine. Plasma 5-HIAA measurement in certain patient populations with difficulty in collecting 24-h urine is possible, although the assay has to be further validated in large clinical series.

CR Number: 2023269004 Implementation Date: 03-Oct-23 Related CR: 2023269004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	5-hydroxyindolacetic acid in urine	Approved as Requested	PT to merge	
To PT	5-hydroxyindolacetic acid		5-hydroxyindolacetic acid in urine	10059972 Current
			To PT	
			5-hydroxyindolacetic acid	10050342

MSSO Comment: The proposal to demote the PT 5-hydroxyindolacetic acid in urine under PT 5-hydroxyindolacetic acid is approved as requested. During the review of SMQ Tumour markers, PT placement for 5-hydroxyindolacetic acid in urine was noted to be noncompliant with MedDRA placement rules. 5-hydroxyindolacetic acid (5-HIAA) is usually measured in 24-h urine. Plasma 5-HIAA measurement in certain patient populations with difficulty in collecting 24-h urine is possible, although the assay has to be further validated in large clinical series.

Supplemental Update Report

CR Number: 2023269005 Implementation Date: 03-Oct-23 Related CR: 2023269005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
PT to merge	Demote a PT <i>BRAF V600E mutation positive</i>	Rejected		
To PT	<i>BRAF gene mutation</i>			

MSSO Comment: The proposal to demote the PT BRAF V600E mutation positive under PT BRAF gene mutation is not approved. One is the mutation and the other the test. Besides, V600E is one of the possible mutations of the BRAF gene in which valine (V) is substituted by glutamic acid (E) at amino acid 600, which confers a poor prognosis in metastatic colorectal and thyroid cancers. Both terms have been used depending on context such as Investigation or Diagnosis.

CR Number: 2023269006 Implementation Date: 03-Oct-23 Related CR: 2023269006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Transvenous pacemaker Implantation</i>	Approved Not as Requested	Proposed LLT <i>Transvenous pacemaker implantation</i>	10090282 Current
			To PT <i>Cardiac pacemaker insertion</i>	10007598

MSSO Comment: The proposal to add a new LLT Transvenous pacemaker Implantation is approved but not as requested. Transvenous access to the heart chambers is the preferable technique for pace maker implantation, commonly via a percutaneous approach of the subclavian vein, the cephalic vein, or rarely the axillary vein, the internal jugular vein or the femoral vein. The requested term will be modified according to MedDRA capitalisation conventions and will be added as LLT Transvenous pacemaker implantation to PT Cardiac pacemaker insertion.

CR Number: 2023269007 Implementation Date: 03-Oct-23 Related CR: 2023269007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Link a PT to a HLT <i>Metapneumovirus infection</i>	Approved Not as Requested	Proposed PT <i>Metapneumovirus infection</i>	10066226
To HLT	<i>Respiratory tract infections NEC</i>		From HLT <i>Viral lower respiratory tract infections</i>	10047468
			To HLT <i>Respiratory tract infections NEC</i>	10057190

MSSO Comment: The proposal to link the PT Metapneumovirus infection to the HLT Respiratory tract infections NEC is approved but not as requested. As Metapneumovirus infection are not limited to the lower respiratory tract the HLT in Respiratory, thoracic and mediastinal disorders SOC will be changed for PT Metapneumovirus infection from HLT Viral lower respiratory tract infections to HLT Respiratory tract infections NEC for better alignment.

Supplemental Update Report

CR Number: 2023269008 **Implementation Date:** 03-Oct-23 **Related CR:** 2023269008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Occipital plagiocephaly</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>Positional plagiocephaly</i>		<i>Acquired occipital plagiocephaly</i>	10090281 Current
			To PT	
			<i>Acquired plagiocephaly</i>	10081440

MSSO Comment: The proposal to add a new LLT Occipital plagiocephaly to PT Positional plagiocephaly is approved but not as requested. Occipital plagiocephaly can be congenital as result of an early fusion of the lambdoid suture or acquired due to long position on the back. Therefore, the requested term will be modified to Acquired occipital plagiocephaly and added as LLT to PT Acquired plagiocephaly.

CR Number: 2023269009 **Implementation Date:** 03-Oct-23 **Related CR:** 2023269009

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>What is post-infectious irritable bowel syndrome</i>	Approved Not as Requested	Proposed LLT	
			<i>Post-infectious irritable bowel syndrome</i>	10090283 Current
			To PT	
			<i>Irritable bowel syndrome</i>	10023003

MSSO Comment: The proposal to add a new LLT What is post-infectious irritable bowel syndrome is approved but not as requested. Post-infectious IBS (PI-IBS) is a type of IBS that is caused by viral and bacterial infections to the gastrointestinal tract (e.g., gastroenteritis) and comprises approximately 10% of all IBS cases. The requested term will be modified to Post-infectious irritable bowel syndrome and added as LLT to PT Irritable bowel syndrome. In a related change, PT Irritable bowel syndrome will be linked to secondary HLT Inflammatory disorders following infection.

CR Number: 2023276003 **Implementation Date:** 03-Oct-23 **Related CR:** 2023269009

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Irritable bowel syndrome</i>	Approved as Requested	Proposed PT	
To HLT	<i>Inflammatory disorders following infection</i>		<i>Irritable bowel syndrome</i>	10023003
			To HLT	
			<i>Inflammatory disorders following infection</i>	10021982

MSSO Comment:

Supplemental Update Report

CR Number: 2023269010 Implementation Date: 03-Oct-23 Related CR: 2023269010

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Phobia neurosis</i>	Rejected		
To PT	<i>Anxiety disorder</i>			

MSSO Comment: The proposal to add a new LLT Phobia neurosis to PT Anxiety disorder is not approved. The term "neurosis" is no longer used in condition names or categories by the World Health Organization's International Classification of Diseases (ICD) or the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM). According to the American Heritage Medical Dictionary of 2007, the term is "no longer used in psychiatric diagnosis".

CR Number: 2023269011 Implementation Date: 03-Oct-23 Related CR: 2023269011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Link (move) an LLT to another PT <i>Floating kidney</i>	Approved Not as Requested	PT to merge	
From PT	<i>Kidney hypermobility</i>		<i>Kidney hypermobility</i>	10023423 Current
To PT	<i>Nephroptosis</i>		To PT <i>Nephroptosis</i>	10029158

MSSO Comment: The proposal to move the LLT Floating kidney from PT Kidney hypermobility to PT Nephroptosis is approved but not as requested. Nephroptosis is the downward displacement of the kidney; called also floating, hypermobile, movable, or wandering kidney. Therefore, PT Kidney hypermobility will be demoted under the medical PT Nephroptosis as synonym LLT.

CR Number: 2023269012 Implementation Date: 03-Oct-23 Related CR: 2023269012

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Wandering Kidney</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>Nephroptosis</i>		<i>Wandering kidney</i>	10090286 Current
			To PT <i>Nephroptosis</i>	10029158

MSSO Comment: The proposal to add a new LLT Wandering Kidney to PT Nephroptosis is approved but not as requested. The requested term will be modified according to MedDRA capitalization standards and added as synonym LLT Wandering kidney to PT Nephroptosis.

Supplemental Update Report

CR Number: 2023270003 Implementation Date: 03-Oct-23 Related CR: 2023270003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Dermatoneuro syndrome</i>	Approved Not as Requested	Proposed PT	
To PT	<i>Lichen myxoedematosus</i>		<i>Dermato-neuro syndrome</i>	10090287
			HLT primary	
			<i>Papulosquamous conditions</i>	10033738
			SOC primary	
			<i>Skin and subcutaneous tissue disorders</i>	10040785
			HLT secondary	
			<i>Nervous system disorders NEC</i>	10057185
			SOC secondary	
			<i>Nervous system disorders</i>	10029205

MSSO Comment: The proposal to add a new LLT Dermatoneuro syndrome to PT Lichen myxoedematosus is approved but not as requested. Dermato-neuro syndrome is an occasionally lethal, acute, neurologic complication of scleromyxedema characterized by fever, confusion, dysarthria, lethargy, convulsions, and coma. Dermato-neuro syndrome often is preceded by flu-like symptoms. The proposed term Dermatoneuro syndrome will be modified to the more common term Dermato-neuro syndrome and added as PT to primary HLT Papulosquamous conditions in line with the placement of PT Lichen myxoedematosus and to secondary HLT Nervous system disorders NEC.

CR Number: 2023270004 Implementation Date: 03-Oct-23 Related CR: 2023270004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Thoracic hypoplasia</i>	Approved Not as Requested	Proposed PT	
To PT	<i>Skeletal dysplasia</i>		<i>Thoracic hypoplasia</i>	10090288
			HLT primary	
			<i>Musculoskeletal and connective tissue disorders of trunk congenital (excl spine)</i>	10028384
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Musculoskeletal and connective tissue disorders of trunk congenital (excl spine)</i>	10028384
			SOC secondary	
			<i>Musculoskeletal and connective tissue disorders</i>	10028395

MSSO Comment: The proposal to add a new LLT Thoracic hypoplasia to PT Skeletal dysplasia is approved but not as requested. Thoracic hypoplasia is characterized by underdevelopment or incomplete growth of the thoracic cavity, leading to various respiratory and developmental problems. Thoracic hypoplasia will be added as PT under primary HLT Musculoskeletal and connective tissue disorders of trunk congenital (excl spine), biaxial at the HLG level with primary link to SOC Congenital, familial and genetic disorders, and secondary link to SOC Musculoskeletal and connective tissue disorders.

Supplemental Update Report

CR Number: 2023270005 Implementation Date: 03-Oct-23 Related CR: 2023270005

[Change Requested](#) Add a New Term [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed Term *Hypertensive cardiovascular disease* Rejected

MSSO Comment: The proposal to add a new term Hypertensive cardiovascular disease 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. This concept can be represented in MedDRA by existing terms, such as LLT Hypertension and LLT Cardiovascular disorder. 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.

CR Number: 2023270006 Implementation Date: 03-Oct-23 Related CR: 2023270006

[Change Requested](#) Add a New Term [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed Term *Mycoplasma pneumoniae infection* Approved as Requested

Proposed LLT
Mycoplasma pneumoniae infection 10090289 Current

To PT
Mycoplasma infection 10061300

MSSO Comment: The proposal to add a new term Mycoplasma pneumoniae infection is approved as requested. Mycoplasma pneumoniae is a bacteria that usually causes upper respiratory tract infections but can also cause pneumonia, and it is one of the most common causes of atypical pneumonia. Many extrapulmonary infections have been attributed to Mycoplasma pneumoniae too. Mycoplasma pneumoniae infection will be added as an LLT to PT Mycoplasma infection.

CR Number: 2023271001 Implementation Date: 03-Oct-23 Related CR: 2023271001

[Change Requested](#) Link (move) an LLT to another PT [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed LLT *Hypersensitive skin* Approved Not as Requested

Proposed LLT
Increased skin sensitivity 10021681 Current

From PT *Sensitive skin*

To PT *Hyperaesthesia* 10020568

To PT
Sensitive skin 10081765

MSSO Comment: The proposal to move the LLT Hypersensitive skin from PT Sensitive skin to PT Hyperaesthesia is approved but not as requested. Sensitive skin and Increased skin sensitivity are terms used to describe skin that is prone to irritation, discomfort, or reactions when exposed to various factors or products, often resulting in physical irritation. However, Hyperesthesia skin and Touch sensitivity increased refer to a heightened sensory perception or increased sensitivity to touch, temperature, or other sensory stimuli and will remain under PT Hyperaesthesia. Therefore, instead of moving LLT Hypersensitive skin to PT Hyperaesthesia, LLT Increased skin sensitivity will be moved from PT Hyperaesthesia to PT Sensitive skin.

Supplemental Update Report

CR Number: 2023271012 Implementation Date: 30-Nov-23 Related CR: 2023271012

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Intentional dose titration adjustment</i>	Rejected After Suspension		

MSSO Comment: The proposal to add a new LLT Intentional dose titration adjustment is not approved after suspension. Drug titration adjustment refers to the process of carefully and systematically adjusting the dosage of a medication to achieve the desired therapeutic effect while minimizing side effects. Dose titration adjustment implies an intentional act.

CR Number: 2023271013 Implementation Date: 09-Oct-23 Related CR: 2023271013

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Potential for medication error</i>	Approved as Requested	Proposed LLT <i>Potential for medication error</i>	10090314 Current
To PT	<i>Circumstance or information capable of leading to medication error</i>		To PT <i>Circumstance or information capable of leading to medication error</i>	10064385

MSSO Comment: The proposal to add a new LLT Potential for medication error to PT Circumstance or information capable of leading to medication error is approved as requested. The potential for medication error refers to the risk that mistakes or errors may occur at any stage of the medication use process, from prescribing and dispensing to administering and monitoring medications.

CR Number: 2023271014 Implementation Date: 30-Nov-23 Related CR: 2023271014

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Potential to lead to wrong drug error</i>	Approved Not as Requested After Suspension	Proposed LLT <i>Potential for medication error, wrong drug</i>	10090603 Current
To PT	<i>Circumstance or information capable of leading to medication error</i>		To PT <i>Circumstance or information capable of leading to medication error</i>	10064385

MSSO Comment: The proposal to add a new LLT Potential to lead to wrong drug error to PT Circumstance or information capable of leading to medication error is approved but not as requested after suspension. The proposed term will be modified for clarity to Potential for medication error, wrong drug and added as LLT to PT Circumstance or information capable of leading to medication error.

Supplemental Update Report

CR Number: 2023271015 **Implementation Date:** 30-Nov-23 **Related CR:** 2023271015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Potential to lead to wrong dose error	Approved Not as Requested After Suspension	Proposed LLT	10090607 Current
To PT	Circumstance or information capable of leading to medication error		To PT Circumstance or information capable of leading to medication error	10064385

MSSO Comment: The proposal to add a new LLT Potential to lead to wrong dose error to PT Circumstance or information capable of leading to medication error is approved but not as requested after suspension. The proposed term will be modified for clarity to Potential for medication error, wrong dose and added as LLT to PT Circumstance or information capable of leading to medication error.

CR Number: 2023271016 **Implementation Date:** 30-Nov-23 **Related CR:** 2023271016

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Potential to lead to wrong route error	Approved Not as Requested After Suspension	Proposed LLT	10090604 Current
To PT	Circumstance or information capable of leading to medication error		To PT Circumstance or information capable of leading to medication error	10064385

MSSO Comment: The proposal to add a new LLT Potential to lead to wrong route error to PT Circumstance or information capable of leading to medication error is approved but not as requested after suspension. The proposed term will be modified for clarity to Potential for medication error, wrong route and added as LLT to PT Circumstance or information capable of leading to medication error.

CR Number: 2023271017 **Implementation Date:** 30-Nov-23 **Related CR:** 2023271017

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Capacity for medication error	Rejected After Suspension		
To PT	Circumstance or information capable of leading to medication error			

MSSO Comment: The proposal to add a new LLT Capacity for medication error to PT Circumstance or information capable of leading to medication error is not approved after suspension. Capacity for medication error is a synonym to LLT Potential for medication error requested in CR 2023271013 and does not provide additional value. Thus, the term is rejected to avoid over granularity on the LLT level.

Supplemental Update Report

CR Number: 2023271018 **Implementation Date:** 30-Nov-23 **Related CR:** 2023271018

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Capacity for device use error	Rejected After Suspension		
To PT	Circumstance or information capable of leading to device use error			

MSSO Comment: The proposal to add a new LLT Capacity for device use error to PT Circumstance or information capable of leading to device use error is not approved after suspension. Capacity for device use error is a synonym to PT Potential for device use error to be added in change request 2023271019, and does not provide additional value. Thus, the term is rejected to avoid over granularity on the LLT level.

CR Number: 2023271019 **Implementation Date:** 09-Oct-23 **Related CR:** 2023271019

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Potential for device use error	Approved as Requested	Proposed LLT	
To PT	Circumstance or information capable of leading to device use error		Potential for device use error	10090316 Current
			To PT	
			Circumstance or information capable of leading to device use error	10074266

MSSO Comment: The proposal to add a new LLT Potential for device use error to PT Circumstance or information capable of leading to device use error is approved as requested. The potential for device use error refers to the risk that mistakes or errors may occur during device use.

CR Number: 2023271020 **Implementation Date:** 30-Nov-23 **Related CR:** 2023271020

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Partial dose administered	Rejected After Suspension		
To PT	Incorrect dose administered			

MSSO Comment: The proposal to add a new LLT Partial dose administered to PT Incorrect dose administered is not approved after suspension. The proposed term can be represented by LLT Incomplete dose administered.

Supplemental Update Report

CR Number: 2023271021 **Implementation Date:** 30-Nov-23 **Related CR:** 2023271021

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Increased dose administered</i>	Approved After Suspension	Proposed LLT	
To PT	<i>Incorrect dose administered</i>		<i>Increased dose administered</i>	10090605 Current
			To PT	
			<i>Incorrect dose administered</i>	10064355

MSSO Comment: The proposal to add a new LLT Increased dose administered to PT Incorrect dose administered is approved as requested after suspension. Increased dose administered offers more specific information at LLT level to PT Incorrect dose administered.

CR Number: 2023271022 **Implementation Date:** 30-Nov-23 **Related CR:** 2023271022

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Needle removed too soon from injection site</i>	Approved Not as Requested After Suspension	Proposed LLT	
To PT	<i>Product administration interrupted</i>		<i>Delivery device removed before complete product administration</i>	10090602 Current
			To PT	
			<i>Product administration interrupted</i>	10081479

MSSO Comment: The proposal to add a new LLT Needle removed too soon from injection site to PT Product administration interrupted is approved but not as requested after suspension. The requested term will be modified to LLT Delivery device removed before complete product administration and added under PT Product administration interrupted.

CR Number: 2023271023 **Implementation Date:** 09-Oct-23 **Related CR:** 2023271023

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Pen markings confusion</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>Device use confusion</i>		<i>Device markings confusion</i>	10090315 Current
			To PT	
			<i>Device use confusion</i>	10083151

MSSO Comment: The proposal to add a new LLT Pen markings confusion to PT Device use confusion is approved but not as requested. The proposed term will be modified to broader concept and to avoid overgranularity to Device markings confusion and added as an LLT to PT Device use confusion.

Supplemental Update Report

CR Number: 2023271024 **Implementation Date:** 09-Oct-23 **Related CR:** 2023271024

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Wrong drug strength prepared</i>	Approved as Requested	Proposed LLT <i>Wrong drug strength prepared</i>	10090317 Current
To PT	<i>Product preparation error</i>		To PT <i>Product preparation error</i>	10076869

MSSO Comment: The proposal to add a new LLT Wrong drug strength prepared to PT Product preparation error is approved as requested.

CR Number: 2023271025 **Implementation Date:** 30-Nov-23 **Related CR:** 2023271025

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Wrong drug strength compounded</i>	Approved After Suspension	Proposed LLT <i>Wrong drug strength compounded</i>	10090608 Current
To PT	<i>Product preparation error</i>		To PT <i>Product preparation error</i>	10076869

MSSO Comment: The proposal to add a new LLT Wrong drug strength compounded to PT Product preparation error is approved as requested after suspension as the term provides more specific information for product preparation errors.

CR Number: 2023271026 **Implementation Date:** 30-Nov-23 **Related CR:** 2023271026

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Product label strength confusion</i>	Approved After Suspension	Proposed LLT <i>Product label strength confusion</i>	10090606 Current
To PT	<i>Product label confusion</i>		To PT <i>Product label confusion</i>	10069273

MSSO Comment: The proposal to add a new LLT Product label strength confusion to PT Product label confusion is approved as requested after suspension. LLT Product label strength confusion specifically captures reports concerning confusions regarding the product strength in the label and is one of the most medically important aspects.

Supplemental Update Report

CR Number: 2023271027 Implementation Date: 09-Oct-23 Related CR: 2023271027

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Wrong device selected	Approved as Requested	Proposed PT Wrong device selected	10090311
			HLT primary Product selection errors and issues	10079153
			SOC primary Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Wrong device selected is approved as requested. There are situations where a wrong device may be selected, which is an error. PT Wrong device selected will be added to primary HLT Product selection errors and issues.

CR Number: 2023271028 Implementation Date: 30-Nov-23 Related CR: 2023271028

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Knowledge deficit	Rejected After Suspension		

MSSO Comment: The proposal to add a new PT Knowledge deficit is not approved after suspension. The requested term has been added in change request 2023283013 as LLT Patient knowledge deficit.

CR Number: 2023271031 Implementation Date: 09-Oct-23 Related CR: 2023271031

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Medication error in transfer of care	Approved as Requested	Proposed PT Medication error in transfer of care	10090312
			HLT primary Product transcribing errors and communication issues	10079155
			SOC primary Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Medication error in transfer of care is approved as requested. A medication error in the context of the transfer of care refers to a mistake that occurs when the responsibility for a patient's medication management is transferred from one healthcare provider or setting to another. To minimize the risk of medication errors during care transitions, healthcare providers must prioritize effective communication, accurate medication reconciliation, and comprehensive patient education. Medication error in transfer of care will be added as PT to HLT Product transcribing errors and communication issues.

Supplemental Update Report

CR Number: 2023271032 **Implementation Date:** 30-Nov-23 **Related CR:** 2023271032

Change Requested Link (move) an LLT to another PT Final Disposition Final Placement MedDRA Code #

Proposed LLT *Inappropriate insertion of multiple contraceptive devices* Rejected After Suspension
From PT *Device use issue*
To PT *Device use error*

MSSO Comment: The proposal to move the LLT Inappropriate insertion of multiple contraceptive devices from PT Device use issue to PT Device use error is not approved after suspension. Inappropriate insertion of multiple contraceptive devices can have different root causes, some of these considered errors. As it might not always be clear whether the inappropriate insertion of multiple contraceptive devices was an error, the term will remain under the unspecific PT Device use issue.

CR Number: 2023271033 **Implementation Date:** 09-Oct-23 **Related CR:** 2023271033

Change Requested Link (move) an LLT to another PT Final Disposition Final Placement MedDRA Code #

Proposed LLT *Injector positioned upside down* Approved as Requested Proposed LLT
From PT *Device use issue* *Injector positioned upside down* 10084372 Current
To PT *Device use error* From PT
Device use issue 10077812
To PT
Device use error 10072878

MSSO Comment: The proposal to move the LLT Injector positioned upside down from PT Device use issue to PT Device use error is approved as requested for better alignment. In certain situations, a patient or caregiver may accidentally position the injector upside down.

CR Number: 2023271034 **Implementation Date:** 09-Oct-23 **Related CR:** 2023271034

Change Requested Link (move) an LLT to another PT Final Disposition Final Placement MedDRA Code #

Proposed LLT *Wet injection* Approved as Requested Proposed LLT
From PT *Injection site discharge* *Wet injection* 10087599 Current
To PT *Product administration interrupted* From PT
Injection site discharge 10065600
To PT
Product administration interrupted 10081479

MSSO Comment: The proposal to move the LLT Wet injection from PT Injection site discharge to PT Product administration interrupted is approved as requested. Wet injection is a colloquial term, which is not well described in medical literature. It is used to describe medication spilled onto the injection site when auto-injectors are prematurely removed.

Supplemental Update Report

CR Number: 2023271035 Implementation Date: 30-Nov-23 Related CR: 2023271035

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Term to modify	<i>Active ingredient not added to diluent</i>	Approved Not as Requested After Suspension	Proposed LLT	
Replacement term	<i>Diluent not added to active ingredient</i>		<i>Diluent not added to active ingredient</i>	10090609 Current
			To PT	
			<i>Product preparation error</i>	10076869

MSSO Comment: The proposal to rename PT/LLT Active ingredient not added to diluent to Diluent not added to active ingredient is approved but not as requested after suspension. Instead of modifying Active ingredient not added to diluent, a new LLT Diluent not added to active ingredient will also be added to PT Product preparation error to provide terms for all scenarios.

CR Number: 2023271036 Implementation Date: 30-Nov-23 Related CR: 2023271036

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Syringe fell apart upon plunger activation</i>	Rejected After Suspension		
To PT	<i>Device safety feature issue</i>			

MSSO Comment: The proposal to add a new LLT Syringe fell apart upon plunger activation to PT Device safety feature issue is not approved after suspension. The proposed term is too granular and describes a too specific scenario.

CR Number: 2023271037 Implementation Date: 30-Nov-23 Related CR: 2023271037

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Needle/shield forcefully ejected</i>	Rejected After Suspension		
To PT	<i>Device safety feature issue</i>			

MSSO Comment: The proposal to add a new LLT Needle/shield forcefully ejected to PT Device safety feature issue is not approved after suspension. A "device safety feature issue" refers to a problem or concern related to the safety features of a medical device. The Needle/shield forcefully ejected is a device quality issue and not the failure of a safety feature. Depending on the situation the concept can be captured by existing LLT/PTs in HLT Device physical property and chemical issues, e.g. LLT/PT Needle issue.

Supplemental Update Report

CR Number: 2023271038 **Implementation Date:** 09-Oct-23 **Related CR:** 2023271038

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Safety mechanism failed to activate	Approved as Requested	Proposed LLT	
To PT	Device safety feature issue		Safety mechanism failed to activate	10090313 Current
			To PT	
			Device safety feature issue	10083639

MSSO Comment: The proposal to add a new LLT Safety mechanism failed to activate to PT Device safety feature issue is approved as requested. A "device safety feature issue" refers to a problem or concern related to the safety features of a medical device. Safety mechanism failed to activate will be added as sub-concept LLT to PT Device safety feature issue.

CR Number: 2023271039 **Implementation Date:** 09-Oct-23 **Related CR:** 2023271039

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Safety mechanism activated prematurely	Approved as Requested	Proposed LLT	
To PT	Device safety feature issue		Safety mechanism activated prematurely	10090319 Current
			To PT	
			Device safety feature issue	10083639

MSSO Comment: The proposal to add a new LLT Safety mechanism activated prematurely to PT Device safety feature issue is approved as requested. A "device safety feature issue" refers to a problem or concern related to the safety features of a medical device. Safety mechanism activated prematurely will be added as sub-concept LLT to PT Device safety feature issue.

CR Number: 2023271040 **Implementation Date:** 30-Nov-23 **Related CR:** 2023271040

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Excessive force required to activate safety mechanism	Rejected After Suspension		
To PT	Device difficult to use			

MSSO Comment: The proposal to add a new LLT Excessive force required to activate safety mechanism to PT Device difficult to use is not approved after suspension. The proposed term is too granular and describes a too specific scenario.

Supplemental Update Report

CR Number: 2023271041 Implementation Date: 09-Oct-23 Related CR: 2023271041

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Language issue barrier	Approved Not as Requested	Proposed LLT	
To PT	Product communication issue		Language barrier issue in product communication	10090318 Current
			To PT	
			Product communication issue	10080099

MSSO Comment: The proposal to add a new LLT Language issue barrier to PT Product communication issue is approved but not as requested. The requested term will be modified for clarity and added as LLT Language barrier issue in product communication to PT Product communication issue. A language barrier in the communication of product information refers to the difficulty in conveying essential details about a product due to differences in language or the inability of individuals from diverse linguistic backgrounds to understand each other effectively.

CR Number: 2023271046 Implementation Date: 30-Nov-23 Related CR: 2023271046

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Product communication error	Rejected After Suspension		

MSSO Comment: The proposal to add a new PT Product communication error is not approved after suspension. It is difficult to ascertain when a communication issue is an error/issue.

CR Number: 2023271047 Implementation Date: 30-Nov-23 Related CR: 2023271047

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Health care provider instructions for product use lacking	Rejected After Suspension		
From PT	Product communication issue			
To PT	Product communication error			

MSSO Comment: The proposal to move the LLT Health care provider instructions for product use lacking from PT Product communication issue to PT Product communication error is not approved after suspension. Since Product communication error was not added in change request 2023271046, this request is rejected.

Supplemental Update Report

CR Number: 2023271048 **Implementation Date:** 30-Nov-23 **Related CR:** 2023271048

Change Requested Link (move) an LLT to another PT Final Disposition Final Placement MedDRA Code #

Proposed LLT *Patient misunderstanding health care provider instructions for product use* Rejected After Suspension

From PT *Product communication issue*

To PT *Product communication error*

MSSO Comment: The proposal to move the LLT Patient misunderstanding health care provider instructions for product use from PT Product communication issue to PT Product communication error is not approved after suspension. Since Product communication error was not added in change request 2023271046, this request is rejected.

CR Number: 2023271049 **Implementation Date:** 30-Nov-23 **Related CR:** 2023271049

Change Requested Link (move) an LLT to another PT Final Disposition Final Placement MedDRA Code #

Proposed LLT *Product information not provided to patient* Rejected After Suspension

From PT *Product communication issue*

To PT *Product communication error*

MSSO Comment: The proposal to move the LLT Product information not provided to patient from PT Product communication issue to PT Product communication error is not approved after suspension. Since Product communication error was not added in change request 2023271046, this request is rejected.

CR Number: 2023272042 **Implementation Date:** 23-Oct-23 **Related CR:** 2023272042

Change Requested Add term to SMQ Final Disposition Final Placement MedDRA Code #

Proposed PT *Beta-fibrinogen-455G A mutation* Approved as Requested

To SMQ *Congenital, familial and genetic disorders (SMQ)*

Term scope *Narrow*

Proposed PT *Beta-fibrinogen-455G A mutation* 10090228

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 Beta-fibrinogen-455G A mutation 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: 2023272043

Implementation Date: 23-Oct-23

Related CR: 2023272043

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT

Congenital aplasia

Approved as Requested

Proposed PT

To SMQ

Congenital, familial and genetic disorders (SMQ)

Congenital aplasia

10090210

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 Congenital aplasia 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: 2023272044

Implementation Date: 23-Oct-23

Related CR: 2023272044

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT

Factor XIII mutation

Approved as Requested

Proposed PT

To SMQ

Congenital, familial and genetic disorders (SMQ)

Factor XIII mutation

10090230

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 Factor XIII mutation 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: 2023272045

Implementation Date: 23-Oct-23

Related CR: 2023272045

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT *Familial chilblain lupus*

Approved as Requested

Proposed PT

To SMQ *Congenital, familial and genetic disorders (SMQ)*

Familial chilblain lupus

10090201

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 chilblain lupus 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: 2023272046

Implementation Date: 23-Oct-23

Related CR: 2023272046

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT *Hepatic lobe agenesis*

Approved as Requested

Proposed PT

To SMQ *Congenital, familial and genetic disorders (SMQ)*

Hepatic lobe agenesis

10090128

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 Hepatic lobe agenesis 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: 2023272047 Implementation Date: 23-Oct-23 Related CR: 2023272047

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Interferonopathy</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Congenital, familial and genetic disorders (SMQ)</i>		<i>Interferonopathy</i>	10090200
Term scope	<i>Narrow</i>		To SMQ	
			<i>Congenital, familial and genetic disorders (SMQ)</i>	20000077
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Interferonopathy 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: 2023272048 Implementation Date: 23-Oct-23 Related CR: 2023272048

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Pseudocoarctation of aorta</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Congenital, familial and genetic disorders (SMQ)</i>		<i>Pseudocoarctation of aorta</i>	10090126
Term scope	<i>Narrow</i>		To SMQ	
			<i>Congenital, familial and genetic disorders (SMQ)</i>	20000077
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Pseudocoarctation of aorta 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: 2023272049

Implementation Date: 23-Oct-23

Related CR: 2023272049

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT *Autoimmune nodopathy*

Approved as Requested

Proposed PT
Autoimmune nodopathy

10090212

To SMQ *Demyelination (SMQ)*

Term scope *Narrow*

To SMQ
Demyelination (SMQ)

20000154

Term scope
Narrow
Term_category
A
Term_weight
0

MSSO Comment: The proposal to add PT Autoimmune nodopathy to Demyelination (SMQ) as a Narrow term is approved as requested. Autoimmune neuropathies are characterized by the presence of antibodies targeting cell adhesion molecules of the node of Ranvier with an association to specific clinicopathological features that are different from classical chronic inflammatory demyelinating polyneuropathy. Because this term describes a specific demyelinative polyneuropathy, it will be added to the narrow search terms of this SMQ.

CR Number: 2023272050

Implementation Date: 23-Oct-23

Related CR: 2023272050

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT *Autoimmune nodopathy*

Approved as Requested

Proposed PT
Autoimmune nodopathy

10090212

To SMQ *Guillain-Barre syndrome (SMQ)*

Term scope *Broad*

To SMQ
Guillain-Barre syndrome (SMQ)

20000131

Term scope
Broad
Term_category
A
Term_weight
0

MSSO Comment: The proposal to add PT Autoimmune nodopathy to Guillain-Barre syndrome (SMQ) as a Broad term is approved as requested. Autoimmune neuropathies are characterized by the presence of antibodies targeting cell adhesion molecules of the node of Ranvier with an association to specific clinicopathological features that are different from classical chronic inflammatory demyelinating polyneuropathy. Because this term describes a demyelinative polyneuropathy which is associated with a diagnostic antibody not found in Guillain-Barre syndrome, it will be added to the broad search terms of this SMQ.

Supplemental Update Report

CR Number: 2023272051

Implementation Date: 23-Oct-23

Related CR: 2023272051

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT	<i>Dopamine supersensitivity psychosis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Noninfectious encephalopathy/delirium (SMQ)</i>		<i>Dopamine supersensitivity psychosis</i>	10090119
Term scope	<i>Broad</i>		To SMQ	
			<i>Noninfectious encephalopathy/delirium (SMQ)</i>	20000133
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Dopamine supersensitivity psychosis to Noninfectious encephalopathy/delirium (SMQ) as a Broad term is approved as requested. Dopamine supersensitivity psychosis may be caused by the dopamine receptor D2 antagonizing effect of antipsychotics, causing a compensatory increase in D2 receptors within the brain that sensitizes neurons to endogenous release of the neurotransmitter dopamine. The activity of dopamine in the presence of supersensitivity may paradoxically give rise to worsening psychotic symptoms despite antipsychotic treatment at a given dose. This term, which describes a pharmacologically-mediated form of encephalopathy, will be added to the broad search terms of this SMQ.

CR Number: 2023272052

Implementation Date: 23-Oct-23

Related CR: 2023272052

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT	<i>Immune effector cell-associated haematotoxicity</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)</i>		<i>Immune effector cell-associated haematotoxicity</i>	10090214
Term scope	<i>Broad</i>		To SMQ	
			<i>Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)</i>	20000028
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Immune effector cell-associated haematotoxicity to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ) as a Broad term is approved as requested. PT Immune effector cell-associated haematotoxicity was added in version 27.0 and represents a diagnosis which is characterized by delayed onset of cytopenia after therapy with immune effector cells like Chimeric antigen receptor T cells (CAR-T) and Tumour infiltrating lymphocytes (TILs). Cytopenias can be profound and long-lasting and can predispose for severe infectious complications. PT Immune effector cell-associated haematotoxicity will be included with broad scope, in line with the already included PT Haematotoxicity.

Supplemental Update Report

CR Number: 2023272053

Implementation Date: 23-Oct-23

Related CR: 2023272053

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Pancreaticobiliary carcinoma</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Non-haematological malignant tumours (SMQ)</i>		<i>Pancreaticobiliary carcinoma</i>	10090088
Term scope	<i>Narrow</i>		To SMQ	
			<i>Non-haematological malignant tumours (SMQ)</i>	20000228
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Pancreaticobiliary carcinoma to Non-haematological malignant tumours (SMQ) as a Narrow term is approved as requested. New term for v27.0 which fits inclusion criteria. Pancreaticobiliary cancers are a group of malignancies affecting the pancreas and biliary tract and are often associated with poor prognosis.

CR Number: 2023272054

Implementation Date: 23-Oct-23

Related CR: 2023272054

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Prostatic urothelial carcinoma</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Non-haematological malignant tumours (SMQ)</i>		<i>Prostatic urothelial carcinoma</i>	10090106
Term scope	<i>Narrow</i>		To SMQ	
			<i>Non-haematological malignant tumours (SMQ)</i>	20000228
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Prostatic urothelial carcinoma to Non-haematological malignant tumours (SMQ) as a Narrow term is approved as requested. New term for v27.0 which fits inclusion criteria. Primary urothelial carcinoma of the prostate, is an extremely rare tumor, accounting for about 1% to 5% of all prostatic carcinomas.

Supplemental Update Report

CR Number: 2023272055

Implementation Date: 23-Oct-23

Related CR: 2023272055

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Prostatic urothelial carcinoma</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Prostate malignant tumours (SMQ)</i>		<i>Prostatic urothelial carcinoma</i>	10090106
Term scope	<i>Narrow</i>		To SMQ	
			<i>Prostate malignant tumours (SMQ)</i>	20000202
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Prostatic urothelial carcinoma to Prostate malignant tumours (SMQ) as a Narrow term is approved as requested. New term for v27.0 which fits inclusion criteria for a narrow in scope term. Primary urothelial carcinoma of the prostate, is an extremely rare tumor, accounting for about 1% to 5% of all prostatic carcinomas.

CR Number: 2023272056

Implementation Date: 23-Oct-23

Related CR: 2023272056

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Binocular visual dysfunction</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Ocular motility disorders (SMQ)</i>		<i>Binocular visual dysfunction</i>	10090124
Term scope	<i>Narrow</i>		To SMQ	
			<i>Ocular motility disorders (SMQ)</i>	20000184
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Binocular visual dysfunction to Ocular motility disorders (SMQ) as a Narrow term is approved as requested. New term for v27.0 which fits inclusion criteria as a narrow in scope term. Binocular vision dysfunction is a condition where the eyes are misaligned, causing each eye to send a different image to the brain. Closely related PT Strabismus and PT Amblyopia strabismic, both types of binocular dysfunction, are included as well with the same scope.

Supplemental Update Report

CR Number: 2023272057 Implementation Date: 23-Oct-23 Related CR: 2023272057

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add term to SMQ <i>Gastrocolic fistula</i>	Approved as Requested	Proposed PT <i>Gastrocolic fistula</i>	10090166
To SMQ	<i>Gastrointestinal perforation (SMQ)</i>		To SMQ <i>Gastrointestinal perforation (SMQ)</i>	20000107
Term scope	<i>Narrow</i>		Term scope <i>Narrow</i>	
			Term_category A	
			Term_weight 0	

MSSO Comment: The proposal to add PT Gastrocolic fistula to Gastrointestinal perforation (SMQ) as a Narrow term is approved as requested. The fistulous connection in a gastrocolic fistula usually arises between the greater curvature of stomach and the distal half of the transverse colon because of their close anatomical proximity separated only by the gastrocolic omentum.

CR Number: 2023272058 Implementation Date: 23-Oct-23 Related CR: 2023272058

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add term to SMQ <i>Infected intestinal ulcer</i>	Approved as Requested	Proposed PT <i>Infected intestinal ulcer</i>	10090205
To SMQ	<i>Gastrointestinal ulceration (SMQ)</i>		To SMQ <i>Gastrointestinal ulceration (SMQ)</i>	20000106
Term scope	<i>Narrow</i>		Term scope <i>Narrow</i>	
			Term_category A	
			Term_weight 0	

MSSO Comment: The proposal to add PT Infected intestinal ulcer to Gastrointestinal ulceration (SMQ) as a Narrow term is approved as requested. Intestinal pseudomembranes, plaques, and ulcerations can suffer a superimposed infection. The most common bacterial agents involved in gastrointestinal infection belong to the normal flora of the mouth and upper respiratory tract, including Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus viridans, and Bacillus species. Polymicrobial infection is common. Significant complications include perforation, fistula formation, and sepsis. Former included PT Infected large intestinal ulcer is now demoted under the new PT Infected intestinal ulcer.

Supplemental Update Report

CR Number: 2023272059

Implementation Date: 23-Oct-23

Related CR: 2023272059

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT *Dopamine supersensitivity psychosis*
To SMQ *Psychosis and psychotic disorders (SMQ)*
Term scope *Narrow*

Approved as Requested

Proposed PT
Dopamine supersensitivity psychosis 10090119
To SMQ
Psychosis and psychotic disorders (SMQ) 20000117
Term scope
Narrow
Term_category
A
Term_weight
0

MSSO Comment: The proposal to add PT Dopamine supersensitivity psychosis to Psychosis and psychotic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Substance-induced psychotic disorder and PT Psychotic disorder due to a general medical condition are already included as narrow scope terms.

CR Number: 2023272060

Implementation Date: 23-Oct-23

Related CR: 2023272060

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT *Immune effector cell-associated HLH-like syndrome*
To SMQ *Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)*
Term scope *Broad*

Approved as Requested

Proposed PT
Immune effector cell-associated HLH-like syndrome 10089622
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 Immune effector cell-associated HLH-like syndrome to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ) as a Broad term is approved as requested. PT Immune effector cell-associated HLH-like syndrome represents a pathological and biochemical hyperinflammatory syndrome that manifests with features of macrophage activation/HLH, is attributable to immune effector cell (IEC) therapy, and is associated with progression or new onset of cytopenias, hyperferritinaemia, coagulopathy with hypofibrinogenaemia, and/or transaminitis. PT Immune effector cell-associated haematotoxicity will be added to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ) with broad scope, in line with the already included PT Haematotoxicity

Supplemental Update Report

CR Number: 2023272061

Implementation Date: 23-Oct-23

Related CR: 2023272061

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT *Radiation anaemia*
To SMQ *Haematopoietic erythropenia (SMQ)*
Term scope *Narrow*

Approved as Requested

Proposed PT *Radiation anaemia* 10085644
To SMQ *Haematopoietic erythropenia (SMQ)* 20000029
Term scope *Narrow*
Term_category *A*
Term_weight *0*

MSSO Comment: The proposal to add PT Radiation anaemia to Haematopoietic erythropenia (SMQ) as a Narrow term is approved as requested. PT Radiation anaemia represents an adverse haematological event after radiotherapy. Reproduction of blood cells is one of the most radio-sensitive processes in the body and acute bone marrow suppression is often seen as a dose limiting side effect in radiation therapy. Depending on the type of blood cell primarily being affected, anaemia, leukopenia, and thrombocytopenia can occur. PT Radiation anaemia will be added to Haematopoietic erythropenia (SMQ) with narrow scope, in line with the already included PT Radiation leukopenia and PT Radiation neutropenia in Haematopoietic leukopenia (SMQ) and PT Radiation thrombocytopenia in Haematopoietic thrombocytopenia (SMQ).

CR Number: 2023272062

Implementation Date: 23-Oct-23

Related CR: 2023272062

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT *Autoimmune pancytopenia*
To SMQ *Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)*
Term scope *Narrow*

Approved as Requested

Proposed PT *Autoimmune pancytopenia* 10069509
To SMQ *Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)* 20000028
Term scope *Narrow*
Term_category *A*
Term_weight *0*

MSSO Comment: The proposal to add PT Autoimmune pancytopenia to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ) as a Narrow term is approved as requested. PT Autoimmune pancytopenia stands for a hematologic condition characterized by a deficiency of all cellular elements of the blood which is caused by autoantibodies against the three lineages of blood cells in the bone marrow. PT Autoimmune pancytopenia will be added to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ) with narrow scope, in line with already included PT Autoimmune aplastic anaemia.

Supplemental Update Report

CR Number: 2023272063		Implementation Date: 23-Oct-23	Related CR: 2023272063	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Ingrown eyelash removal</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Periorbital and eyelid disorders (SMQ)</i>		<i>Ingrown eyelash removal</i>	10090178
Term scope	<i>Narrow</i>		To SMQ	
			<i>Periorbital and eyelid disorders (SMQ)</i>	20000179
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Ingrown eyelash removal to Periorbital and eyelid disorders (SMQ) as a Narrow term is approved as requested. New term which fits inclusion; terms for eyelid procedures, eyelash terms and periorbital terms are included.

CR Number: 2023272064		Implementation Date: 23-Oct-23	Related CR: 2023272064	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Immune effector cell-associated haematotoxicity</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)</i>		<i>Immune effector cell-associated haematotoxicity</i>	10090214
Term scope	<i>Broad</i>		To SMQ	
			<i>Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)</i>	20000225
			Term scope	
			<i>Broad</i>	
			Term_category	
			B	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Immune effector cell-associated haematotoxicity 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 which includes terms related to skin manifestations and systemic involvement. Similar terms such as PT Immune effector cell-associated neurotoxicity syndrome are already included as broad scope terms.

Supplemental Update Report

CR Number: 2023272065 Implementation Date: 23-Oct-23 Related CR: 2023272065

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Factor VII activity decreased</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Haemorrhage laboratory terms (SMQ)</i>		<i>Factor VII activity decreased</i>	10090247
Term scope	<i>Broad</i>		To SMQ	
			<i>Haemorrhage laboratory terms (SMQ)</i>	20000040
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Factor VII activity decreased to Haemorrhage laboratory terms (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Factor VIII activity decreased and PT Factor VIII activity abnormal are already included as broad scope terms.

CR Number: 2023272066 Implementation Date: 23-Oct-23 Related CR: 2023272066

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Factor XII activity decreased</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Haemorrhage laboratory terms (SMQ)</i>		<i>Factor XII activity decreased</i>	10090225
Term scope	<i>Broad</i>		To SMQ	
			<i>Haemorrhage laboratory terms (SMQ)</i>	20000040
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Factor XII activity decreased to Haemorrhage laboratory terms (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Factor VIII activity decreased and PT Factor VIII activity abnormal are already included as broad scope terms.

Supplemental Update Report

CR Number: 2023272067

Implementation Date: 23-Oct-23

Related CR: 2023272067

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Prognathism</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Congenital, familial and genetic disorders (SMQ)</i>		<i>Prognathism</i>	10051481
Term scope	<i>Narrow</i>		To SMQ	
			<i>Congenital, familial and genetic disorders (SMQ)</i>	20000077
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Prognathism 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: 2023272068

Implementation Date: 23-Oct-23

Related CR: 2023272068

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Breast hypoplasia</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Congenital, familial and genetic disorders (SMQ)</i>		<i>Breast hypoplasia</i>	10049070
Term scope	<i>Narrow</i>		To SMQ	
			<i>Congenital, familial and genetic disorders (SMQ)</i>	20000077
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Breast 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.

Supplemental Update Report

CR Number: 2023272069

Implementation Date: 23-Oct-23

Related CR: 2023272069

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT *Encapsulating peritoneal sclerosis*

Approved as Requested

Proposed PT

To SMQ *Gastrointestinal obstruction (SMQ)*

Encapsulating peritoneal sclerosis

10075012

Term scope *Narrow*

To SMQ

Gastrointestinal obstruction (SMQ)

20000105

Term scope

Narrow

Term_category

A

Term_weight

0

MSSO The proposal to add PT Encapsulating peritoneal sclerosis to Gastrointestinal obstruction (SMQ) as a Narrow term is approved as requested. Encapsulating peritoneal sclerosis is a rare chronic inflammatory condition of the peritoneum with an unknown aetiology. Also known as abdominal cocoon, the condition occurs when loops of the bowel are encased within the peritoneal cavity by a membrane, leading to intestinal obstruction. The condition presents with recurrent episodes of small bowel obstruction and can be idiopathic or secondary.

CR Number: 2023272070

Implementation Date: 23-Oct-23

Related CR: 2023272070

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT *Hepatic lobe agenesis*

Approved as Requested

Proposed PT

To SMQ *Congenital, familial, neonatal and genetic disorders of the liver (SMQ)*

Hepatic lobe agenesis

10090128

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 The proposal to add PT Hepatic lobe agenesis to Congenital, familial, neonatal and genetic disorders of the liver (SMQ) as a Narrow term is approved as requested. Agenesis of a lobe of the liver is a rare finding and is defined as the absence of liver tissue, with preservation of the middle hepatic vein, without previous disease or surgery.

Supplemental Update Report

CR Number: 2023272071 Implementation Date: 23-Oct-23 Related CR: 2023272071

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Disseminated herpes simplex</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Opportunistic infections (SMQ)</i>		<i>Disseminated herpes simplex</i>	10090164
Term scope	<i>Narrow</i>		To SMQ	
			<i>Opportunistic infections (SMQ)</i>	20000235
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Disseminated herpes simplex to Opportunistic infections (SMQ) as a Narrow term is approved as requested. Disseminated herpes simplex is a severe and widespread form of HSV infection that occurs when the virus spreads beyond the initial site of infection. This condition is more common in individuals with compromised immune systems.

CR Number: 2023272072 Implementation Date: 23-Oct-23 Related CR: 2023272072

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Binocular visual dysfunction</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Hypoglycaemia (SMQ)</i>		<i>Binocular visual dysfunction</i>	10090124
Term scope	<i>Broad</i>		To SMQ	
			<i>Hypoglycaemia (SMQ)</i>	20000226
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Binocular visual dysfunction to Hypoglycaemia (SMQ) as a Broad term is approved as requested. PT Binocular visual dysfunction was added in MedDRA version 27.0 and represents an eye disorder where the eyes are misaligned, causing each eye to send a different image to the brain. PT Binocular visual dysfunction will be added to Hypoglycaemia (SMQ) with broad scope, in line with the already included LLT Double vision, PT Vision blurred and PT Visual impairment.

Supplemental Update Report

CR Number: 2023272073

Implementation Date: 23-Oct-23

Related CR: 2023272073

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Cholecystokinin increased</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Acute pancreatitis (SMQ)</i>		<i>Cholecystokinin increased</i>	10090129
Term scope	<i>Broad</i>		To SMQ	
			<i>Acute pancreatitis (SMQ)</i>	20000022
			Term scope	
			<i>Broad</i>	
			Term_category	
			<i>B</i>	
			Term_weight	
			<i>0</i>	

MSSO Comment: The proposal to add PT Cholecystokinin increased to Acute pancreatitis (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Bile acids increased and PT Amylase increased are already included as broad scope terms.

CR Number: 2023272074

Implementation Date: 23-Oct-23

Related CR: 2023272074

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Disseminated herpes simplex</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Sepsis (SMQ)</i>		<i>Disseminated herpes simplex</i>	10090164
Term scope	<i>Broad</i>		To SMQ	
			<i>Sepsis (SMQ)</i>	20000234
			Term scope	
			<i>Broad</i>	
			Term_category	
			<i>A</i>	
			Term_weight	
			<i>0</i>	

MSSO Comment: The proposal to add PT Disseminated herpes simplex 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 Disseminated varicella zoster virus infection and PT Disseminated varicella are already included as broad scope terms.

Supplemental Update Report

CR Number: 2023272075 Implementation Date: 23-Oct-23 Related CR: 2023272075

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Maxillary osteotomy	Approved as Requested	Proposed PT	
To SMQ	Osteonecrosis (SMQ)		Maxillary osteotomy	10090162
Term scope	Broad		To SMQ	
			Osteonecrosis (SMQ)	20000180
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Maxillary osteotomy to Osteonecrosis (SMQ) as a Broad term is approved as requested. The PT Maxillary osteotomy was added in V27.0 as a routine procedure for the correction of dentofacial deformities, and can be performed in one or multiple bone segments. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Maxillofacial operation and PT Osteotomy are already included as broad scope terms.

CR Number: 2023272076 Implementation Date: 23-Oct-23 Related CR: 2023272076

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Familial chilblain lupus	Approved as Requested	Proposed PT	
To SMQ	Systemic lupus erythematosus (SMQ)		Familial chilblain lupus	10090201
Term scope	Narrow		To SMQ	
			Systemic lupus erythematosus (SMQ)	20000045
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Familial chilblain lupus to Systemic lupus erythematosus (SMQ) as a Narrow term is approved as requested. The PT Familial chilblain lupus was added in V27.0. Familial chilblain lupus is a rare, autosomal dominant form of lupus erythematosus characterized by cold-induced inflammatory lesions at acral locations presenting in early childhood. The PT Familial chilblain lupus will be added to this SMQ with a Narrow scope in alignment with inclusion criteria in line with already included PT Neonatal lupus erythematosus.

Supplemental Update Report

CR Number: 2023272077 Implementation Date: 23-Oct-23 Related CR: 2023272077

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add term to SMQ <i>Anogenital granulomatosis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Immune-mediated/autoimmune disorders (SMQ)</i>		<i>Anogenital granulomatosis</i>	10090172
Term scope	<i>Broad</i>		To SMQ	
			<i>Immune-mediated/autoimmune disorders (SMQ)</i>	20000236
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Anogenital granulomatosis to Immune-mediated/autoimmune disorders (SMQ) as a Broad term is approved as requested. Anogenital granulomatosis is a rare chronic inflammatory granulomatous disease of unknown etiology, which is characterized by histological evidence of non-caseating granulomatous inflammation and can present with diffuse penile, scrotal, vulvar, or anoperineal swelling. It is frequently associated with Crohn disease, which is in the narrow scope of this SMQ.

CR Number: 2023272078 Implementation Date: 23-Oct-23 Related CR: 2023272078

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add term to SMQ <i>Autoimmune nodopathy</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Immune-mediated/autoimmune disorders (SMQ)</i>		<i>Autoimmune nodopathy</i>	10090212
Term scope	<i>Narrow</i>		To SMQ	
			<i>Immune-mediated/autoimmune disorders (SMQ)</i>	20000236
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Autoimmune nodopathy to Immune-mediated/autoimmune disorders (SMQ) as a Narrow term is approved as requested. Autoimmune nodopathies are characterized by antibody formation against certain nodal-paranodal cell-adhesion molecules. Unlike typical chronic inflammatory demyelinating polyneuropathy (CIDP), patients with these antibodies generally have specific clinical features and significantly elevated cerebrospinal fluid (CSF) protein.

Supplemental Update Report

CR Number: 2023272079

Implementation Date: 23-Oct-23

Related CR: 2023272079

<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Immune effector cell-associated haematotoxicity</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Immune-mediated/autoimmune disorders (SMQ)</i>		<i>Immune effector cell-associated haematotoxicity</i>	10090214
Term scope	<i>Narrow</i>		To SMQ	
			<i>Immune-mediated/autoimmune disorders (SMQ)</i>	20000236
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Immune effector cell-associated haematotoxicity to Immune-mediated/autoimmune disorders (SMQ) as a Narrow term is approved as requested. Hematological toxicity represents the most common adverse event following chimeric antigen receptor (CAR) T-cell therapy. Cytopenias can be profound, long-lasting, and can predispose for severe infectious complications. Like other already included immune effector cell toxicities, this term will be included in the SMQ. Related PTs Immune effector cell-associated neurotoxicity syndrome and Immune effector cell-associated HLH-like syndrome are already included in the narrow scope of this SMQ.

CR Number: 2023272080

Implementation Date: 23-Oct-23

Related CR: 2023272080

<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Anti-liver cytosol antibody type 1 positive</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Immune-mediated/autoimmune disorders (SMQ)</i>		<i>Anti-liver cytosol antibody type 1 positive</i>	10086970
Term scope	<i>Broad</i>		To SMQ	
			<i>Immune-mediated/autoimmune disorders (SMQ)</i>	20000236
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Anti-liver cytosol antibody type 1 positive to Immune-mediated/autoimmune disorders (SMQ) as a Broad term is approved as requested. Liver cytosol specific antibody type 1 (anti-LC1) was first described in a proportion of patients with liver/kidney microsomal antibody type 1 (anti-LKM1)-positive autoimmune hepatitis (AIH) and is routinely evaluated by immunodiffusion (ID). This term, added in 25.0, is a relevant investigation term for immune-mediated processes, and such investigations are included as broad scope terms in this SMQ.

Supplemental Update Report

CR Number: 2023272081

Implementation Date: 23-Oct-23

Related CR: 2023272081

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT	<i>Anti-reflux device placement</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Gastrointestinal nonspecific symptoms and therapeutic procedures (SMQ)</i>		<i>Anti-reflux device placement</i>	10090224
Term scope	<i>Broad</i>		To SMQ	
			<i>Gastrointestinal nonspecific symptoms and therapeutic procedures (SMQ)</i>	20000140
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Anti-reflux device placement to Gastrointestinal nonspecific symptoms and therapeutic procedures (SMQ) as a Broad term is approved as requested. PT Gastroesophageal reflux disease and Gastroesophageal sphincter insufficiency are both narrow scope terms included in the related SMQ Gastrointestinal nonspecific dysfunction. Anti-reflux device placement represents the treatment of these conditions and will be added to the Broad scope of the Gastrointestinal nonspecific symptoms and therapeutic procedures (SMQ).

CR Number: 2023272082

Implementation Date: 23-Oct-23

Related CR: 2023272082

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA Code #

Proposed PT	<i>Factor VII activity decreased</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Liver-related coagulation and bleeding disturbances (SMQ)</i>		<i>Factor VII activity decreased</i>	10090247
Term scope	<i>Narrow</i>		To SMQ	
			<i>Liver-related coagulation and bleeding disturbances (SMQ)</i>	20000015
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Factor VII activity decreased to Liver-related coagulation and bleeding disturbances (SMQ) as a Narrow term is approved as requested. Factor VII has the shortest half-life of all procoagulant factors (3-6 h). Hence, when a problem with synthesis occurs, as in liver failure, vitamin K deficiency, or warfarin therapy, the factor VII level first decreases in the plasma, followed by a decrease in other vitamin K-dependent factors. The related PT Coagulation factor VII level decreased is already included in the narrow scope of this SMQ.

Supplemental Update Report

CR Number: 2023272083 Implementation Date: 23-Oct-23 Related CR: 2023272083

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Disseminated herpes simplex</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Infective pneumonia (SMQ)</i>		<i>Disseminated herpes simplex</i>	10090164
Term scope	<i>Broad</i>		To SMQ	
			<i>Infective pneumonia (SMQ)</i>	20000231
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Disseminated herpes simplex to Infective pneumonia (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ for a broad scope term. Disseminated herpes simplex is a severe and widespread form of herpes simplex virus infection that occurs when the virus spreads beyond the initial site of infection. Disseminated herpes simplex virus disease can be associated with internal organ involvement such as liver, lungs, central nervous system, adrenal glands, bone marrow involvement, kidneys, and gastrointestinal tract. This condition is more common in individuals with compromised immune systems. It can lead to serious symptoms and complications and can be life-threatening if not treated promptly. Other pathogens that may be associated with pneumonia are included in the broad search.

CR Number: 2023275001 Implementation Date: 06-Oct-23 Related CR: 2023275001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Accessory thyroid</i>	Approved as Requested	Proposed LLT	
To PT	<i>Ectopic thyroid</i>		<i>Accessory thyroid</i>	10090292 Current
			To PT	
			<i>Ectopic thyroid</i>	10069503

MSSO Comment: The proposal to add a new LLT Accessory thyroid to PT Ectopic thyroid is approved as requested. Accessory thyroid gland is an uncommon developmental abnormality whereby aberrant thyroid tissue is found anywhere other than the normal anatomic position.

Supplemental Update Report

CR Number: 2023275002 Implementation Date: 06-Oct-23 Related CR: 2023275002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Retrograde cricopharyngeal dysfunction</i>	Approved as Requested	Proposed LLT <i>Retrograde cricopharyngeal dysfunction</i>	10090291 Current
			To PT <i>Cricopharyngeal dysfunction</i>	10090290

MSSO Comment: The proposal to add a new LLT Retrograde cricopharyngeal dysfunction is approved as requested. Retrograde cricopharyngeal dysfunction, also described as retrograde upper esophageal sphincter dysfunction, results from the abnormal retrograde function of the upper esophageal sphincter, which does not relax to permit eructation. Retrograde cricopharyngeal dysfunction will be added as an LLT to PT Cricopharyngeal dysfunction. In a related change, PT Cricopharyngeal dysfunction will be added to primary HLT Gastrointestinal dyskinetic disorders and secondary HLT Pharyngeal disorders (excl infections and neoplasms). Furthermore, PT Cricopharyngeal achalasia will be demoted under the new broader PT Cricopharyngeal dysfunction.

CR Number: 2023279005 Implementation Date: 06-Oct-23 Related CR: 2023275002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Cricopharyngeal dysfunction</i>	Approved as Requested	Proposed PT <i>Cricopharyngeal dysfunction</i>	10090290
HLT primary	<i>Gastrointestinal dyskinetic disorders</i>		HLT primary <i>Gastrointestinal dyskinetic disorders</i>	10017950
SOC primary	<i>Gastrointestinal disorders</i>		SOC primary <i>Gastrointestinal disorders</i>	10017947
			HLT secondary <i>Pharyngeal disorders (excl infections and neoplasms)</i>	10034823
			SOC secondary <i>Respiratory, thoracic and mediastinal disorders</i>	10038738

MSSO Comment:

Supplemental Update Report

CR Number: 2023279006 **Implementation Date:** 06-Oct-23 **Related CR:** 2023275002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Cricopharyngeal achalasia</i>	Approved as Requested	PT to merge	
To PT	<i>Cricopharyngeal dysfunction</i>		<i>Cricopharyngeal achalasia</i>	10080659 Current
			To PT	
			<i>Cricopharyngeal dysfunction</i>	10090290

MSSO
Comment:

CR Number: 2023275003 **Implementation Date:** 23-Oct-23 **Related CR:** 2023275003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Self-destructive behaviour</i>	Rejected		
From SMQ	<i>Depression (excl suicide and self injury) (SMQ)</i>			
To SMQ	<i>Suicide/self-injury (SMQ)</i>			

MSSO Comment: The proposal to move the PT Self-destructive behaviour from Depression (excl suicide and self injury) (SMQ) to Suicide/self-injury (SMQ) is not approved. Upon review, Self-destructive behaviour will remain as broad term in Depression (excl suicide and self injury) (SMQ) and will not be represented in Suicide/self-injury (SMQ) as the concept is too broad for Suicide/self-injury (SMQ).

CR Number: 2023275004 **Implementation Date:** 06-Oct-23 **Related CR:** 2023275004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Cognitive impairment associated with schizophrenia (CIAS)</i>	Approved Not as Requested	Proposed LLT	
			<i>Cognitive impairment associated with schizophrenia</i>	10090296 Current
			To PT	
			<i>Schizophrenia</i>	10039626

MSSO Comment: The proposal to add a new LLT Cognitive impairment associated with schizophrenia (CIAS) is approved but not as requested. Cognitive impairment represents 1 of the 3 core symptom domains of schizophrenia, distinct from positive and negative symptoms, that can significantly impair a person's ability to learn, solve problems, and communicate clearly. Proposed term will be modified and added without the acronym as LLT Cognitive impairment associated with schizophrenia under PT Schizophrenia.

Supplemental Update Report

CR Number: 2023275005 Implementation Date: 06-Oct-23 Related CR: 2023275005

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New PT Proposed PT <i>Basidiobolomycosis</i>	Approved as Requested	Proposed PT <i>Basidiobolomycosis</i>	10090300
		HLT primary <i>Fungal infections NEC</i>	10017536
		SOC primary <i>Infections and infestations</i>	10021881
		HLT secondary <i>Skin and subcutaneous tissue fungal infections</i>	10040791
		SOC secondary <i>Skin and subcutaneous tissue disorders</i>	10040785

MSSO Comment: The proposal to add a new PT Basidiobolomycosis is approved as requested. Basidiobolomycosis or subcutaneous zygomycosis or subcutaneous phycomycosis is a chronic granulomatous infection of skin and subcutaneous tissue, caused by a saprophytic filamentous fungus, Basidiobolus ranarum, clinically characterized by firm, painless subcutaneous swelling with smooth and rounded edges. Basidiobolomycosis will be added as PT to primary HLT Fungal infections NEC and secondary HLT Skin and subcutaneous tissue fungal infections.

CR Number: 2023275006 Implementation Date: 06-Oct-23 Related CR: 2023275006

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New LLT Proposed LLT <i>Basidiobolus ranarum infection</i>	Approved as Requested	Proposed LLT <i>Basidiobolus ranarum infection</i>	10090304 Current
		To PT <i>Basidiobolomycosis</i>	10090300

MSSO Comment: The proposal to add a new LLT Basidiobolus ranarum infection is approved as requested. Basidiobolus ranarum infection, indicating the species, will be added as LLT to PT Basidiobolomycosis, added in change request 2023275005.

Supplemental Update Report

CR Number: 2023275007 Implementation Date: 06-Oct-23 Related CR: 2023275007

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New LLT			
Proposed LLT <i>Port blockage</i>	Approved Not as Requested	Proposed LLT <i>Port occlusion</i>	10090303 Current
		To PT <i>Device occlusion</i>	10064685

MSSO Comment: The proposal to add a new LLT Port blockage is approved but not as requested. Over time ports can become blocked, either with a clot within the tubing or by a fibrin sheath which can form over the end of the tubing. The requested term will be modified for clarity and added as LLT Port occlusion to PT Device occlusion.

CR Number: 2023275008 Implementation Date: 06-Oct-23 Related CR: 2023275008

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New PT			
Proposed PT <i>Localised melanoma</i>	Approved as Requested	Proposed PT <i>Localised melanoma</i>	10090297
		HLT primary <i>Skin melanomas (excl ocular)</i>	10027156
		SOC primary <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
		HLT secondary <i>Skin melanomas (excl ocular)</i>	10027156
		SOC secondary <i>Skin and subcutaneous tissue disorders</i>	10040785

MSSO Comment: The proposal to add a new PT Localised melanoma is approved as requested. Localised melanomas are early melanomas referring to stages 0 and 1. Localised melanoma will be added as PT to bi-axial HLT Skin melanomas (excl ocular) with primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and secondary SOC Skin and subcutaneous tissue disorders.

Supplemental Update Report

CR Number: 2023275009	Implementation Date: 06-Oct-23	Related CR: 2023275009		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Localized melanoma</i>	Approved as Requested	Proposed LLT <i>Localized melanoma</i>	10090308 Current
			To PT <i>Localised melanoma</i>	10090297

MSSO Comment: The proposal to add a new LLT Localized melanoma is approved as requested. Localized melanoma, the American spelled counterpart will be added to PT Localised melanoma, added in change request 2023275008.

CR Number: 2023275010	Implementation Date: 06-Oct-23	Related CR: 2023275010		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Vertebral surgery</i>	Approved as Requested	Proposed LLT <i>Vertebral surgery</i>	10090305 Current
			To PT <i>Spinal operation</i>	10062262

MSSO Comment: The proposal to add a new LLT Vertebral surgery is approved as requested. Spinal surgery commonly consists of performing surgery to correct possible structural abnormalities which may involve the vertebrae or associated nerves. Vertebral surgery will be added as sub-concept LLT under PT Spinal operation.

CR Number: 2023275011	Implementation Date: 06-Oct-23	Related CR: 2023275011		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Joint deformity</i>	Approved Not as Requested	Proposed PT <i>Joint deformity</i>	10090301
			HLT primary <i>Extremity deformities</i>	10012139
			SOC primary <i>Musculoskeletal and connective tissue disorders</i>	10028395

MSSO Comment: The proposal to add a new LLT Joint deformity is approved but not as requested. Joint deformity will be added as a PT to HLT Extremity deformities.

Supplemental Update Report

CR Number: 2023275012 Implementation Date: 06-Oct-23 Related CR: 2023275012

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Clonal hematopoiesis of indeterminate potential</i>	Approved as Requested	Proposed LLT <i>Clonal hematopoiesis of indeterminate potential</i>	10090309 Current
			To PT <i>Clonal haematopoiesis</i>	10083367

MSSO Comment: The proposal to add a new LLT Clonal hematopoiesis of indeterminate potential is approved as requested. Clonal hematopoiesis of indeterminate potential (CHIP) is a medical condition characterized by the presence of clonal populations of blood cells with somatic mutations in the hematopoietic stem and progenitor cells of the bone marrow. CHIP is often considered a pre-malignant condition, as it increases the risk of developing blood-related malignancies, particularly myeloid malignancies like leukemia, myelodysplastic syndromes (MDS), or myeloproliferative neoplasms. Clonal hematopoiesis of indeterminate potential will be added as an LLT to PT Clonal haematopoiesis.

CR Number: 2023275013 Implementation Date: 06-Oct-23 Related CR: 2023275013

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Clonal haematopoiesis of indeterminate potential</i>	Approved Not as Requested	Proposed LLT <i>Clonal haematopoiesis of indeterminate potential</i>	10090306 Current
			To PT <i>Clonal haematopoiesis</i>	10083367

MSSO Comment: The proposal to add a new PT Clonal haematopoiesis of indeterminate potential is approved but not as requested. Clonal haematopoiesis of indeterminate potential will be added as an LLT to PT Clonal haematopoiesis. Clonal haematopoiesis of indeterminate potential is the British English spelled counterpart to LLT Clonal hematopoiesis of indeterminate potential, added in change request 2023275012.

CR Number: 2023275014 Implementation Date: 06-Oct-23 Related CR: 2023275014

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Idiopathic dysplasia of unknown significance</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Idiopathic dysplasia of unknown significance is not approved. The proposed term has been added as PT in change request 2023275015. All new PTs are automatically replicated at LLT level without the need of a specific change request.

Supplemental Update Report

CR Number: 2023275015 Implementation Date: 06-Oct-23 Related CR: 2023275015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Idiopathic dysplasia of unknown significance</i>	Approved as Requested	Proposed PT <i>Idiopathic dysplasia of unknown significance</i>	10090298
			HLT primary <i>Haematological disorders</i>	10018847
			SOC primary <i>Blood and lymphatic system disorders</i>	10005329

MSSO Comment: The proposal to add a new PT Idiopathic dysplasia of unknown significance is approved as requested. Idiopathic dysplasia of unknown significance is characterized by the absence of peripheral cytopenia with MDS criteria not fulfilled, no MDS-related mutation found, the presence of dysplasia in $\geq 10\%$ of neutrophilic, erythroid, and/or megakaryocytes lineages and blast cells $< 5\%$. Idiopathic dysplasia of unknown significance will be added as PT to HLT Haematological disorders.

CR Number: 2023275016 Implementation Date: 06-Oct-23 Related CR: 2023275016

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Idiopathic cytopenia of undetermined significance</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Idiopathic cytopenia of undetermined significance is not approved. The proposed term has been added as PT in change request 2023275017. All new PTs are automatically replicated at LLT level without the need of a specific change request.

CR Number: 2023275017 Implementation Date: 06-Oct-23 Related CR: 2023275017

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Idiopathic cytopenia of undetermined significance</i>	Approved as Requested	Proposed PT <i>Idiopathic cytopenia of undetermined significance</i>	10090302
			HLT primary <i>Haematological disorders</i>	10018847
			SOC primary <i>Blood and lymphatic system disorders</i>	10005329

MSSO Comment: The proposal to add a new PT Idiopathic cytopenia of undetermined significance is approved as requested. Idiopathic cytopenia of undetermined significance is defined by the presence of one or several peripheral cytopenias, with MDS criteria not fulfilled, no MDS-related mutation found, the absence (or only mild presence, $< 10\%$) of dysplasia and blast cells bellow 5%. Idiopathic cytopenia of undetermined significance will be added as PT to HLT Haematological disorders.

Supplemental Update Report

CR Number: 2023275018	Implementation Date: 06-Oct-23	Related CR: 2023275018	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	Add a New LLT <i>Clonal cytopenia of unknown significance</i>	Rejected	

MSSO Comment: The proposal to add a new LLT Clonal cytopenia of unknown significance is not approved. The proposed term has been added as PT in change request 2023275019. All new PTs are automatically replicated at LLT level without the need of a specific change request.

CR Number: 2023275019	Implementation Date: 06-Oct-23	Related CR: 2023275019	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed PT	Add a New PT <i>Clonal cytopaenia of unknown significance</i>	Approved Not as Requested	Proposed PT <i>Clonal cytopenia of undetermined significance</i> 10090299 HLT primary <i>Haematological disorders</i> 10018847 SOC primary <i>Blood and lymphatic system disorders</i> 10005329

MSSO Comment: The proposal to add a new PT Clonal cytopaenia of unknown significance is approved but not as requested. Clonal cytopenia of undetermined significance is defined by the presence of one or several peripheral cytopenias, MDS criteria not fulfilled, the finding of one or more MDS-related mutations, the absence (or only mild presence, <10%) of dysplasia and blast cells bellow 5%. The proposed term will modified with correct spelling and added as PT Clonal cytopenia of undetermined significance to HLT Haematological disorders.

CR Number: 2023275020	Implementation Date: 06-Oct-23	Related CR: 2023275020	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	Add a New LLT <i>Age-related clonal hematopoiesis</i>	Approved as Requested	Proposed LLT <i>Age-related clonal hematopoiesis</i> 10090307 Current To PT <i>Clonal haematopoiesis</i> 10083367

MSSO Comment: The proposal to add a new LLT Age-related clonal hematopoiesis is approved as requested. Age-related clonal hematopoiesis refers to the presence of clonal populations of blood cells with somatic mutations in the hematopoietic system that occur as a natural consequence of aging. These mutations may or may not have clinical significance and can be associated with an increased risk of hematologic malignancies. Age-related clonal hematopoiesis will be added as sub-concept LLT to PT Clonal haematopoiesis.

Supplemental Update Report

CR Number: 2023275021	Implementation Date: 06-Oct-23	Related CR: 2023275021		
Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Age-related clonal haematopoiesis</i>	Approved Not as Requested	Proposed LLT <i>Age-related clonal haematopoiesis</i> To PT <i>Clonal haematopoiesis</i>	10090310 Current 10083367

MSSO Comment: The proposal to add a new PT Age-related clonal haematopoiesis is approved but not as requested. The British English spelled counterpart Age-related clonal haematopoiesis will also be added as an LLT to PT Clonal haematopoiesis, see change request 2023275020.

CR Number: 2023275022	Implementation Date: 06-Oct-23	Related CR: 2023275022		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Neuropathy of Feet</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Neuropathy of Feet is not approved. Neuropathy of Feet is a mere anatomical descriptor for the manifestation of peripheral neuropathy and does not provide any benefit to the terminology.

CR Number: 2023275023	Implementation Date: 06-Oct-23	Related CR: 2023275023		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Neuropathy of Hands</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Neuropathy of Hands is not approved. Neuropathy of Hands is a mere anatomical descriptor for the manifestation of peripheral neuropathy and does not provide any benefit to the terminology.

Supplemental Update Report

CR Number: 2023276005 **Implementation Date:** 06-Oct-23 **Related CR:** 2023276005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Spleen-stomach disharmony</i>	Rejected		

MSSO Comment: The proposal to add a new term Spleen-stomach disharmony is not approved. The core belief of traditional Chinese medicine is about the yin-yang, or qi balance in the body and its organs. Traditional Chinese Medicine concepts are not in scope of MedDRA.

CR Number: 2023277001 **Implementation Date:** 06-Oct-23 **Related CR:** 2023277001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Intrathoracic goiter</i>	Approved as Requested	Proposed LLT <i>Intrathoracic goiter</i>	10090294 Current
To PT	<i>Goitre</i>		<i>Goitre</i>	10018498

MSSO Comment: The proposal to add a new LLT Intrathoracic goiter is approved as requested. An intrathoracic goiter, also known as a retrosternal goiter or substernal goiter, is a type of thyroid enlargement that extends downward into the chest or thoracic cavity. Intrathoracic goiter will be added as sub-concept LLT to PT Goitre. In a related change, the British English spelled counterpart LLT Intrathoracic goitre will be added to PT Goitre.

CR Number: 2023279007 **Implementation Date:** 06-Oct-23 **Related CR:** 2023277001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Intrathoracic goitre</i>	Approved as Requested	Proposed LLT <i>Intrathoracic goitre</i>	10090295 Current
To PT	<i>Goitre</i>		<i>Goitre</i>	10018498

MSSO Comment:

Supplemental Update Report

CR Number: 2023277002 Implementation Date: 06-Oct-23 Related CR: 2023277002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Renal coloboma syndrome</i>	Approved as Requested	Proposed PT <i>Renal coloboma syndrome</i>	10090293
			HLT primary <i>Renal disorders congenital</i>	10038431
			SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Congenital posterior segment disorders (incl optic nerve)</i>	10010595
			SOC secondary <i>Eye disorders</i>	10015919

MSSO Comment: The proposal to add a new PT Renal coloboma syndrome is approved as requested. Renal coloboma syndrome, also known as Papillorenal syndrome, is a rare genetic disorder that primarily affects the development of the eyes and kidneys. It is characterized by two main features - optic nerve coloboma and kidney abnormalities. Renal coloboma syndrome will be added as PT to primary HLT Renal disorders congenital as well as to secondary HLT Congenital posterior segment disorders (incl optic nerve) and further secondary HLT Renal disorders NEC.

CR Number: 2023279008 Implementation Date: 06-Oct-23 Related CR: 2023277002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Renal coloboma syndrome</i>	Approved as Requested	Proposed PT <i>Renal coloboma syndrome</i>	10090293
To HLT	<i>Renal disorders NEC</i>		To HLT <i>Renal disorders NEC</i>	10027695

MSSO Comment:

Supplemental Update Report

CR Number: 2023277003	Implementation Date: 13-Oct-23	Related CR: 2023277003		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Vaginal suture</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Vaginal suture is not approved. MedDRA cannot provide a suture term for every possible anatomical site.

CR Number: 2023277004	Implementation Date: 13-Oct-23	Related CR: 2023277004		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Non-childbearing potential</i>	Approved Not as Requested	Proposed PT <i>Woman of non-childbearing potential</i>	10090323
			HLT primary <i>Pregnancy related circumstances</i>	10036569
			SOC primary <i>Social circumstances</i>	10041244

MSSO Comment: The proposal to add a new LLT Non-childbearing potential is approved but not as requested. The requested term will be modified for clarity and added as PT Woman of non-childbearing potential to HLT Pregnancy related circumstances.

CR Number: 2023277005	Implementation Date: 13-Oct-23	Related CR: 2023277005		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Last menstrual period</i>	Approved Not as Requested	Proposed PT <i>Last menstrual period determination</i>	10090324
			HLT primary <i>Physical examination procedures and organ system status</i>	10071941
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new LLT Last menstrual period is approved but not as requested. Last menstrual period (LMP) refers to the start date of the most recent menstrual period. The proposed term will be modified for clarity and spelling correction and added as PT Last menstrual period determination to HLT Physical examination procedures and organ system status.

Supplemental Update Report

CR Number: 2023277006 **Implementation Date:** 06-Oct-23 **Related CR:** 2023277006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Hyperactive prostate</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Hyperactive prostate is not approved. No references found in medical literature. Hyperactive bladder in context of benign prostatic hyperplasia (BPH) is described but hyperactive prostate does not seem to be a valid concept.

CR Number: 2023278001 **Implementation Date:** 13-Oct-23 **Related CR:** 2023278001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term <i>Gag reflex</i>	Rejected		

MSSO Comment: The proposal to add a new term Gag reflex is not approved. The gag reflex, also known as the pharyngeal reflex, is an involuntary reflex involving bilateral pharyngeal muscle contraction and elevation of the soft palate. This reflex may be evoked by stimulation of the posterior pharyngeal wall, tonsillar area, or base of the tongue. Proposed addition is not approved because PT Gag reflex test qualifying the term as an investigation already exists.

CR Number: 2023278002 **Implementation Date:** 13-Oct-23 **Related CR:** 2023278002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Pharyngeal reflex</i>	Approved Not as Requested	Proposed LLT <i>Pharyngeal reflex test</i> To PT <i>Gag reflex test</i>	10090326 Current 10088807

MSSO Comment: The proposal to add a new LLT Pharyngeal reflex is approved but not as requested. The pharyngeal reflex or gag reflex is a reflex muscular contraction of the back of the throat, evoked by touching the roof of the mouth, back of the tongue, area around the tonsils, uvula, and back of the throat. Pharyngeal reflex will be modified for clarity to Pharyngeal reflex test and added as synonym LLT to PT Gag reflex test.

Supplemental Update Report

CR Number: 2023278003 **Implementation Date:** 13-Oct-23 **Related CR:** 2023278003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Transarterial radioembolization</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>Radioembolization</i>		<i>Transarterial radioembolization</i>	10090320 Current
			To PT	
			<i>Radioembolisation</i>	10073946

MSSO Comment: The proposal to add a new LLT Transarterial radioembolization to PT Radioembolization is approved but not as requested. Transarterial radioembolization is a type selective internal radiation therapy which is used to treat certain types of cancer, mainly primary liver cancer or liver metastases. This method combines embolization of a blood vessel that nourishes the malignant tumor and radiation therapy. Transarterial radioembolization and Transarterial radioembolisation will both be added as LLTs to the British English spelled PT Radioembolisation.

CR Number: 2023286022 **Implementation Date:** 13-Oct-23 **Related CR:** 2023278003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Transarterial radioembolisation</i>	Approved as Requested	Proposed LLT	
To PT	<i>Radioembolisation</i>		<i>Transarterial radioembolisation</i>	10090321 Current
			To PT	
			<i>Radioembolisation</i>	10073946

MSSO Comment:

CR Number: 2023278004 **Implementation Date:** 13-Oct-23 **Related CR:** 2023278004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Acute cholecystitis necrotic</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Cholecystitis and cholelithiasis</i>		<i>Acute cholecystitis necrotic</i>	10090325
SOC primary	<i>Hepatobiliary disorders</i>		HLT primary	
			<i>Cholecystitis and cholelithiasis</i>	10008616
			SOC primary	
			<i>Hepatobiliary disorders</i>	10019805

MSSO Comment: The proposal to add a new PT Acute cholecystitis necrotic to primary HLT Cholecystitis and cholelithiasis in SOC Hepatobiliary disorders is approved as requested. Acute cholecystitis necrotic, or gangrenous cholecystitis, is defined as necrosis and perforation of the gallbladder wall as a result of ischemia following progressive vascular insufficiency. In a related change, LLT Gangrenous cholecystitis and LLT Gallbladder gangrene will both be moved from PT Cholecystitis infective to new PT Acute cholecystitis necrotic. Furthermore PT Gallbladder necrosis will be demoted under new PT Acute cholecystitis necrotic.

Supplemental Update Report

CR Number: 2023286023 Implementation Date: 13-Oct-23 Related CR: 2023278004

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Gangrenous cholecystitis</i>	Approved as Requested	Proposed LLT	
From PT	<i>Cholecystitis infective</i>		<i>Gangrenous cholecystitis</i>	10063158 Current
To PT	<i>Acute cholecystitis necrotic</i>		From PT	
			<i>Cholecystitis infective</i>	10062631
			To PT	
			<i>Acute cholecystitis necrotic</i>	10090325

MSSO
Comment:

CR Number: 2023286024 Implementation Date: 13-Oct-23 Related CR: 2023278004

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Gallbladder gangrene</i>	Approved as Requested	Proposed LLT	
From PT	<i>Cholecystitis infective</i>		<i>Gallbladder gangrene</i>	10049554 Current
To PT	<i>Acute cholecystitis necrotic</i>		From PT	
			<i>Cholecystitis infective</i>	10062631
			To PT	
			<i>Acute cholecystitis necrotic</i>	10090325

MSSO
Comment:

CR Number: 2023286025 Implementation Date: 13-Oct-23 Related CR: 2023278004

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	<i>Gallbladder necrosis</i>	Approved as Requested	PT to merge	
To PT	<i>Acute cholecystitis necrotic</i>		<i>Gallbladder necrosis</i>	10059446 Current
			To PT	
			<i>Acute cholecystitis necrotic</i>	10090325

MSSO
Comment:

Supplemental Update Report

CR Number: 2023278005 Implementation Date: 23-Oct-23 Related CR: 2023278005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Rhupus syndrome</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Systemic lupus erythematosus (SMQ)</i>		<i>Rhupus syndrome</i>	10089050
Term scope	<i>Narrow</i>		To SMQ	
			<i>Systemic lupus erythematosus (SMQ)</i>	20000045
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Rhupus syndrome to Systemic lupus erythematosus (SMQ) as a narrow term is approved as requested. PT Rhupus syndrome was added in MedDRA V26.1 representing a rare overlap syndrome in which patients display manifestations of both systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA). Rhupus syndrome will be added with a Narrow scope in alignment with inclusion criteria.

CR Number: 2023278006 Implementation Date: 20-Oct-23 Related CR: 2023278006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Pelvic floor myalgia</i>	Approved as Requested	Proposed LLT	
From PT	<i>Pelvic pain</i>		<i>Pelvic floor myalgia</i>	10089313 Current
To PT	<i>Pelvic floor dysfunction</i>		From PT	
			<i>Pelvic pain</i>	10034263
			To PT	
			<i>Pelvic floor dysfunction</i>	10083246

MSSO Comment: The proposal to move the LLT Pelvic floor myalgia from PT Pelvic pain to PT Pelvic floor dysfunction is approved as requested. Pelvic floor myalgia is better represented under PT Pelvic floor dysfunction. In a related change, PT Pelvic floor dysfunction will also be linked to HLT Reproductive tract signs and symptoms NEC. Furthermore, the primary SOC for PT Pelvic floor dysfunction will be re-assigned from SOC Gastrointestinal disorders to SOC Reproductive system and breast disorders.

Supplemental Update Report

CR Number: 2023293019	Implementation Date: 20-Oct-23	Related CR: 2023278006	
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed PT	<i>Pelvic floor dysfunction</i>	Approved as Requested	Proposed PT
To HLT	<i>Reproductive tract signs and symptoms NEC</i>		<i>Pelvic floor dysfunction</i> 10083246
			To HLT
			<i>Reproductive tract signs and symptoms NEC</i> 10040674

MSSO
Comment:

CR Number: 2023293020	Implementation Date: 20-Oct-23	Related CR: 2023278006	
<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed PT	<i>Pelvic floor dysfunction</i>	Approved as Requested	Proposed PT
Old Primary SOC	<i>Gastrointestinal disorders</i>		<i>Pelvic floor dysfunction</i> 10083246
New Primary SOC	<i>Reproductive system and breast disorders</i>		Old Primary SOC
			<i>Gastrointestinal disorders</i> 10017947
			New Primary SOC
			<i>Reproductive system and breast disorders</i> 10038604

MSSO
Comment:

CR Number: 2023278007	Implementation Date: 09-Nov-23	Related CR: 2023278007	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Device plunger issue</i>	Approved After Suspension	Proposed LLT
			<i>Device plunger issue</i> 10090420 Current
			To PT
			<i>Device issue</i> 10069868

MSSO Comment: The proposal to add a new LLT Device plunger issue is approved as requested after suspension. Device plunger issue will be added as a sub-concept LLT to PT Device issue, aligned with existing LLT Device component issue.

Supplemental Update Report

CR Number: 2023278008	Implementation Date: 13-Oct-23	Related CR: 2023278008		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Supply shortage</i>	Approved as Requested	Proposed LLT	
To PT	<i>Product supply issue</i>		<i>Supply shortage</i>	10090327 Current
			To PT	
			<i>Product supply issue</i>	10077801

MSSO Comment: The proposal to add a new LLT Supply shortage to PT Product supply issue is approved as requested. Supply shortage describes a scenario of a supply issue.

CR Number: 2023279001	Implementation Date: 13-Oct-23	Related CR: 2023279001		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Cerebral radiation edema</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Cerebral radiation edema is not approved. This is a combination concept including causality. Usually coding without causality is more objective, as assessing causality requires a comprehensive analysis, which may involve medical expertise and detailed investigation, including review of cumulative cases.

CR Number: 2023279002	Implementation Date: 13-Oct-23	Related CR: 2023279002		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>CCUS</i>	Rejected		

MSSO Comment: The proposal to add a new LLT CCUS is not approved. The acronym CCUS is not uniquely used for clonal cytopenia of undetermined significance in medical literature.

Supplemental Update Report

CR Number: 2023279003 **Implementation Date:** 13-Oct-23 **Related CR:** 2023279003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Automated chest compression device</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Automated chest compression device is not approved. Proposed term is a device (type) name and is out of the scope of MedDRA.

CR Number: 2023279004 **Implementation Date:** 13-Oct-23 **Related CR:** 2023279004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Pleuropericardial cyst</i>	Approved as Requested	Proposed LLT <i>Pleuropericardial cyst</i>	10090322 Current
To PT			<i>Pericardial cyst</i>	10051730

MSSO Comment: The proposal to add a new LLT Pleuropericardial cyst is approved as requested. Pericardial cysts are thought to often result from aberrations in the formation of celomic cavities. They can occur as well as sequelae of previous pericarditis. Pleuropericardial cyst will be added as a synonym LLT to PT Pericardial cyst.

CR Number: 2023279009 **Implementation Date:** 09-Nov-23 **Related CR:** 2023279009

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Pretreatment medication error</i>	Rejected After Suspension		
To PT			<i>Product administration error</i>	

MSSO Comment: The proposal to add a new LLT Pretreatment medication error to PT Product administration error is not approved after suspension. Pretreatment medication errors are considered as medication errors. MedDRA cannot accommodate specific terms including drug/treatment specifics in addition to the medication error. The general rule is that medication error terms include the type of the error with or without the various stages in the product use process.

Supplemental Update Report

CR Number: 2023282001	Implementation Date: 13-Oct-23	Related CR: 2023282001		MedDRA Code #
Change Requested		Final Disposition	Final Placement	
Proposed Term	Add a New Term <i>Endoscopic vocal cord medialization</i>	Approved as Requested	Proposed LLT <i>Endoscopic vocal cord medialization</i>	10090328 Current
			To PT <i>Laryngoplasty</i>	10080158

MSSO Comment: The proposal to add a new term Endoscopic vocal cord medialization is approved as requested. Endoscopic vocal cord medialization is a new procedure designed to move the immobile vocal cord inward, towards the functional vocal cord by injection a filler material which displaces the paralyzed vocal cord medially. It does not require the conventional external cervical incision surgical method for a case of unilateral laryngeal nerve paralysis. Endoscopic vocal cord medialization and its British English counterpart Endoscopic vocal cord medialisation both will be added as LLTs to PT Laryngoplasty as sub-concepts. In a related change, PT Thyroplasty will be merged under PT Laryngoplasty, as this is the former name for Medialization laryngoplasty.

CR Number: 2023286026	Implementation Date: 13-Oct-23	Related CR: 2023282001		MedDRA Code #
Change Requested		Final Disposition	Final Placement	
Proposed LLT	Add a New LLT <i>Endoscopic vocal cord medialisation</i>	Approved as Requested	Proposed LLT <i>Endoscopic vocal cord medialisation</i>	10090330 Current
To PT	<i>Laryngoplasty</i>		To PT <i>Laryngoplasty</i>	10080158

MSSO Comment:

CR Number: 2023286027	Implementation Date: 13-Oct-23	Related CR: 2023282001		MedDRA Code #
Change Requested		Final Disposition	Final Placement	
PT to merge	Demote a PT <i>Thyroplasty</i>	Approved as Requested	PT to merge <i>Thyroplasty</i>	10074455 Current
To PT	<i>Laryngoplasty</i>		To PT <i>Laryngoplasty</i>	10080158

MSSO Comment:

Supplemental Update Report

CR Number: 2023282002	Implementation Date: 13-Oct-23	Related CR: 2023282002		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Anterior cervical corpectomy</i>	Approved as Requested	Proposed LLT <i>Anterior cervical corpectomy</i> To PT <i>Spondylectomy</i>	10090329 Current 10090067

MSSO Comment: The proposal to add a new term Anterior cervical corpectomy is approved as requested. Anterior cervical corpectomy is a surgical procedure performed for patients who have experienced degenerative changes in the cervical spine that have resulted in the formation of bone spurs and/or herniated discs. Anterior cervical corpectomy will be added as sub-concept LLT to PT Spondylectomy.

CR Number: 2023282003	Implementation Date: 13-Oct-23	Related CR: 2023282003		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Movement and Neurocognitive Toxicity (MNT)</i>	Rejected		

MSSO Comment: The proposal to add a new PT Movement and Neurocognitive Toxicity (MNT) is not approved. Even though this cluster of symptoms related to toxicity of certain CAR T-cell therapies, movement and neurocognitive toxicity does not seem yet to be a fully established standalone concept.

Supplemental Update Report

CR Number: 2023282004 Implementation Date: 13-Oct-23 Related CR: 2023282004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Cyclodialysis cleft</i>	Approved as Requested	Proposed PT <i>Cyclodialysis cleft</i>	10090331
			HLT primary <i>Iris and ciliary body structural change, deposit and degeneration</i>	10022952
			SOC primary <i>Eye disorders</i>	10015919
			HLT secondary <i>Eye injuries NEC</i>	10027674
			SOC secondary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new PT Cyclodialysis cleft is approved as requested. Cyclodialysis cleft or cyclodialysis is the result of the separation of the longitudinal ciliary muscle fibers from the scleral spur, which creates an abnormal pathway for aqueous humor drainage that may lead to ocular hypotony. Cyclodialysis cleft will be added as a new PT to primary HLT Iris and ciliary body structural change, deposit and degeneration and to secondary HLT Eye injuries NEC.

CR Number: 2023283001 Implementation Date: 13-Oct-23 Related CR: 2023283001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Reflux hypersensitivity</i>	Approved as Requested	Proposed LLT <i>Reflux hypersensitivity</i>	10090338 Current
			To PT <i>Gastroesophageal reflux disease</i>	10017885

MSSO Comment: The proposal to add a new term Reflux hypersensitivity is approved as requested. Reflux hypersensitivity is one of the phenotypes of gastroesophageal reflux disease. The latest Rome IV defines reflux hypersensitivity as a condition with typical reflux symptoms and positive reflux-symptom association despite normal acid exposure. Reflux hypersensitivity will be added as sub-concept LLT under PT Gastroesophageal reflux disease.

Supplemental Update Report

CR Number: 2023283002		Implementation Date: 13-Oct-23	Related CR: 2023283002	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Snapping scapula syndrome</i>	Approved as Requested	Proposed PT <i>Snapping scapula syndrome</i>	10090333
			HLT primary <i>Joint related signs and symptoms</i>	10023226
			SOC primary <i>Musculoskeletal and connective tissue disorders</i>	10028395

MSSO Comment: The proposal to add a new term Snapping scapula syndrome is approved as requested. Snapping scapula syndrome is defined as an audible or palpable clicking of the scapula during movements of the scapulothoracic joint. Often reported with a history of pain, resulting from overuse, during rapid shoulder movements or during sports activities. Snapping scapula syndrome will be added as new PT under HLT Joint related signs and symptoms.

CR Number: 2023283003		Implementation Date: 13-Oct-23	Related CR: 2023283003	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Iliotibial band release</i>	Approved as Requested	Proposed LLT <i>Iliotibial band release</i>	10090335 Current
			To PT <i>Fasciotomy</i>	10016237

MSSO Comment: The proposal to add a new term Iliotibial band release is approved as requested. A Fasciotomy is an Iliotibial band release technique in which a small release in the fascia is performed over the area of maximum tightness. The surgery that lengthens the iliotibial band is usually combined with arthroscopy surgery on the knee, and involves an extra incision on the outside of the knee just above the knee cap. Iliotibial band release will be added as sub-concept LLT under PT Fasciotomy. In a related change, PT Fascia release will be demoted under PT Fasciotomy.

CR Number: 2023286028		Implementation Date: 13-Oct-23	Related CR: 2023283003	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Fascia release</i>	Approved as Requested	PT to merge <i>Fascia release</i>	10016223 Current
To PT	<i>Fasciotomy</i>		To PT <i>Fasciotomy</i>	10016237

MSSO Comment:

Supplemental Update Report

CR Number: 2023283004	Implementation Date: 13-Oct-23	Related CR: 2023283004		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Torn earlobe</i>	Approved as Requested	Proposed LLT <i>Torn earlobe</i>	10090336 Current
			To PT <i>Ear injury</i>	10057446

MSSO Comment: The proposal to add a new term Torn earlobe is approved as requested. Torn earlobes may occur due to heavy jewelry worn in the earlobe or through accidental tearing caused by an incident. Torn earlobe will be added as LLT under PT Ear injury.

CR Number: 2023283005	Implementation Date: 13-Oct-23	Related CR: 2023283005		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Arachnoid granulation</i>	Rejected		

MSSO Comment: The proposal to add a new term Arachnoid granulation is not approved. Arachnoid granulations are small protrusions of the arachnoid mater into the outer membrane of the dura mater. They protrude into the dural venous sinuses of the brain, and allow cerebrospinal fluid to exit the subarachnoid space and enter the blood stream. Arachnoid granulations are normal structures and therefore out of scope of MedDRA.

CR Number: 2023283006	Implementation Date: 13-Oct-23	Related CR: 2023283006		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Lymphaticovenous anastomosis</i>	Approved Not as Requested	Proposed LLT <i>Lymphaticovenous anastomosis surgery</i>	10090339 Current
			To PT <i>Lymphovenous bypass</i>	10084980

MSSO Comment: The proposal to add a new term Lymphaticovenous anastomosis is approved but not as requested. A lymphovenous bypass or lymphaticovenular anastomosis is a new technique that requires identification of patent, residual lymphatic channels and performing an anastomosis to a recipient venule, thereby allowing outflow of lymphatic fluid and improvement in a patient's lymphedema. The proposed term will be modified to clarify it as a procedure term and added as LLT Lymphaticovenous anastomosis surgery to PT Lymphovenous bypass.

Supplemental Update Report

CR Number: 2023283007 Implementation Date: 13-Oct-23 Related CR: 2023283007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Olfactory groove meningiomas</i>	Approved Not as Requested	Proposed PT <i>Olfactory groove meningioma</i>	10090334
			HLT primary <i>Meningiomas benign</i>	10027195
			SOC primary <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary <i>Meningiomas benign</i>	10027195
			SOC secondary <i>Nervous system disorders</i>	10029205

MSSO Comment: The proposal to add a new term Olfactory groove meningiomas is approved but not as requested. Olfactory groove meningiomas are rare types of meningiomas that are benign and slow growing and located in the anterior cranial fossa that grow along the nerves between the brain and the nose. They account for 2% of all primary brain tumors. Proposed term will be modified into singular form and added as new PT Olfactory groove meningioma under bi-axial HLT Meningiomas benign (primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and secondary SOC Nervous system disorders).

CR Number: 2023283008 Implementation Date: 13-Oct-23 Related CR: 2023283008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Gastrointestinal intolerance</i>	Rejected		

MSSO Comment: The proposal to add a new term Gastrointestinal intolerance is not approved. Gastrointestinal intolerance may be represented by existing PT Food intolerance and other appropriate concepts based on scenario.

Supplemental Update Report

CR Number: 2023283009	Implementation Date: 13-Oct-23	Related CR: 2023283009	MedDRA Code #
Change Requested	Final Disposition	Final Placement	
Add a New Term			
Proposed Term <i>Nuss procedure</i>	Approved as Requested	Proposed LLT <i>Nuss procedure</i>	10090337 Current
		To PT <i>Thorax deformity correction</i>	10090332

MSSO Comment: The proposal to add a new term Nuss procedure is approved as requested. The Nuss procedure is a minimally invasive procedure for surgical correction of pectus excavatum. The purpose of the procedure is to realign a depressed sternum and support it with a specially designed metal bar. Nuss procedure will be added as an LLT to a new broader PT Thorax deformity correction, which will be added, in a related change, to HLT Chest wall and mediastinal therapeutic procedures. Furthermore, PT Ravitch procedure will be demoted under the new broader PT Thorax deformity correction.

CR Number: 2023286029	Implementation Date: 13-Oct-23	Related CR: 2023283009	MedDRA Code #
Change Requested	Final Disposition	Final Placement	
Add a New PT			
Proposed PT <i>Thorax deformity correction</i>	Approved as Requested	Proposed PT <i>Thorax deformity correction</i>	10090332
HLT primary <i>Chest wall and mediastinal therapeutic procedures</i>		HLT primary <i>Chest wall and mediastinal therapeutic procedures</i>	10008494
SOC primary <i>Surgical and medical procedures</i>		SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment:

CR Number: 2023286030	Implementation Date: 13-Oct-23	Related CR: 2023283009	MedDRA Code #
Change Requested	Final Disposition	Final Placement	
Demote a PT			
PT to merge <i>Ravitch procedure</i>	Approved as Requested	PT to merge <i>Ravitch procedure</i>	10086625 Current
To PT <i>Thorax deformity correction</i>		To PT <i>Thorax deformity correction</i>	10090332

MSSO Comment:

Supplemental Update Report

CR Number: 2023283010 **Implementation Date:** 13-Oct-23 **Related CR:** 2023283010

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Pruritic erythematous plaque</i>	Rejected		

MSSO Comment: The proposal to add a new term Pruritic erythematous plaque is not approved. A plaque is defined as a solid, raised, plateau-like (flat-topped) lesion greater than 1 cm in diameter with a red or reddish color often associated with inflammation or irritation. Proposed term is a description of a typical plaque and may be found in multiple possible skin pathologies.

CR Number: 2023283011 **Implementation Date:** 30-Nov-23 **Related CR:** 2023283011

Change Requested		Final Disposition	Final Placement	MedDRA Code #
PT to merge	<i>Exposure via father</i>	Approved Not as Requested After Suspension	Proposed PT	
To PT	<i>Paternal exposure timing unspecified</i>		<i>Exposure via father</i>	10071403 Current
			With LLT	
			<i>Foetal exposure via father</i>	10071416

MSSO Comment: The proposal to demote the PT Exposure via father under PT Paternal exposure timing unspecified is approved but not as requested after suspension. PT Exposure via father will be swapped with LLT Foetal exposure via father for greater clarity of exposure during pregnancy.

CR Number: 2023283012 **Implementation Date:** 30-Nov-23 **Related CR:** 2023283012

Change Requested		Final Disposition	Final Placement	MedDRA Code #
LLT to change	<i>Exposure via father</i>	Rejected After Suspension		
Status	<i>non-current</i>			

MSSO Comment: The proposal to change status of LLT Exposure via father to non-current is not approved after suspension. The concept is still valid and may impact legacy data.

Supplemental Update Report

CR Number: 2023283013	Implementation Date: 18-Oct-23	Related CR: 2023283013		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Knowledge deficit</i>	Approved Not as Requested	Proposed LLT <i>Patient knowledge deficit</i>	10090342
			To PT <i>Circumstance or information capable of leading to medication error</i>	10064385

MSSO Comment: The proposal to add a new PT Knowledge deficit is approved but not as requested. A knowledge deficit in relation to healthcare is a lack of information needed for a thorough understanding of a disease process and recommended treatments and the ability to make informed choices or carry out tasks in alignment with health maintenance. A huge barrier to understanding health-related information is low health literacy. Patients with low health literacy are less likely to be able to manage complex diseases resulting in more frequent hospitalizations and increased mortality. The requested term will be modified for clarity and added as LLT Patient knowledge deficit to PT Circumstance or information capable of leading to medication error - See CR 2023271028 with the same request in suspension - Batch 10117957 - may be the same subscriber - see as well CR 2023271041 where we added LLT Language barrier issue in product communication to PT Product communication issue.

CR Number: 2023283015	Implementation Date: 18-Oct-23	Related CR: 2023283015		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Syringe fell apart upon plunger activation</i>	Rejected		
To PT	<i>Device breakage</i>			

MSSO Comment: The proposal to add a new LLT Syringe fell apart upon plunger activation to PT Device breakage is not approved. The proposed term is too granular and describes a too specific scenario.

CR Number: 2023283016	Implementation Date: 18-Oct-23	Related CR: 2023283016		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Excessive force required to activate safety mechanism</i>	Rejected		
To PT	<i>Device safety feature issue</i>			

MSSO Comment: The proposal to add a new LLT Excessive force required to activate safety mechanism to PT Device safety feature issue is not approved. The proposed term is too granular and describes a too specific scenario.

Supplemental Update Report

CR Number: 2023283017 **Implementation Date:** 18-Oct-23 **Related CR:** 2023283017

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Device label look alike</i>	Approved as Requested	Proposed LLT <i>Device label look alike</i>	10090345 Current
			To PT <i>Product label confusion</i>	10069273

MSSO Comment: The proposal to add a new LLT Device label look alike is approved as requested. Device label look alike will be added to describe a look alike situation where a device label looks like another device label. Device label look alike will be added as LLT to PT Product label confusion.

CR Number: 2023283018 **Implementation Date:** 18-Oct-23 **Related CR:** 2023283018

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Device packaging confusion</i>	Approved as Requested	Proposed LLT <i>Device packaging confusion</i>	10090341 Current
			To PT <i>Product packaging confusion</i>	10074776

MSSO Comment: The proposal to add a new LLT Device packaging confusion is approved as requested. Device packaging confusion represent cases where the packaging on a device leads to confusion that can lead to an error in selection or usage. Device packaging confusion will be added as LLT to PT Product packaging confusion

CR Number: 2023283019 **Implementation Date:** 18-Oct-23 **Related CR:** 2023283019

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Device error</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Device error is not approved. The proposed term is too ambiguous and may need to be reworded to provide context or clarity. As such it may refer to device itself or in any stage of the device manufacturing, distribution or use.

Supplemental Update Report

CR Number: 2023283020 Implementation Date: 18-Oct-23 Related CR: 2023283020

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New PT			
Proposed PT <i>Wrong device</i>	Approved as Requested	Proposed PT <i>Wrong device</i>	10090340
		HLT primary <i>Medication errors, product use errors and issues NEC</i>	10079146
		SOC primary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new PT Wrong device is approved as requested. Wrong device will be added to represent cases where, for instance, a wrong device is prepared or selected for treatment without reported information whether it was actually used. Wrong device will be added as a PT to HLT Medication errors, product use errors and issues NEC.

CR Number: 2023283021 Implementation Date: 18-Oct-23 Related CR: 2023283021

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New LLT			
Proposed LLT <i>Computer software interoperability</i>	Approved Not as Requested	Proposed LLT <i>Software interoperability issue</i>	10090343 Current
		To PT <i>Circumstance or information capable of leading to medication error</i>	10064385

MSSO Comment: The proposal to add a new LLT Computer software interoperability is approved but not as requested. Medical device interoperability is the ability to safely, securely, and effectively exchange and use information among one or more devices, products, technologies, or systems. The requested concept will be modified for greater clarity and added as LLT Software interoperability issue to the PT Circumstance or information capable of leading to medication error, to represent potential root causes of medication errors.

CR Number: 2023283022 Implementation Date: 18-Oct-23 Related CR: 2023283022

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New LLT			
Proposed LLT <i>Systems issue contributing factor</i>	Approved Not as Requested	Proposed LLT <i>Organizational systems issue contributing factor</i>	10090344 Current
		To PT <i>Circumstance or information capable of leading to medication error</i>	10064385

MSSO Comment: The proposal to add a new LLT Systems issue contributing factor is approved but not as requested. The proposed term takes into account social, political, and organizational factors that impact system-to-system performance. The requested concept will be modified for greater clarity and added as the LLT Organizational systems issue contributing factor to the PT Circumstance or information capable of leading to medication error. In a related change, its British counterpart term Organisational systems issue contributing factor will also be added as LLT to PT Circumstance or information capable of leading to medication error.

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CR Number: 2023291002 **Implementation Date:** 18-Oct-23 **Related CR:** 2023283022

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT	Approved as Requested	Proposed LLT	
To PT	Organisational systems issue contributing factor		Organisational systems issue contributing factor	10090346 Current
	Circumstance or information capable of leading to medication error		To PT	
			Circumstance or information capable of leading to medication error	10064385

MSSO
Comment:

CR Number: 2023283023 **Implementation Date:** 18-Oct-23 **Related CR:** 2023283023

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT	Approved Not as Requested	Proposed PT	
	Monoamine oxidase increased		Monoamine oxidase increased	10090347
			HLT primary	
			Tissue enzyme analyses NEC	10043891
			SOC primary	
			Investigations	10022891

MSSO
Comment: The proposal to add a new LLT Monoamine oxidase increased is approved but not as requested. Monoamine oxidase (MAO) is a group of enzymes that play a crucial role in the metabolism of monoamine neurotransmitters in the human body. There are two main types of MAO enzymes, known as MAO-A and MAO-B. These enzymes are found in various tissues throughout the body, including the brain, liver, and gastrointestinal tract. MAO can be measured through various laboratory techniques. Monoamine oxidase increased will be added as a new PT to HLT Tissue enzyme analyses NEC.

CR Number: 2023284001 **Implementation Date:** 18-Oct-23 **Related CR:** 2023284001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term	Rejected		
	Respiratory syncytial virus			

MSSO
Comment: The proposal to add a new term Respiratory syncytial virus is not approved. Proposed term currently exists in MedDRA as PT Respiratory syncytial virus infection to represent the infection as well as PT Respiratory syncytial virus test to represent the investigative test.

Supplemental Update Report

CR Number: 2023284002 Implementation Date: 18-Oct-23 Related CR: 2023284002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Tyndall effect</i>	Approved Not as Requested	Proposed LLT <i>Cutaneous Tyndall effect</i>	10090348 Current
			To PT <i>Dermal filler reaction</i>	10086476

MSSO Comment: The proposal to add a new LLT Tyndall effect is approved but not as requested. the Tyndall effect describes a bluish discolouration of the skin caused by too superficial placement of dermal filler. The proposed term will be modified for clarity as Cutaneous Tyndall effect will be added as an LLT to PT Dermal filler reaction.

CR Number: 2023285001 Implementation Date: 18-Oct-23 Related CR: 2023285001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term <i>Cortical hand strokes</i>	Approved Not as Requested	Proposed PT <i>Cortical hand stroke</i>	10090349
			HLT primary <i>Central nervous system haemorrhages and cerebrovascular accidents</i>	10007948
			SOC primary <i>Nervous system disorders</i>	10029205
			HLT secondary <i>Cerebrovascular and spinal necrosis and vascular insufficiency</i>	10008192
			SOC secondary <i>Vascular disorders</i>	10047065

MSSO Comment: The proposal to add a new term Cortical hand strokes is approved but not as requested. Cortical ischemic stroke affecting the precentral "hand knob" area is a rare but well known stroke entity. To date, little is known about the underlying stroke mechanisms and the prognosis. Ischemic infarcts affecting the cortical "hand knob" area are frequently associated with atherosclerotic changes of the carotid artery, suggesting an arterio-arterial thromboembolic stroke mechanism. Cortical hand stroke, in singular form, will be added as PT to primary HLT Central nervous system haemorrhages and cerebrovascular accidents and secondary HLT Cerebrovascular and spinal necrosis and vascular insufficiency and HLT Muscle weakness conditions.

Supplemental Update Report

CR Number: 2023291003	Implementation Date: 18-Oct-23	Related CR: 2023285001		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Cortical hand stroke</i>	Approved as Requested	Proposed PT	
To HLT	<i>Muscle weakness conditions</i>		<i>Cortical hand stroke</i>	10090349
			To HLT	
			<i>Muscle weakness conditions</i>	10062913

MSSO
Comment:

CR Number: 2023285002	Implementation Date: 18-Oct-23	Related CR: 2023285002		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Isolated hand weakness</i>	Rejected		

MSSO The proposal to add a new LLT Isolated hand weakness is not approved. The proposed term is not an internationally recognized synonym of Cortical-hand syndrome.
Comment:

CR Number: 2023285003	Implementation Date: 18-Oct-23	Related CR: 2023285003		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Cortical-hand syndrome</i>	Approved Not as Requested	Proposed LLT	
			<i>Cortical hand syndrome</i>	10090350 Current
			To PT	
			<i>Cortical hand stroke</i>	10090349

MSSO The proposal to add a new LLT Cortical-hand syndrome is approved but not as requested. Cortical-hand syndrome, is a well-recognised, but rare presentation of the Cortical hand stroke. Cortical hand syndrome, modified without hyphen, will be added as LLT to the new PT Cortical hand stroke, added in change request 2023285001.
Comment:

Supplemental Update Report

CR Number: 2023285004 **Implementation Date:** 20-Oct-23 **Related CR:** 2023285004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Photoreceptor atrophy</i>	Approved Not as Requested	Proposed LLT	
HLT primary	<i>Retinal structural change, deposit and degeneration</i>		<i>Photoreceptor atrophy</i>	10090352 Current
SOC primary	<i>Eye disorders</i>		To PT <i>Retinal degeneration</i>	10038845

MSSO Comment: The proposal to add a new PT Photoreceptor atrophy to primary HLT Retinal structural change, deposit and degeneration in SOC Eye disorders is approved but not as requested. Photoreceptor atrophy is characterized by the degeneration or loss of photoreceptor cells in the retina of the eye. Photoreceptor atrophy is a subtype of retinal atrophy. Photoreceptor atrophy will be added as an LLT to PT Retinal degeneration.

CR Number: 2023285005 **Implementation Date:** 20-Oct-23 **Related CR:** 2023285005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Disruption of the photoreceptor inner segment-outer segment</i>	Rejected		
To PT	<i>Photoreceptor atrophy</i>			

MSSO Comment: The proposal to demote the PT Disruption of the photoreceptor inner segment-outer segment under PT Photoreceptor atrophy is not approved. Not all disruptions in the IS/OS junction result from photoreceptor atrophy, as other retinal conditions, such as epiretinal membranes, can also affect this junction.

CR Number: 2023285006 **Implementation Date:** 20-Oct-23 **Related CR:** 2023285006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>CT CHEST WITH CONTRAST</i>	Approved Not as Requested	Proposed LLT	
			<i>Contrast enhanced chest CT</i>	10090353 Current
			To PT <i>Computerised tomogram thorax</i>	10053875

MSSO Comment: The proposal to add a new LLT CT CHEST WITH CONTRAST is approved but not as requested. The requested term will be modified for naming conventions and in accordance with MedDRA capitalization standards and added as LLT Contrast enhanced chest CT to PT Computerised tomogram thorax. CT is commonly used to diagnose, stage, and plan treatment for lung cancer, other primary neoplastic processes involving the chest, and metastatic disease. The need for contrast varies on a case-by-case basis.

Supplemental Update Report

CR Number: 2023286021	Implementation Date: 18-Oct-23	Related CR: 2023286021	MedDRA Code #
Change Requested	Add a New Term	Final Disposition	Final Placement
Proposed Term	<i>Warehousemen's itch</i>	Rejected	

MSSO Comment: The proposal to add a new term Warehousemen's itch is not approved. The proposed term is vague and may refer to eczema or vesicular dermatitis or even a specific mite originating cutaneous condition depending on context, and it is not an internationally accepted colloquial expression.

CR Number: 2023289001	Implementation Date: 18-Oct-23	Related CR: 2023289001	MedDRA Code #
Change Requested	Add a New PT	Final Disposition	Final Placement
Proposed PT	<i>Yale-Brown Obsessive-Compulsive Scale</i>	Approved Not as Requested	Proposed PT
HLT primary	<i>Psychiatric investigations</i>		<i>Yale-Brown obsessive-compulsive scale</i> 10090351
SOC primary	<i>Investigations</i>		HLT primary
			<i>Psychiatric investigations</i> 10067226
			SOC primary
			<i>Investigations</i> 10022891

MSSO Comment: The proposal to add a new PT Yale-Brown Obsessive-Compulsive Scale to primary HLT Psychiatric investigations in SOC Investigations is approved but not as requested. The Yale-Brown obsessive-compulsive scale is a standardized rating scale with both clinician-administered and self-report versions available, measuring 10 items pertaining to obsessions and compulsions on a five-point scale. The proposed term will be modified as Yale-Brown obsessive-compulsive scale according to MedDRA capitalization conventions and added as a PT under HLT Psychiatric investigations.

CR Number: 2023289002	Implementation Date: 20-Oct-23	Related CR: 2023289002	MedDRA Code #
Change Requested	Add a New Term	Final Disposition	Final Placement
Proposed Term	<i>Infectious shock</i>	Rejected	

MSSO Comment: The proposal to add a new term Infectious shock is not approved. The proposed term is rarely used expression and can best be represented by LLT/PT Septic shock.

Supplemental Update Report

CR Number: 2023290001 Implementation Date: 20-Oct-23 Related CR: 2023290001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Rhombencephalosynapsis</i>	Approved Not as Requested	Proposed PT <i>Rhombencephalosynapsis</i>	10090354
			HLT primary <i>Cerebellar disorders congenital</i>	10052633
			SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Congenital cerebellar disorders</i>	10010413
			SOC secondary <i>Nervous system disorders</i>	10029205

MSSO Comment: The proposal to add a new PT Rhombencephalosynapsis is approved but not as requested. Rhombencephalosynapsis is a rare congenital malformation of the posterior fossa characterized by hypogenesis or agenesis of the vermis, dorsal fusion of the cerebellar hemispheres, fusion of dentate nuclei and superior cerebellar peduncles. The proposed term will be slightly modified and added as a PT Rhombencephalosynapsis to primary HLT Cerebellar disorders congenital and to secondary HLT Congenital cerebellar disorders.

CR Number: 2023290002 Implementation Date: 20-Oct-23 Related CR: 2023290002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Hypoargininaemia</i>	Approved as Requested	Proposed PT <i>Hypoargininaemia</i>	10090355
			HLT primary <i>Amino acid metabolism disorders NEC</i>	10036999
			SOC primary <i>Metabolism and nutrition disorders</i>	10027433

MSSO Comment: The proposal to add a new term Hypoargininaemia is approved as requested. Hypoargininaemia is a common feature exhibited in both children and adults with severe malaria. It can also be a consequence of arginase 1 deficiency treatment with some novel arginine-lowering drugs. Hypoargininaemia will be added as PT to the HLT Amino acid metabolism disorders NEC. In a related change, the American spelled term Hypoargininemia will be added as LLT under the new PT Hypoargininaemia.

Supplemental Update Report

CR Number: 2023293015	Implementation Date: 20-Oct-23	Related CR: 2023290002		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Hypoargininemia</i>	Approved as Requested	Proposed LLT	
To PT	<i>Hypoargininaemia</i>		<i>Hypoargininemia</i>	10090358 Current
			To PT	
			<i>Hypoargininaemia</i>	10090355

MSSO
Comment:

CR Number: 2023290003	Implementation Date: 20-Oct-23	Related CR: 2023290003		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Hyperargininaemia</i>	Approved as Requested	Proposed LLT	
			<i>Hyperargininaemia</i>	10090356 Current
			To PT	
			<i>Arginase deficiency</i>	10062695

MSSO Comment: The proposal to add a new term Hyperargininaemia is approved as requested. Hyperargininaemia is used synonymously to the existing PT Arginase deficiency, and will be added as its LLT. In a related change, its counterpart American spelled term LLT Hyperargininemia will also be added under PT Arginase deficiency.

CR Number: 2023293016	Implementation Date: 20-Oct-23	Related CR: 2023290003		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Hyperargininemia</i>	Approved as Requested	Proposed LLT	
To PT	<i>Arginase deficiency</i>		<i>Hyperargininemia</i>	10090357 Current
			To PT	
			<i>Arginase deficiency</i>	10062695

MSSO
Comment:

Supplemental Update Report

CR Number: 2023290030	Implementation Date: 20-Oct-23	Related CR: 2023290030		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Edematous myositis</i>	Approved as Requested	Proposed LLT <i>Edematous myositis</i>	10090359 Current
			To PT <i>Myositis</i>	10028653

MSSO Comment: The proposal to add a new term Edematous myositis is approved as requested. Edematous myositis is a relatively homogeneous clinical phenotype characterized by a severe myopathy (severe muscle weakness frequently associated with dysphagia) with a high mortality rate related to a high risk of malignancy. Edematous myositis will be added as subconcept LLT under PT Myositis. In a related change, the British English spelled counterpart LLT Oedematous myositis will also be added under PT Myositis.

CR Number: 2023293017	Implementation Date: 20-Oct-23	Related CR: 2023290030		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Oedematous myositis</i>	Approved as Requested	Proposed LLT <i>Oedematous myositis</i>	10090362 Current
To PT	<i>Myositis</i>		To PT <i>Myositis</i>	10028653

MSSO Comment:

CR Number: 2023290031	Implementation Date: 20-Oct-23	Related CR: 2023290031		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Hair fragility</i>	Approved as Requested	Proposed LLT <i>Hair fragility</i>	10090361 Current
			To PT <i>Trichorrhexis</i>	10044625

MSSO Comment: The proposal to add a new term Hair fragility is approved as requested. Hair fragility is hair that is dry, brittle, and breaks easily with minimal amount of handling. Hair fragility will be added as synonym to existing LLT Brittle hair under PT Trichorrhexis.

Supplemental Update Report

CR Number: 2023290032	Implementation Date: 20-Oct-23	Related CR: 2023290032		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>TMJ derangement</i>	Rejected		

MSSO Comment: The proposal to add a new term TMJ derangement is not approved. The proposed term may be represented existing by LLT Joint dislocation temporomandibular. However, in a related change, existing LLT Joint dislocation temporomandibular will be moved from PT Joint dislocation to PT Temporomandibular joint syndrome for better alignment.

CR Number: 2023293018	Implementation Date: 20-Oct-23	Related CR: 2023290032		
<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Joint dislocation temporomandibular</i>	Approved as Requested	Proposed LLT	
From PT	<i>Joint dislocation</i>		<i>Joint dislocation temporomandibular</i>	10023209 Current
To PT	<i>Temporomandibular joint syndrome</i>		From PT	
			<i>Joint dislocation</i>	10023204
			To PT	
			<i>Temporomandibular joint syndrome</i>	10043220 Current

MSSO Comment:

CR Number: 2023290033	Implementation Date: 20-Oct-23	Related CR: 2023290033		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Coracoid process fracture</i>	Approved as Requested	Proposed LLT	
			<i>Coracoid process fracture</i>	10090360 Current
			To PT	
			<i>Scapula fracture</i>	10039579

MSSO Comment: The proposal to add a new term Coracoid process fracture is approved as requested. Coracoid fractures are rare fractures. In the shoulder girdle, coracoid process fractures generally accompany dislocation of the acromioclavicular joint or glenohumeral joint, scapula corpus fracture, clavicular fracture, humerus proximal end fracture or rotator cuff tear. Coracoid process fracture will be added as subconcept LLT under PT Scapula fracture.

Supplemental Update Report

CR Number: 2023291001 Implementation Date: 20-Oct-23 Related CR: 2023291001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Congenital clasped thumb</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		<i>Congenital clasped thumb</i>	10090363
SOC primary	<i>Congenital, familial and genetic disorders</i>		HLT primary	
			<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>	10028381
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>	10028381
			SOC secondary	
			<i>Musculoskeletal and connective tissue disorders</i>	10028395

MSSO Comment: The proposal to add a new PT Congenital clasped thumb to primary HLT Musculoskeletal and connective tissue disorders of limbs congenital in SOC Congenital, familial and genetic disorders is approved as requested. Congenital clasped thumb describes an anomaly which is characterized by a fixed thumb into the palm at the metacarpophalangeal joint in one or both hands. The PT Congenital clasped thumb will be added to bi-axial HLT Musculoskeletal and connective tissue disorders of limbs congenital (primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders).

CR Number: 2023291004 Implementation Date: 25-Oct-23 Related CR: 2023291004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>External iliac artery stenosis</i>	Approved as Requested	Proposed LLT	
			<i>External iliac artery stenosis</i>	10090377 Current
			To PT	
			<i>Iliac artery stenosis</i>	10053216

MSSO Comment: The proposal to add a new term External iliac artery stenosis is approved as requested. The common iliac arteries bifurcate into the external and internal iliac arteries at the level of the sacroiliac joints on either side. The external iliac artery is the main blood supply to the lower limb. External iliac artery stenosis will be added as sub-concept LLT to PT Iliac artery stenosis.

Supplemental Update Report

CR Number: 2023291005 Implementation Date: 25-Oct-23 Related CR: 2023291005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Copper deficiency anemia</i>	Approved Not as Requested	Proposed PT	
HLT primary	<i>Anaemia deficiencies</i>		<i>Copper deficiency anaemia</i>	10090378
SOC primary	<i>Blood and lymphatic system disorders</i>		HLT primary	
			<i>Anaemia deficiencies</i>	10002042
			SOC primary	
			<i>Blood and lymphatic system disorders</i>	10005329
			HLT secondary	
			<i>Copper metabolism disorders</i>	10010962
			SOC secondary	
			<i>Metabolism and nutrition disorders</i>	10027433

MSSO Comment: The proposal to add a new PT Copper deficiency anemia to primary HLT Anaemia deficiencies in SOC Blood and lymphatic system disorders is approved but not as requested. Copper deficiency anemia, also known as hypocupremic anemia, is a rare type of anemia. The proposed term will be modified to British English PT Copper deficiency anaemia and added to primary HLT Anaemia deficiencies and to secondary HLT Copper metabolism disorders. In a related change, the American English spelled counterpart Copper deficiency anemia will be added as LLT to PT Copper deficiency anaemia.

CR Number: 2023298007 Implementation Date: 25-Oct-23 Related CR: 2023291005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Copper deficiency anemia</i>	Approved as Requested	Proposed LLT	
To PT	<i>Copper deficiency anaemia</i>		<i>Copper deficiency anemia</i>	10090379 Current
			To PT	
			<i>Copper deficiency anaemia</i>	10090378

MSSO Comment:

CR Number: 2023292001 Implementation Date: 25-Oct-23 Related CR: 2023292001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Postoperative wound inflammation</i>	Rejected		
To PT	<i>Postoperative wound complication</i>			

MSSO Comment: The proposal to add a new LLT Postoperative wound inflammation to PT Postoperative wound complication is not approved. This is a multiple concept/combination term. MedDRA limits inclusion of combination terms to internationally recognized, distinct and robust medical concepts, in which the additional medical information provides important information on pathophysiology or etiology. Please refer to Section 3.5 of the MedDRA Term Selection: Points to Consider Document regarding coding approaches/considerations.

Supplemental Update Report

CR Number: 2023292002 Implementation Date: 09-Nov-23 Related CR: 2023292002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Tobacco use disorder</i>	Approved After Suspension	Proposed LLT	
From PT	<i>Tobacco abuse</i>		<i>Tobacco use disorder</i>	10043906
			From PT	
			<i>Tobacco abuse</i>	10043903
			HLT primary	
			<i>Substance related and addictive disorders</i>	10079102
			SOC primary	
			<i>Psychiatric disorders</i>	10037175

MSSO Comment: The proposal to promote the LLT Tobacco use disorder from PT Tobacco abuse is approved as requested after suspension. LLT Tobacco use disorder will be promoted from under PT Tobacco abuse to PT level under HLT Substance related and addictive disorders for consistent alignment with other substance use disorders.

CR Number: 2023292025 Implementation Date: 25-Oct-23 Related CR: 2023292025

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Inspissated bile syndrome</i>	Approved as Requested	Proposed PT	
			<i>Inspissated bile syndrome</i>	10090364
			HLT primary	
			<i>Cholestasis and jaundice</i>	10008636
			SOC primary	
			<i>Hepatobiliary disorders</i>	10019805
			HLT secondary	
			<i>Neonatal hepatobiliary disorders</i>	10028942
			SOC secondary	
			<i>Pregnancy, puerperium and perinatal conditions</i>	10036585

MSSO Comment: The proposal to add a new term Inspissated bile syndrome is approved as requested. Inspissated bile syndrome is a rare cause of cholestatic jaundice in infancy, occurring due to obstruction of the biliary ducts and gallbladder by biliary sludge and accounts for 8% of all types of surgical jaundice during infancy. Inspissated bile syndrome will be added as PT under primary HLT Cholestasis and jaundice and secondary HLT Neonatal hepatobiliary disorders.

Supplemental Update Report

CR Number: 2023292026	Implementation Date: 25-Oct-23	Related CR: 2023292026	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New Term			<u>MedDRA Code #</u>
Proposed Term <i>Nasal laser mucotomy</i>		Approved as Requested	Proposed LLT <i>Nasal laser mucotomy</i> 10090372 Current
			To PT <i>Nasal mucotomy</i> 10090368

MSSO Comment: The proposal to add a new term Nasal laser mucotomy is approved as requested. Nasal laser mucotomy is a simple procedure performed under local anaesthesia on an ambulatory basis most often indicated for sneezing, rhinorrhoea, or nasal obstruction. A controlled amount of tissue from the inferior turbinates is ablated with improvement in the symptoms. Nasal laser mucotomy will be added as an LLT to new PT Nasal mucotomy which will be added, in a related change, to HLT Nasal therapeutic procedures.

CR Number: 2023298004	Implementation Date: 25-Oct-23	Related CR: 2023292026	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New PT			<u>MedDRA Code #</u>
Proposed PT <i>Nasal mucotomy</i>		Approved as Requested	Proposed PT <i>Nasal mucotomy</i> 10090368
HLT primary <i>Nasal therapeutic procedures</i>			HLT primary <i>Nasal therapeutic procedures</i> 10028752
SOC primary <i>Surgical and medical procedures</i>			SOC primary <i>Surgical and medical procedures</i> 10042613

MSSO Comment:

CR Number: 2023292027	Implementation Date: 25-Oct-23	Related CR: 2023292027	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New Term			<u>MedDRA Code #</u>
Proposed Term <i>Total femoral replacement</i>		Approved as Requested	Proposed PT <i>Total femoral replacement</i> 10090366
			HLT primary <i>Limb therapeutic procedures</i> 10024502
			SOC primary <i>Surgical and medical procedures</i> 10042613

MSSO Comment: The proposal to add a new term Total femoral replacement is approved as requested. Total femoral replacement is a well-recognized salvage procedure performed after multiple failed endoprosthetic replacements. It is performed as an alternative to lower limb amputation, restoring femoral integrity and enabling patients to resume ambulation. Total femoral replacement will be added as new PT under HLT Limb therapeutic procedures.

Supplemental Update Report

CR Number: 2023292028 Implementation Date: 25-Oct-23 Related CR: 2023292028

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term <i>Left ventricular asynergy</i>	Approved as Requested	Proposed LLT <i>Left ventricular asynergy</i>	10090373 Current
			To PT <i>Ventricular dyssynchrony</i>	10071186

MSSO Comment: The proposal to add a new term Left ventricular asynergy is approved as requested. Left ventricular asynergy is a localized morphologic disturbance of ventricular wall motion which disrupts the normal coordinated pattern of left ventricular contraction. Left ventricular asynergy will be added as synonym LLT of existing LLT Left ventricular asynchrony under PT Ventricular dyssynchrony.

CR Number: 2023292029 Implementation Date: 25-Oct-23 Related CR: 2023292029

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term <i>Parasagittal Craniotomy</i>	Approved Not as Requested	Proposed LLT <i>Parasagittal craniotomy</i>	10090374 Current
			To PT <i>Craniotomy</i>	10011322

MSSO Comment: The proposal to add a new term Parasagittal Craniotomy is approved but not as requested. The parasagittal craniotomy exposes lesions along the paramedian hemispheres and superior sagittal sinus and provides access to the superior sagittal sinus. Proposed term will be modified for MedDRA capitalization conventions and added as LLT Parasagittal craniotomy under PT Craniotomy.

CR Number: 2023292030 Implementation Date: 25-Oct-23 Related CR: 2023292030

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term <i>Adnexal Tumors</i>	Approved Not as Requested	Proposed LLT <i>Female reproductive adnexal tumor</i>	10090375 Current
			To PT <i>Female reproductive neoplasm</i>	10061153

MSSO Comment: The proposal to add a new term Adnexal Tumors is approved but not as requested. Adnexal tumors are tumors that grow on organs such as the eyes, skin, and uterus. The word 'adnexa' refers to ancillary structures, or appendages, on organ. The term is most commonly applied to structures around the uterus, including ligaments, fallopian tubes, and ovaries. The proposed term will be modified for clarity to LLT Female reproductive adnexal tumor along with its British English spelled counterpart LLT Female reproductive adnexal tumour will both be added to PT Female reproductive neoplasm.

Supplemental Update Report

CR Number: 2023298005		Implementation Date: 25-Oct-23	Related CR: 2023292030	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Female reproductive adnexal tumour	Approved as Requested	Proposed LLT	
To PT	Female reproductive neoplasm		Female reproductive adnexal tumour	10090369 Current
			To PT	
			Female reproductive neoplasm	10061153

MSSO
Comment:

CR Number: 2023292031		Implementation Date: 25-Oct-23	Related CR: 2023292031	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Laparoscopic Resection of Pelvic Schwannomas	Approved Not as Requested	Proposed LLT	
			Laparoscopic resection of pelvic schwannoma	10090370 Current
			To PT	
			Schwannoma resection	10090367

MSSO
Comment: The proposal to add a new term Laparoscopic Resection of Pelvic Schwannomas is approved but not as requested. Laparoscopic resection of pelvic schwannomas may offer several advantages as the direct high-definition vision deeply into this narrow anatomical space provides a detailed view that makes it easier to isolate and spear the anatomical structures surrounding the tumor. Proposed term will be modified for MedDRA capitalization conventions and added in singular form as new LLT Laparoscopic resection of pelvic schwannoma to new PT Schwannoma resection, which will be added, in a related change, to HLT Nervous system therapeutic procedures NEC.

CR Number: 2023298006		Implementation Date: 25-Oct-23	Related CR: 2023292031	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Schwannoma resection	Approved as Requested	Proposed PT	
HLT primary	Nervous system therapeutic procedures NEC		Schwannoma resection	10090367
SOC primary	Surgical and medical procedures		HLT primary	
			Nervous system therapeutic procedures NEC	10052731
			SOC primary	
			Surgical and medical procedures	10042613

MSSO
Comment:

Supplemental Update Report

CR Number: 2023292032 **Implementation Date:** 25-Oct-23 **Related CR:** 2023292032

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Inframammary pain</i>	Rejected		

MSSO Comment: The proposal to add a new term Inframammary pain is not approved. The proposed concept is too granular and may be represented by LLT/PT Breast pain.

CR Number: 2023292033 **Implementation Date:** 25-Oct-23 **Related CR:** 2023292033

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Hysteroplasty</i>	Approved as Requested	Proposed LLT <i>Hysteroplasty</i>	10090371 Current
			To PT <i>Uterine repair</i>	10052963

MSSO Comment: The proposal to add a new term Hysteroplasty is approved as requested. Surgical correction techniques performed on uterine malformations are known as hysteroplasties and metroplasties. The procedure involves using hysteroscopy techniques to perform a hysteroplasty through a section of the uterine wall and not a resection. Hysteroplasty will be added as an LLT to PT Uterine repair.

CR Number: 2023292034 **Implementation Date:** 25-Oct-23 **Related CR:** 2023292034

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Dental bone graft</i>	Approved as Requested	Proposed PT <i>Dental bone graft</i>	10090365
			HLT primary <i>Dental and gingival therapeutic procedures</i>	10012317
			SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new term Dental bone graft is approved as requested. A dental bone graft is a procedure performed to add volume and density to the jaw in areas where bone loss has occurred. The bone graft material may be autogenous, an allograft or an xenograft. Dental bone graft will be added as a new PT under HLT Dental and gingival therapeutic procedures.

Supplemental Update Report

CR Number: 2023292035		Implementation Date: 25-Oct-23	Related CR: 2023292035	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Transient asymptomatic pulmonary opacity</i>	Approved as Requested	Proposed LLT <i>Transient asymptomatic pulmonary opacity</i>	10090376 Current
			To PT <i>Lung opacity</i>	10081792

MSSO Comment: The proposal to add a new term Transient asymptomatic pulmonary opacity is approved as requested. Transient asymptomatic pulmonary opacities may be a previously unrecognized, benign feature associated with some epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor therapies. They may be mistaken for isolated pulmonary progression or the beginning of more severe pneumonitis. Transient asymptomatic pulmonary opacity will be added as sub-concept LLT under PT Lung opacity.

CR Number: 2023293004		Implementation Date: 25-Oct-23	Related CR: 2023293004	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Promote an LLT <i>Sentinel lymphadenectomy</i>	Approved as Requested	Proposed LLT <i>Sentinel lymphadenectomy</i>	10068478
From PT	<i>Lymphadenectomy</i>		From PT <i>Lymphadenectomy</i>	10048956
			HLT primary <i>Lymphoid tissue therapeutic procedures</i>	10025308
			SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to promote the LLT Sentinel lymphadenectomy from PT Lymphadenectomy is approved as requested. Sentinel lymphadenectomy involves the identification and removal of the sentinel lymph node, which is the first lymph node to which cancer is likely to spread from the primary tumor. It is an important tool in the management of cancer, as it aids in cancer staging, guides treatment decisions, reduces the risk of complications, and improves the overall quality of life for patients. LLT Sentinel lymphadenectomy will be promoted from PT Lymphadenectomy as a new PT under HLT Lymphoid tissue therapeutic procedures.

CR Number: 2023293005		Implementation Date: 25-Oct-23	Related CR: 2023293005	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Recurrent leg ulcer</i>	Rejected		

MSSO Comment: The proposal to add a new term Recurrent leg ulcer is not approved. The MSSO refrains from adding new terms with a qualifier of aggravation / worsening / exacerbation etc. unless such a term represents an internationally accepted unique medical concept. LLTs under PT Skin ulcer provide a variety of coding options for this medical concept, depending on data entry and coding conventions.

Supplemental Update Report

CR Number: 2023293006	Implementation Date: 25-Oct-23	Related CR: 2023293006		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Hydrostatic bulla</i>	Approved as Requested	Proposed LLT <i>Hydrostatic bulla</i> To PT <i>Oedema blister</i>	10090380 Current 10080039

MSSO Comment: The proposal to add a new term Hydrostatic bulla is approved as requested. Hydrostatic bulla (including edema blister, stasis blister) is a common noninfectious blistering condition. Hydrostatic bullae develop due to the rapid accumulation of interstitial fluid in patients with an acute exacerbation of localized or generalized edema (anasarca). Hydrostatic bulla will be added as synonym LLT to PT Oedema blister.

CR Number: 2023293007	Implementation Date: 25-Oct-23	Related CR: 2023293007		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Immune-mediated pancreatic insufficiency</i>	Rejected		

MSSO Comment: The proposal to add a new term Immune-mediated pancreatic insufficiency is not approved. Immune-mediated pancreatic insufficiency, also known as autoimmune pancreatitis, is a rare type of chronic pancreatitis in which the immune system mistakenly attacks and damages the pancreas. The MSSO considers the proposed Immune-mediated pancreatic insufficiency to be of a "due to" nature. Terms that state or imply a "due to" concept are generally not added to MedDRA because causality is not inherent in the coded term but is instead determined by the reporter/investigator or by the sponsor. Pancreatic insufficiency is a late stage of several pancreatic disorders. LLTs Immune-mediated pancreatitis and LLT Autoimmune pancreatitis exist.

CR Number: 2023293008	Implementation Date: 25-Oct-23	Related CR: 2023293008		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Immune-mediated rhinitis</i>	Rejected		

MSSO Comment: The proposal to add a new term Immune-mediated rhinitis is not approved. The MSSO considers the proposed term Immune-mediated rhinitis to be of a "due to" nature. Terms that state or imply a "due to" concept are generally not added to MedDRA because causality is not inherent in the coded term but is instead determined by the reporter/investigator or by the sponsor.

Supplemental Update Report

CR Number: 2023293009 **Implementation Date:** 25-Oct-23 **Related CR:** 2023293009

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Immune-mediated ulcerated duodenitis</i>	Rejected		

MSSO Comment: The proposal to add a new term Immune-mediated ulcerated duodenitis is not approved. Immune-mediated ulcerated duodenitis is often considered a secondary condition associated with underlying illnesses or diseases, rather than a primary disease itself. While the exact causes and triggers of immune-mediated ulcerated duodenitis may vary from one individual to another, certain conditions and factors can contribute to its development: Autoimmune diseases like celiac disease, Crohn's disease, and systemic lupus erythematosus (SLE), Graft-versus-Host Disease (GVHD). 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 because causality is not inherent in the coded term but is instead determined by the reporter/investigator or by the sponsor.

CR Number: 2023293010 **Implementation Date:** 25-Oct-23 **Related CR:** 2023293010

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Pleurostomy</i>	Approved as Requested	Proposed LLT <i>Pleurostomy</i>	10090381 Current
			To PT <i>Thoracic cavity drainage</i>	10053975

MSSO Comment: The proposal to add a new term Pleurostomy is approved as requested. A pleurostomy, also known as a pleural drain or chest tube insertion, is a medical procedure used to remove air, fluid, or other substances from the pleural space within the chest. Pleurostomy will be added as subconcept LLT to PT Thoracic cavity drainage.

CR Number: 2023293011 **Implementation Date:** 25-Oct-23 **Related CR:** 2023293011

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Empyema decortication</i>	Rejected		

MSSO Comment: The proposal to add a new term Empyema decortication is not approved. Empyema decortication is a surgical procedure performed to treat empyema. This term can be represented by LLT/PT Pleural decortication or recently added LLT Empyemectomy (supplemental term for version 27.0, change request #2023179003).

Supplemental Update Report

CR Number: 2023293012 **Implementation Date:** 25-Oct-23 **Related CR:** 2023293012

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Ring-shaped lateral ventricular nodules	Rejected		

MSSO Comment: The proposal to add a new term Ring-shaped lateral ventricular nodules is not approved. Ring-shaped lateral ventricular nodules are incidentally detected by postcontrast brain magnetic resonance (MR) imaging. Absence of changes during the follow-up period seemed to indicate that the nodules have no clinical significance. MedDRA cannot represent a high level of granularity for imaging and histopathologic findings. Only if the finding is medically significant and leads to a pathological diagnosis, it will be considered for placement as a disorder term or under the available appropriate disorder PT.

CR Number: 2023296001 **Implementation Date:** 01-Nov-23 **Related CR:** 2023296001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Forehead laceration	Rejected		
To PT	Skin laceration			

MSSO Comment: The proposal to add a new LLT Forehead laceration to PT Skin laceration is not approved. PT Skin laceration includes LLT Laceration of face and LLT Laceration of head. Thus, coding to either or, will not lead to signal dispersion over several PTs. In order to avoid the overpopulation of terms in MedDRA, the MSSO generally refrains from adding site-specific terms or concepts which can be represented by existing terms.

CR Number: 2023296002 **Implementation Date:** 01-Nov-23 **Related CR:** 2023296002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Bruise of forehead	Rejected		
To PT	Contusion			

MSSO Comment: The proposal to add a new LLT Bruise of forehead to PT Contusion is not approved. PT Contusion includes LLT Bruise of head and LLT Bruising of face. Thus, coding to either or, will not lead to signal dispersion over several PTs. In order to avoid the overpopulation of terms in MedDRA, the MSSO generally refrains from adding site-specific terms or concepts which can be represented by existing terms.

Supplemental Update Report

CR Number: 2023296006 **Implementation Date:** 01-Nov-23 **Related CR:** 2023296006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Canthus squamous cell carcinoma</i>	Rejected		

MSSO Comment: The proposal to add a new term Canthus squamous cell carcinoma is not approved. MedDRA cannot accommodate a term for every possible specific anatomical site for existing broader concepts. The proposed term can be represented by existing LLT Squamous cell cancer of the eyelid. Canthus is the outer or inner corner of the eye, where the upper and lower lids meet.

CR Number: 2023297012 **Implementation Date:** 01-Nov-23 **Related CR:** 2023297012

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Idiopathic pleural effusion</i>	Approved as Requested	Proposed LLT <i>Idiopathic pleural effusion</i>	10090392 Current
			To PT <i>Pleural effusion</i>	10035598

MSSO Comment: The proposal to add a new term Idiopathic pleural effusion is approved as requested. Idiopathic effusion is usually defined as any effusion that remains undiagnosed after biochemical study, cytology studies and pleural biopsy, without taking into account the use of other examinations. Idiopathic pleural effusion will be added as LLT to PT Pleural effusion.

CR Number: 2023297034 **Implementation Date:** 01-Nov-23 **Related CR:** 2023297034

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Spleen nodule calcification</i>	Rejected		

MSSO Comment: The proposal to add a new term Spleen nodule calcification is not approved. The requested term can be represented by existing LLT Splenic calcification.

Supplemental Update Report

CR Number: 2023298001 Implementation Date: 01-Nov-23 Related CR: 2023298001

<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Vomiting post radiotherapy</i>	Approved as Requested	Proposed LLT	
From PT	<i>Vomiting</i>		<i>Vomiting post radiotherapy</i>	10057591 Current
To PT	<i>Procedural vomiting</i>		From PT	
			<i>Vomiting</i>	10047700
			To PT	
			<i>Procedural vomiting</i>	10066963

MSSO Comment: The proposal to move the LLT Vomiting post radiotherapy from PT Vomiting to PT Procedural vomiting is approved as requested for better alignment with similar related terms.

CR Number: 2023298002 Implementation Date: 01-Nov-23 Related CR: 2023298002

<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Nausea post radiotherapy</i>	Approved as Requested	Proposed LLT	
From PT	<i>Nausea</i>		<i>Nausea post radiotherapy</i>	10072679 Current
To PT	<i>Procedural nausea</i>		From PT	
			<i>Nausea</i>	10028813
			To PT	
			<i>Procedural nausea</i>	10066962

MSSO Comment: The proposal to move the LLT Nausea post radiotherapy from PT Nausea to PT Procedural nausea is approved as requested for better alignment with similar related terms.

Supplemental Update Report

CR Number: 2023298003 Implementation Date: 01-Nov-23 Related CR: 2023298003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Penile angioma</i>	Approved Not as Requested	Proposed PT <i>Penile haemangioma</i>	10090393
			HLT primary <i>Reproductive neoplasms male benign NEC</i>	10038598
			SOC primary <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary <i>Penile disorders NEC (excl erection and ejaculation)</i>	10034304
			SOC secondary <i>Reproductive system and breast disorders</i>	10038604

MSSO Comment: The proposal to add a new term Penile angioma is approved but not as requested. Angiomas are benign growths made of blood vessels or lymphatic vessels, whereas hemangiomas are small growths made of blood vessels only. The rare, benign growths of this type in the anogenital area are referred to as penile haemangiomas. Proposed term will be modified to the form most commonly found in literature and added as a new PT Penile haemangioma under primary HLT Reproductive neoplasms male benign NEC and secondary HLT Penile disorders NEC (excl erection and ejaculation) and secondary HLT Vascular neoplasms. In a related change, the American English counterpart LLT Penile hemangioma will also be added under new PT Penile haemangioma.

CR Number: 2023305005 Implementation Date: 01-Nov-23 Related CR: 2023298003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Penile haemangioma</i>	Approved as Requested	Proposed PT <i>Penile haemangioma</i>	10090393
To HLT	<i>Vascular neoplasms</i>		To HLT <i>Vascular neoplasms</i>	10057189

MSSO Comment:

Supplemental Update Report

CR Number: 2023305006 Implementation Date: 01-Nov-23 Related CR: 2023298003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Penile hemangioma</i>	Approved as Requested	Proposed LLT	
To PT	<i>Penile haemangioma</i>		<i>Penile hemangioma</i>	10090394 Current
			To PT	
			<i>Penile haemangioma</i>	10090393

MSSO
Comment:

CR Number: 2023298008 Implementation Date: 01-Nov-23 Related CR: 2023298008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Podoconiosis</i>	Approved Not as Requested	Proposed PT	
HLT primary	<i>Dermal and epidermal conditions NEC</i>		<i>Podoconiosis</i>	10090382
SOC primary	<i>Skin and subcutaneous tissue disorders</i>		HLT primary	
			<i>Lymphoedemas</i>	10052790
			SOC primary	
			<i>Vascular disorders</i>	10047065
			HLT secondary	
			<i>Lymphatic system disorders NEC</i>	10025198
			SOC secondary	
			<i>Blood and lymphatic system disorders</i>	10005329

MSSO
Comment: The proposal to add a new PT Podoconiosis to primary HLT Dermal and epidermal conditions NEC in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Podoconiosis, also known as non-filarial elephantiasis, is a debilitating tropical disease that primarily affects the lower extremities of individuals who are exposed to certain types of irritant mineral particles in the soil. It is a type of lymphedema, caused by walking barefoot on mineral-rich soil which can penetrate the skin and trigger an inflammatory response in the lymphatic system. Podoconiosis will be added as PT to primary HLT Lymphoedemas, secondary HLT Lymphatic system disorders NEC and secondary HLT Dermal and epidermal conditions NEC.

Supplemental Update Report

CR Number: 2023305001	Implementation Date: 01-Nov-23	Related CR: 2023298008	
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed PT	<i>Podoconiosis</i>	Approved as Requested	Proposed PT
To HLT	<i>Dermal and epidermal conditions NEC</i>		<i>Podoconiosis</i>
			10090382
			To HLT
			<i>Dermal and epidermal conditions NEC</i>
			10012424

MSSO
Comment:

CR Number: 2023298009	Implementation Date: 01-Nov-23	Related CR: 2023298009	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Cuneiform tooth defect</i>	Approved Not as Requested	Proposed LLT
To PT	<i>Tooth injury</i>		<i>Cuneiform tooth defect</i>
			10090385 Current
			To PT
			<i>Dental abfraction</i>
			10080651

MSSO Comment: The proposal to add a new LLT Cuneiform tooth defect to PT Tooth injury is approved but not as requested. Cuneiform tooth defect will be added as LLT to PT Dental abfraction aligned with synonym LLT Wedge-shaped defect tooth.

CR Number: 2023298010	Implementation Date: 01-Nov-23	Related CR: 2023298010	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Scrotal ablation</i>	Approved Not as Requested	Proposed LLT
To PT	<i>Scrotal operation</i>		<i>Scrotal ablation</i>
			10090387 Current
			To PT
			<i>Scrotectomy</i>
			10090384

MSSO Comment: The proposal to add a new LLT Scrotal ablation to PT Scrotal operation is approved but not as requested. Scrotectomy or scrotal ablation. Scrotectomy may be performed for various medical reasons, such as the presence of scrotal tumors or as part of a more complex gender-affirming surgery for transgender individuals. Scrotal ablation will be added as LLT under a new PT Scrotectomy, which will be added, in a related change, to HLT Testicular and scrotal therapeutic procedures.

Supplemental Update Report

CR Number: 2023305002		Implementation Date: 01-Nov-23	Related CR: 2023298010	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Scrotoctomy</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Testicular and scrotal therapeutic procedures</i>		<i>Scrotoctomy</i>	10090384
SOC primary	<i>Surgical and medical procedures</i>		HLT primary	
			<i>Testicular and scrotal therapeutic procedures</i>	10043297
			SOC primary	
			<i>Surgical and medical procedures</i>	10042613

MSSO
Comment:

CR Number: 2023298011		Implementation Date: 01-Nov-23	Related CR: 2023298011	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Pilarowski-Bjornsson Syndrome</i>	Approved Not as Requested	Proposed PT	
HLT primary	<i>Chromosomal abnormalities NEC</i>		<i>Pilarowski-Bjornsson syndrome</i>	10090383
SOC primary	<i>Congenital, familial and genetic disorders</i>		HLT primary	
			<i>Autosomal chromosomal abnormalities</i>	10003842
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Intellectual disabilities</i>	10077548
			SOC secondary	
			<i>Nervous system disorders</i>	10029205

MSSO
Comment: The proposal to add a new PT Pilarowski-Bjornsson Syndrome to primary HLT Chromosomal abnormalities NEC in SOC Congenital, familial and genetic disorders is approved but not as requested. Pilarowski-Bjornsson syndrome is an autosomal dominant neurodevelopmental disorder characterized by delayed development, intellectual disability, often with autistic features, speech apraxia, and mild dysmorphic features. The proposed term will be modified in accordance with MedDRA capitalization standards as Pilarowski-Bjornsson syndrome and will be added as PT to primary HLT Autosomal chromosomal abnormalities and secondary HLT Intellectual disabilities and secondary HLT Musculoskeletal and connective tissue deformities of skull, face and buccal cavity.

Supplemental Update Report

CR Number: 2023305003 Implementation Date: 01-Nov-23 Related CR: 2023298011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Pilarowski-Bjornsson syndrome</i>	Approved as Requested	Proposed PT	
To HLT	<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		<i>Pilarowski-Bjornsson syndrome</i>	10090383
			To HLT	
			<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>	10028378

MSSO
Comment:

CR Number: 2023298012 Implementation Date: 01-Nov-23 Related CR: 2023298012

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Disruptive behavior</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>Abnormal behaviour</i>		<i>Disruptive behavior</i>	10090386 Current
			To PT	
			<i>Defiant behaviour</i>	10077244

MSSO Comment: The proposal to add a new LLT Disruptive behavior to PT Abnormal behaviour is approved but not as requested. Disruptive behavior refers to actions or conduct that significantly and often negatively interfere with or disturb the normal functioning of a group, organization, or social context. Disruptive behavior and the British spelled counterpart Disruptive behaviour will both be added as LLTs to PT Defiant behaviour.

CR Number: 2023305004 Implementation Date: 01-Nov-23 Related CR: 2023298012

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Disruptive behaviour</i>	Approved as Requested	Proposed LLT	
To PT	<i>Defiant behaviour</i>		<i>Disruptive behaviour</i>	10090389 Current
			To PT	
			<i>Defiant behaviour</i>	10077244

MSSO
Comment:

Supplemental Update Report

CR Number: 2023298013

Implementation Date: 01-Nov-23

Related CR: 2023298013

Change Requested

Add a New LLT

Final Disposition

Final Placement

MedDRA Code #

Proposed LLT

Cobalt allergy

Approved as Requested

Proposed LLT

10090388 Current

To PT

Allergy to metals

Cobalt allergy

To PT

Allergy to metals

10066414

MSSO Comment: The proposal to add a new LLT Cobalt allergy to PT Allergy to metals is approved as requested. Cobalt allergy, also known as cobalt hypersensitivity or cobalt dermatitis, is an allergic reaction to cobalt, a naturally occurring metallic element.

CR Number: 2023298014

Implementation Date: 01-Nov-23

Related CR: 2023298014

Change Requested

Add a New LLT

Final Disposition

Final Placement

MedDRA Code #

Proposed LLT

Urodynia

Rejected

To PT

Urinary tract pain

MSSO Comment: The proposal to add a new LLT Urodynia to PT Urinary tract pain is not approved. Urodynia is a very rarely used term in medical literature and is used with different definitions (pain of the urinary tract or pain on urination). Based on this, the term is ambiguous and rare and will not be added to MedDRA.

Supplemental Update Report

CR Number: 2023299001 Implementation Date: 29-Nov-23 Related CR: 2023299001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Temporomandibular disorders</i>	Approved Not as Requested After Suspension	Proposed PT <i>Temporomandibular pain and dysfunction syndrome</i>	10090578
HLT primary	<i>Joint related disorders NEC</i>		HLT primary <i>Joint related disorders NEC</i>	10027685
SOC primary	<i>Musculoskeletal and connective tissue disorders</i>		SOC primary <i>Musculoskeletal and connective tissue disorders</i>	10028395
			HLT secondary <i>Headaches NEC</i>	10019233
			SOC secondary <i>Nervous system disorders</i>	10029205

MSSO Comment: The proposal to add a new PT Temporomandibular disorders to primary HLT Joint related disorders NEC in SOC Musculoskeletal and connective tissue disorders and secondary HLT Headaches NEC in SOC Nervous system disorders is approved but not as requested after suspension. Instead of implementing PT Temporomandibular disorders a new PT Temporomandibular pain and dysfunction syndrome to primary HLT Joint related disorders NEC and to secondary HLT Headaches NEC. In related change, PT Temporomandibular joint syndrome will be demoted to an LLT level under new PT Temporomandibular pain and dysfunction syndrome. Furthermore, LLT Joint dislocation temporomandibular will be moved from PT Temporomandibular joint syndrome to PT Joint dislocation because Temporomandibular joint/jaw dislocation can also be caused by traumatic injury and is not always a part of Temporomandibular joint syndrome/Temporomandibular pain and dysfunction syndrome.

CR Number: 2023333134 Implementation Date: 29-Nov-23 Related CR: 2023299001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	Demote a PT <i>Temporomandibular joint syndrome</i>	Approved as Requested	PT to merge <i>Temporomandibular joint syndrome</i>	10043220 Current
To PT	<i>Temporomandibular pain and dysfunction syndrome</i>		To PT <i>Temporomandibular pain and dysfunction syndrome</i>	10090578

MSSO Comment:

Supplemental Update Report

CR Number: 2023333135 Implementation Date: 29-Nov-23 Related CR: 2023299001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Link (move) an LLT to another PT <i>Joint dislocation temporomandibular</i>	Approved as Requested	Proposed LLT <i>Joint dislocation temporomandibular</i>	10023209 Current
From PT	<i>Temporomandibular joint syndrome</i>		From PT <i>Temporomandibular joint syndrome</i>	10043220 Current
To PT	<i>Joint dislocation</i>		To PT <i>Joint dislocation</i>	10023204

MSSO
Comment:

CR Number: 2023299002 Implementation Date: 29-Nov-23 Related CR: 2023299002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	Demote a PT <i>Temporomandibular joint syndrome</i>	Rejected After Suspension		
To PT	<i>Temporomandibular disorders</i>			

MSSO
Comment: The proposal to demote the PT Temporomandibular joint syndrome under PT Temporomandibular disorders is not approved after suspension. This is a technical rejection as the proposed PT Temporomandibular disorders, submitted in change request 2023299001, was not approved.

CR Number: 2023299003 Implementation Date: 29-Nov-23 Related CR: 2023299003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Link (move) an LLT to another PT <i>Jaw dislocation</i>	Rejected After Suspension		
From PT	<i>Joint dislocation</i>			
To PT	<i>Temporomandibular disorders</i>			

MSSO
Comment: The proposal to move the LLT Jaw dislocation from PT Joint dislocation to PT Temporomandibular disorders is not approved after suspension. This is a technical rejection as the proposed PT Temporomandibular disorders, submitted in change request 2023299001, was not approved.

Supplemental Update Report

CR Number: 2023299004 **Implementation Date:** 29-Nov-23 **Related CR:** 2023299004

[Change Requested](#) Link (move) an LLT to another PT [Final Disposition](#) [Final Placement](#)

[MedDRA
Code #](#)

Proposed LLT *Dislocated jaw* Rejected After Suspension
From PT *Joint dislocation*
To PT *Temporomandibular disorders*

MSSO Comment: The proposal to move the LLT Dislocated jaw from PT Joint dislocation to PT Temporomandibular disorders is not approved after suspension. This is a technical rejection as the proposed PT Temporomandibular disorders, submitted in change request 2023299001, was not approved.

CR Number: 2023299005 **Implementation Date:** 29-Nov-23 **Related CR:** 2023299005

[Change Requested](#) Link (move) an LLT to another PT [Final Disposition](#) [Final Placement](#)

[MedDRA
Code #](#)

Proposed LLT *Closed dislocation of jaw* Rejected After Suspension
From PT *Joint dislocation*
To PT *Temporomandibular disorders*

MSSO Comment: The proposal to move the LLT Closed dislocation of jaw from PT Joint dislocation to PT Temporomandibular disorders is not approved after suspension. This is a technical rejection as the proposed PT Temporomandibular disorders, submitted in change request 2023299001, was not approved.

CR Number: 2023299006 **Implementation Date:** 29-Nov-23 **Related CR:** 2023299006

[Change Requested](#) Link (move) an LLT to another PT [Final Disposition](#) [Final Placement](#)

[MedDRA
Code #](#)

Proposed LLT *Dislocation of jaw* Rejected After Suspension
From PT *Joint dislocation*
To PT *Temporomandibular disorders*

MSSO Comment: The proposal to move the LLT Dislocation of jaw from PT Joint dislocation to PT Temporomandibular disorders is not approved after suspension. This is a technical rejection as the proposed PT Temporomandibular disorders, submitted in change request 2023299001, was not approved.

Supplemental Update Report

CR Number: 2023299007 **Implementation Date:** 29-Nov-23 **Related CR:** 2023299007

[Change Requested](#) Link (move) an LLT to another PT [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed LLT *Joint dislocation temporomandib* Rejected After Suspension
From PT *Joint dislocation*
To PT *Temporomandibular disorders*

MSSO Comment: The proposal to move the LLT Joint dislocation temporomandib from PT Joint dislocation to PT Temporomandibular disorders is not approved after suspension. This is a technical rejection as the proposed PT Temporomandibular disorders, submitted in change request 2023299001, was not approved.

CR Number: 2023299008 **Implementation Date:** 29-Nov-23 **Related CR:** 2023299008

[Change Requested](#) Link (move) an LLT to another PT [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed LLT *Simple dislocation of jaw* Rejected After Suspension
From PT *Joint dislocation*
To PT *Temporomandibular disorders*

MSSO Comment: The proposal to move the LLT Simple dislocation of jaw from PT Joint dislocation to PT Temporomandibular disorders is not approved after suspension. This is a technical rejection as the proposed PT Temporomandibular disorders, submitted in change request 2023299001, was not approved.

CR Number: 2023299009 **Implementation Date:** 29-Nov-23 **Related CR:** 2023299009

[Change Requested](#) Link (move) an LLT to another PT [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed LLT *Open dislocation of jaw* Rejected After Suspension
From PT *Joint dislocation*
To PT *Temporomandibular disorders*

MSSO Comment: The proposal to move the LLT Open dislocation of jaw from PT Joint dislocation to PT Temporomandibular disorders is not approved after suspension. This is a technical rejection as the proposed PT Temporomandibular disorders, submitted in change request 2023299001, was not approved.

Supplemental Update Report

CR Number: 2023299010 **Implementation Date:** 29-Nov-23 **Related CR:** 2023299010

[Change Requested](#) Link (move) an LLT to another PT [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed LLT *Compound dislocation of jaw* Rejected After Suspension
From PT *Joint dislocation*
To PT *Temporomandibular disorders*

MSSO Comment: The proposal to move the LLT Compound dislocation of jaw from PT Joint dislocation to PT Temporomandibular disorders is not approved after suspension. This is a technical rejection as the proposed PT Temporomandibular disorders, submitted in change request 2023299001, was not approved.

CR Number: 2023299011 **Implementation Date:** 29-Nov-23 **Related CR:** 2023299011

[Change Requested](#) Link (move) an LLT to another PT [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed LLT *Subluxation jaw* Rejected After Suspension
From PT *Joint dislocation*
To PT *Temporomandibular disorders*

MSSO Comment: The proposal to move the LLT Subluxation jaw from PT Joint dislocation to PT Temporomandibular disorders is not approved after suspension. This is a technical rejection as the proposed PT Temporomandibular disorders, submitted in change request 2023299001, was not approved.

CR Number: 2023299012 **Implementation Date:** 01-Nov-23 **Related CR:** 2023299012

[Change Requested](#) Add a New LLT [Final Disposition](#) [Final Placement](#) [MedDRA Code #](#)

Proposed LLT *Transoral incisionless fundoplication (TIF)* Approved Not as Requested Proposed LLT
To PT *fundoplication* *Transoral incisionless fundoplication* 10090391 Current
To PT *Oesophagogastric fundoplasty* 10048852

MSSO Comment: The proposal to add a new LLT Transoral incisionless fundoplication (TIF) to PT fundoplication is approved but not as requested. Transoral incisionless fundoplication is a minimally invasive surgical procedure used to treat gastroesophageal reflux disease. Transoral incisionless fundoplication (TIF) will be modified according to the MedDRA term naming conventions and added as LLT Transoral incisionless fundoplication to PT Oesophagogastric fundoplasty.

Supplemental Update Report

CR Number: 2023299013 **Implementation Date:** 01-Nov-23 **Related CR:** 2023299013

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Removal of scrotum</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Removal of scrotum is not approved. The requested term can be represented by the newly added PT Scrotectomy in change request 2023298010.

CR Number: 2023299014 **Implementation Date:** 01-Nov-23 **Related CR:** 2023299014

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Corporal injury</i>	Approved Not as Requested	Proposed PT <i>Corporal injury</i>	10090390
			HLT primary <i>Criminal activity</i>	10011391
			SOC primary <i>Social circumstances</i>	10041244

MSSO Comment: The proposal to add a new LLT Corporal injury is approved but not as requested. Corporal injury is defined as any willful and unlawful use of force or violence against another person that results in a traumatic condition. Corporal injury will be added as a PT to HLT Criminal activity.

CR Number: 2023300001 **Implementation Date:** 01-Nov-23 **Related CR:** 2023300001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Sugar allergy</i>	Rejected		
To PT	<i>Food allergy</i>			

MSSO Comment: The proposal to add a new LLT Sugar allergy to PT Food allergy is not approved. Allergies are typically immune system reactions to proteins found in certain foods, pollen, or other substances, and sugar itself is not a protein. However, some people may experience adverse reactions to foods or drinks that are high in sugar or contain certain types of sugars, but these reactions are not considered allergies.

Supplemental Update Report

CR Number: 2023300002 **Implementation Date:** 01-Nov-23 **Related CR:** 2023300002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Sugar intolerance</i>	Approved as Requested	Proposed LLT <i>Sugar intolerance</i>	10090398 Current
			To PT <i>Carbohydrate intolerance</i>	10071200

MSSO Comment: The proposal to add a new LLT Sugar intolerance is approved as requested. Sugar intolerance refers to difficulty digesting or absorbing certain sugars, leading to gastrointestinal symptoms. It is not an allergic reaction but rather a digestive issue. Sugar intolerance will be added as synonym LLT to PT Carbohydrate intolerance.

CR Number: 2023300003 **Implementation Date:** 01-Nov-23 **Related CR:** 2023300003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>EDEMAWEAR</i>	Rejected		

MSSO Comment: The proposal to add a new LLT EDEMAWEAR is not approved. EdemaWear is a trade name for compression garments. No tradenames are being added to MedDRA. Coding can be accomplished by choosing any appropriate LLT under PT Compression garment application.

CR Number: 2023300004 **Implementation Date:** 01-Nov-23 **Related CR:** 2023300004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Striated muscle autoantibody test</i>	Approved Not as Requested	Proposed PT <i>Striated muscle autoantibody test</i>	10090397
			HLT primary <i>Autoimmunity analyses</i>	10003828
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new LLT Striated muscle autoantibody test is approved but not as requested. Some myasthenia gravis patients have antibodies that bind in a cross-striational pattern to skeletal and heart muscle tissue sections. They were known as "striational antibodies." These autoantibodies recognize epitopes on skeletal muscle proteins including myosin, actin, actinin, and filamin. Striated muscle autoantibody test will be added as PT to HLT Autoimmunity analyses.

Supplemental Update Report

CR Number: 2023300005 Implementation Date: 01-Nov-23 Related CR: 2023300005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Gastrointestinal immunotoxicity</i>	Approved Not as Requested	Proposed PT <i>Immune-mediated gastrointestinal disorder</i>	10090395
			HLT primary <i>Gastrointestinal inflammatory disorders NEC</i>	10017921
			SOC primary <i>Gastrointestinal disorders</i>	10017947
			HLT secondary <i>Immune and associated conditions NEC</i>	10027682
			SOC secondary <i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new LLT Gastrointestinal immunotoxicity is approved but not as requested. Patients with advanced malignancies treated with immune checkpoint inhibitors are at increased risk for developing immune-related gastrointestinal complications. The requested term will be modified for naming consistency and added as PT Immune-mediated gastrointestinal disorder to primary HLT Gastrointestinal inflammatory disorders NEC and secondary HLT Immune and associated conditions NEC.

CR Number: 2023300006 Implementation Date: 01-Nov-23 Related CR: 2023300006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Potential immunotoxic pneumopathy</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Potential immunotoxic pneumopathy is not approved. The requested term may be represented by LLT Immune-mediated pneumonitis or PT Immune-mediated lung disease. Please note that MedDRA does not include diseases qualified with "potential".

CR Number: 2023300007 Implementation Date: 01-Nov-23 Related CR: 2023300007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Immune-mediated renal toxicity</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Immune-mediated renal toxicity is not approved. The requested term may be represented by LLT Immune-mediated nephropathy and PT Immune-mediated renal disorder.

Supplemental Update Report

CR Number: 2023300008	Implementation Date: 01-Nov-23	Related CR: 2023300008		MedDRA Code #
Change Requested		Final Disposition	Final Placement	
Proposed LLT	Add a New LLT <i>HMG CoA reductase antibodies serum</i>	Approved Not as Requested	Proposed PT <i>HMG CoA reductase antibody test</i>	10090396
			HLT primary <i>Autoimmunity analyses</i>	10003828
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new LLT HMG CoA reductase antibodies serum is approved but not as requested. Anti-hydroxy-methyl-glutaryl-coenzyme A reductase (HMGCR) antibody-associated myopathy is a recognised form of immune-mediated necrotising myopathy. The requested term will be modified for clarity and without indicating the specimen "serum" and added as PT HMG CoA reductase antibody test to HLT Autoimmunity analyses.

CR Number: 2023300009	Implementation Date: 01-Nov-23	Related CR: 2023300009		MedDRA Code #
Change Requested		Final Disposition	Final Placement	
Proposed LLT	Add a New LLT <i>Post herpetic pruritus</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Post herpetic pruritus is not approved. The requested term is represented by LLT Postherpetic pruritus.

CR Number: 2023300010	Implementation Date: 01-Nov-23	Related CR: 2023300010		MedDRA Code #
Change Requested		Final Disposition	Final Placement	
Proposed PT	Add a New PT <i>Foreign body ear lobe</i>	Approved Not as Requested	Proposed LLT <i>Foreign body ear lobe</i>	10090399 Current
			To PT <i>Foreign body in ear</i>	10017010

MSSO Comment: The proposal to add a new PT Foreign body ear lobe is approved but not as requested. Earrings or posts may become embedded in a piercing site due to swelling, skin ischemia or inflammation, along with penetration of a portion or the entire object into the pinna. Foreign body ear lobe will be added as LLT to the PT Foreign body in ear.

Supplemental Update Report

CR Number: 2023304001 **Implementation Date:** 09-Nov-23 **Related CR:** 2023304001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Hyperargininaemia</i>	Rejected		

MSSO Comment: The proposal to add a new term Hyperargininaemia is not approved. Hyperargininaemia is associated with Arginase I deficiency and often used synonymously and therefore will stay as an LLT under PT Arginase deficiency. However, to provide an investigation term new LLT Arginine level increased will be added to PT Amino acid level increased.

CR Number: 2023313032 **Implementation Date:** 09-Nov-23 **Related CR:** 2023304001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Arginine level increased</i>	Approved as Requested	Proposed LLT	
To PT	<i>Amino acid level increased</i>		<i>Arginine level increased</i>	10090400 Current
			To PT	
			<i>Amino acid level increased</i>	10063259

MSSO Comment:

CR Number: 2023304002 **Implementation Date:** 09-Nov-23 **Related CR:** 2023304002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Hypodynamia</i>	Approved as Requested	Proposed LLT	
			<i>Hypodynamia</i>	10090401 Current
			To PT	
			<i>Asthenia</i>	10003549

MSSO Comment: The proposal to add a new term Hypodynamia is approved as requested. Hypodynamia will be added as synonym LLT of LLT Adynamia to PT Asthenia.

Supplemental Update Report

CR Number: 2023304003 **Implementation Date:** 09-Nov-23 **Related CR:** 2023304003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Wooden chest syndrome	Approved as Requested	Proposed LLT Wooden chest syndrome	10090405 Current
			To PT Chest wall rigidity	10090402

MSSO Comment: The proposal to add a new LLT Wooden chest syndrome is approved as requested. Wooden chest syndrome refers to opioid-induced chest wall rigidity, occurring as a complication of administering high doses of opioids during anaesthesia. Wooden chest syndrome will be added as a synonym LLT to PT Chest wall rigidity, added in change request 2023304005.

CR Number: 2023304004 **Implementation Date:** 09-Nov-23 **Related CR:** 2023304004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Chest wall rigidity	Rejected		

MSSO Comment: The proposal to add a new LLT Chest wall rigidity is not approved. Every MedDRA PT is replicated at the LLT level, therefore, the proposed term will automatically be added in change request 2023304005, where this very same concept is added as PT.

Supplemental Update Report

CR Number: 2023304005 Implementation Date: 09-Nov-23 Related CR: 2023304005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Chest wall rigidity</i>	Approved as Requested	Proposed PT <i>Chest wall rigidity</i>	10090402
			HLT primary <i>Musculoskeletal and connective tissue conditions NEC</i>	10080711
			SOC primary <i>Musculoskeletal and connective tissue disorders</i>	10028395
			HLT secondary <i>Thoracic musculoskeletal disorders</i>	10043475
			SOC secondary <i>Respiratory, thoracic and mediastinal disorders</i>	10038738

MSSO Comment: The proposal to add a new PT Chest wall rigidity is approved as requested. Chest wall rigidity is frequently caused by opioids, but also due to injuries with increased rigidity due to inflammation and muscle spasm, spine and rib cage deformities as well as rare genetic disorders. Chest wall rigidity will be added as a PT with a primary link to HLT Musculoskeletal and connective tissue conditions NEC, to secondary HLT Thoracic musculoskeletal disorders and to secondary HLT Anaesthetic and allied procedural complications.

CR Number: 2023313033 Implementation Date: 09-Nov-23 Related CR: 2023304005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Chest wall rigidity</i>	Approved as Requested	Proposed PT <i>Chest wall rigidity</i>	10090402
To HLT	<i>Anaesthetic and allied procedural complications</i>		To HLT <i>Anaesthetic and allied procedural complications</i>	10080709

MSSO Comment:

Supplemental Update Report

CR Number: 2023304006	Implementation Date: 09-Nov-23	Related CR: 2023304006	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed LLT	<i>Diffuse alveolar hemorrhage</i>	Approved as Requested	Proposed LLT <i>Diffuse alveolar hemorrhage</i> 10090406 Current To PT <i>Pulmonary alveolar haemorrhage</i> 10037313

MSSO Comment: The proposal to add a new LLT Diffuse alveolar hemorrhage is approved as requested. Diffuse alveolar hemorrhage is persistent or recurrent pulmonary hemorrhage that originates from the lung parenchyma (ie, the alveoli) as opposed to the airways. There are numerous causes, but autoimmune disorders are most common. Diffuse alveolar hemorrhage and the British spelled counterpart Diffuse alveolar haemorrhage will both be added as sub-concept LLTs to PT Pulmonary alveolar haemorrhage. In a related change, PT Pulmonary alveolar haemorrhage will be linked to HLT Immune and associated conditions NEC as it is often associated with immune diseases.

CR Number: 2023313034	Implementation Date: 09-Nov-23	Related CR: 2023304006	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed LLT	<i>Diffuse alveolar haemorrhage</i>	Approved as Requested	Proposed LLT <i>Diffuse alveolar haemorrhage</i> 10090404 Current To PT <i>Pulmonary alveolar haemorrhage</i> 10037313

MSSO Comment:

CR Number: 2023313035	Implementation Date: 09-Nov-23	Related CR: 2023304006	
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed PT	<i>Pulmonary alveolar haemorrhage</i>	Approved as Requested	Proposed PT <i>Pulmonary alveolar haemorrhage</i> 10037313 To HLT <i>Immune and associated conditions NEC</i> 10027682

MSSO Comment:

Supplemental Update Report

CR Number: 2023304007 Implementation Date: 09-Nov-23 Related CR: 2023304007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Disseminated enteroviral infection</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Disseminated enteroviral infection is not approved. Every MedDRA PT is replicated at the LLT level, and therefore, the proposed term will automatically be added in change request 2023304008, where this very same concept is added as PT.

CR Number: 2023304008 Implementation Date: 09-Nov-23 Related CR: 2023304008

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Disseminated enteroviral infection</i>	Approved as Requested	Proposed PT <i>Disseminated enteroviral infection</i>	10090403
			HLT primary <i>Enteroviral infections NEC</i>	10070971
			SOC primary <i>Infections and infestations</i>	10021881

MSSO Comment: The proposal to add a new PT Disseminated enteroviral infection is approved as requested. Antibodies are the main form of defense against enteroviruses, and severe, chronic, and disseminated enteroviral infections are generally limited to neonates, patients with profound B-cell deficiencies (XLA or hematopoietic stem cell transplantation), and certain lymphoma treatments with anti-CD 20 monoclonal antibodies. The clinical features described mostly relate to chronic meningoencephalitis but several reports describe a dermatomyositis-like syndrome with edema and hepatitis. Disseminated enteroviral infection will be added as PT to HLT Enteroviral infections NEC.

CR Number: 2023306001 Implementation Date: 09-Nov-23 Related CR: 2023306001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>VARK Analysis</i>	Rejected		
HLT primary	<i>Psychiatric investigations</i>			
SOC primary	<i>Investigations</i>			

MSSO Comment: The proposal to add a new PT VARK Analysis to primary HLT Psychiatric investigations in SOC Investigations is not approved. VARK is a test to gauge the learning style model of a normal person, and not a scale or score to measure psychiatric or neurocognitive pathological conditions. It is therefore out of the scope of MedDRA.

Supplemental Update Report

CR Number: 2023306002 Implementation Date: 09-Nov-23 Related CR: 2023306002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT			
HLT primary	Dental cone beam computerised tomography	Approved Not as Requested	Proposed LLT	
SOC primary	Gastrointestinal and abdominal imaging procedures		Dental cone beam computerised tomography	10090409 Current
	Investigations		To PT	
			Computerised tomogram dental	10090407

MSSO Comment: The proposal to add a new PT Dental cone beam computerised tomography to primary HLT Gastrointestinal and abdominal imaging procedures in SOC Investigations is approved but not as requested. Dental cone beam computed tomography is a special type of x-ray equipment used when regular dental or facial x-rays are not sufficient. This technology produces three dimensional (3-D) images of the teeth, soft tissues, nerve pathways and bone in a single scan. Dental cone beam computerised tomography and the American spelled counterpart Dental cone beam computerized tomography will both be added as sub-concept LLTs to a new PT Computerised tomogram dental. In a related change, PT Computerised tomogram dental will be added under HLT Gastrointestinal and abdominal imaging procedures. In addition, the American spelled counterpart LLT Computerized tomogram dental will also be added under the new PT Computerised tomogram dental.

CR Number: 2023313036 Implementation Date: 09-Nov-23 Related CR: 2023306002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT			
To PT	Dental cone beam computerized tomography	Approved as Requested	Proposed LLT	
	Computerised tomogram dental		Dental cone beam computerized tomography	10090411 Current
			To PT	
			Computerised tomogram dental	10090407

MSSO Comment:

CR Number: 2023313037 Implementation Date: 09-Nov-23 Related CR: 2023306002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT			
HLT primary	Computerised tomogram dental	Approved as Requested	Proposed PT	
SOC primary	Gastrointestinal and abdominal imaging procedures		Computerised tomogram dental	10090407
	Investigations		HLT primary	
			Gastrointestinal and abdominal imaging procedures	10017963
			SOC primary	
			Investigations	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2023313038 **Implementation Date:** 09-Nov-23 **Related CR:** 2023306002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Computerized tomogram dental</i>	Approved as Requested	Proposed LLT <i>Computerized tomogram dental</i>	10090410 Current
To PT	<i>Computerised tomogram dental</i>		To PT <i>Computerised tomogram dental</i>	10090407

MSSO
Comment:

CR Number: 2023306003 **Implementation Date:** 09-Nov-23 **Related CR:** 2023306003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Actinic cystitis</i>	Approved as Requested	Proposed LLT <i>Actinic cystitis</i>	10090408 Current
To PT	<i>Cystitis radiation</i>		To PT <i>Cystitis radiation</i>	10011800

MSSO
Comment: The proposal to add a new LLT Actinic cystitis to PT Cystitis radiation is approved as requested. Actinic cystitis is the manifestation of symptoms and signs caused by a chronic inflammatory process within the bladder following pelvic radiotherapy.

CR Number: 2023307001 **Implementation Date:** 09-Nov-23 **Related CR:** 2023307001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Add a New PT <i>Axonal sensorimotor polyradiculoneuropathy</i>	Approved Not as Requested	Proposed LLT <i>Axonal sensorimotor polyradiculoneuropathy</i>	10090412 Current
			To PT <i>Axonal neuropathy</i>	10003882

MSSO
Comment: The proposal to add a new PT Axonal sensorimotor polyradiculoneuropathy is approved but not as requested. Causes of axonal sensorimotor neuropathy may be metabolic, toxic, nutritional, iatrogenic, infectious, immune-mediated, vascular, neoplastic, paraneoplastic, and genetic. Axonal sensorimotor polyradiculoneuropathy will be added as LLT to PT Axonal neuropathy.

Supplemental Update Report

CR Number: 2023307002	Implementation Date: 15-Nov-23	Related CR: 2023307002		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Non-pontine diffuse midline glioma H3K27-altered</i>	Approved as Requested	Proposed LLT <i>Non-pontine diffuse midline glioma H3K27-altered</i>	10090421 Current
			To PT <i>Brain stem glioma</i>	10006143
MSSO Comment:	The proposal to add a new term Non-pontine diffuse midline glioma H3K27-altered is approved as requested. Compared with non-pontine diffuse midline glioma, diffuse intrinsic pontine glioma is better correlated with pontine size and T2-weighted fluid-attenuated inversion recovery (T2-FLAIR) measurements. Although the pons is the most common location, H3 K27-altered gliomas also occur in the thalamus, spinal cord, and other midline sites and can affect both children and adults. Non-pontine diffuse midline glioma H3K27-altered will be added as sub-concept LLT under PT Brain stem glioma.			

CR Number: 2023309001	Implementation Date: 09-Nov-23	Related CR: 2023309001		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>CT scan-guided lung biopsy</i>	Approved as Requested	Proposed LLT <i>CT scan-guided lung biopsy</i>	10090413 Current
			To PT <i>Biopsy lung</i>	10004794
MSSO Comment:	The proposal to add a new term CT scan-guided lung biopsy is approved as requested. CT-guided lung biopsy is a minimally invasive and established method for the diagnosis mainly used for lung lesions with diagnostic failure by transbronchial examination, which often are present in peripheral areas of the lungs. CT scan-guided lung biopsy will be added as LLT to PT Biopsy lung.			

CR Number: 2023310001	Implementation Date: 09-Nov-23	Related CR: 2023310001		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Pruritic Erythema</i>	Approved Not as Requested	Proposed LLT <i>Pruritic erythema</i>	10090414 Current
			To PT <i>Erythema</i>	10015150
MSSO Comment:	The proposal to add a new term Pruritic Erythema is approved but not as requested. Although the proposed term is a combination of two existing concepts in MedDRA, the association of pruritus and erythema is a particularly frequent description in clinical dermatology. For instance, it is one of the main manifestation of atopic dermatitis, which is characterized by pruritic, erythematous, and scaly lesions often located on the flexor surfaces. Pruritic erythema will be modified in accordance with MedDRA capitalization conventions and added as LLT Pruritic erythema under PT Erythema.			

Supplemental Update Report

CR Number: 2023310004 **Implementation Date:** 09-Nov-23 **Related CR:** 2023310004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Hip osteoarthritis</i>	Approved as Requested	Proposed LLT	
To PT	<i>Osteoarthritis</i>		<i>Hip osteoarthritis</i>	10090417 Current
			To PT	
			<i>Osteoarthritis</i>	10031161

MSSO Comment: The proposal to add a new LLT Hip osteoarthritis to PT Osteoarthritis is approved as requested. The singular form of concept will be added as LLT Hip osteoarthritis under PT Osteoarthritis to complement existing "plural" form of concept LLT Hips osteoarthritis.

CR Number: 2023310005 **Implementation Date:** 09-Nov-23 **Related CR:** 2023310005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Infected spider bite</i>	Rejected		
To PT	<i>Infected bite</i>			

MSSO Comment: The proposal to add a new LLT Infected spider bite to PT Infected bite is not approved. It is not possible to have a combination term for every possible type of bite which becomes infected. Please consider selection of two existing LLTs in combination to capture the reported concept.

CR Number: 2023310006 **Implementation Date:** 15-Nov-23 **Related CR:** 2023310006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Radiation pneumonia</i>	Rejected		
To PT	<i>Radiation pneumonitis</i>			

MSSO Comment: The proposal to add a new LLT Radiation pneumonia to PT Radiation pneumonitis is not approved. Radiation pneumonia is rarely found in medical literature. Please consider to represent the requested term with either of existing LLTs such as LLT Radiation pneumonitis, LLT Radiation fibrosis - lung, LLT Pulmonary radiation injury. Radiation-induced lung injury encompasses any lung toxicity induced by radiation therapy and manifests acutely as radiation pneumonitis and chronically as radiation pulmonary fibrosis.

Supplemental Update Report

CR Number: 2023311001 **Implementation Date:** 09-Nov-23 **Related CR:** 2023311001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Rheumatic arthritis acute</i>	Approved as Requested	Proposed LLT	
From PT	<i>Rheumatoid arthritis</i>		<i>Rheumatic arthritis acute</i>	10075557 Current
To PT	<i>Rheumatic fever</i>		From PT	
			<i>Rheumatoid arthritis</i>	10039073
			To PT	
			<i>Rheumatic fever</i>	10039054

MSSO Comment: The proposal to move the LLT Rheumatic arthritis acute from PT Rheumatoid arthritis to PT Rheumatic fever is approved as requested for better alignment. Acute rheumatic arthritis is defined as joint tenderness and swelling due to rheumatic fever.

CR Number: 2023311002 **Implementation Date:** 09-Nov-23 **Related CR:** 2023311002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Stilling-Turk-Duane Syndrome</i>	Approved Not as Requested	Proposed LLT	
			<i>Stilling-Turk-Duane syndrome</i>	10090416 Current
			To PT	
			<i>Duane's syndrome</i>	10013799

MSSO Comment: The proposal to add a new LLT Stilling-Turk-Duane Syndrome is approved but not as requested. The requested term will be modified according to MedDRA capitalisation conventions and added as synonym LLT Stilling-Turk-Duane syndrome to PT Duane's syndrome. In a related change, PT Duane's syndrome will change from the existing HLT Congenital eye disorders NEC to HLT Ocular nerve and muscle disorders for better alignment in relation with strabismus.

CR Number: 2023313039 **Implementation Date:** 09-Nov-23 **Related CR:** 2023311002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Duane's syndrome</i>	Approved as Requested	Proposed PT	
From HLT	<i>Congenital eye disorders NEC</i>		<i>Duane's syndrome</i>	10013799
To HLT	<i>Ocular nerve and muscle disorders</i>		From HLT	
			<i>Congenital eye disorders NEC</i>	10010464
			To HLT	
			<i>Ocular nerve and muscle disorders</i>	10030059

MSSO Comment:

Supplemental Update Report

CR Number: 2023311003 **Implementation Date:** 09-Nov-23 **Related CR:** 2023311003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Duane Retraction Syndrome</i>	Approved Not as Requested	Proposed LLT <i>Duane's retraction syndrome</i>	10090415 Current
			To PT <i>Duane's syndrome</i>	10013799

MSSO Comment: The proposal to add a new LLT Duane Retraction Syndrome is approved but not as requested. The requested term will be modified according to MedDRA capitalisation conventions and and with apostrophe and added as synonym LLT Duane's retraction syndrome to PT Duane's syndrome.

CR Number: 2023311004 **Implementation Date:** 09-Nov-23 **Related CR:** 2023311004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Congenital and non-progressive strabismus syndrome</i>	Rejected		
To PT	<i>Duane's syndrome</i>			

MSSO Comment: The proposal to add a new LLT Congenital and non-progressive strabismus syndrome to PT Duane's syndrome is not approved as it only provides the clinical description of the syndrome.

CR Number: 2023311005 **Implementation Date:** 09-Nov-23 **Related CR:** 2023311005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term <i>Enterococcus avium test positive</i>	Approved as Requested	Proposed LLT <i>Enterococcus avium test positive</i>	10090418 Current
			To PT <i>Enterococcus test positive</i>	10070024

MSSO Comment: The proposal to add a new term Enterococcus avium test positive is approved as requested. Enterococcus avium, a species of Enterococcus, is most commonly found in birds. Rarely, it is also a cause of infection in humans. Enterococcus avium test positive will be added as sub-concept LLT to PT Enterococcus test positive.

Supplemental Update Report

CR Number: 2023311006 **Implementation Date:** 09-Nov-23 **Related CR:** 2023311006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Interdigital mycosis</i>	Approved as Requested	Proposed LLT	10089134 Current
From PT	<i>Fungal infection</i>		<i>Interdigital mycosis</i>	
To PT	<i>Fungal foot infection</i>		From PT	
			<i>Fungal infection</i>	10017533
			To PT	
			<i>Fungal foot infection</i>	10067612

MSSO Comment: The proposal to move the LLT Interdigital mycosis from PT Fungal infection to PT Fungal foot infection is approved as requested. Upon review, LLT Interdigital mycosis is better placed under the more specific PT Fungal foot infection.

CR Number: 2023311007 **Implementation Date:** 09-Nov-23 **Related CR:** 2023311007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Pyriform aperture stenosis</i>	Approved as Requested	Proposed PT	10089480
To HLT	<i>Congenital upper respiratory tract disorders</i>		<i>Pyriform aperture stenosis</i>	
			To HLT	
			<i>Congenital upper respiratory tract disorders</i>	10046303

MSSO Comment: The proposal to link the PT Pyriform aperture stenosis to the HLT Congenital upper respiratory tract disorders is approved as requested. Based upon a review, an additional link to HLT Congenital upper respiratory tract disorders in SOC Respiratory, thoracic and mediastinal disorders is warranted to improve the representation of PT Pyriform aperture stenosis in MedDRA.

CR Number: 2023311008 **Implementation Date:** 09-Nov-23 **Related CR:** 2023311008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Head and neck plastic surgery</i>	Approved as Requested	Proposed PT	10090419
HLT primary	<i>Head, neck and oral cavity therapeutic procedures NEC</i>		<i>Head and neck plastic surgery</i>	
SOC primary	<i>Surgical and medical procedures</i>		HLT primary	
			<i>Head, neck and oral cavity therapeutic procedures NEC</i>	10052723
			SOC primary	
			<i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new PT Head and neck plastic surgery to primary HLT Head, neck and oral cavity therapeutic procedures NEC in SOC Surgical and medical procedures is approved as requested. Upon review, the MSSO proposes to add a new PT Head and neck plastic surgery to HLT Head, neck and oral cavity therapeutic procedures NEC, demote existing PT Neck plastic surgery and move LLT Temporalis myofascial flap to new PT Head and neck plastic surgery. These changes are proposed to improve the placement and alignment of these concepts in MedDRA. See the next two change requests (CR) for the demotion of PT Neck plastic surgery (CR 2023311009) and move LLT Temporalis myofascial flap (CR 2023311010).

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CR Number: 2023311009 Implementation Date: 09-Nov-23 Related CR: 2023311009

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Demote a PT				
PT to merge	Neck plastic surgery	Approved as Requested	PT to merge	
To PT	Head and neck plastic surgery		Neck plastic surgery	10071766 Current
			To PT	
			Head and neck plastic surgery	10090419

MSSO Comment: The proposal to demote the PT Neck plastic surgery under PT Head and neck plastic surgery is approved as requested. To improve the placement of PT Neck plastic surgery, this PT will be demoted to new PT Head and neck plastic surgery. See the change request 2023311008 for the addition of new PT Head and neck plastic surgery.

CR Number: 2023311010 Implementation Date: 09-Nov-23 Related CR: 2023311010

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Link (move) an LLT to another PT				
Proposed LLT	Temporalis myofascial flap	Approved as Requested	Proposed LLT	
From PT	Muscle flap operation		Temporalis myofascial flap	10089474 Current
To PT	Head and neck plastic surgery		From PT	
			Muscle flap operation	10066878
			To PT	
			Head and neck plastic surgery	10090419

MSSO Comment: The proposal to move the LLT Temporalis myofascial flap from PT Muscle flap operation to PT Head and neck plastic surgery is approved as requested. To improve the placement of LLT Temporalis myofascial flap, it will be moved to new PT Head and neck plastic surgery. See change request 2023311008 for the addition of new PT Head and neck plastic surgery.

CR Number: 2023311011 Implementation Date: 09-Nov-23 Related CR: 2023311011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Change Status of LLT				
LLT to change	RCL infection	Approved as Requested	LLT to change	
Status	non-current		RCL infection	10089815 Non-Current
			Status	
			non-current	

MSSO Comment: The proposal to change status of LLT RCL infection to non-current is approved as requested. While the LLT RCL infection ends with the word "infection" which helps provide more clarity to the concept, RCL also may stand for "Recurrent Cutaneous Leishmaniasis". Therefore, after consideration, the MSSO will change the status LLT RCL infection to non-current to avoid confusion.

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CR Number: 2023312001 **Implementation Date:** 15-Nov-23 **Related CR:** 2023312001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Percutaneous transluminal angioplasty of arteriovenous fistula</i>	Approved as Requested	Proposed LLT <i>Percutaneous transluminal angioplasty of arteriovenous fistula</i>	10090422 Current
			To PT <i>Arteriovenous fistula operation</i>	10003190

MSSO Comment: The proposal to add a new term Percutaneous transluminal angioplasty of arteriovenous fistula is approved as requested. Percutaneous transluminal angioplasty of an arteriovenous fistula is a medical procedure used to treat stenosis or narrowing in the blood vessels that make up an arteriovenous fistula. Percutaneous transluminal angioplasty of arteriovenous fistula will be added as subconcept LLT to PT Arteriovenous fistula operation to align with LLT Arteriovenous fistula revision.

CR Number: 2023312002 **Implementation Date:** 15-Nov-23 **Related CR:** 2023312002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Juvenile hypertension</i>	Approved as Requested	Proposed LLT <i>Juvenile hypertension</i>	10090425 Current
			To PT <i>Hypertension</i>	10020772

MSSO Comment: The proposal to add a new LLT Juvenile hypertension is approved as requested. There is increasing evidence that adult hypertension has its antecedents during childhood as childhood blood pressure predicts adult blood pressure. Hypertension in childhood and adolescence may contribute to premature atherosclerosis and the early development of cardiovascular disease. Juvenile hypertension will be added as subconcept LLT under PT Hypertension. In a related change, Paediatric hypertension and the American English counterpart Pediatric hypertension will both be added as LLTs to PT Hypertension.

CR Number: 2023319017 **Implementation Date:** 15-Nov-23 **Related CR:** 2023312002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Paediatric hypertension</i>	Approved as Requested	Proposed LLT <i>Paediatric hypertension</i>	10090424 Current
To PT	<i>Hypertension</i>		To PT <i>Hypertension</i>	10020772

MSSO Comment:

Supplemental Update Report

CR Number: 2023319018	Implementation Date: 15-Nov-23	Related CR: 2023312002	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Pediatric hypertension</i>	Approved as Requested	Proposed LLT
To PT	<i>Hypertension</i>		<i>Pediatric hypertension</i>
			10090423 Current
			To PT
			<i>Hypertension</i>
			10020772

MSSO
Comment:

CR Number: 2023312003	Implementation Date: 29-Nov-23	Related CR: 2023312003	
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>
PT to merge	<i>Generalised resistance to thyroid hormone</i>	Approved as Requested	PT to merge
To PT	<i>Resistance to thyroid hormone</i>		<i>Generalised resistance to thyroid hormone</i>
			10018096 Current
			To PT
			<i>Resistance to thyroid hormone</i>
			10090554

MSSO
Comment: The proposal to demote the PT Generalised resistance to thyroid hormone under PT Resistance to thyroid hormone is approved as requested. Thyroid hormone resistance used to be classified on the basis of tissue resistance into pituitary, peripheral or generalised (which includes both pituitary and peripheral) types. Most recent literature classifies resistance to thyroid hormone (RTH) into RTH-beta; RTH-alpha and RTH of unknown etiology based on the underlying defect in thyroid hormone receptors. Please see change request 2023312012 for adding new PT Resistance to thyroid hormone.

CR Number: 2023312004	Implementation Date: 29-Nov-23	Related CR: 2023312004	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Peripheral resistance to thyroid hormone</i>	Approved as Requested	Proposed LLT
To PT	<i>Resistance to thyroid hormone</i>		<i>Peripheral resistance to thyroid hormone</i>
			10090565 Current
			To PT
			<i>Resistance to thyroid hormone</i>
			10090554

MSSO
Comment: The proposal to add a new LLT Peripheral resistance to thyroid hormone to PT Resistance to thyroid hormone is approved as requested. Thyroid hormone resistance used to be classified on the basis of tissue resistance into pituitary, peripheral or generalised (which includes both pituitary and peripheral) types. Currently, three forms are distinguished, in which resistance to hormonal action is due, respectively, to mutations in the gene that encodes the T3 TR nuclear receptor, to alterations in the cellular transport of T4 and T3, and to defects in the conversion of T4 to T3 mediated by deiodinases. Please see change request 2023312012 for adding new PT Resistance to thyroid hormone.

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CR Number: 2023312005 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Pituitary resistance to thyroid hormone</i>	Approved as Requested	Proposed LLT	
To PT	<i>Resistance to thyroid hormone</i>		<i>Pituitary resistance to thyroid hormone</i>	10090567 Current
			To PT	
			<i>Resistance to thyroid hormone</i>	10090554

MSSO Comment: The proposal to add a new LLT Pituitary resistance to thyroid hormone to PT Resistance to thyroid hormone is approved as requested. Thyroid hormone resistance used to be classified on the basis of tissue resistance into pituitary, peripheral or generalised (which includes both pituitary and peripheral) types. Most recent literature classifies resistance to thyroid hormone (RTH) into RTH-beta; RTH-alpha and RTH of unknown etiology based on the underlying defect in thyroid hormone receptors. Please see change request 2023312012 for adding new PT Resistance to thyroid hormone.

CR Number: 2023312006 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Isolated thyroid stimulating hormone deficiency</i>	Approved as Requested	Proposed LLT	
To PT	<i>Congenital hypothyroidism</i>		<i>Isolated thyroid stimulating hormone deficiency</i>	10090564 Current
			To PT	
			<i>Congenital hypothyroidism</i>	10010510

MSSO Comment: The proposal to add a new LLT Isolated thyroid stimulating hormone deficiency to PT Congenital hypothyroidism is approved as requested. Isolated thyroid stimulating hormone deficiency is a type of central congenital hypothyroidism, a permanent thyroid deficiency that is present from birth, characterised by low levels of thyroid hormones due to a deficiency in TSH synthesis.

CR Number: 2023312007 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Young-Simpson syndrome</i>	Rejected		
To HLT	<i>Intellectual disabilities</i>			

MSSO Comment: The proposal to link the PT Young-Simpson syndrome to the HLT Intellectual disabilities is not approved. See change request 2023312015 for the addition Young-Simpson syndrome along with all related secondary HLTs.

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CR Number: 2023312008 Implementation Date: 29-Nov-23 Related CR: 2023312008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Kocher-Debre-Semelaigne syndrome</i>	Rejected		
To HLT	<i>Musculoskeletal and connective tissue conditions NEC</i>			

MSSO Comment: The proposal to link the PT Kocher-Debre-Semelaigne syndrome to the HLT Musculoskeletal and connective tissue conditions NEC is not approved. See change request 2023312017 for the addition Kocher-Debre-Semelaigne syndrome along with all related secondary HLTs.

CR Number: 2023312009 Implementation Date: 29-Nov-23 Related CR: 2023312009

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Hoffmann syndrome</i>	Approved as Requested	Proposed LLT	
To PT	<i>Hypothyroid myopathy</i>		<i>Hoffmann syndrome</i>	10090563 Current
			To PT	
			<i>Hypothyroid myopathy</i>	10090562

MSSO Comment: The proposal to add a new LLT Hoffmann syndrome to PT Hypothyroid myopathy is approved as requested. Hoffmann syndrome is a specific and very rare form of hypothyroid myopathy occurring in individuals of long standing hypothyroidism in which proximal muscle weakness, muscle stiffness and pseudohypertrophy is seen. The etiology of pseudo hypertrophy in Hoffman's syndrome remains obscure and myopathy may be only clinical findings in these patients to indicate hypothyroidism - see change request 2023312018 for addition of new PT Hypothyroid myopathy.

CR Number: 2023312010 Implementation Date: 29-Nov-23 Related CR: 2023312010

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Gestational hyperthyroidism</i>	Rejected		
To HLT	<i>Metabolic disorders NEC</i>			

MSSO Comment: The proposal to link the PT Gestational hyperthyroidism to the HLT Metabolic disorders NEC is not approved. Please see change request 2023312019 for addition of Gestational hyperthyroidism including addition of all HLTs.

Supplemental Update Report

CR Number: 2023312011 Implementation Date: 29-Nov-23 Related CR: 2023312011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Gestational thyrotoxicosis</i>	Approved as Requested	Proposed LLT	
To PT	<i>Gestational hyperthyroidism</i>		<i>Gestational thyrotoxicosis</i>	10090566 Current
			To PT	
			<i>Gestational hyperthyroidism</i>	10090561

MSSO Comment: The proposal to add a new LLT Gestational thyrotoxicosis to PT Gestational hyperthyroidism is approved as requested. Gestational hyperthyroidism is a transient form of thyrotoxicosis caused by excessive stimulation of thyroid gland by hCG and usually limited to the first 12-16 weeks of pregnancy. PT Gestational hyperthyroidism will be added in change request 2023312019.

CR Number: 2023312012 Implementation Date: 29-Nov-23 Related CR: 2023312012

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Resistance to thyroid hormone</i>	Approved Not as Requested	Proposed PT	
HLT primary	<i>Thyroid disorders congenital</i>		<i>Resistance to thyroid hormone</i>	10090554
SOC primary	<i>Congenital, familial and genetic disorders</i>		HLT primary	
			<i>Thyroid disorders congenital</i>	10043711
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Thyroid disorders NEC</i>	10043712
			SOC secondary	
			<i>Endocrine disorders</i>	10014698

MSSO Comment: The proposal to add a new PT Resistance to thyroid hormone to primary HLT Thyroid disorders congenital in SOC Congenital, familial and genetic disorders and secondary HLT Thyroid hypofunction disorders in SOC Endocrine disorders is approved but not as requested. PT Resistance to thyroid hormone will be added to primary HLT Thyroid disorders congenital and to secondary HLT Thyroid disorders NEC as it may manifest as either hypo or hyper.

Supplemental Update Report

CR Number: 2023312013 Implementation Date: 29-Nov-23 Related CR: 2023312013

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Thyroid agenesis</i>	Approved as Requested	Proposed PT <i>Thyroid agenesis</i>	10090555
HLT primary	<i>Thyroid disorders congenital</i>		HLT primary <i>Thyroid disorders congenital</i>	10043711
SOC primary	<i>Congenital, familial and genetic disorders</i>		SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Thyroid disorders NEC</i>	10043712
			SOC secondary <i>Endocrine disorders</i>	10014698

MSSO Comment: The proposal to add a new PT Thyroid agenesis to primary HLT Thyroid disorders congenital in SOC Congenital, familial and genetic disorders and secondary HLT Thyroid disorders NEC in SOC Endocrine disorders is approved as requested. Thyroid agenesis (also called Athyreosis) is the complete absence of thyroid tissue and is present from birth.

CR Number: 2023312014 Implementation Date: 29-Nov-23 Related CR: 2023312014

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Resistance to thyrotropin releasing hormone</i>	Approved Not as Requested	Proposed PT <i>Resistance to thyrotropin releasing hormone</i>	10090558
HLT primary	<i>Thyroid disorders congenital</i>		HLT primary <i>Thyroid disorders congenital</i>	10043711
SOC primary	<i>Congenital, familial and genetic disorders</i>		SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Anterior pituitary hypofunction</i>	10002701
			SOC secondary <i>Endocrine disorders</i>	10014698

MSSO Comment: The proposal to add a new PT Resistance to thyrotropin releasing hormone to primary HLT Thyroid disorders congenital in SOC Congenital, familial and genetic disorders and secondary HLT Thyroid hypofunction disorders in SOC Endocrine disorders is approved but not as requested. Resistance to thyrotropin-releasing hormone (TRH) is a rare disorder that is transmitted as an autosomal recessive trait. It is due to an inactivating mutation in the TRH receptor. The patient with resistance to TRH presented with findings of central hypothyroidism: normal serum TSH, low thyroxine (T4) and triiodothyronine (T3) concentrations, and no serum TSH or prolactin responses to the administration of TRH. Resistance to thyrotropin releasing hormone will be added as a PT to primary HLT Thyroid disorders congenital and to secondary HLT Anterior pituitary hypofunction.

Supplemental Update Report

CR Number: 2023312015 Implementation Date: 29-Nov-23 Related CR: 2023312015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Young-Simpson syndrome</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Thyroid disorders congenital</i>		<i>Young-Simpson syndrome</i>	10090556
SOC primary	<i>Congenital, familial and genetic disorders</i>		HLT primary	
			<i>Thyroid disorders congenital</i>	10043711
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Thyroid hypofunction disorders</i>	10043741
			SOC secondary	
			<i>Endocrine disorders</i>	10014698

MSSO
 Comment: The proposal to add a new PT Young-Simpson syndrome to primary HLT Thyroid disorders congenital in SOC Congenital, familial and genetic disorders and secondary HLT Thyroid hypofunction disorders in SOC Endocrine disorders is approved as requested. This change request is part of the ICD-11 to MedDRA mapping initiative. Young-Simpson syndrome is characterised by the association of congenital hypothyroidism, facial dysmorphism (microcephaly, blepharophimosis, a bulbous nose, thin lip, low-set ears and micrognathia), postaxial polydactyly and severe intellectual deficit. Less than 20 cases have been reported so far. Cryptorchidism is present in affected males. Some patients also have cardiac anomalies (interventricular communication), hypotonia and growth delay. Autosomal recessive inheritance has been suggested. PT Young-Simpson syndrome will also be linked to secondary HLT Intellectual disabilities and to secondary HLT Musculoskeletal and connective tissue conditions NEC.

CR Number: 2023333094 Implementation Date: 29-Nov-23 Related CR: 2023312015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Young-Simpson syndrome</i>	Approved as Requested	Proposed PT	
To HLT	<i>Intellectual disabilities</i>		<i>Young-Simpson syndrome</i>	10090556
			To HLT	
			<i>Intellectual disabilities</i>	10077548

MSSO
 Comment:

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CR Number: 2023333095		Implementation Date: 29-Nov-23	Related CR: 2023312015	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Young-Simpson syndrome</i>	Approved as Requested	Proposed PT	
To HLT	<i>Musculoskeletal and connective tissue conditions NEC</i>		<i>Young-Simpson syndrome</i>	10090556
			To HLT	
			<i>Musculoskeletal and connective tissue conditions NEC</i>	10080711

MSSO
Comment:

CR Number: 2023312016		Implementation Date: 29-Nov-23	Related CR: 2023312016	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Bamforth-Lazarus syndrome</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Thyroid disorders congenital</i>		<i>Bamforth-Lazarus syndrome</i>	10090559
SOC primary	<i>Congenital, familial and genetic disorders</i>		HLT primary	
			<i>Thyroid disorders congenital</i>	10043711
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Thyroid hypofunction disorders</i>	10043741
			SOC secondary	
			<i>Endocrine disorders</i>	10014698

MSSO Comment: The proposal to add a new PT Bamforth-Lazarus syndrome to primary HLT Thyroid disorders congenital in SOC Congenital, familial and genetic disorders and secondary HLT Thyroid hypofunction disorders in SOC Endocrine disorders is approved as requested. Bamforth syndrome is a rare form of syndromic congenital hypothyroidism that associates athyreosis and cleft palate. PT Bamforth-Lazarus syndrome will also be linked to secondary HLT Cleft lip and cleft palate disorders.

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CR Number: 2023333096		Implementation Date: 29-Nov-23	Related CR: 2023312016	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Bamforth-Lazarus syndrome</i>	Approved as Requested	Proposed PT <i>Bamforth-Lazarus syndrome</i>	10090559
To HLT	<i>Cleft lip and cleft palate disorders</i>		To HLT <i>Cleft lip and cleft palate disorders</i>	10009261

MSSO
Comment:

CR Number: 2023312017		Implementation Date: 29-Nov-23	Related CR: 2023312017	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Kocher-Debre-Semelaigne syndrome</i>	Approved as Requested	Proposed PT <i>Kocher-Debre-Semelaigne syndrome</i>	10090560
HLT primary	<i>Thyroid disorders congenital</i>		HLT primary <i>Thyroid disorders congenital</i>	10043711
SOC primary	<i>Congenital, familial and genetic disorders</i>		SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Thyroid hypofunction disorders</i>	10043741
			SOC secondary <i>Endocrine disorders</i>	10014698

MSSO
Comment: The proposal to add a new PT Kocher-Debre-Semelaigne syndrome to primary HLT Thyroid disorders congenital in SOC Congenital, familial and genetic disorders and secondary HLT Thyroid hypofunction disorders in SOC Endocrine disorders is approved as requested. Kocher-Debre-Semelaigne syndrome is a myopathy of hypothyroidism in infancy or childhood characterised by lower extremity or generalised muscular hypertrophy, myxoedema, short stature and cretinism. PT Kocher-Debre-Semelaigne syndrome will also be linked to HLT Musculoskeletal and connective tissue conditions NEC.

Supplemental Update Report

CR Number: 202333097 Implementation Date: 29-Nov-23 Related CR: 2023312017

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Kocher-Debre-Semelaigne syndrome</i>	Approved as Requested	Proposed PT <i>Kocher-Debre-Semelaigne syndrome</i>	10090560
To HLT	<i>Musculoskeletal and connective tissue conditions NEC</i>		To HLT <i>Musculoskeletal and connective tissue conditions NEC</i>	10080711

MSSO
Comment:

CR Number: 2023312018 Implementation Date: 29-Nov-23 Related CR: 2023312018

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Hypothyroid myopathy</i>	Approved as Requested	Proposed PT <i>Hypothyroid myopathy</i>	10090562
HLT primary	<i>Myopathies</i>		HLT primary <i>Myopathies</i>	10028640
SOC primary	<i>Musculoskeletal and connective tissue disorders</i>		SOC primary <i>Musculoskeletal and connective tissue disorders</i>	10028395
			HLT secondary <i>Thyroid hypofunction disorders</i>	10043741
			SOC secondary <i>Endocrine disorders</i>	10014698

MSSO
Comment: The proposal to add a new PT Hypothyroid myopathy to primary HLT Myopathies in SOC Musculoskeletal and connective tissue disorders and secondary HLT Thyroid hypofunction disorders in SOC Endocrine disorders is approved as requested. Hypothyroid myopathy is a common clinical feature in patients with hypothyroidism affecting about 79% of patients. It is seen in both congenital and acquired hypothyroidism, and generalized myalgias and muscle weakness characterize it. Patients with severe or untreated hypothyroidism can develop significant muscle disease leading to severe functional limitations.

Supplemental Update Report

CR Number: 2023312019 Implementation Date: 29-Nov-23 Related CR: 2023312019

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Gestational hyperthyroidism</i>	Approved as Requested	Proposed PT <i>Gestational hyperthyroidism</i>	10090561
HLT primary	<i>Maternal complications of pregnancy NEC</i>		HLT primary <i>Maternal complications of pregnancy NEC</i>	10026909
SOC primary	<i>Pregnancy, puerperium and perinatal conditions</i>		SOC primary <i>Pregnancy, puerperium and perinatal conditions</i>	10036585
			HLT secondary <i>Thyroid hyperfunction disorders</i>	10043740
			SOC secondary <i>Endocrine disorders</i>	10014698

MSSO Comment: The proposal to add a new PT Gestational hyperthyroidism to primary HLT Maternal complications of pregnancy NEC in SOC Pregnancy, puerperium and perinatal conditions and secondary HLT Thyroid hyperfunction disorders in SOC Endocrine disorders is approved as requested. Gestational hyperthyroidism is a transient form of thyrotoxicosis caused by excessive stimulation of thyroid gland by hCG and usually limited to the first 12-16 weeks of pregnancy. PT Gestational hyperthyroidism will also be linked to secondary HLT Metabolic disorders NEC.

CR Number: 2023333098 Implementation Date: 29-Nov-23 Related CR: 2023312019

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Gestational hyperthyroidism</i>	Approved as Requested	Proposed PT <i>Gestational hyperthyroidism</i>	10090561
To HLT	<i>Metabolic disorders NEC</i>		To HLT <i>Metabolic disorders NEC</i>	10027428

MSSO Comment:

Supplemental Update Report

CR Number: 2023312020 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312020

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Thyroiditis bacterial</i>	Rejected		
HLT primary	<i>Bacterial infections NEC</i>			
SOC primary	<i>Infections and infestations</i>			

MSSO Comment: The proposal to add a new PT Thyroiditis bacterial to primary HLT Bacterial infections NEC in SOC Infections and infestations and secondary HLT Acute and chronic thyroiditis in SOC Endocrine disorders is not approved. Thyroiditis due to an infection is an extremely rare form of thyroiditis and may be represented by PT Infectious thyroiditis.

CR Number: 2023312021 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312021

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Thyroiditis fungal</i>	Rejected		
HLT primary	<i>Fungal infections NEC</i>			
SOC primary	<i>Infections and infestations</i>			

MSSO Comment: The proposal to add a new PT Thyroiditis fungal to primary HLT Fungal infections NEC in SOC Infections and infestations and secondary HLT Acute and chronic thyroiditis in SOC Endocrine disorders is not approved. Thyroiditis due to an infection is an extremely rare form of thyroiditis and may be represented by PT Infectious thyroiditis.

CR Number: 2023312022 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312022

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Thyrotropin releasing hormone deficiency</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Hypothalamic and pituitary disorders NEC</i>		<i>Thyrotropin releasing hormone deficiency</i>	10090557
SOC primary	<i>Endocrine disorders</i>		HLT primary	
			<i>Hypothalamic and pituitary disorders NEC</i>	10021109
			SOC primary	
			<i>Endocrine disorders</i>	10014698

MSSO Comment: The proposal to add a new PT Thyrotropin releasing hormone deficiency to primary HLT Hypothalamic and pituitary disorders NEC in SOC Endocrine disorders is approved as requested. Tertiary hypothyroidism is caused by thyrotropin-releasing hormone (TRH) deficiency. This can be caused by any disorder that damages the hypothalamus or interferes with hypothalamic-pituitary portal blood flow, thereby preventing delivery of TRH to the pituitary. It can also be caused by mutations in the gene for the TRH receptor. Like TSH deficiency, TRH deficiency can be isolated or occur in combination with other hormonal deficiencies. Hypothalamic damage results from tumors, trauma, radiation therapy, or infiltrative diseases.

Supplemental Update Report

CR Number: 2023312023 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312023

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Wolcott-Rallison syndrome</i>	Rejected		
To HLT	<i>Neonatal metabolic and endocrine disorders</i>			

MSSO Comment: The proposal to link the PT Wolcott-Rallison syndrome to the HLT Neonatal metabolic and endocrine disorders is not approved. See change request 2023312031 for the addition Wolcott-Rallison syndrome along with all related secondary HLTs.

CR Number: 2023312024 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312024

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Wolcott-Rallison syndrome</i>	Rejected		
To HLT	<i>Musculoskeletal and connective tissue conditions NEC</i>			

MSSO Comment: The proposal to link the PT Wolcott-Rallison syndrome to the HLT Musculoskeletal and connective tissue conditions NEC is not approved. See change request 2023312031 for the addition Wolcott-Rallison syndrome along with all related secondary HLTs.

CR Number: 2023312025 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312025

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Familial isolated hypoparathyroidism</i>	Rejected		
To HLT	<i>Hypoparathyroid disorders</i>			

MSSO Comment: The proposal to link the PT Familial isolated hypoparathyroidism to the HLT Hypoparathyroid disorders is not approved. See change request 2023312035 for the addition Familial isolated hypoparathyroidism along with all related secondary HLTs.

Supplemental Update Report

CR Number: 2023312026 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312026

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Pseudopseudohypoparathyroidism</i>	Rejected		
To HLT	<i>Intellectual disabilities</i>			

MSSO Comment: The proposal to link the PT Pseudopseudohypoparathyroidism to the HLT Intellectual disabilities is not approved. See change request 2023312034 for the addition Pseudopseudohypoparathyroidism along with all related secondary HLTs.

CR Number: 2023312027 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312027

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Familial parathyroid adenoma</i>	Rejected		
To HLT	<i>Parathyroid disorders NEC</i>			

MSSO Comment: The proposal to link the PT Familial parathyroid adenoma to the HLT Parathyroid disorders NEC is not approved. See change request 2023312035 for the addition Familial parathyroid adenoma along with all related secondary HLTs.

CR Number: 2023312028 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312028

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Hyperparathyroidism-jaw tumour syndrome</i>	Rejected		
To HLT	<i>Hyperparathyroid disorders</i>			

MSSO Comment: The proposal to link the PT Hyperparathyroidism-jaw tumour syndrome to the HLT Hyperparathyroid disorders is not approved. See change request 2023312036 for the addition Hyperparathyroidism-jaw tumour syndrome along with all related secondary HLTs.

Supplemental Update Report

CR Number: 2023312029 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312029

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Link a PT to a HLT <i>Hyperparathyroidism-jaw tumour syndrome</i>	Rejected		
To HLT	<i>Calcium metabolism disorder</i>			

MSSO Comment: The proposal to link the PT Hyperparathyroidism-jaw tumour syndrome to the HLT Calcium metabolism disorder is not approved. See change request 2023312036 for the addition Hyperparathyroidism-jaw tumour syndrome along with all related secondary HLTs.

CR Number: 2023312030 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312030

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Link a PT to a HLT <i>Hyperparathyroidism-jaw tumour syndrome</i>	Rejected		
To HLT	<i>Benign musculoskeletal and connective tissue neoplasms</i>			

MSSO Comment: The proposal to link the PT Hyperparathyroidism-jaw tumour syndrome to the HLT Benign musculoskeletal and connective tissue neoplasms is not approved. See change request 2023312036 for the addition Hyperparathyroidism-jaw tumour syndrome along with all related secondary HLTs.

CR Number: 2023312031 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312031

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Add a New PT <i>Wolcott-Rallison syndrome</i>	Approved as Requested	Proposed PT <i>Wolcott-Rallison syndrome</i>	10090582
HLT primary	<i>Endocrine disorders congenital NEC</i>		HLT primary <i>Endocrine disorders congenital NEC</i>	10027671
SOC primary	<i>Congenital, familial and genetic disorders</i>		SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Diabetes mellitus (incl subtypes)</i>	10012602
			SOC secondary <i>Endocrine disorders</i>	10014698

MSSO Comment: The proposal to add a new PT Wolcott-Rallison syndrome to primary HLT Endocrine disorders congenital NEC in SOC Congenital, familial and genetic disorders and secondary HLT Diabetes mellitus (incl subtypes) in SOC Endocrine disorders is approved as requested. Wolcott-Rallison syndrome (WRS) is a rare autosomal recessive disease, characterized by neonatal/early-onset non-autoimmune insulin-requiring diabetes associated with skeletal dysplasia and growth retardation. In a related change, New PT Wolcott-Rallison syndrome will also be linked to secondary HLT Neonatal metabolic and endocrine disorders and secondary HLT Musculoskeletal and connective tissue conditions NEC.

Supplemental Update Report

CR Number: 2023333122	Implementation Date: 29-Nov-23	Related CR: 2023312031		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Wolcott-Rallison syndrome</i>	Approved as Requested	Proposed PT	
To HLT	<i>Neonatal metabolic and endocrine disorders</i>		<i>Wolcott-Rallison syndrome</i>	10090582
			To HLT	
			<i>Neonatal metabolic and endocrine disorders</i>	10028961

MSSO
Comment:

CR Number: 2023333123	Implementation Date: 29-Nov-23	Related CR: 2023312031		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Wolcott-Rallison syndrome</i>	Approved as Requested	Proposed PT	
To HLT	<i>Musculoskeletal and connective tissue conditions NEC</i>		<i>Wolcott-Rallison syndrome</i>	10090582
			To HLT	
			<i>Musculoskeletal and connective tissue conditions NEC</i>	10080711

MSSO
Comment:

Supplemental Update Report

CR Number: 2023312032 Implementation Date: 29-Nov-23 Related CR: 2023312032

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Familial isolated hypoparathyroidism</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Endocrine disorders congenital NEC</i>		<i>Familial isolated hypoparathyroidism</i>	10090580
SOC primary	<i>Congenital, familial and genetic disorders</i>		HLT primary	
			<i>Endocrine disorders congenital NEC</i>	10027671
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Calcium metabolism disorders</i>	10006975
			SOC secondary	
			<i>Metabolism and nutrition disorders</i>	10027433

MSSO Comment: The proposal to add a new PT Familial isolated hypoparathyroidism to primary HLT Endocrine disorders congenital NEC in SOC Congenital, familial and genetic disorders and secondary HLT Calcium metabolism disorders in SOC Metabolism and nutrition disorders is approved as requested. Familial isolated hypoparathyroidism is a rare heterogeneous group of metabolic disorders characterised by abnormal calcium metabolism due to deficient secretion of parathormone (PTH), without other endocrine disorders or developmental defects, with autosomal dominant or recessive inheritance. In a related change, new PT Familial isolated hypoparathyroidism will also be linked to secondary HLT Hypoparathyroid disorders.

CR Number: 2023333128 Implementation Date: 29-Nov-23 Related CR: 2023312032

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Familial isolated hypoparathyroidism</i>	Approved as Requested	Proposed PT	
To HLT	<i>Hypoparathyroid disorders</i>		<i>Familial isolated hypoparathyroidism</i>	10090580
			To HLT	
			<i>Hypoparathyroid disorders</i>	10021040

MSSO Comment:

Supplemental Update Report

CR Number: 2023312033 Implementation Date: 29-Nov-23 Related CR: 2023312033

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Radiation hypoparathyroidism</i>	Approved as Requested	Proposed PT <i>Radiation hypoparathyroidism</i>	10090581
HLT primary	<i>Radiation injuries</i>		HLT primary <i>Radiation injuries</i>	10037759
SOC primary	<i>Injury, poisoning and procedural complications</i>		SOC primary <i>Injury, poisoning and procedural complications</i>	10022117
			HLT secondary <i>Hypoparathyroid disorders</i>	10021040
			SOC secondary <i>Endocrine disorders</i>	10014698

MSSO Comment: The proposal to add a new PT Radiation hypoparathyroidism to primary HLT Radiation injuries in SOC Injury, poisoning and procedural complications and secondary HLT Hypoparathyroid disorders in SOC Endocrine disorders is approved as requested. Radiation hypoparathyroidism refers to a decreased function of the parathyroid glands with underproduction of parathyroid hormone due to external radiation. In a related change, PT Radiation hypoparathyroidism will also be linked to secondary HLT Calcium metabolism disorders.

CR Number: 2023333124 Implementation Date: 29-Nov-23 Related CR: 2023312033

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Radiation hypoparathyroidism</i>	Approved as Requested	Proposed PT <i>Radiation hypoparathyroidism</i>	10090581
To HLT	<i>Calcium metabolism disorders</i>		To HLT <i>Calcium metabolism disorders</i>	10006975

MSSO Comment:

Supplemental Update Report

CR Number: 2023312034 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312034

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Pseudopseudohypoparathyroidism</i>	Approved Not as Requested	Proposed LLT	
HLT primary	<i>Endocrine disorders congenital NEC</i>		<i>Pseudopseudohypoparathyroidism</i>	10090584 Current
SOC primary	<i>Congenital, familial and genetic disorders</i>		To PT	
			<i>Pseudohypoparathyroidism</i>	10037126

MSSO Comment: The proposal to add a new PT Pseudopseudohypoparathyroidism to primary HLT Endocrine disorders congenital NEC in SOC Congenital, familial and genetic disorders and secondary HLT Musculoskeletal and connective tissue conditions NEC in SOC Musculoskeletal and connective tissue disorders is approved but not as requested. Pseudopseudohypoparathyroidism is a variant of pseudohypoparathyroidism type 1 and will be added as an LLT to PT Pseudohypoparathyroidism.

CR Number: 2023312035 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312035

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Familial parathyroid adenoma</i>	Approved Not as Requested	Proposed LLT	
HLT primary	<i>Endocrine disorders congenital NEC</i>		<i>Familial parathyroid adenoma</i>	10090583 Current
SOC primary	<i>Congenital, familial and genetic disorders</i>		To PT	
			<i>Familial isolated hyperparathyroidism</i>	10080773

MSSO Comment: The proposal to add a new PT Familial parathyroid adenoma to primary HLT Endocrine disorders congenital NEC in SOC Congenital, familial and genetic disorders and secondary HLT Endocrine neoplasms benign NEC in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved but not as requested. Familial parathyroid adenoma will be added as a sub-concept LLT to PT Familial isolated hyperparathyroidism. In a related change, PT Familial isolated hyperparathyroidism will also linked to secondary HLT Endocrine neoplasms benign NEC.

CR Number: 2023333125 **Implementation Date:** 29-Nov-23 **Related CR:** 2023312035

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Familial isolated hyperparathyroidism</i>	Approved as Requested	Proposed PT	
To HLT	<i>Endocrine neoplasms benign NEC</i>		<i>Familial isolated hyperparathyroidism</i>	10080773
			To HLT	
			<i>Endocrine neoplasms benign NEC</i>	10014711

MSSO Comment:

Supplemental Update Report

CR Number: 2023312036 Implementation Date: 29-Nov-23 Related CR: 2023312036

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Hyperparathyroidism-jaw tumour syndrome</i>	Approved Not as Requested	Proposed LLT	
HLT primary	<i>Endocrine disorders congenital NEC</i>		<i>Hyperparathyroidism-jaw tumour syndrome</i>	10090585 Current
SOC primary	<i>Congenital, familial and genetic disorders</i>		To PT	
			<i>Familial isolated hyperparathyroidism</i>	10080773

MSSO Comment: The proposal to add a new PT Hyperparathyroidism-jaw tumour syndrome to primary HLT Endocrine disorders congenital NEC in SOC Congenital, familial and genetic disorders and secondary HLT Endocrine neoplasms benign NEC in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved but not as requested. Hyperparathyroidism-jaw tumour syndrome and its American English spelled counterpart Hyperparathyroidism-jaw tumor syndrome will be both added as a sub-concept LLTs to PT Familial isolated hyperparathyroidism.

CR Number: 2023333126 Implementation Date: 29-Nov-23 Related CR: 2023312036

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Hyperparathyroidism-jaw tumor syndrome</i>	Approved as Requested	Proposed LLT	
To PT	<i>Familial isolated hyperparathyroidism</i>		<i>Hyperparathyroidism-jaw tumor syndrome</i>	10090586 Current
			To PT	
			<i>Familial isolated hyperparathyroidism</i>	10080773

MSSO Comment:

Supplemental Update Report

CR Number: 2023312037 Implementation Date: 29-Nov-23 Related CR: 2023312037

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Thyroid gangrene</i>	Approved as Requested	Proposed PT <i>Thyroid gangrene</i>	10090579
HLT primary	<i>Bacterial infections NEC</i>		HLT primary <i>Bacterial infections NEC</i>	10004047
SOC primary	<i>Infections and infestations</i>		SOC primary <i>Infections and infestations</i>	10021881
			HLT secondary <i>Thyroid disorders NEC</i>	10043712
			SOC secondary <i>Endocrine disorders</i>	10014698

MSSO Comment: The proposal to add a new PT Thyroid gangrene to primary HLT Bacterial infections NEC in SOC Infections and infestations and secondary HLT Thyroid disorders NEC in SOC Endocrine disorders is approved as requested. Thyroid gangrene refers to the death or necrosis of thyroid tissue. It is a rare and serious condition that can be caused by various factors, often related to impaired blood supply to the thyroid gland. PT Thyroid gangrene will also be linked to secondary HLT Site specific necrosis and vascular insufficiency NEC.

CR Number: 2023333127 Implementation Date: 29-Nov-23 Related CR: 2023312037

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Thyroid gangrene</i>	Approved as Requested	Proposed PT <i>Thyroid gangrene</i>	10090579
To HLT	<i>Site specific necrosis and vascular insufficiency NEC</i>		To HLT <i>Site specific necrosis and vascular insufficiency NEC</i>	10052781

MSSO Comment:

CR Number: 2023312038 Implementation Date: 15-Nov-23 Related CR: 2023312038

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Steroid-induced intraocular pressure increase</i>	Rejected		

MSSO Comment: The proposal to add a new term Steroid-induced intraocular pressure increase is not approved. The MSSO refrains from adding further drug induced terms to MedDRA.

Supplemental Update Report

CR Number: 2023312039 **Implementation Date:** 15-Nov-23 **Related CR:** 2023312039

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT	Approved Not as Requested	Proposed LLT	
HLT primary	<i>Transfusion dependent thalassemia beta</i>		<i>Transfusion dependent thalassemia beta</i>	10090437 Current
SOC primary	<i>Haemoglobinopathies congenital</i>		To PT	
	<i>Congenital, familial and genetic disorders</i>		<i>Thalassaemia beta</i>	10043391

MSSO Comment: The proposal to add a new PT Transfusion dependent thalassemia beta to primary HLT Haemoglobinopathies congenital in SOC Congenital, familial and genetic disorders and secondary HLT Thalassaemic disorders in SOC Blood and lymphatic system disorders is approved but not as requested. Beta-thalassemia and particularly its transfusion-dependent form is a demanding clinical condition, requiring life-long care and follow-up. Transfusion dependent thalassemia beta and the British spelled counterpart Transfusion dependent thalassaemia beta will both be added as LLTs to PT Thalassaemia beta.

CR Number: 2023319019 **Implementation Date:** 15-Nov-23 **Related CR:** 2023312039

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT	Approved as Requested	Proposed LLT	
To PT	<i>Transfusion dependent thalassaemia beta</i>		<i>Transfusion dependent thalassaemia beta</i>	10090438 Current
	<i>Thalassaemia beta</i>		To PT	
			<i>Thalassaemia beta</i>	10043391

MSSO Comment:

CR Number: 2023312040 **Implementation Date:** 15-Nov-23 **Related CR:** 2023312040

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT	Approved as Requested	Proposed PT	
HLT primary	<i>Delayed neutrophil engraftment</i>		<i>Delayed neutrophil engraftment</i>	10090434
SOC primary	<i>Transplantation complications</i>		HLT primary	
	<i>Injury, poisoning and procedural complications</i>		<i>Transplantation complications</i>	10074474
			SOC primary	
			<i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new PT Delayed neutrophil engraftment to primary HLT Transplantation complications in SOC Injury, poisoning and procedural complications is approved as requested. Delayed neutrophil engraftment is most commonly defined as the delay in the first of three consecutive days of achieving a sustained peripheral blood neutrophil count of >500 × 10⁶/L after a bone marrow transplantation.

Supplemental Update Report

CR Number: 2023312041 Implementation Date: 15-Nov-23 Related CR: 2023312041

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Neutrophil engraftment failure</i>	Approved as Requested	Proposed PT <i>Neutrophil engraftment failure</i>	10090431
HLT primary	<i>Transplantation complications</i>		HLT primary <i>Transplantation complications</i>	10074474
SOC primary	<i>Injury, poisoning and procedural complications</i>		SOC primary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new PT Neutrophil engraftment failure to primary HLT Transplantation complications in SOC Injury, poisoning and procedural complications is approved as requested. Neutrophil engraftment failure is defined as the lack of neutrophil engraftment following autologous or allogeneic stem cell transplantation. It is classically divided into primary - when there is no evidence of engraftment or hematological recovery of donor cells, within the first month after transplant- or secondary graft failure, which refers to the loss of a previously functioning graft. In a related change, LLT Failure to engraft neutrophils will be moved from PT Engraft failure to new PT Neutrophil engraftment failure for better alignment.

CR Number: 2023319020 Implementation Date: 15-Nov-23 Related CR: 2023312041

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Link (move) an LLT to another PT <i>Failure to engraft neutrophils</i>	Approved as Requested	Proposed LLT <i>Failure to engraft neutrophils</i>	10068083 Current
From PT	<i>Engraft failure</i>		From PT <i>Engraft failure</i>	10068081
To PT	<i>Neutrophil engraftment failure</i>		To PT <i>Neutrophil engraftment failure</i>	10090431

MSSO Comment:

Supplemental Update Report

CR Number: 2023312042 Implementation Date: 15-Nov-23 Related CR: 2023312042

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Delayed platelet engraftment</i>	Approved as Requested	Proposed PT <i>Delayed platelet engraftment</i>	10090435
HLT primary	<i>Transplantation complications</i>		HLT primary <i>Transplantation complications</i>	10074474
SOC primary	<i>Injury, poisoning and procedural complications</i>		SOC primary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new PT Delayed platelet engraftment to primary HLT Transplantation complications in SOC Injury, poisoning and procedural complications is approved as requested. Delayed platelet engraftment is defined as a delay in achieving independence from platelet transfusion for at least 7 days with a platelet count of more than >20 x 109/L.

CR Number: 2023312043 Implementation Date: 15-Nov-23 Related CR: 2023312043

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Platelet engraftment failure</i>	Approved as Requested	Proposed PT <i>Platelet engraftment failure</i>	10090432
HLT primary	<i>Transplantation complications</i>		HLT primary <i>Transplantation complications</i>	10074474
SOC primary	<i>Injury, poisoning and procedural complications</i>		SOC primary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new PT Platelet engraftment failure to primary HLT Transplantation complications in SOC Injury, poisoning and procedural complications is approved as requested. Platelet engraftment failure is defined as the lack of platelet engraftment following autologous or allogeneic stem cell transplantation. It is classically divided into primary - when there is no evidence of engraftment or hematological recovery of donor cells, within the first month after transplant- or secondary graft failure, which refers to the loss of a previously functioning graft. In a related change LLT Failure to engraft platelets will be moved from PT Engraft failure to PT Platelet engraftment failure for better alignment.

Supplemental Update Report

CR Number: 2023319021 **Implementation Date:** 15-Nov-23 **Related CR:** 2023312043

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Link (move) an LLT to another PT <i>Failure to engraft platelets</i>	Approved as Requested	Proposed LLT	
From PT	<i>Engraft failure</i>		<i>Failure to engraft platelets</i>	10068082 Current
To PT	<i>Platelet engraftment failure</i>		From PT	
			<i>Engraft failure</i>	10068081
			To PT	
			<i>Platelet engraftment failure</i>	10090432

MSSO
Comment:

CR Number: 2023312044 **Implementation Date:** 15-Nov-23 **Related CR:** 2023312044

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Secondary failure of platelet recovery</i>	Approved Not as Requested	Proposed LLT	
HLT primary	<i>Transplantation complications</i>		<i>Secondary failure of platelet recovery</i>	10090436 Current
SOC primary	<i>Injury, poisoning and procedural complications</i>		To PT	
			<i>Platelet engraftment failure</i>	10090432

MSSO
Comment: The proposal to add a new PT Secondary failure of platelet recovery to primary HLT Transplantation complications in SOC Injury, poisoning and procedural complications is approved but not as requested. Secondary failure of platelet recovery is defined as the lack of platelet recovery on a previously functioning graft, following autologous or allogeneic stem cell transplantation . Secondary failure of platelet recovery will be added as LLT to PT the Platelet engraftment failure which was added in change request 2023312043.

CR Number: 2023312045 **Implementation Date:** 15-Nov-23 **Related CR:** 2023312045

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>SFPR</i>	Rejected		
To PT	<i>Secondary failure of platelet recovery</i>			

MSSO
Comment: The proposal to add a new LLT SFPR to PT Secondary failure of platelet recovery is not approved. The proposed acronym may represent other concepts in medicine, such as "Selective functional posterior rhizotomy".

Supplemental Update Report

CR Number: 2023312046		Implementation Date: 15-Nov-23	Related CR: 2023312046	MedDRA Code #
Change Requested		Final Disposition	Final Placement	
Proposed PT	<i>Platelet engraftment</i>	Approved Not as Requested	Proposed PT	
HLT primary	<i>Platelet analyses</i>		<i>Platelet engraftment analysis</i>	10090433
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Platelet analyses</i>	10035523
			SOC primary	
			<i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Platelet engraftment to primary HLT Platelet analyses in SOC Investigations is approved but not as requested. The proposed term will be modified for clarity to Platelet engraftment analysis and added as PT to HLT Platelet analyses.

CR Number: 2023312047		Implementation Date: 15-Nov-23	Related CR: 2023312047	MedDRA Code #
Change Requested		Final Disposition	Final Placement	
Proposed PT	<i>Neutrophil engraftment</i>	Approved Not as Requested	Proposed PT	
HLT primary	<i>White blood cell analyses</i>		<i>Neutrophil engraftment analysis</i>	10090430
SOC primary	<i>Investigations</i>		HLT primary	
			<i>White blood cell analyses</i>	10047938
			SOC primary	
			<i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Neutrophil engraftment to primary HLT White blood cell analyses in SOC Investigations is approved but not as requested. The proposed term will be modified for clarity to PT Neutrophil engraftment analysis to HLT White blood cell analyses.

CR Number: 2023312048		Implementation Date: 15-Nov-23	Related CR: 2023312048	MedDRA Code #
Change Requested		Final Disposition	Final Placement	
Proposed LLT	<i>Generalized pruritic rash</i>	Rejected		
To PT	<i>Rash pruritic</i>			

MSSO Comment: The proposal to add a new LLT Generalized pruritic rash to PT Rash pruritic is not approved. MedDRA cannot accommodate a specific term for every possible combination of dermatological descriptive terms with anatomical localization.

Supplemental Update Report

CR Number: 2023312049 **Implementation Date:** 15-Nov-23 **Related CR:** 2023312049

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Out of specification test results active pharmaceutical ingredient impurity</i>	Approved Not as Requested	Proposed LLT <i>Out of specification test results active pharmaceutical ingredient impurity</i>	10090439 Current
To PT	<i>Out of Specification test results</i>		To PT <i>Out of specification test results</i>	10071067

MSSO Comment: The proposal to add a new LLT Out of specification test results active pharmaceutical ingredient impurity to PT Out of Specification test results is approved but not as requested. Out of Specification test results for active pharmaceutical ingredient impurity describes a situation where the test results for impurities in a particular pharmaceutical ingredient fall outside the predefined specifications or acceptance criteria. Out of specification test results active pharmaceutical ingredient impurity will be added as LLT to the correct capitalization of PT Out of specification test results.

CR Number: 2023313001 **Implementation Date:** 15-Nov-23 **Related CR:** 2023313001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Arteriovenous fistula reconstruction</i>	Rejected		

MSSO Comment: The proposal to add a new term Arteriovenous fistula reconstruction is not approved. The requested term can be represented by LLT Arteriovenous fistula revision or LLT Percutaneous transluminal angioplasty of arteriovenous fistula.

CR Number: 2023313002 **Implementation Date:** 15-Nov-23 **Related CR:** 2023313002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Charcot-Leyden crystals present</i>	Approved as Requested	Proposed PT <i>Charcot-Leyden crystals present</i>	10090429
			HLT primary <i>Immunology analyses NEC</i>	10021504
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Charcot-Leyden crystals present is approved as requested. Charcot-Leyden crystals are microscopic crystals composed of eosinophil protein galectin-10 found in people who have allergic diseases such as asthma or parasitic infections such as parasitic pneumonia or ascariasis. Charcot-Leyden crystals present will be added as new PT under HLT Immunology analyses NEC.

Supplemental Update Report

CR Number: 2023313003 Implementation Date: 15-Nov-23 Related CR: 2023313003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Charcot-Leyden crystals absent</i>	Approved as Requested	Proposed PT <i>Charcot-Leyden crystals absent</i>	10090428
			HLT primary <i>Immunology analyses NEC</i>	10021504
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Charcot-Leyden crystals absent is approved as requested. Charcot-Leyden crystals are microscopic crystals composed of eosinophil protein galectin-10 found in people who have allergic diseases such as asthma or parasitic infections such as parasitic pneumonia or ascariasis. Charcot-Leyden crystals absent will be added as a new PT under HLT Immunology analyses NEC as the absent counterpart of PT Charcot-Leyden crystals present.

CR Number: 2023313004 Implementation Date: 15-Nov-23 Related CR: 2023313004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Outer retinal tubulation</i>	Approved Not as Requested	Proposed PT <i>Outer retinal tubulation</i>	10090426
To PT	<i>Disruption of the photoreceptor inner segment-outer segment</i>		HLT primary <i>Retinal structural change, deposit and degeneration</i>	10038896
			SOC primary <i>Eye disorders</i>	10015919

MSSO Comment: The proposal to add a new LLT Outer retinal tubulation to PT Disruption of the photoreceptor inner segment-outer segment is approved but not as requested. Outer retinal tubulation specifically refers to the formation of tubular structures in the outer retina, while disruption of the IS/OS junction refers to a loss of the normal architecture at the junction between the inner and outer segments of the photoreceptor cells. Outer retinal tubulation will be added as PT to HLT Retinal structural change, deposit and degeneration.

Supplemental Update Report

CR Number: 2023313005 **Implementation Date:** 15-Nov-23 **Related CR:** 2023313005

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT <i>Breast flat epithelial atypia</i>	Approved Not as Requested	Proposed PT <i>Flat epithelial atypia</i>	10090427
		HLT primary <i>Breast disorders NEC</i>	10040675
		SOC primary <i>Reproductive system and breast disorders</i>	10038604

MSSO Comment: The proposal to add a new PT Breast flat epithelial atypia is approved but not as requested. Flat epithelial atypia is a descriptive term that encompasses lesions of the breast terminal duct lobular units in which variably dilated acini are lined by one to several layers of epithelial cells, which are usually columnar in shape and which display low-grade cytologic atypia. Proposed term will be modified for the term most commonly found in literature and added as new PT Flat epithelial atypia under HLT Breast disorders NEC.

CR Number: 2023313018 **Implementation Date:** 15-Nov-23 **Related CR:** 2023313018

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT <i>Drug monitoring interval too long</i>	Approved as Requested	Proposed LLT <i>Drug monitoring interval too long</i>	10090442 Current
		To PT <i>Drug monitoring procedure incorrectly performed</i>	10075461

MSSO Comment: The proposal to add a new LLT Drug monitoring interval too long is approved as requested. Drug monitoring interval too long will be added as a sub-concept LLT to PT Drug monitoring procedure incorrectly performed. Please note that LLT Drug monitoring procedure performed at incorrect intervals has been added in change request 2023237005 for version 27.0.

CR Number: 2023313027 **Implementation Date:** 15-Nov-23 **Related CR:** 2023313027

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT <i>Product emptying ahead of scheduled therapie end</i>	Approved Not as Requested	Proposed LLT <i>Product depletion before scheduled therapy end</i>	10090440 Current
		To PT <i>Product use issue</i>	10076309

MSSO Comment: The proposal to add a new LLT Product emptying ahead of scheduled therapie end is approved but not as requested. Product emptying ahead of scheduled therapy end typically refers to a situation where a product, such as a medical device or a container of medication, is depleted or runs out before the anticipated or scheduled completion of a therapeutic or treatment course. The term will be modified for clarity to Product depletion before scheduled therapy end and added as LLT to PT Product use issue, aligned with the placement of LLT Patient ran out of medication.

Supplemental Update Report

CR Number: 2023313028		Implementation Date: 15-Nov-23	Related CR: 2023313028	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Labelled renal monitoring not performed</i>	Approved Not as Requested	Proposed LLT <i>Labelled renal function monitoring not performed</i>	10090441 Current
To PT			To PT <i>Drug monitoring procedure not performed</i>	10075462

MSSO Comment: The proposal to add a new term Labelled renal monitoring not performed is approved but not as requested. The concept may capture the scenario where a patient was not clinically monitored for renal function even though it is labelled for the drug that the patient needs renal function monitoring. The proposed term will be modified for clarity to Labelled renal function monitoring not performed and its American English counterpart Labeled renal function monitoring not performed will both be added as LLTs to PT Drug monitoring procedure not performed.

CR Number: 2023319022		Implementation Date: 15-Nov-23	Related CR: 2023313028	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Labeled renal function monitoring not performed</i>	Approved as Requested	Proposed LLT <i>Labeled renal function monitoring not performed</i>	10090443 Current
To PT			To PT <i>Drug monitoring procedure not performed</i>	10075462

MSSO Comment:

CR Number: 2023313029		Implementation Date: 15-Nov-23	Related CR: 2023313029	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Aseptic joint prosthesis loosening</i>	Approved as Requested	Proposed LLT <i>Aseptic joint prosthesis loosening</i>	10090445 Current
To PT			To PT <i>Device loosening</i>	10076364

MSSO Comment: The proposal to add a new LLT Aseptic joint prosthesis loosening to PT Device loosening is approved as requested. Aseptic loosening is the loosening of a prosthesis from bone in the absence of infection or trauma. It is the most common cause for failure and revision surgery after primary total joint arthroplasty. In a related change, PT Device loosening will be linked to secondary HLT Complications associated with device NEC.

Supplemental Update Report

CR Number: 2023319023	Implementation Date: 15-Nov-23	Related CR: 2023313029		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Device loosening</i>	Approved as Requested	Proposed PT	
To HLT	<i>Complications associated with device NEC</i>		<i>Device loosening</i>	10076364
			To HLT	
			<i>Complications associated with device NEC</i>	10069785

MSSO
Comment:

CR Number: 2023313030	Implementation Date: 15-Nov-23	Related CR: 2023313030		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Septic device loosening</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Infections NEC</i>		<i>Septic device loosening</i>	10090444
SOC primary	<i>Infections and infestations</i>		HLT primary	
			<i>Infections NEC</i>	10021902
			SOC primary	
			<i>Infections and infestations</i>	10021881
			HLT secondary	
			<i>Device issues NEC</i>	10069794
			SOC secondary	
			<i>Product issues</i>	10077536

MSSO
Comment: The proposal to add a new PT Septic device loosening to primary HLT Infections NEC in SOC Infections and infestations and secondary HLT Device issues NEC is approved as requested. Septic loosening is defined by the presence of chronic infection at the implant site. In a related change, PT Septic device loosening will also be linked to secondary HLT Complications associated with device NEC.

CR Number: 2023319024	Implementation Date: 15-Nov-23	Related CR: 2023313030		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Septic device loosening</i>	Approved as Requested	Proposed PT	
To HLT	<i>Complications associated with device NEC</i>		<i>Septic device loosening</i>	10090444
			To HLT	
			<i>Complications associated with device NEC</i>	10069785

MSSO
Comment:

Supplemental Update Report

CR Number: 2023313031 **Implementation Date:** 15-Nov-23 **Related CR:** 2023313031

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Septic joint prosthesis loosening</i>	Approved as Requested	Proposed LLT	
To PT	<i>Septic device loosening</i>		<i>Septic joint prosthesis loosening</i>	10090446 Current
			To PT	
			<i>Septic device loosening</i>	10090444

MSSO Comment: The proposal to add a new LLT Septic joint prosthesis loosening to PT Septic device loosening is approved as requested. Septic loosening is defined by the presence of chronic infection at the implant site. LLT Septic joint prosthesis loosening is an important sub-concept of PT Septic device loosening.

CR Number: 2023314001 **Implementation Date:** 15-Nov-23 **Related CR:** 2023314001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Partial lung lobectomy</i>	Rejected		
From PT	<i>Pulmonary resection</i>			
To PT	<i>Lung lobectomy</i>			

MSSO Comment: The proposal to move the LLT Partial lung lobectomy from PT Pulmonary resection to PT Lung lobectomy is not approved. Partial lung lobectomy and partial lung resection are synonymously used as only part of a lobe is removed (sublobular).

CR Number: 2023315001 **Implementation Date:** 15-Nov-23 **Related CR:** 2023315001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Coronary artery atherosclerotic heart disease</i>	Approved as Requested	Proposed LLT	
To PT	<i>Arteriosclerosis coronary artery</i>		<i>Coronary artery atherosclerotic heart disease</i>	10090447 Current
			To PT	
			<i>Arteriosclerosis coronary artery</i>	10003211

MSSO Comment: The proposal to add a new LLT Coronary artery atherosclerotic heart disease to PT Arteriosclerosis coronary artery is approved as requested to facilitate coding of synonyms.

Supplemental Update Report

CR Number: 2023317001 **Implementation Date:** 15-Nov-23 **Related CR:** 2023317001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term <i>Chest sepsis</i>	Rejected		

MSSO Comment: The proposal to add a new term Chest sepsis is not approved. The proposed term is not clearly defined. Although there are PTs for important septic foci, the chest includes very different organs, which could be the origin, as such the term is ambiguous and warrants follow-up.

CR Number: 2023317003 **Implementation Date:** 20-Nov-23 **Related CR:** 2023317003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Chemotherapy induced peripheral sensory neuropathy</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Chemotherapy induced peripheral sensory neuropathy is not approved. The MSSO refrains from adding further combination of drug induced concepts.

CR Number: 2023317004 **Implementation Date:** 20-Nov-23 **Related CR:** 2023317004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>MRI Paranasal sinuses</i>	Approved Not as Requested	Proposed LLT <i>MRI paranasal sinuses</i> To PT <i>Magnetic resonance imaging head</i>	10090449 Current 10085255

MSSO Comment: The proposal to add a new LLT MRI Paranasal sinuses is approved but not as requested. A wide range of sinus abnormalities can be visualized during brain MRI scanning, which gives the advantage of cross-sectional imaging. Proposed term will be modified for MedDRA capitalization conventions and added as sub-concept LLT MRI paranasal sinuses under PT Magnetic resonance imaging head.

Supplemental Update Report

CR Number: 2023317005	Implementation Date: 20-Nov-23	Related CR: 2023317005		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Hydroxy-methylglutaryl-coenzyme A reductase</i>	Approved Not as Requested	Proposed LLT <i>Hydroxy-methylglutaryl-coenzyme A reductase test</i>	10090448 Current
			To PT <i>HMG CoA reductase antibody test</i>	10090396

MSSO Comment: The proposal to add a new term Hydroxy-methylglutaryl-coenzyme A reductase is approved but not as requested. The proposed term will be modified for clarity and added as the spelled out version LLT Hydroxy-methylglutaryl-coenzyme A reductase test to PT HMG CoA reductase antibody test.

CR Number: 2023317006	Implementation Date: 20-Nov-23	Related CR: 2023317006		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Extramedullary hemopoiesis mass</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Extramedullary hemopoiesis 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. Existing LLT Extramedullary haemopoiesis or LLT Cutaneous extramedullary haemopoiesis can be considered for coding depending on the concrete situation.

CR Number: 2023317007	Implementation Date: 20-Nov-23	Related CR: 2023317007		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Titanium breast marker placement</i>	Approved Not as Requested	Proposed LLT <i>Titanium marker placement</i>	10090450 Current
			To PT <i>Fiducial marker placement</i>	10075872

MSSO Comment: The proposal to add a new LLT Titanium breast marker placement is approved but not as requested. Titanium markers are small metals placed in the area of interest for later reference. The requested term will be modified to a broader concept and added as LLT Titanium marker placement to PT Fiducial marker placement. In a related change, PT Fiducial marker placement will be moved from HLT Radiotherapies site unspecified to HLT Therapeutic procedures NEC for better alignment.

Supplemental Update Report

CR Number: 2023324001		Implementation Date: 20-Nov-23	Related CR: 2023317007	
<u>Change Requested</u>	Link (move) a PT to another HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Fiducial marker placement</i>	Approved as Requested	Proposed PT	
From HLT	<i>Radiotherapies site unspecified</i>		<i>Fiducial marker placement</i>	10075872
To HLT	<i>Therapeutic procedures NEC</i>		From HLT	
			<i>Radiotherapies site unspecified</i>	10037796
			To HLT	
			<i>Therapeutic procedures NEC</i>	10027700

MSSO
Comment:

CR Number: 2023317008		Implementation Date: 15-Nov-23	Related CR: 2023317008	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Type 2 diabetes mellitus complication</i>	Rejected		

MSSO
Comment: The proposal to add a new term Type 2 diabetes mellitus complication is not approved. The broad PT Diabetic complication covers complications for all types of DM especially for cases where no specific complication is reported. Although the pathogenesis of the two types of diabetes differs, the complications are similar depending on the duration of the disease. The proposed term is a combination of two existing concepts represented by LLT Diabetic complication and LLT Type 2 diabetes mellitus, which may be selected in combination.

CR Number: 2023318001		Implementation Date: 15-Nov-23	Related CR: 2023318001	
<u>Change Requested</u>	Link (move) a PT to another HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Intraductal papillary breast neoplasm</i>	Approved as Requested	Proposed PT	
From HLT	<i>Breast and nipple neoplasms malignant</i>		<i>Intraductal papillary breast neoplasm</i>	10073540
To HLT	<i>Breast neoplasms unspecified malignancy</i>		From HLT	
			<i>Breast and nipple neoplasms malignant</i>	10006290
			To HLT	
			<i>Breast neoplasms unspecified malignancy</i>	10006292

MSSO
Comment: The proposal to move the PT Intraductal papillary breast neoplasm from HLT Breast and nipple neoplasms malignant to HLT Breast neoplasms unspecified malignancy is approved as requested. Intraductal papillary breast neoplasm represents a broad array of intraductal breast lesions, ranging from benign monoclonal proliferations to malignant papillary lesions with an intermediate spectrum of dysplastic lesions presenting with atypical ductal hyperplasia.

Supplemental Update Report

CR Number: 2023318002	Implementation Date: 20-Nov-23	Related CR: 2023318002	MedDRA Code #
Change Requested	Add a New LLT	Final Disposition	Final Placement
Proposed LLT	<i>DVT of leg</i>	Rejected	
To PT	<i>Deep vein thrombosis</i>		

MSSO Comment: The proposal to add a new LLT DVT of leg to PT Deep vein thrombosis is not approved. The requested concept can be represented by the LLT Deep vein thrombosis leg.

CR Number: 2023319000	Implementation Date: 20-Nov-23	Related CR: 2023319000	MedDRA Code #
Change Requested	Add a New LLT	Final Disposition	Final Placement
Proposed LLT	<i>Right sided colon cancer</i>	Approved Not as Requested	Proposed LLT <i>Right-sided colon cancer</i> 10090457 Current
			To PT <i>Colon cancer</i> 10009944

MSSO Comment: The proposal to add a new LLT Right sided colon cancer is approved but not as requested. Research suggests that there are biological differences between left-sided and right-sided colon cancers. Right side colon includes cecum, ascending colon, right half of transverse colon, and hepatic flexure. The proposed term will be modified by adding a hyphen to Right-sided colon cancer and added as LLT to PT Colon cancer.

CR Number: 2023319001	Implementation Date: 20-Nov-23	Related CR: 2023319001	MedDRA Code #
Change Requested	Add a New LLT	Final Disposition	Final Placement
Proposed LLT	<i>Left sided colon cancer</i>	Approved Not as Requested	Proposed LLT <i>Left-sided colon cancer</i> 10090455 Current
			To PT <i>Colon cancer</i> 10009944

MSSO Comment: The proposal to add a new LLT Left sided colon cancer is approved but not as requested. Research suggests that there are biological differences between left-sided and right-sided colon cancers. Left side colon includes splenic flexure, descending and sigmoid colon, left half of transverse colon, rectosigmoid and rectum. The proposed term will be modified by adding a hyphen to Left-sided colon cancer and added as LLT to PT Colon cancer.

Supplemental Update Report

CR Number: 2023319002 **Implementation Date:** 20-Nov-23 **Related CR:** 2023319002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Cancer of ascending colon	Rejected		

MSSO Comment: The proposal to add a new LLT Cancer of ascending colon is not approved. The requested term can be represented by existing LLT Malignant neoplasm of ascending colon.

CR Number: 2023319003 **Implementation Date:** 20-Nov-23 **Related CR:** 2023319003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Stercoral perforation	Approved as Requested	Proposed LLT Stercoral perforation To PT Large intestine perforation	10090454 Current 10023804

MSSO Comment: The proposal to add a new LLT Stercoral perforation is approved as requested. Stercoral perforation is defined as a bowel perforation due to pressure necrosis from a fecal mass (fecaloma). It is an uncommon, but life-threatening, complication of unresolved fecal impaction and can be a cause of acute abdomen secondary to fecal peritonitis. Stercoral perforation will be added as an LLT to PT Large intestine perforation.

CR Number: 2023319004 **Implementation Date:** 20-Nov-23 **Related CR:** 2023319004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Dilatation of the large bowel	Rejected		

MSSO Comment: The proposal to add a new LLT Dilatation of the large bowel is not approved. The proposed term is well represented by existing LLT Large bowel dilatation. The MSSO reserves the option of using different arguments to defend the incorporation of a new term. In the case of change request 2023116007, a definition was used based on the threshold from which it is considered that there is a case of dilation.

Supplemental Update Report

CR Number: 2023319005 Implementation Date: 20-Nov-23 Related CR: 2023319005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Dilatation of the small bowel</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Dilatation of the small bowel is not approved. The proposed term is well represented by existing LLT Small bowel dilatation. The MSSO reserves the option of using different arguments to defend the incorporation of a new term. In the case of change request 2023116006, a definition was used based on the threshold from which it is considered that there is a case of dilation.

CR Number: 2023319006 Implementation Date: 01-Dec-23 Related CR: 2023319006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Unavailability of medication history</i>	Approved Not as Requested After Suspension	Proposed LLT <i>Medication history unavailable</i> To PT <i>Circumstance or information capable of leading to medication error</i>	10090617 Current 10064385

MSSO Comment: The proposal to add a new LLT Unavailability of medication history is approved but not as requested after suspension. Medication histories are important in preventing prescription errors and consequent risks to patients. Apart from preventing prescription errors, accurate medication histories are also useful in detecting drug-related pathology or changes in clinical signs that may be the result of drug therapy. The proposed term will be modified for clarity and added as LLT Medication history unavailable to PT Circumstance or information capable of leading to medication error.

CR Number: 2023319007 Implementation Date: 20-Nov-23 Related CR: 2023319007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Blue vomit</i>	Approved as Requested	Proposed LLT <i>Blue vomit</i> To PT <i>Discoloured vomit</i>	10090456 Current 10079120

MSSO Comment: The proposal to add a new LLT Blue vomit is approved as requested. Bluish vomiting is a symptom of poisoning e.g. copper sulphate and of important diagnostic value. Blue vomit will be added as an LLT to PT Discoloured vomit.

Supplemental Update Report

CR Number: 2023319008 **Implementation Date:** 20-Nov-23 **Related CR:** 2023319008

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Reassign Primary SOC <i>Salivary hypersecretion</i>	Approved Not as Requested	Proposed PT <i>Salivary hypersecretion</i>	10039424
Old Primary SOC	<i>Gastrointestinal disorders</i>		To HLT	
New Primary SOC	<i>Nervous system disorders</i>		<i>Neurological signs and symptoms NEC</i>	10029306

MSSO Comment: The proposal to reassign the primary SOC of PT Salivary hypersecretion from current SOC Gastrointestinal disorders to SOC Nervous system disorders is approved but not as requested. Salivary hypersecretion is not always of neurologic origin. Therefore, the primary SOC Gastrointestinal disorders is appropriate. However, PT Salivary hypersecretion will also be linked to secondary HLT Neurological signs and symptoms NEC aligned with placement of PT Drooling.

CR Number: 2023319009 **Implementation Date:** 20-Nov-23 **Related CR:** 2023319009

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Anticholinergic delirium</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Anticholinergic delirium 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 because causality is not inherent in the coded term but is instead determined by the reporter/investigator or by the sponsor.

CR Number: 2023319010 **Implementation Date:** 29-Nov-23 **Related CR:** 2023319010

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Werner-His disease</i>	Approved as Requested	Proposed LLT <i>Werner-His disease</i>	10090568 Current
To PT	<i>Trench fever</i>		To PT <i>Trench fever</i>	10044582

MSSO Comment: The proposal to add a new LLT Werner-His disease to PT Trench fever is approved as requested. LLT Werner-His disease is a synonym of PT Trench fever.

Supplemental Update Report

CR Number: 2023319011	Implementation Date: 29-Nov-23	Related CR: 2023319011		
Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	<i>His disease</i>	Approved as Requested	LLT to change	
Status	<i>non-current</i>		<i>His disease</i>	10089393 Non-Current
			Status	
			<i>non-current</i>	

MSSO Comment: The proposal to change status of LLT His disease to non-current is approved as requested. His disease is ambiguous and my lead to confusion.

CR Number: 2023319012	Implementation Date: 20-Nov-23	Related CR: 2023319012		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Hibernoma</i>	Approved as Requested	Proposed LLT	
			<i>Hibernoma</i>	10090451 Current
			To PT	
			<i>Lipoma</i>	10024612

MSSO Comment: The proposal to add a new LLT Hibernoma is approved as requested. A hibernoma is a rare noncancerous (benign) tumor that forms in soft tissues. It causes a tumor made of brown fat to form underneath skin or within the musculoskeletal system. Hibernoma will be added as LLT under PT Lipoma.

CR Number: 2023319013	Implementation Date: 20-Nov-23	Related CR: 2023319013		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Myotonic dystrophy type 1</i>	Approved as Requested	Proposed LLT	
			<i>Myotonic dystrophy type 1</i>	10090453 Current
			To PT	
			<i>Myotonic dystrophy</i>	10068871

MSSO Comment: The proposal to add a new LLT Myotonic dystrophy type 1 is approved as requested. Myotonic dystrophy type 1, long known as Steinert disease, occurs when a gene on chromosome 19 called DMPK contains an abnormally expanded section located close to the regulation region of another gene, SIX5. Myotonic dystrophy type 1 will be added as a synonym LLT to existing LLT Steinert disease under PT Myotonic dystrophy.

Supplemental Update Report

CR Number: 2023319014	Implementation Date: 20-Nov-23	Related CR: 2023319014		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Myotonic dystrophy type 2</i>	Approved as Requested	Proposed LLT <i>Myotonic dystrophy type 2</i>	10090452 Current
			To PT <i>Myotonic dystrophy</i>	10068871

MSSO Comment: The proposal to add a new LLT Myotonic dystrophy type 2 is approved as requested. Myotonic dystrophy type 2, recognized in 1994 as a milder version of Myotonic dystrophy type 1, is caused by an abnormally expanded section in a gene on chromosome 3 called ZNF9. Myotonic dystrophy type 2 was originally called PROMM, for proximal myotonic myopathy, a term that has remained in use but is somewhat less common than the term Myotonic dystrophy type 2. Myotonic dystrophy type 2 will be added as subconcept LLT under PT Myotonic dystrophy.

CR Number: 2023319015	Implementation Date: 30-Nov-23	Related CR: 2023319015		
<u>Change Requested</u>	Rename PT/LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Term to modify	<i>Patient knowledge deficit</i>	Approved Not as Requested	Term to modify <i>Patient knowledge deficit</i>	10090342
Replacement term	<i>Medication knowledge deficit</i>		Replacement term <i>Product knowledge deficit</i>	10090342

MSSO Comment: The proposal to rename PT/LLT Patient knowledge deficit to Medication knowledge deficit is approved but not as requested. LLT Patient knowledge deficit will be renamed to LLT Product knowledge deficit. In a related change, LLT Product knowledge deficit will be promoted from PT Circumstance or information capable of leading to medication error to PT level and placed under HLT Medication errors, product use errors and issues NEC. The following new LLTs will be added to PT Product knowledge deficit: LLT Medication knowledge deficit, LLT Not trained on proper medication use, LLT Not trained on proper device use.

CR Number: 2023334160	Implementation Date: 30-Nov-23	Related CR: 2023319015		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Medication knowledge deficit</i>	Approved as Requested	Proposed LLT <i>Medication knowledge deficit</i>	10090600 Current
To PT	<i>Product knowledge deficit</i>		To PT <i>Product knowledge deficit</i>	10090342

MSSO Comment:

Supplemental Update Report

CR Number: 2023334161	Implementation Date: 30-Nov-23	Related CR: 2023319015	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Not trained on proper medication use</i>	Approved as Requested	Proposed LLT
To PT	<i>Product knowledge deficit</i>		<i>Not trained on proper medication use</i>
			10090601 Current
			To PT
			<i>Product knowledge deficit</i>
			10090342

MSSO
Comment:

CR Number: 2023334162	Implementation Date: 30-Nov-23	Related CR: 2023319015	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Not trained on proper device use</i>	Approved as Requested	Proposed LLT
To PT	<i>Product knowledge deficit</i>		<i>Not trained on proper device use</i>
			10090599 Current
			To PT
			<i>Product knowledge deficit</i>
			10090342

MSSO
Comment:

CR Number: 2023334163	Implementation Date: 30-Nov-23	Related CR: 2023319015	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Product knowledge deficit</i>	Approved as Requested	Proposed LLT
From PT	<i>Circumstance or information capable of leading to medication error</i>		<i>Product knowledge deficit</i>
			10090342
HLT primary	<i>Medication errors, product use errors and issues NEC</i>		From PT
			<i>Circumstance or information capable of leading to medication error</i>
			10064385
			HLT primary
			<i>Medication errors, product use errors and issues NEC</i>
			10079146
			SOC primary
			<i>Injury, poisoning and procedural complications</i>
			10022117

MSSO
Comment:

Supplemental Update Report

CR Number: 2023319016 Implementation Date: 20-Nov-23 Related CR: 2023319016

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Lyme borreliosis ocular manifestations</i>	Approved Not as Requested	Proposed PT	
To PT	<i>Lyme disease</i>		<i>Ocular manifestation of Lyme disease</i>	10090458
			HLT primary	
			<i>Borrelial infections</i>	10006038
			SOC primary	
			<i>Infections and infestations</i>	10021881
			HLT secondary	
			<i>Ocular infections, inflammations and associated manifestations</i>	10030045
			SOC secondary	
			<i>Eye disorders</i>	10015919

MSSO Comment: The proposal to add a new LLT Lyme borreliosis ocular manifestations to PT Lyme disease is approved but not as requested. Ocular inflammation can occur in patients with documented Lyme disease and has been reported to involve any part of the eye. Uveitis is uncommon, but case reports and small series demonstrate a wide variety of presentations including iridocyclitis, vitritis, multifocal choroiditis, exudative retinal detachment and panophthalmitis. The requested term will be modified and added in natural word order as PT Ocular manifestation of Lyme disease to primary HLT Borrelial infections and to secondary HLT Ocular infections, inflammations and associated manifestations.

CR Number: 2023320000 Implementation Date: 21-Nov-23 Related CR: 2023320000

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Scleromyositis</i>	Approved Not as Requested	Proposed LLT	
HLT primary	<i>Connective tissue disorders</i>		<i>Scleromyositis</i>	10090459 Current
SOC primary	<i>Skin and subcutaneous tissue disorders</i>		To PT	
			<i>Scleroderma overlap syndrome</i>	10089253

MSSO Comment: The proposal to add a new PT Scleromyositis to primary HLT Connective tissue disorders in SOC Skin and subcutaneous tissue disorders and secondary HLT Autoimmune disorders NEC in SOC Immune system disorders is approved but not as requested. Scleromyositis is a rare autoimmune disease that is considered a distinct novel entity within the systemic sclerosis and autoimmune myositis spectrum. Scleromyositis will be added as LLT to the promoted PT Scleroderma overlap syndrome. In a related change LLT Scleroderma overlap syndrome will be promoted to be a PT level and linked to primary HLT Connective tissue disorders NEC, to secondary HLT Connective tissue disorders, and to secondary HLT Scleroderma and associated disorders.

Supplemental Update Report

CR Number: 2023325003 Implementation Date: 21-Nov-23 Related CR: 2023320000

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Promote an LLT	Approved as Requested	Proposed LLT	
From PT	<i>Scleroderma overlap syndrome</i>		<i>Scleroderma overlap syndrome</i>	10089253
HLT primary	<i>Systemic scleroderma</i>			
	<i>Connective tissue disorders NEC</i>			
			From PT	
			<i>Systemic scleroderma</i>	10078638
			HLT primary	
			<i>Connective tissue disorders NEC</i>	10074472
			SOC primary	
			<i>Musculoskeletal and connective tissue disorders</i>	10028395
			HLT secondary	
			<i>Connective tissue disorders</i>	10010760
			SOC secondary	
			<i>Skin and subcutaneous tissue disorders</i>	10040785

MSSO
Comment:

CR Number: 2023325004 Implementation Date: 21-Nov-23 Related CR: 2023320000

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT	Approved as Requested	Proposed PT	
To HLT	<i>Scleroderma overlap syndrome</i>		<i>Scleroderma overlap syndrome</i>	10089253
	<i>Scleroderma and associated disorders</i>		To HLT	
			<i>Scleroderma and associated disorders</i>	10039711

MSSO
Comment:

Supplemental Update Report

CR Number: 2023320001 Implementation Date: 28-Nov-23 Related CR: 2023320001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Dias-Logan syndrome</i>	Approved Not as Requested	Proposed PT <i>Dias-Logan syndrome</i>	10090512
			HLT primary <i>Neurological disorders congenital NEC</i>	10029300
			SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>	10028378
			SOC secondary <i>Musculoskeletal and connective tissue disorders</i>	10028395

MSSO Comment: The proposal to add a new LLT Dias-Logan syndrome is approved but not as requested. Dias-Logan syndrome is an intellectual developmental disorder with persistence of foetal haemoglobin, psychomotor retardation and intellectual disability of variable severity, various types of epilepsy; strabismus; and variable craniofacial anomalies. Dias-Logan syndrome will be added as PT with a primary link to HLT Neurological disorders congenital NEC and to secondary HLT Musculoskeletal and connective tissue deformities of skull, face and buccal cavity, to secondary HLT Seizures and seizure disorders NEC and to secondary HLT Haemoglobinopathies NEC.

CR Number: 2023332302 Implementation Date: 28-Nov-23 Related CR: 2023320001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Dias-Logan syndrome</i>	Approved as Requested	Proposed PT <i>Dias-Logan syndrome</i>	10090512
To HLT	<i>Seizures and seizure disorders NEC</i>		To HLT <i>Seizures and seizure disorders NEC</i>	10039912

MSSO Comment:

Supplemental Update Report

CR Number: 2023332303	Implementation Date: 28-Nov-23	Related CR: 2023320001		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Dias-Logan syndrome</i>	Approved as Requested	Proposed PT	
To HLT	<i>Haemoglobinopathies NEC</i>		<i>Dias-Logan syndrome</i>	10090512
			To HLT	
			<i>Haemoglobinopathies NEC</i>	10018904

MSSO
Comment:

CR Number: 2023320002	Implementation Date: 28-Nov-23	Related CR: 2023320002		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Acroasphyxia</i>	Rejected		
HLT primary	<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>			
SOC primary	<i>Vascular disorders</i>			

MSSO Comment: The proposal to add a new PT Acroasphyxia to primary HLT Peripheral vasoconstriction, necrosis and vascular insufficiency in SOC Vascular disorders is not approved. Acroasphyxia is an obsolete term for compromised blood flow at the extremities. The requested concept can be represented by LLT Acrocyanosis.

CR Number: 2023320003	Implementation Date: 28-Nov-23	Related CR: 2023320003		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Weight reduction</i>	Approved Not as Requested	Proposed LLT	
HLT primary	<i>Therapeutic procedures NEC</i>		<i>Weight reduction therapy</i>	10090518 Current
SOC primary	<i>Surgical and medical procedures</i>		To PT	
			<i>Weight control</i>	10050300

MSSO Comment: The proposal to add a new PT Weight reduction to primary HLT Therapeutic procedures NEC in SOC Surgical and medical procedures is approved but not as requested. The requested term will be modified for clarity and added as LLT Weight reduction therapy to PT Weight control.

Supplemental Update Report

CR Number: 2023320004 Implementation Date: 28-Nov-23 Related CR: 2023320004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Inappropriate sinus tachycardia</i>	Approved as Requested	Proposed PT <i>Inappropriate sinus tachycardia</i>	10090513
HLT primary	<i>Supraventricular arrhythmias</i>		HLT primary <i>Supraventricular arrhythmias</i>	10042600
SOC primary	<i>Cardiac disorders</i>		SOC primary <i>Cardiac disorders</i>	10007541

MSSO Comment: The proposal to add a new PT Inappropriate sinus tachycardia to primary HLT Supraventricular arrhythmias in SOC Cardiac disorders is approved as requested. Inappropriate sinus tachycardia, also called chronic nonparoxysmal sinus tachycardia, is an unusual condition that occurs in individuals without apparent heart disease or other cause for sinus tachycardia, such as hyperthyroidism or fever, and it is defined as a resting heart rate >100 beats per minute frequently associated with highly symptomatic palpitations. In a related change, the synonym LLT Chronic nonparoxysmal sinus tachycardia will also be added to PT Inappropriate sinus tachycardia.

CR Number: 2023332304 Implementation Date: 28-Nov-23 Related CR: 2023320004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Chronic nonparoxysmal sinus tachycardia</i>	Approved as Requested	Proposed LLT <i>Chronic nonparoxysmal sinus tachycardia</i>	10090521 Current
To PT	<i>Inappropriate sinus tachycardia</i>		To PT <i>Inappropriate sinus tachycardia</i>	10090513

MSSO Comment:

CR Number: 2023320005 Implementation Date: 28-Nov-23 Related CR: 2023320005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Appetite stimulant</i>	Rejected		

MSSO Comment: The proposal to add a new PT Appetite stimulant is not approved. Appetite stimulant represents a ATC drug group. For the indication field, the underlining medical condition such as PT/LLT Decreased appetite can be used. Please refer to the MedDRA® TERM SELECTION: POINTS TO CONSIDER in section 3.26 Indication for Product Use.

Supplemental Update Report

CR Number: 2023320006 Implementation Date: 28-Nov-23 Related CR: 2023320006

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT <i>Milk bleb</i>	Approved Not as Requested	Proposed LLT <i>Milk bleb</i>	10090520 Current
		To PT <i>Nipple blister</i>	10090514

MSSO Comment: The proposal to add a new PT Milk bleb is approved but not as requested. A nipple bleb (or "milk blister") is a white bleb or dot on the nipple. It is caused by obstruction of the nipple pore ducts due to ductal inflammation. Milk bleb will be added as LLT to a more medically recognized new PT Nipple blister which will be added, in a related change to primary HLT Lactation disorders and to secondary HLT Postpartum breast disorders.

CR Number: 2023332305 Implementation Date: 28-Nov-23 Related CR: 2023320006

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT <i>Nipple blister</i>	Approved as Requested	Proposed PT <i>Nipple blister</i>	10090514
HLT primary <i>Lactation disorders</i>		HLT primary <i>Lactation disorders</i>	10013316
SOC primary <i>Reproductive system and breast disorders</i>		SOC primary <i>Reproductive system and breast disorders</i>	10038604
		HLT secondary <i>Postpartum breast disorders</i>	10006234
		SOC secondary <i>Pregnancy, puerperium and perinatal conditions</i>	10036585

MSSO Comment:

Supplemental Update Report

CR Number: 2023320007	Implementation Date: 28-Nov-23	Related CR: 2023320007	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed PT	<i>Irregular ovulation</i>	Approved Not as Requested	Proposed LLT <i>Irregular ovulation</i> 10090516 Current
			To PT <i>Menstruation irregular</i> 10027339

MSSO Comment: The proposal to add a new PT Irregular ovulation is approved but not as requested. Women with irregular ovulation have cycles that occur outside of the 28-34-day window. Irregular ovulation can be the result of a medical condition such as polycystic ovary syndrome. Irregular ovulation can be considered a sub-concept LLT of PT Menstruation irregular.

CR Number: 2023320008	Implementation Date: 28-Nov-23	Related CR: 2023320008	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed PT	<i>Mood stabilizer</i>	Rejected	

MSSO Comment: The proposal to add a new PT Mood stabilizer is not approved. The proposed concept refers to a group of psychiatric medication used to treat mood disorders characterized by intense and sustained mood shifts, such as bipolar disorder and the bipolar type of schizoaffective disorder. Drug classification is out of MedDRA scope. For specific therapeutic uses or indications pursuing mood stabilization, the specific type of treatment can be proposed or selected (e.g. PT Bipolar disorder relapse prophylaxis).

CR Number: 2023320009	Implementation Date: 28-Nov-23	Related CR: 2023320009	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed LLT	<i>Shame</i>	Approved as Requested	Proposed LLT <i>Shame</i> 10090519 Current
To PT	<i>Emotional distress</i>		To PT <i>Emotional distress</i> 10049119

MSSO Comment: The proposal to add a new LLT Shame to PT Emotional distress is approved as requested. Shame is a painful feeling of humiliation or distress caused by the consciousness of wrong or foolish behavior.

Supplemental Update Report

CR Number: 2023320010	Implementation Date: 28-Nov-23	Related CR: 2023320010		
Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Nasal spray addiction</i>	Rejected		

MSSO Comment: The proposal to add a new PT Nasal spray addiction is not approved. Nasal spray addiction is not a true "addiction,". Only e.g. α -Sympathomimetika containing nasal sprays can cause addiction. This may be represented by LLT Addiction to drugs.

CR Number: 2023320011	Implementation Date: 28-Nov-23	Related CR: 2023320011		
Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Loss of empathy</i>	Approved Not as Requested	Proposed LLT <i>Loss of empathy</i> To PT <i>Lack of empathy</i>	10090517 Current 10090515

MSSO Comment: The proposal to add a new PT Loss of empathy is approved but not as requested. Empathy is defined as the ability to understand and share the feelings of another. A lack of empathy implies disregarding other people's opinions and underlying emotions and is one of the hallmarks of psychopathy. Loss of empathy will be added as an LLT to a new PT Lack of empathy, representing this personality feature more distinctly. In a related change, PT Lack of empathy will be added under HLT Behaviour and socialisation disturbances.

CR Number: 2023332306	Implementation Date: 28-Nov-23	Related CR: 2023320011		
Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Lack of empathy</i>	Approved as Requested	Proposed PT <i>Lack of empathy</i>	10090515
HLT primary	<i>Behaviour and socialisation disturbances</i>		HLT primary <i>Behaviour and socialisation disturbances</i>	10004209
SOC primary	<i>Psychiatric disorders</i>		SOC primary <i>Psychiatric disorders</i>	10037175

MSSO Comment:

Supplemental Update Report

CR Number: 2023320012 Implementation Date: 28-Nov-23 Related CR: 2023320012

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Involuntary medical treatment</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Therapeutic procedures NEC</i>		<i>Involuntary medical treatment</i>	10090511
SOC primary	<i>Surgical and medical procedures</i>		HLT primary	
			<i>Therapeutic procedures NEC</i>	10027700
			SOC primary	
			<i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new PT Involuntary medical treatment to primary HLT Therapeutic procedures NEC in SOC Surgical and medical procedures is approved as requested. Involuntary treatment refers to medical treatment undertaken without the consent of the person being treated.

CR Number: 2023320013 Implementation Date: 28-Nov-23 Related CR: 2023320013

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Term to modify	<i>Vaginal ring placement</i>	Rejected		
Replacement term	<i>Vaginal ring</i>			

MSSO Comment: The proposal to rename PT/LLT Vaginal ring placement to Vaginal ring is not approved. Even if there is some historical exceptions, MedDRA refrains from adding both the name of a device and the resulting action of its placement, favoring this second option to represent a device therapeutic intervention.

CR Number: 2023320014 Implementation Date: 27-Nov-23 Related CR: 2023320014

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Septate gallbladder</i>	Approved as Requested	Proposed LLT	
			<i>Septate gallbladder</i>	10090488 Current
			To PT	
			<i>Gallbladder anomaly congenital</i>	10061163

MSSO Comment: The proposal to add a new term Septate gallbladder is approved as requested. A septate gallbladder is a rare congenital variant where there may be a single septum or multiple septa in the gallbladder splitting its lumen into several parts. Septate gallbladder will be added as LLT to PT Gallbladder anomaly congenital.

Supplemental Update Report

CR Number: 2023320015 Implementation Date: 27-Nov-23 Related CR: 2023320015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Patellofemoral arthrosis</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>Patellofemoral pain syndrome</i>		<i>Patellofemoral arthrosis</i>	10090489 Current
			To PT	
			<i>Osteoarthritis</i>	10031161

MSSO Comment: The proposal to add a new LLT Patellofemoral arthrosis to PT Patellofemoral pain syndrome is approved but not as requested. Patellofemoral arthrosis will be added as a sub-concept LLT to PT Osteoarthritis.

CR Number: 2023320016 Implementation Date: 27-Nov-23 Related CR: 2023320016

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Premature orgasm</i>	Approved as Requested	Proposed LLT	
To PT	<i>Orgasm abnormal</i>		<i>Premature orgasm</i>	10090505 Current
			To PT	
			<i>Orgasm abnormal</i>	10031085

MSSO Comment: The proposal to add a new LLT Premature orgasm to PT Orgasm abnormal is approved as requested to provide a gender neutral term.

CR Number: 2023320017 Implementation Date: 27-Nov-23 Related CR: 2023320017

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Anorectal fistula repair</i>	Approved Not as Requested	Proposed LLT	
			<i>Anorectal fistula repair</i>	10090503 Current
			To PT	
			<i>Anal fistula repair</i>	10082792

MSSO Comment: The proposal to add a new PT Anorectal fistula repair is approved but not as requested. Anorectal fistula repair will be added as a sub-concept LLT to PT Anal fistula repair. In a related change, PT Rectal fistula repair will be demoted under PT Anal fistula repair to have consistent assignment for anal/rectal and anorectal fistulae and their repair terms.

Supplemental Update Report

CR Number: 2023331002 Implementation Date: 27-Nov-23 Related CR: 2023320017

Change Requested		Final Disposition	Final Placement	MedDRA Code #
PT to merge	Rectal fistula repair	Approved as Requested	PT to merge	10053267 Current
To PT	Anal fistula repair		To PT	
			Anal fistula repair	10082792

MSSO
Comment:

CR Number: 2023320018 Implementation Date: 27-Nov-23 Related CR: 2023320018

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Breast paraesthesia	Approved Not as Requested	Proposed PT	10090477
			HLT primary	10052767
			Reproductive system and breast disorders	10038604
			Paraesthesias and dysaesthesias	10033788
			Nervous system disorders	10029205

MSSO
Comment: The proposal to add a new LLT Breast paraesthesia is approved but not as requested. Tingling sensation and tenderness often are an early sign of pregnancy due to hormonal changes. Beast paraesthesia will be added as PT to primary HLT Breast signs and symptoms and to secondary HLT Paraesthesias and dysaesthesias. In a related change the American spelled counterpart LLT Breast paresthesia will be added as LLT to the new PT Breast paraesthesia.

CR Number: 2023331003 Implementation Date: 27-Nov-23 Related CR: 2023320018

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Breast paresthesia	Approved as Requested	Proposed LLT	10090484 Current
To PT	Breast paraesthesia		To PT	
			Breast paraesthesia	10090477

MSSO
Comment:

Supplemental Update Report

CR Number: 2023320019	Implementation Date: 27-Nov-23	Related CR: 2023320019		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Petersen hernia</i>	Approved as Requested	Proposed LLT	
To PT	<i>Internal hernia</i>		<i>Petersen hernia</i>	10090486 Current
			To PT	
			<i>Internal hernia</i>	10051989

MSSO Comment: The proposal to add a new LLT Petersen hernia to PT Internal hernia is approved as requested. A Petersen hernia is an internal hernia that occurs after a gastrojejunostomy surgery. In a related change, PT Internal hernia will be linked to HLT Gastrointestinal and hepatobiliary procedural complications as internal hernias are often seen after bariatric surgeries.

CR Number: 2023331004	Implementation Date: 27-Nov-23	Related CR: 2023320019		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Internal hernia</i>	Approved as Requested	Proposed PT	
To HLT	<i>Gastrointestinal and hepatobiliary procedural complications</i>		<i>Internal hernia</i>	10051989
			To HLT	
			<i>Gastrointestinal and hepatobiliary procedural complications</i>	10017927

MSSO Comment:

CR Number: 2023320020	Implementation Date: 27-Nov-23	Related CR: 2023320020		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Postpartum preeclampsia</i>	Approved Not as Requested	Proposed LLT	
			<i>Postpartum pre-eclampsia</i>	10090494 Current
			To PT	
			<i>Pre-eclampsia</i>	10036485

MSSO Comment: The proposal to add a new LLT Postpartum preeclampsia is approved but not as requested. High blood pressure in the postpartum period is most commonly seen in women with antenatal hypertensive disorders, but it can develop de novo in the postpartum time frame. Whether postpartum preeclampsia or eclampsia represents a separate entity from preeclampsia or eclampsia with antepartum onset is unclear. The requested term will be hyphenated and added as LLT Postpartum pre-eclampsia to PT Pre-eclampsia.

Supplemental Update Report

CR Number: 2023320021	Implementation Date: 01-Dec-23	Related CR: 2023320021		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Gene therapy</i>	Approved After Suspension	Proposed PT <i>Gene therapy</i>	10090618
			HLT primary <i>Gene therapies</i>	10018059
			SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new PT Gene therapy is approved as requested after suspension. Gene therapy is a medical technology which aims to produce a therapeutic effect through the manipulation of gene expression or through altering the biological properties of living cells. The broad term Gene therapy will be added as PT to HLT Gene therapies.

CR Number: 2023320022	Implementation Date: 27-Nov-23	Related CR: 2023320022		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Flared iliac wings</i>	Approved Not as Requested	Proposed LLT <i>Flared iliac wing</i>	10090490 Current
			To PT <i>Skeletal dysplasia</i>	10072610

MSSO Comment: The proposal to add a new PT Flared iliac wings is approved but not as requested. Flared iliac wing is defined as widening of the ilium ala combined with external rotation, leading to a flared appearance of the iliac wing and can be seen in hip dysplasia or as a characteristic radiological sign in e.g. achondroplasia. The proposed term will be added in the singular form as LLT Flared iliac wing to PT Skeletal dysplasia.

CR Number: 2023320023	Implementation Date: 27-Nov-23	Related CR: 2023320023		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Gastrointestinal lesion excision</i>	Rejected		

MSSO Comment: The proposal to add a new PT Gastrointestinal lesion excision is not approved. Gastrointestinal lesion excision is a very broad and unspecific term which does not provide any real information. The MSSO refrains from adding further lesion excision terms in addition to the umbrella PT Lesion excision to MedDRA.

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CR Number: 2023320024	Implementation Date: 27-Nov-23	Related CR: 2023320024		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Orchiolysis</i>	Approved as Requested	Proposed PT <i>Orchiolysis</i>	10090472
			HLT primary <i>Testicular and scrotal therapeutic procedures</i>	10043297
			SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new PT Orchiolysis is approved as requested. Orchiolysis, defined as correction of the undescended testicle without fixation, will be added as PT to HLT Testicular and scrotal therapeutic procedures.

CR Number: 2023320025	Implementation Date: 27-Nov-23	Related CR: 2023320025		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Abernethy malformation</i>	Approved as Requested	Proposed LLT <i>Abernethy malformation</i>	10090495 Current
			To PT <i>Portal venous system anomaly</i>	10076609

MSSO Comment: The proposal to add a new LLT Abernethy malformation is approved as requested. Congenital extrahepatic portosystemic shunt is a condition in which portal blood is shunted partially or completely into the systemic circulation via an abnormal communication of the portal system with the systemic circulation. Abernethy malformation will be added as a sub-concept LLT to PT Portal venous system anomaly.

CR Number: 2023320026	Implementation Date: 27-Nov-23	Related CR: 2023320026		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Mild cognitive impairment</i>	Approved Not as Requested	Proposed LLT <i>Mild cognitive impairment</i>	10090501 Current
			To PT <i>Cognitive disorder</i>	10057668

MSSO Comment: The proposal to add a new PT Mild cognitive impairment is approved but not as requested. Mild cognitive impairment will be added as synonym LLT of LLT Mild neurocognitive disorder under PT Cognitive disorder.

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CR Number: 2023320027 Implementation Date: 27-Nov-23 Related CR: 2023320027

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Skin temperature increased</i>	Approved as Requested	Proposed PT <i>Skin temperature increased</i>	10090473
			HLT primary <i>Physical examination procedures and organ system status</i>	10071941
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Skin temperature increased is approved as requested. Skin assessment should include skin temperature, color, turgor, moisture status, and integrity. In some instances, differences in local skin temperature can provide relevant clinical diagnostic details. Skin temperature increased will be added as PT under HLT Physical examination procedures and organ system status.

CR Number: 2023320028 Implementation Date: 27-Nov-23 Related CR: 2023320028

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Skin temperature decreased</i>	Approved as Requested	Proposed PT <i>Skin temperature decreased</i>	10090478
			HLT primary <i>Physical examination procedures and organ system status</i>	10071941
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Skin temperature decreased is approved as requested. Skin assessment should include skin temperature, color, turgor, moisture status, and integrity. In some instances, differences in local skin temperature can provide relevant clinical diagnostic details. Skin temperature decreased will be added as PT under HLT Physical examination procedures and organ system status.

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CR Number: 2023320029	Implementation Date: 27-Nov-23	Related CR: 2023320029		MedDRA Code #
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	
Proposed LLT	<i>Chondrodesis</i>	Approved Not as Requested	Proposed PT <i>Chondrodesis</i>	10090475
			HLT primary <i>Cartilage therapeutic procedures</i>	10052732
			SOC primary <i>Surgical and medical procedures</i>	10042613
MSSO Comment:	The proposal to add a new LLT Chondrodesis is approved but not as requested. Chondrodesis typically refers to a surgical procedure in which cartilage is intentionally destroyed or altered. The purpose of chondrodesis is often to eliminate the growth plates in bones, usually in the context of treating conditions related to bone growth or deformities. Chondrodesis will be added as a PT under HLT Cartilage therapeutic procedures.			

CR Number: 2023320030	Implementation Date: 27-Nov-23	Related CR: 2023320030		MedDRA Code #
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	
Proposed LLT	<i>Gastroscopy normal</i>	Approved Not as Requested	Proposed LLT <i>Gastroscopy normal</i>	10090496 Current
To PT	<i>Endoscopy upper gastrointestinal tract normal</i>		To PT <i>Oesophagogastroscopy normal</i>	10072165
MSSO Comment:	The proposal to add a new LLT Gastroscopy normal to PT Endoscopy upper gastrointestinal tract normal is approved but not as requested. Gastroscopy normal will be added as a sub-concept LLT to PT Oesophagogastroscopy normal. In a related change, LLT Gastroscopy abnormal be moved from PT Endoscopy upper gastrointestinal tract abnormal to PT Oesophagogastroscopy abnormal and LLT Gastroscopy and LLT Fibrogastroscopy will both be moved from PT Endoscopy upper gastrointestinal tract to PT Oesophagogastroscopy.			

CR Number: 2023331005	Implementation Date: 27-Nov-23	Related CR: 2023320030		MedDRA Code #
<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	
Proposed LLT	<i>Gastroscopy abnormal</i>	Approved as Requested	Proposed LLT <i>Gastroscopy abnormal</i>	10065714 Current
From PT	<i>Endoscopy upper gastrointestinal tract abnormal</i>		From PT <i>Endoscopy upper gastrointestinal tract abnormal</i>	10014820
To PT	<i>Oesophagogastroscopy abnormal</i>		To PT <i>Oesophagogastroscopy abnormal</i>	10072166
MSSO Comment:				

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CR Number: 2023331006 Implementation Date: 27-Nov-23 Related CR: 2023320030

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Gastroscopy	Approved as Requested	Proposed LLT	
From PT	Endoscopy upper gastrointestinal tract		Gastroscopy	10018047 Current
To PT	Oesophagogastroscopy		From PT	
			Endoscopy upper gastrointestinal tract	10014819
			To PT	
			Oesophagogastroscopy	10053058

MSSO
Comment:

CR Number: 2023331007 Implementation Date: 27-Nov-23 Related CR: 2023320030

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Fibrogastroscopy	Approved as Requested	Proposed LLT	
From PT	Endoscopy upper gastrointestinal tract		Fibrogastroscopy	10084919 Current
To PT	Oesophagogastroscopy		From PT	
			Endoscopy upper gastrointestinal tract	10014819
			To PT	
			Oesophagogastroscopy	10053058

MSSO
Comment:

CR Number: 2023320031 Implementation Date: 27-Nov-23 Related CR: 2023320031

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Organomegaly	Rejected		

MSSO
Comment: The proposal to add a new PT Organomegaly is not approved. Organomegaly refers to the abnormal enlargement of one or more organs in the body. This enlargement can be caused by various underlying medical conditions or diseases. As mentioned in the justification MedDRA includes specific organomegalies and syndromes associated with organomegalies. If more specific information is not reported, follow up requests should be considered to improve data quality or coding to a less specific term can be considered.

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CR Number: 2023320032	Implementation Date: 27-Nov-23	Related CR: 2023320032	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New LLT			
Proposed LLT <i>Blake's pouch cyst</i>		Approved as Requested	Proposed LLT <i>Blake's pouch cyst</i> 10090502 Current
			To PT <i>Congenital arachnoid cyst</i> 10085780

MSSO Comment: The proposal to add a new LLT Blake's pouch cyst is approved as requested. Blake's pouch cyst, also known as retrocerebellar arachnoid cyst or posterior fossa arachnoid cyst, is a rare congenital condition that involves the cerebellum and the fourth ventricle of the brain. Blake's pouch cyst will be added as sub-concept LLT to PT Congenital arachnoid cyst.

CR Number: 2023320033	Implementation Date: 27-Nov-23	Related CR: 2023320033	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New Term			
Proposed Term <i>Prevertebral abscess</i>		Approved as Requested	Proposed LLT <i>Prevertebral abscess</i> 10090500 Current
			To PT <i>Paraspinal abscess</i> 10070631

MSSO Comment: The proposal to add a new term Prevertebral abscess is approved as requested. A prevertebral abscess is a collection of pus that forms in the tissue in front of the vertebral column. This type of abscess typically occurs in the deep tissues of the neck and is often associated with infections or inflammation in the structures in that region. Prevertebral abscess will be added as an LLT to PT Paraspinal abscess. In a related change, for PT Paraspinal abscess the primary link will be changed from HLT Bone and joint infections to HLT Muscle and soft tissue infections then the secondary link will be changed from HLT Bone and joint infections (excl arthritis) to HLT Musculoskeletal and connective tissue infections and inflammations NEC.

CR Number: 2023331008	Implementation Date: 27-Nov-23	Related CR: 2023320033	MedDRA Code #
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Link (move) a PT to another HLT			
Proposed PT <i>Paraspinal abscess</i>		Approved as Requested	Proposed PT <i>Paraspinal abscess</i> 10070631
From HLT <i>Bone and joint infections</i>			From HLT <i>Bone and joint infections</i> 10005940
To HLT <i>Muscle and soft tissue infections</i>			To HLT <i>Muscle and soft tissue infections</i> 10057192

MSSO Comment:

Supplemental Update Report

CR Number: 2023331009		Implementation Date: 27-Nov-23	Related CR: 2023320033	
<u>Change Requested</u>	Link (move) a PT to another HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Paraspinal abscess</i>	Approved as Requested	Proposed PT	
From HLT	<i>Bone and joint infections (excl arthritis)</i>		<i>Paraspinal abscess</i>	10070631
To HLT	<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		From HLT	
			<i>Bone and joint infections (excl arthritis)</i>	10005941
			To HLT	
			<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>	10052776

MSSO
Comment:

CR Number: 2023320034		Implementation Date: 27-Nov-23	Related CR: 2023320034	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Laryngeal swelling</i>	Approved Not as Requested	Proposed LLT	
			<i>Laryngeal swelling</i>	10090491 Current
			To PT	
			<i>Laryngeal oedema</i>	10023845

MSSO
Comment: The proposal to add a new PT Laryngeal swelling is approved but not as requested. In relation to the larynx, swelling and edema are used synonymously and therefore Laryngeal swelling will be added as LLT under PT Laryngeal oedema.

CR Number: 2023320035		Implementation Date: 27-Nov-23	Related CR: 2023320035	
<u>Change Requested</u>	Change Status of LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
LLT to change	<i>Benign melanoma</i>	Approved as Requested	LLT to change	
Status	<i>non-current</i>		<i>Benign melanoma</i>	10068390 Non-Current
			Status	
			<i>non-current</i>	

MSSO
Comment: The proposal to change status of LLT Benign melanoma to non-current is approved as requested. The expression benign melanoma is misleading, potentially causing confusion and is not well recognized in medical literature.

Supplemental Update Report

CR Number: 2023320036 Implementation Date: 27-Nov-23 Related CR: 2023320036

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Uterine cervix agenesis	Approved Not as Requested	Proposed PT Cervical agenesis	10090480
			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 Uterine cervix agenesis is approved but not as requested. Cervical agenesis is a rare congenital Müllerian anomaly with a clinical appearance of an absence of menstruation which is accompanied by cyclic abdominal pain and abdominal bloating. The proposed term will be modified to Cervical agenesis and added as a PT with a primary link to HLT Female reproductive tract disorders congenital and a secondary link to HLT Congenital female reproductive tract disorders.

CR Number: 2023320037 Implementation Date: 27-Nov-23 Related CR: 2023320037

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Leukocyte adhesion deficiency type II	Approved as Requested	Proposed LLT Leukocyte adhesion deficiency type II	10090497 Current
			To PT Leukocyte adhesion deficiency	10090483

MSSO Comment: The proposal to add a new term Leukocyte adhesion deficiency type II is approved as requested. Leukocyte adhesion deficiency type II is a rare, autosomal recessive syndrome that is due to the absence of fucosylated carbohydrate ligands, resulting in defective rolling of hematopoietic cells. Leukocyte adhesion deficiency type II will be added as an LLT to new PT Leukocyte adhesion deficiency, which will be added, in a related change request to primary HLT Immune system abnormalities congenital, to secondary HLT Immunodeficiency disorders NEC and to secondary HLT White blood cell abnormal findings NEC. Furthermore, PT Leukocyte adhesion deficiency type I will be demoted under the new broader PT Leukocyte adhesion deficiency.

Supplemental Update Report

CR Number: 2023331010 Implementation Date: 27-Nov-23 Related CR: 2023320037

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Leukocyte adhesion deficiency</i>	Approved as Requested	Proposed PT <i>Leukocyte adhesion deficiency</i>	10090483
HLT primary	<i>Immune system abnormalities congenital</i>		HLT primary <i>Immune system abnormalities congenital</i>	10021424
SOC primary	<i>Congenital, familial and genetic disorders</i>		SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Immunodeficiency disorders NEC</i>	10052739
			SOC secondary <i>Immune system disorders</i>	10021428

MSSO
Comment:

CR Number: 2023331011 Implementation Date: 27-Nov-23 Related CR: 2023320037

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Leukocyte adhesion deficiency</i>	Approved as Requested	Proposed PT <i>Leukocyte adhesion deficiency</i>	10090483
To HLT	<i>White blood cell abnormal findings NEC</i>		To HLT <i>White blood cell abnormal findings NEC</i>	10047936

MSSO
Comment:

CR Number: 2023331012 Implementation Date: 27-Nov-23 Related CR: 2023320037

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	Demote a PT <i>Leukocyte adhesion deficiency type I</i>	Approved as Requested	PT to merge <i>Leukocyte adhesion deficiency type I</i>	10083936 Current
To PT	<i>Leukocyte adhesion deficiency</i>		To PT <i>Leukocyte adhesion deficiency</i>	10090483

MSSO
Comment:

Supplemental Update Report

CR Number: 2023320038 Implementation Date: 27-Nov-23 Related CR: 2023320038

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Soft tissue surgery</i>	Approved Not as Requested	Proposed PT <i>Soft tissue surgery</i>	10090479
To PT	<i>Soft tissue therapy</i>		HLT primary <i>Soft tissue therapeutic procedures NEC</i>	10052876
			SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new LLT Soft tissue surgery to PT Soft tissue therapy is approved but not as requested. Soft-tissue surgeries have multiple applications depending on the anatomical site where they are practiced. Soft tissue surgery will be added as a PT to HLT Soft tissue therapeutic procedures NEC.

CR Number: 2023320039 Implementation Date: 27-Nov-23 Related CR: 2023320039

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Missing information in patient's record</i>	Approved as Requested	Proposed LLT <i>Missing information in patient's record</i>	10090506 Current
To PT	<i>Circumstance or information capable of leading to medication error</i>		To PT <i>Circumstance or information capable of leading to medication error</i>	10064385

MSSO Comment: The proposal to add a new LLT Missing information in patient's record to PT Circumstance or information capable of leading to medication error is approved as requested aligned with existing LLT Incorrect information in patient's record.

CR Number: 2023320040 Implementation Date: 27-Nov-23 Related CR: 2023320040

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Dental socket preservation</i>	Approved as Requested	Proposed LLT <i>Dental socket preservation</i>	10090504 Current
			To PT <i>Dental bone graft</i>	10090365

MSSO Comment: The proposal to add a new term Dental socket preservation is approved as requested. Socket preservation or alveolar ridge preservation is a procedure to reduce bone loss after tooth extraction by grafting the socket immediately after a tooth extraction. Dental socket preservation will be added as an LLT to PT Dental bone graft.

Supplemental Update Report

CR Number: 2023320041

Implementation Date: 27-Nov-23

Related CR: 2023320041

[Change Requested](#)

Add a New LLT

[Final Disposition](#)

[Final Placement](#)

[MedDRA Code #](#)

Proposed LLT *Acne removal*

Rejected

MSSO Comment: The proposal to add a new LLT Acne removal is not approved. The requested term is non specific and maybe represented by existing LLT/PT Skin lesion removal. MedDRA cannot provide for all possible dermatological lesion/disease terms a removal term.

CR Number: 2023320042

Implementation Date: 27-Nov-23

Related CR: 2023320042

[Change Requested](#)

Add a New Term

[Final Disposition](#)

[Final Placement](#)

[MedDRA Code #](#)

Proposed Term *Splenopneumopexy*

Approved as Requested

Proposed LLT
Splenopneumopexy
To PT
Portal shunt procedure

10090507 Current

10077479

MSSO Comment: The proposal to add a new term Splenopneumopexy is approved as requested. Splenopneumopexy is a procedure designed to create a portopulmonary shunt in patients with esophageal variceal bleeding who are not candidates for conventional portosystemic shunts. It is performed by creating a parenchymatous venous anastomosis between the portal and pulmonary circulation systems, usually between the superior pole of the spleen and the left lung lower lobe vasculature. Splenopneumopexy will be added as LLT to PT Portal shunt procedure.

Supplemental Update Report

CR Number: 2023320043 Implementation Date: 27-Nov-23 Related CR: 2023320043

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term Add a New Term <i>Post ligation cardiac syndrome</i>	Approved as Requested	Proposed PT <i>Post ligation cardiac syndrome</i>	10090474
		HLT primary <i>Cardiac and vascular procedural complications</i>	10007602
		SOC primary <i>Injury, poisoning and procedural complications</i>	10022117
		HLT secondary <i>Neonatal cardiovascular disorders (excl cardiorespiratory arrest)</i>	10028926
		SOC secondary <i>Pregnancy, puerperium and perinatal conditions</i>	10036585

MSSO Comment: The proposal to add a new term Post ligation cardiac syndrome is approved as requested. Diastolic dysfunction, which may be exacerbated by persistent ducts arteriosus (PDA) ligation, may lead to pulmonary venous congestion and further impair pulmonary mechanics. Post ligation cardiac syndrome is a maladaptive pulmonary response after PDA ligation, which coupled with the cardiovascular changes also seen, frequently leads to pulmonary decompensation in the immediate postoperative period. Post ligation cardiac syndrome will be added as PT with a primary link to HLT Cardiac and vascular procedural complications and secondary link to HLT Neonatal cardiovascular disorders (excl cardiorespiratory arrest). In a related change, LLT Post patent ductus arteriosus ligation syndrome will be added to new PT Post ligation cardiac syndrome.

CR Number: 2023331013 Implementation Date: 27-Nov-23 Related CR: 2023320043

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT Add a New LLT <i>Post patent ductus arteriosus ligation syndrome</i>	Approved as Requested	Proposed LLT <i>Post patent ductus arteriosus ligation syndrome</i>	10090485 Current
To PT <i>Post ligation cardiac syndrome</i>		To PT <i>Post ligation cardiac syndrome</i>	10090474

MSSO Comment:

Supplemental Update Report

CR Number: 2023320044	Implementation Date: 27-Nov-23	Related CR: 2023320044		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Laryngotracheal stenosis</i>	Approved as Requested	Proposed LLT <i>Laryngotracheal stenosis</i>	10090487 Current
			To PT <i>Laryngeal stenosis</i>	10023862

MSSO Comment: The proposal to add a new term Laryngotracheal stenosis is approved as requested, aligned with LLT Subglottic stenosis. Laryngotracheal stenosis (LTS) is a narrowing of the upper airway between the larynx and the trachea with potentially devastating consequences, including respiratory failure, cardiopulmonary arrest, and death. Laryngotracheal stenosis will be added as subconcept LLT under PT Laryngeal stenosis.

CR Number: 2023320045	Implementation Date: 27-Nov-23	Related CR: 2023320045		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Bile duct leak</i>	Approved as Requested	Proposed LLT <i>Bile duct leak</i>	10090492 Current
			To PT <i>Perforation bile duct</i>	10034405

MSSO Comment: The proposal to add a new term Bile duct leak is approved as requested. The cause of bile duct leaks can be either iatrogenic or more rarely, traumatic. The most common cause is related to laparoscopic cholecystectomy. Bile duct leak will be added as a sub-concept LLT under PT Perforation bile duct.

CR Number: 2023320046	Implementation Date: 27-Nov-23	Related CR: 2023320046		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Blood draw</i>	Approved as Requested	Proposed LLT <i>Blood draw</i>	10090498 Current
			To PT <i>Venipuncture</i>	10059445

MSSO Comment: The proposal to add a new term Blood draw is approved as requested. In medicine, venipuncture or venepuncture is the process of obtaining intravenous access for the purpose of venous blood sampling (also called phlebotomy) or intravenous therapy. Blood draw will be added as an LLT under PT Venipuncture. In a related change, PT Phlebotomy will demoted under PT Venipuncture.

Supplemental Update Report

CR Number: 2023331014	Implementation Date: 27-Nov-23	Related CR: 2023320046		
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Phlebotomy</i>	Approved as Requested	PT to merge	
To PT	<i>Venipuncture</i>		<i>Phlebotomy</i>	10059648 Current
			To PT	
			<i>Venipuncture</i>	10059445

MSSO
Comment:

CR Number: 2023320047	Implementation Date: 27-Nov-23	Related CR: 2023320047		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Duchenne muscular dystrophy cardiomyopathy</i>	Rejected		

MSSO Comment: The proposal to add a new term Duchenne muscular dystrophy cardiomyopathy is not approved. Although an internationally recognized medical concept, this is a combination term of a rare genetic disorder and one of its complications.

CR Number: 2023320048	Implementation Date: 27-Nov-23	Related CR: 2023320048		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Escutheonectomy</i>	Approved Not as Requested	Proposed PT	
			<i>Escutheonectomy</i>	10090481
			HLT primary	
			<i>Penile therapeutic procedures</i>	10034309
			SOC primary	
			<i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new term Escutheonectomy is approved but not as requested. Escutheonectomy is defined as a procedure involving removal of the pad of fat just above the pubic area for treatment of a buried penis. The proposed term will be modified to the more common spelling as PT Escutheonectomy under HLT Penile therapeutic procedures.

Supplemental Update Report

CR Number: 2023320049 Implementation Date: 27-Nov-23 Related CR: 2023320049

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term	Approved as Requested	Proposed PT	
	<i>Akinetopsia</i>		<i>Akinetopsia</i>	10090482
			HLT primary	
			<i>Cortical dysfunction NEC</i>	10011168
			SOC primary	
			<i>Nervous system disorders</i>	10029205
			HLT secondary	
			<i>Specific cognitive ability disturbances</i>	10041427
			SOC secondary	
			<i>Psychiatric disorders</i>	10037175

MSSO Comment: The proposal to add a new term Akinetopsia is approved as requested. Akinetopsia refers to "motion blindness", which is a higher visual processing disorder from an extra-striate lesion, in which a patient has difficulty specifically perceiving objects in motion with variable severity and rarely complete. Akinetopsia will be added as a new PT under primary HLT Cortical dysfunction NEC and secondary HLT Specific cognitive ability disturbances.

CR Number: 2023320050 Implementation Date: 27-Nov-23 Related CR: 2023320050

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term	Approved as Requested	Proposed LLT	
	<i>Paroxysmal complete atrioventricular block</i>		<i>Paroxysmal complete atrioventricular block</i>	10090493 Current
			To PT	
			<i>Atrioventricular block complete</i>	10003673

MSSO Comment: The proposal to add a new term Paroxysmal complete atrioventricular block is approved as requested. Complete atrioventricular block may be persistent or paroxysmal and is associated with a junctional or ventricular escape rhythm. Paroxysmal complete atrioventricular block will be added as sub-concept LLT under PT Atrioventricular block complete.

CR Number: 2023320051 Implementation Date: 27-Nov-23 Related CR: 2023320051

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Add a New Term	Approved as Requested	Proposed LLT	
	<i>Ocular mucous membrane pemphigoid</i>		<i>Ocular mucous membrane pemphigoid</i>	10090508 Current
			To PT	
			<i>Ocular pemphigoid</i>	10067776

MSSO Comment: The proposal to add a new term Ocular mucous membrane pemphigoid is approved as requested. Ocular mucous membrane pemphigoid is a chronic, bilateral, progressive scarring and shrinkage of the conjunctiva with opacification of the cornea. Ocular mucous membrane pemphigoid will be added as LLT under PT Ocular pemphigoid.

Supplemental Update Report

CR Number: 2023320052 **Implementation Date:** 27-Nov-23 **Related CR:** 2023320052

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Deep vein thromboembolism	Rejected		

MSSO Comment: The proposal to add a new term Deep vein thromboembolism is not approved. The requested term is a combination of two pathologies representing cause and complication.

CR Number: 2023320053 **Implementation Date:** 27-Nov-23 **Related CR:** 2023320053

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Laser surgery	Approved as Requested	Proposed LLT	
To PT	Surgery		Laser surgery	10090499 Current
			To PT	
			Surgery	10042609

MSSO Comment: The proposal to add a new LLT Laser surgery to PT Surgery is approved as requested. The term may have a dual meaning, as it may stand for a type of surgery that uses special light beams instead of instruments or any of the specific laser driven procedures in different organs. For clarity, Laser surgery will be added as subconcept LLT under PT Surgery.

Supplemental Update Report

CR Number: 2023320054 Implementation Date: 27-Nov-23 Related CR: 2023320054

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Failed vacuum extraction delivery</i>	Approved as Requested	Proposed PT <i>Failed vacuum extraction delivery</i>	10090476
			HLT primary <i>Reproductive tract and breast procedural complications</i>	10038609
			SOC primary <i>Injury, poisoning and procedural complications</i>	10022117
			HLT secondary <i>Maternal complications of delivery NEC</i>	10026905
			SOC secondary <i>Pregnancy, puerperium and perinatal conditions</i>	10036585

MSSO Comment: The proposal to add a new term Failed vacuum extraction delivery is approved as requested. A failed vacuum extraction delivery was defined as a delivery that was started as vacuum extraction but was converted to a cesarean section because of failure to progress. Failed vacuum extraction delivery will be added as a new PT under primary HLT Reproductive tract and breast procedural complications and secondary HLT Maternal complications of delivery NEC.

CR Number: 2023320055 Implementation Date: 21-Nov-23 Related CR: 2023320055

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Voice Spectrography Test</i>	Approved Not as Requested	Proposed PT <i>Voice spectrography</i>	10090460
			HLT primary <i>Respiratory and pulmonary function diagnostic procedures</i>	10037385
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new LLT Voice Spectrography Test is approved but not as requested. Voice spectrography is a visualising method to analyse speech, voice and language deficits as well it can be used for forensic reasons. The requested term will be modified according MedDRA capitalisation conventions and without test and added as PT Voice spectrography to HLT Respiratory and pulmonary function diagnostic procedures.

Supplemental Update Report

CR Number: 2023320056	Implementation Date: 21-Nov-23	Related CR: 2023320056	MedDRA Code #
Change Requested	Add a New Term	Final Disposition	Final Placement
Proposed Term	<i>Saliva aspirator</i>	Rejected	

MSSO Comment: The proposal to add a new term Saliva aspirator is not approved. MedDRA does not add device names.

CR Number: 2023321000	Implementation Date: 21-Nov-23	Related CR: 2023321000	MedDRA Code #
Change Requested	Add a New Term	Final Disposition	Final Placement
Proposed Term	<i>Immune mediated diarrhea</i>	Rejected	

MSSO Comment: The proposal to add a new term Immune mediated diarrhea is not approved. Diarrhoea only is the clinical symptom of an immune mediated reaction. Please consider PT Immune-mediated enterocolitis or any LLT under it for your coding needs.

CR Number: 2023321001	Implementation Date: 21-Nov-23	Related CR: 2023321001	MedDRA Code #
Change Requested	Add a New LLT	Final Disposition	Final Placement
Proposed LLT	<i>Chronic hyperplastic candidiasis</i>	Approved Not as Requested	Proposed PT
To PT	<i>Oral candidiasis</i>		<i>Chronic hyperplastic candidiasis</i> 10090461
			HLT primary <i>Candida infections</i> 10007134
			SOC primary <i>Infections and infestations</i> 10021881
			HLT secondary <i>Oral soft tissue infections</i> 10031017
			SOC secondary <i>Gastrointestinal disorders</i> 10017947

MSSO Comment: The proposal to add a new LLT Chronic hyperplastic candidiasis to PT Oral candidiasis is approved but not as requested. Chronic hyperplastic candidiasis is a chronic oral mucosal infection caused by Candida. It is characterized mainly by leukoplakia and hyperplasia with a nodular or speckled appearance. Most lesions involve the cheeks, tongue, and palate, often accompanied by angular stomatitis. Persistent hyperplastic lesions may lead to epithelial dysplasia and malignant transformation. Chronic hyperplastic candidiasis will be added as a PT with a primary link to HLT Candida infections and a secondary link to HLT Oral soft tissue infections.

Supplemental Update Report

CR Number: 2023321002 Implementation Date: 21-Nov-23 Related CR: 2023321002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Chronic hyperplastic laryngitis	Approved Not as Requested	Proposed PT	
To PT	Laryngitis		Chronic hyperplastic laryngitis	10090462
			HLT primary	
			Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	10023819
			SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new LLT Chronic hyperplastic laryngitis to PT Laryngitis is approved but not as requested. Chronic hyperplastic laryngitis is a condition characterized by the long-term inflammation and swelling of the vocal cords. This inflammation can lead to changes in the structure and function of the vocal cords, resulting in hoarseness and other voice-related issues. Chronic hyperplastic laryngitis will be added as a PT to primary HLT Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms).

CR Number: 2023321003 Implementation Date: 21-Nov-23 Related CR: 2023321003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Popliteal vein aneurysm	Rejected		

MSSO Comment: The proposal to add a new LLT Popliteal vein aneurysm is not approved. Popliteal vein aneurysms are very rare. Generally, new terms for structures such as arteries, veins, and nerves, are not added beyond the tertiary branch unless medically significant.

CR Number: 2023321004 Implementation Date: 28-Nov-23 Related CR: 2023321004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Difficulty eating	Rejected		

MSSO Comment: The proposal to add a new LLT Difficulty eating is not approved. The proposed term is ambiguous out of context.

Supplemental Update Report

CR Number: 2023321005 Implementation Date: 28-Nov-23 Related CR: 2023321005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Cardiac mri (magnetic resonance imaging heart) normal and abnormal	Approved Not as Requested	Proposed PT Magnetic resonance imaging heart abnormal	10090464
			HLT primary Cardiac imaging procedures	10007574
			SOC primary Investigations	10022891

MSSO Comment: The proposal to add a new LLT Cardiac mri (magnetic resonance imaging heart) normal and abnormal is approved but not as requested. Cardiac MRI abnormal results may be due to varying conditions, including heart valve disorders, pericardial effusion, cardiac tumors (such a trial myxoma), congenital heart disease, etc. The proposed term will be modified to represent the abnormal result of existing PT Magnetic resonance imaging heart. Magnetic resonance imaging heart abnormal will be added as a PT to HLT Cardiac imaging procedures. In a related change, a new PT Magnetic resonance imaging heart normal, will also be added under HLT Cardiac imaging procedures to represent the normal result.

CR Number: 2023325005 Implementation Date: 28-Nov-23 Related CR: 2023321005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Magnetic resonance imaging heart normal	Approved as Requested	Proposed PT Magnetic resonance imaging heart normal	10090467
HLT primary	Cardiac imaging procedures		HLT primary Cardiac imaging procedures	10007574
SOC primary	Investigations		SOC primary Investigations	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2023321006 Implementation Date: 28-Nov-23 Related CR: 2023321006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Mri / Magnetic resonance imaging neck abnormal/normal neck</i>	Approved Not as Requested	Proposed PT <i>Magnetic resonance imaging neck abnormal</i>	10090463
			HLT primary <i>Musculoskeletal and soft tissue imaging procedures</i>	10028386
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new LLT Mri / Magnetic resonance imaging neck abnormal/normal neck is approved but not as requested. Magnetic resonance imaging neck abnormal could be associated to cases of severe neck, shoulder, or arm pain, myelitis, spinal trauma, multiple sclerosis, severe scoliosis, spine neoplasms, spinal degenerative disease, etc. The proposed term will be modified to represent the abnormal result of existing PT Magnetic resonance imaging neck. Magnetic resonance imaging neck abnormal will be added as a PT to HLT Musculoskeletal and soft tissue imaging procedures. In a related change, a new PT named Magnetic resonance imaging neck normal, will also be added under HLT Cardiac imaging procedures to represent the normal result.

CR Number: 2023325006 Implementation Date: 28-Nov-23 Related CR: 2023321006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Magnetic resonance imaging neck normal</i>	Approved as Requested	Proposed PT <i>Magnetic resonance imaging neck normal</i>	10090466
HLT primary	<i>Cardiac imaging procedures</i>		HLT primary <i>Cardiac imaging procedures</i>	10007574
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2023321007 Implementation Date: 28-Nov-23 Related CR: 2023321007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Ct (computerized tomogram) neck abnormal and normal</i>	Approved Not as Requested	Proposed PT <i>Computerised tomogram neck abnormal</i>	10090465
			HLT primary <i>Musculoskeletal and soft tissue imaging procedures</i>	10028386
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new LLT Ct (computerized tomogram) neck abnormal and normal is approved but not as requested. A computerised tomogram neck abnormal could be related to degenerative changes due to age, fractures, osteoarthritis, disk herniation, etc. The proposed term will be modified to represent the abnormal result of existing PT Computerised tomogram neck. Computerised tomogram neck abnormal will be added as a PT to HLT Musculoskeletal and soft tissue imaging procedures. In a related change, a new PT named Computerised tomogram neck normal, will also be added under HLT Musculoskeletal and soft tissue imaging procedures to represent the normal result. Furthermore, American spelled counterparts of both terms - LLT Computerized tomogram neck abnormal will be added to PT Computerised tomogram neck abnormal and LLT Computerized tomogram neck normal will be added to PT Computerised tomogram neck normal.

CR Number: 2023325007 Implementation Date: 28-Nov-23 Related CR: 2023321007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Computerized tomogram neck abnormal</i>	Approved as Requested	Proposed LLT <i>Computerized tomogram neck abnormal</i>	10090527 Current
To PT	<i>Computerised tomogram neck abnormal</i>		To PT <i>Computerised tomogram neck abnormal</i>	10090465

MSSO Comment:

CR Number: 2023325008 Implementation Date: 28-Nov-23 Related CR: 2023321007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Computerized tomogram neck normal</i>	Approved as Requested	Proposed LLT <i>Computerized tomogram neck normal</i>	10090525 Current
To PT	<i>Computerised tomogram neck normal</i>		To PT <i>Computerised tomogram neck normal</i>	10090468

MSSO Comment:

Supplemental Update Report

CR Number: 2023325009 Implementation Date: 28-Nov-23 Related CR: 2023321007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Computerised tomogram neck normal</i>	Approved as Requested	Proposed PT <i>Computerised tomogram neck normal</i>	10090468
HLT primary	<i>Musculoskeletal and soft tissue imaging procedures</i>		HLT primary <i>Musculoskeletal and soft tissue imaging procedures</i>	10028386
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO
Comment:

CR Number: 2023321008 Implementation Date: 28-Nov-23 Related CR: 2023321008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Spinal lesion</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Spinal lesion is not approved. To avoid the overpopulation of the terminology, the MSSO refrains from adding new "lesion" terms. Such terms may only be considered for inclusion in MedDRA when the word "lesion" is part of the wording of a medical concept (e.g., PT Glomerulonephritis minimal lesion) or is itself a well-documented medical concept (e.g., LLT Bankart lesion). It is considered that, generally, a broad "lesion" term only adds an additional imprecise term to an existing "disorder" concept, such as existing PT Spinal disorder.

CR Number: 2023321009 Implementation Date: 28-Nov-23 Related CR: 2023321009

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Hot/cold flashes</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Hot/cold flashes is not approved. LT Hot flashes exists but cold flashes is an expression not internationally recognized and is likely to lead to translation problems.

Supplemental Update Report

CR Number: 2023321010	Implementation Date: 28-Nov-23	Related CR: 2023321010		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Adrenaline rush</i>	Approved as Requested	Proposed LLT <i>Adrenaline rush</i>	10090523 Current
			To PT <i>Sympathomimetic effect</i>	10062119

MSSO Comment: The proposal to add a new LLT Adrenaline rush is approved as requested. Adrenaline rush will be added as sub-concept LLT to PT Sympathomimetic effect.

CR Number: 2023321011	Implementation Date: 28-Nov-23	Related CR: 2023321011		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Basic metabolic panel/ bmp normal and abnormal</i>	Approved Not as Requested	Proposed LLT <i>Basic metabolic panel abnormal</i>	10090524 Current
			To PT <i>Metabolic function test abnormal</i>	10061286

MSSO Comment: The proposal to add a new LLT Basic metabolic panel/ bmp normal and abnormal is approved but not as requested. A basic metabolic panel is a blood sample test that measures eight different substances in blood. The panel provides helpful information about chemical balance and metabolism. The proposed term will be modified to represent the abnormal result of existing LLT Basic metabolic panel. Basic metabolic panel abnormal will be added as an LLT to PT Metabolic function test abnormal. In a related change, a new LLT Basic metabolic panel normal, will be added under PT Metabolic function test normal to represent the normal result.

CR Number: 2023325010	Implementation Date: 28-Nov-23	Related CR: 2023321011		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Basic metabolic panel normal</i>	Approved as Requested	Proposed LLT <i>Basic metabolic panel normal</i>	10090528 Current
To PT	<i>Metabolic function test normal</i>		To PT <i>Metabolic function test normal</i>	10062192

MSSO Comment:

Supplemental Update Report

CR Number: 2023321012		Implementation Date: 28-Nov-23	Related CR: 2023321012	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Comprehensive metabolic panel/cmp normal and abnormal</i>	Approved Not as Requested	Proposed LLT <i>Comprehensive metabolic panel abnormal</i>	10090522 Current
			To PT <i>Metabolic function test abnormal</i>	10061286

MSSO Comment: The proposal to add a new LLT Comprehensive metabolic panel/cmp normal and abnormal is approved but not as requested. A comprehensive metabolic panel is a test that measures 14 different substances in blood, providing important information about chemical balance and metabolism. The proposed term will be modified to represent the abnormal result of existing LLT Comprehensive metabolic panel. Comprehensive metabolic panel abnormal will be added as an LLT to PT Metabolic function test abnormal. In a related change, a new LLT Comprehensive metabolic panel normal, will be added under PT Metabolic function test normal to represent the normal result.

CR Number: 2023325011		Implementation Date: 28-Nov-23	Related CR: 2023321012	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Comprehensive metabolic panel normal</i>	Approved as Requested	Proposed LLT <i>Comprehensive metabolic panel normal</i>	10090526 Current
To PT	<i>Metabolic function test normal</i>		To PT <i>Metabolic function test normal</i>	10062192

MSSO Comment:

CR Number: 2023321013		Implementation Date: 28-Nov-23	Related CR: 2023321013	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Unable or inability to function normally</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Unable or inability to function normally is not approved. The proposed concept is an ambiguous expression, as it may refer to a very wide spectrum of different kind of functions, from psychomotor to physiologic or even metabolic ones.

Supplemental Update Report

CR Number: 2023321014 Implementation Date: 29-Nov-23 Related CR: 2023321014

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Non-inflammatory anterior chamber pigmented cells</i>	Approved Not as Requested	Proposed LLT <i>Non-inflammatory anterior chamber pigmented cells</i>	10090569 Current
HLT primary	<i>Anterior chamber structural change, deposit and degeneration</i>		To PT	
SOC primary	<i>Eye disorders</i>		<i>Anterior chamber pigmentation</i>	10057400

MSSO Comment: The proposal to add a new PT Non-inflammatory anterior chamber pigmented cells to primary HLT Anterior chamber structural change, deposit and degeneration in SOC Eye disorders is approved but not as requested. Non-inflammatory processes resulting in cells or particles in the anterior chamber which appear between 12-20 weeks following intravitreal gene therapy administration and resolve spontaneously without treatment or intervention. Slit lamp biomicroscopy shows small, pigmented cells or granules in the anterior chamber (aqueous humor) without additional findings and in the absence of inflammatory cells. Non-inflammatory anterior chamber pigmented cells will be added as a sub-concept LLT to PT Anterior chamber pigmentation.

CR Number: 2023324000 Implementation Date: 27-Nov-23 Related CR: 2023324000

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Capsulectomy eye</i>	Approved Not as Requested	Proposed LLT <i>Lens capsulectomy</i>	10090469
			To PT <i>Phacocystectomy</i>	10053294 Current

MSSO Comment: The proposal to add a new term Capsulectomy eye is approved but not as requested. Phacocystectomy is excision of a portion of the capsule of the lens for cataract while capsulectomy is excision of the capsule of the lens. Proposed term will be modified to natural word order and added as LLT Lens capsulectomy under PT Phacocystectomy. In a related change, LLT Lens capsulectomy will be swapped with PT Phacocystectomy to represent the more correct and modern term at PT level.

CR Number: 2023331001 Implementation Date: 27-Nov-23 Related CR: 2023324000

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Swap a PT with an LLT <i>Phacocystectomy</i>	Approved as Requested	Proposed PT <i>Phacocystectomy</i>	10053294 Current
With LLT	<i>Lens capsulectomy</i>		With LLT <i>Lens capsulectomy</i>	10090469

MSSO Comment:

Supplemental Update Report

CR Number: 2023324004 Implementation Date: 28-Nov-23 Related CR: 2023324004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	Demote a PT <i>Electrocardiogram ST-T change</i>	Approved as Requested	PT to merge <i>Electrocardiogram ST-T change</i>	10061117 Current
To PT	<i>Electrocardiogram ST-T segment abnormal</i>		To PT <i>Electrocardiogram ST-T segment abnormal</i>	10052333

MSSO Comment: The proposal to demote the PT Electrocardiogram ST-T change under PT Electrocardiogram ST-T segment abnormal is approved as requested. Nonspecific ST-segment and T-wave (ST-T) changes represent one of the most prevalent electrocardiographic abnormalities

CR Number: 2023324005 Implementation Date: 28-Nov-23 Related CR: 2023324005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Superoxide dismutase activity decreased</i>	Approved as Requested	Proposed PT <i>Superoxide dismutase activity decreased</i>	10090529
HLT primary	<i>Tissue enzyme analyses NEC</i>		HLT primary <i>Tissue enzyme analyses NEC</i>	10043891
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Superoxide dismutase activity decreased to primary HLT Tissue enzyme analyses NEC in SOC Investigations is approved as requested. Superoxide dismutase is a crucial enzyme required to maintain the redox potential of the cells. It plays a vital role in protecting normal cells from reactive oxygen species produced during many intracellular pathogens infections. Superoxide dismutase activity decreased represents the counterpart result of existing PT Superoxide dismutase activity increased.

CR Number: 2023325000 Implementation Date: 28-Nov-23 Related CR: 2023325000

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Link (move) an LLT to another PT <i>Radiotherapy to spine NOS</i>	Approved as Requested	Proposed LLT <i>Radiotherapy to spine NOS</i>	10052207 Current
From PT	<i>Radiotherapy to bone</i>		From PT <i>Radiotherapy to bone</i>	10062089
To PT	<i>Spinal radiotherapy</i>		To PT <i>Spinal radiotherapy</i>	10089344

MSSO Comment: The proposal to move the LLT Radiotherapy to spine NOS from PT Radiotherapy to bone to PT Spinal radiotherapy is approved as requested for better alignment.

Supplemental Update Report

CR Number: 2023325001 Implementation Date: 28-Nov-23 Related CR: 2023325001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	STXBP1-DEE and/or STXBP1 encephalopathy	Approved Not as Requested	Proposed LLT STXBP1 developmental and epileptic encephalopathy	10090536 Current
			To PT Early infantile epileptic encephalopathy with burst-suppression	10071545

MSSO Comment: The proposal to add a new term STXBP1-DEE and/or STXBP1 encephalopathy is approved but not as requested. The proposed term will be modified and added as a synonym LLT STXBP1 developmental and epileptic encephalopathy to PT Early infantile epileptic encephalopathy with burst-suppression. In a related change, PT Early infantile epileptic encephalopathy with burst-suppression will be linked to HLT Neurological disorders congenital NEC and in a second step, primary SOC will be changed from SOC Nervous system disorders to SOC Congenital, familial and genetic disorders. Furthermore, Early infantile epileptic encephalopathy with burst-suppression will be moved from HLT Cognitive and attention disorders and disturbances NEC to HLT Pervasive developmental disorders NEC for better grouping with related terms.

CR Number: 2023332307 Implementation Date: 28-Nov-23 Related CR: 2023325001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Early infantile epileptic encephalopathy with burst-suppression	Approved as Requested	Proposed PT Early infantile epileptic encephalopathy with burst-suppression	10071545
To HLT	Neurological disorders congenital NEC		To HLT Neurological disorders congenital NEC	10029300

MSSO Comment:

CR Number: 2023332308 Implementation Date: 28-Nov-23 Related CR: 2023325001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Early infantile epileptic encephalopathy with burst-suppression	Approved as Requested	Proposed PT Early infantile epileptic encephalopathy with burst-suppression	10071545
Old Primary SOC	Nervous system disorders		Old Primary SOC Nervous system disorders	10029205
New Primary SOC	Congenital, familial and genetic disorders		New Primary SOC Congenital, familial and genetic disorders	10010331

MSSO Comment:

Supplemental Update Report

CR Number: 2023332310 Implementation Date: 28-Nov-23 Related CR: 2023325001

<u>Change Requested</u>	<u>Link (move) a PT to another HLT</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Early infantile epileptic encephalopathy with burst-suppression</i>	Approved as Requested	Proposed PT	
From HLT	<i>Cognitive and attention disorders and disturbances NEC</i>		<i>Early infantile epileptic encephalopathy with burst-suppression</i>	10071545
To HLT	<i>Pervasive developmental disorders NEC</i>		From HLT	
			<i>Cognitive and attention disorders and disturbances NEC</i>	10009842
			To HLT	
			<i>Pervasive developmental disorders NEC</i>	10034740

MSSO
Comment:

CR Number: 2023325002 Implementation Date: 28-Nov-23 Related CR: 2023325002

<u>Change Requested</u>	<u>Add a New Term</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>SLC6A1-NDD and/or SLC6A1 neurodevelopmental disorder</i>	Approved Not as Requested	Proposed PT	
			<i>SLC6A1 neurodevelopmental disorder</i>	10090535
			HLT primary	
			<i>Neurological disorders congenital NEC</i>	10029300
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Seizures and seizure disorders NEC</i>	10039912
			SOC secondary	
			<i>Nervous system disorders</i>	10029205

MSSO
Comment: The proposal to add a new term SLC6A1-NDD and/or SLC6A1 neurodevelopmental disorder is approved but not as requested. SLC6A1-related disorder is a recently identified, rare, genetic neurodevelopmental disorder that is associated with loss-of-function variants in SLC6A1. This gene encodes GABA transporter type I that is responsible for re-uptake of GABA from the synapse into the pre-synaptic terminal or circulating neuroglia. The phenotypic spectrum is broad and includes developmental delay, epilepsy, and autism or autistic traits. SLC6A1-NDD and/or SLC6A1 neurodevelopmental disorder will be modified to SLC6A1 neurodevelopmental disorder and added as PT to primary HLT Neurological disorders congenital NEC, secondary HLT Seizures and seizure disorders NEC, and to secondary HLT Pervasive developmental disorders NEC.

Supplemental Update Report

CR Number: 2023332309	Implementation Date: 28-Nov-23	Related CR: 2023325002		
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>SLC6A1 neurodevelopmental disorder</i>	Approved as Requested	Proposed PT	
To HLT	<i>Pervasive developmental disorders NEC</i>		<i>SLC6A1 neurodevelopmental disorder</i>	10090535
			To HLT	
			<i>Pervasive developmental disorders NEC</i>	10034740

MSSO
Comment:

CR Number: 2023325012	Implementation Date: 28-Nov-23	Related CR: 2023325012		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Gastric cyst excision</i>	Rejected		
HLT primary	<i>Gastric therapeutic procedures</i>			
SOC primary	<i>Surgical and medical procedures</i>			

MSSO Comment: The proposal to add a new PT Gastric cyst excision to primary HLT Gastric therapeutic procedures in SOC Surgical and medical procedures is not approved. MedDRA cannot provide a term for all possible site specific excision/removal of cysts. For indications for a surgical procedures the underlying pathology can be used for coding purposes.

CR Number: 2023325013	Implementation Date: 28-Nov-23	Related CR: 2023325013		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Chronic neuromuscular respiratory failure</i>	Rejected		
HLT primary	<i>Thoracic musculoskeletal disorders</i>			
SOC primary	<i>Respiratory, thoracic and mediastinal disorders</i>			

MSSO Comment: The proposal to add a new PT Chronic neuromuscular respiratory failure to primary HLT Thoracic musculoskeletal disorders in SOC Respiratory, thoracic and mediastinal disorders is not approved. The requested term represents a combination concept with a causal relationship (due to underlying pathology). The MSSO refrains from adding such combinations.

Supplemental Update Report

CR Number: 2023325014	Implementation Date: 28-Nov-23	Related CR: 2023325014		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Idiopathic infantile hypercalcemia</i>	Approved as Requested	Proposed LLT <i>Idiopathic infantile hypercalcemia</i> To PT <i>Idiopathic infantile hypercalcaemia</i>	10090539 Current 10090537

MSSO Comment: The proposal to add a new term Idiopathic infantile hypercalcemia is approved as requested. Idiopathic infantile hypercalcemia is an uncommon disorder characterized by elevated serum concentrations of 1,25 dihydroxyvitamin D and low parathyroid hormone levels, which presents with mild to severe hypercalcemia during the first months of life. Biallelic variants in the CYP24A1 or SLC34A1 genes are associated with severe severe forms. Idiopathic infantile hypercalcemia will be added as an LLT to a new PT Idiopathic infantile hypercalcaemia representing the British spelling of the concept, which will be linked to the bi-axial HLT Inborn errors of metabolism NEC (primary SOC Congenital, familial and genetic disorders and secondary SOC Metabolism and nutrition disorders).

CR Number: 2023332311	Implementation Date: 28-Nov-23	Related CR: 2023325014		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Idiopathic infantile hypercalcaemia</i>	Approved as Requested	Proposed PT <i>Idiopathic infantile hypercalcaemia</i>	10090537
HLT primary	<i>Inborn errors of metabolism NEC</i>		HLT primary <i>Inborn errors of metabolism NEC</i>	10021606
SOC primary	<i>Congenital, familial and genetic disorders</i>		SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Inborn errors of metabolism NEC</i>	10021606
			SOC secondary <i>Metabolism and nutrition disorders</i>	10027433

MSSO Comment:

Supplemental Update Report

CR Number: 2023325015 Implementation Date: 28-Nov-23 Related CR: 2023325015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Infantile hypercalcemia-1</i>	Approved Not as Requested	Proposed LLT <i>Infantile hypercalcemia type 1</i>	10090540 Current
			To PT <i>Idiopathic infantile hypercalcaemia</i>	10090537

MSSO Comment: The proposal to add a new term Infantile hypercalcemia-1 is approved but not as requested. Infantile hypercalcemia type 1 is caused by homozygous or compound heterozygous mutation in the CYP24A1 gene on chromosome 20q13. Individuals with infantile hypercalcemia 1 have normal levels of blood phosphate, in contrast with type 2, which have low levels of phosphate. The proposed term will be modified to Infantile hypercalcemia type 1 for greater clarity and added as LLT to PT Idiopathic infantile hypercalcaemia, which was added in CR 2023325014. In a related change, the British spelling of the term Infantile hypercalcaemia type 1 will also be added as LLT to PT Idiopathic infantile hypercalcaemia.

CR Number: 2023332312 Implementation Date: 28-Nov-23 Related CR: 2023325015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Infantile hypercalcaemia type 1</i>	Approved as Requested	Proposed LLT <i>Infantile hypercalcaemia type 1</i>	10090542 Current
To PT	<i>Idiopathic infantile hypercalcaemia</i>		To PT <i>Idiopathic infantile hypercalcaemia</i>	10090537

MSSO Comment:

CR Number: 2023325016 Implementation Date: 28-Nov-23 Related CR: 2023325016

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Infantile hypercalcemia-2</i>	Approved Not as Requested	Proposed LLT <i>Infantile hypercalcemia type 2</i>	10090538 Current
			To PT <i>Idiopathic infantile hypercalcaemia</i>	10090537

MSSO Comment: The proposal to add a new term Infantile hypercalcemia-2 is approved but not as requested. Idiopathic infantile hypercalcemia type 2 is caused by homozygous or compound heterozygous mutation in the SLC34A1 gene on chromosome 5q35. Although most signs and symptoms are similar between the two known types of idiopathic infantile hypercalcemia, individuals with infantile hypercalcemia 2 have low levels of blood phosphate, while phosphate levels are typically normal in people with infantile hypercalcemia 1. The proposed term will be modified to Infantile hypercalcemia type 2 for greater clarity and added as LLT to PT Idiopathic infantile hypercalcaemia, which was added in CR 2023325014. In a related change, the British spelling of the term Infantile hypercalcaemia type 2 will also be added as LLT to PT Idiopathic infantile hypercalcaemia.

Supplemental Update Report

CR Number: 2023332313 Implementation Date: 28-Nov-23 Related CR: 2023325016

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Infantile hypercalcaemia type 2</i>	Approved as Requested	Proposed LLT	
To PT	<i>Idiopathic infantile hypercalcaemia</i>		<i>Infantile hypercalcaemia type 2</i>	10090541 Current
			To PT	
			<i>Idiopathic infantile hypercalcaemia</i>	10090537

MSSO
Comment:

CR Number: 2023326000 Implementation Date: 28-Nov-23 Related CR: 2023326000

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Cerulean cataract</i>	Approved as Requested	Proposed PT	
			<i>Cerulean cataract</i>	10090531
			HLT primary	
			<i>Lens disorders congenital</i>	10024205
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Cataract conditions</i>	10007772
			SOC secondary	
			<i>Eye disorders</i>	10015919

MSSO
Comment: The proposal to add a new term Cerulean cataract is approved as requested. Cerulean cataract is a rare form of congenital cataract which usually presents as bilateral, blue-white opacities in the lens arranged in concentric layers. Cerulean cataract will be added as PT to primary HLT Lens disorders congenital and to secondary HLT Cataract conditions.

Supplemental Update Report

CR Number: 2023326001		Implementation Date: 28-Nov-23	Related CR: 2023326001	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Ebola virus test</i>	Approved as Requested	Proposed PT <i>Ebola virus test</i>	10090530
			HLT primary <i>Virus identification and serology</i>	10047490
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Ebola virus test is approved as requested. Ebola virus test will be added as PT to HLT Virus identification and serology aligned with PT Ebola virus test positive.

CR Number: 2023326002		Implementation Date: 28-Nov-23	Related CR: 2023326002	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Sapovirus test</i>	Approved as Requested	Proposed PT <i>Sapovirus test</i>	10090532
			HLT primary <i>Virus identification and serology</i>	10047490
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Sapovirus test is approved as requested. Sapovirus test will be added as PT to HLT Virus identification and serology aligned with PT Sapovirus test positive.

CR Number: 2023326003		Implementation Date: 28-Nov-23	Related CR: 2023326003	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Adiponectin decreased</i>	Approved as Requested	Proposed PT <i>Adiponectin decreased</i>	10090534
			HLT primary <i>Endocrine analyses and imaging NEC</i>	10014693
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Adiponectin decreased is approved as requested. Adiponectin, an adipose-derived hormone, exhibits various biological functions, such as increasing insulin sensitivity, protecting hypertension, and suppression of atherosclerosis, liver fibrosis, and tumor growth. Adiponectin decreased will be added as PT to HLT Endocrine analyses and imaging NEC aligned with PT Adiponectin increased.

Supplemental Update Report

CR Number: 2023326004

Implementation Date: 28-Nov-23

Related CR: 2023326004

[Change Requested](#)

Add a New PT

[Final Disposition](#)

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Code #](#)

Proposed PT

Performance status

Rejected

MSSO Comment: The proposal to add a new PT Performance status is not approved. Performance status without as a broad test term is ambiguous as there are several possible performance status scales.

CR Number: 2023326005

Implementation Date: 28-Nov-23

Related CR: 2023326005

[Change Requested](#)

Add a New PT

[Final Disposition](#)

[Final Placement](#)

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Proposed PT

Aortic wall hypotrophy

Rejected

MSSO Comment: The proposal to add a new PT Aortic wall hypotrophy is not approved. Only aortic wall hypertrophy represents in medical literature a valid concept in context of arterial wall remodeling in hypertensive diseases. Please resend the request by providing medical references. The justification that the term is not available in MedDRA is not sufficient.

CR Number: 2023326006

Implementation Date: 28-Nov-23

Related CR: 2023326006

[Change Requested](#)

Add a New PT

[Final Disposition](#)

[Final Placement](#)

[MedDRA
Code #](#)

Proposed PT

Ostomy bag removal

Rejected

MSSO Comment: The proposal to add a new PT Ostomy bag removal is not approved. The removal of the ostomy bag or pouch is a routine task for individuals who have undergone ostomy surgery.

Supplemental Update Report

CR Number: 2023326007 **Implementation Date:** 28-Nov-23 **Related CR:** 2023326007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Sternum surgery</i>	Rejected		

MSSO Comment: The proposal to add a new PT Sternum surgery is not approved. Sternum surgery is a rather vague expression without any benefit to the terminology. Terms already exist for specific sternal surgeries like Sternotomy, Sternectomy, Sternal wiring and Sternal stabilisation

CR Number: 2023326008 **Implementation Date:** 28-Nov-23 **Related CR:** 2023326008

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Product difficult to use</i>	Rejected		
To PT	<i>Product use complaint</i>			

MSSO Comment: The proposal to add a new LLT Product difficult to use to PT Product use complaint is not approved. To avoid over population of MedDRA, please consider whether PT Device difficult to use or provide further information of the kind of product other than devices.

CR Number: 2023326009 **Implementation Date:** 28-Nov-23 **Related CR:** 2023326009

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Metagenomic analysis</i>	Approved as Requested	Proposed PT <i>Metagenomic analysis</i>	10090533
			HLT primary <i>Microbiology and serology tests NEC</i>	10027530
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Metagenomic analysis is approved as requested. Metagenomics is the study of the structure and function of entire nucleotide sequences isolated and analyzed from all the organisms e.g on the skin of humans. Metagenomics is often used to study a specific community of microorganisms. Metagenomic analysis will be added as PT to HLT Microbiology and serology tests NEC.

Supplemental Update Report

CR Number: 2023326054 Implementation Date: 28-Nov-23 Related CR: 2023326054

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Documented hypersensitivity to administered product</i>	Approved Not as Requested	Proposed PT <i>Documented hypersensitivity to administered product</i>	10076470
To HLT	<i>Product administration errors and issues</i>		From HLT <i>Product monitoring errors and issues</i>	10079150
			To HLT <i>Product administration errors and issues</i>	10079147

MSSO Comment: The proposal to link the PT Documented hypersensitivity to administered product to the HLT Product administration errors and issues is approved but not as requested. PT Documented hypersensitivity to administered product will be moved from HLT Product monitoring errors and issues to HLT Product administration errors and issues.

CR Number: 2023326055 Implementation Date: 28-Nov-23 Related CR: 2023326055

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Term to modify	<i>Temporal disorientation</i>	Rejected		
Replacement term	<i>Temporary disorientation</i>			

MSSO Comment: The proposal to rename PT/LLT Temporal disorientation to Temporary disorientation is not approved. Temporal in context of disorientation refers to time (tempus) in general and not to a temporary event.

CR Number: 2023326887 Implementation Date: 29-Nov-23 Related CR: 2023326887

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Term to modify	<i>Ocular manifestation of Lyme disease</i>	Approved as Requested	Term to modify <i>Ocular manifestation of Lyme disease</i>	10090458
Replacement term	<i>Ocular manifestation of Lyme disease</i>		Replacement term <i>Ocular manifestation of Lyme disease</i>	10090458

MSSO Comment: The proposal to rename PT/LLT Ocular manifestation of Lyme disease to Ocular manifestation of Lyme disease is approved as requested, to correct the spelling of the word "disease".

Supplemental Update Report

CR Number: 2023326888	Implementation Date: 28-Nov-23	Related CR: 2023326888		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Temple headache</i>	Rejected		

MSSO Comment: The proposal to add a new term Temple headache is not approved. This concept can be represented by LLT Temporal headache.

CR Number: 2023327000	Implementation Date: 28-Nov-23	Related CR: 2023327000		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Leukocyte alkaline phosphatase abnormal</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Tissue enzyme analyses NEC</i>		<i>Leukocyte alkaline phosphatase abnormal</i>	10090510
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Tissue enzyme analyses NEC</i>	10043891
			SOC primary	
			<i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Leukocyte alkaline phosphatase abnormal to primary HLT Tissue enzyme analyses NEC in SOC Investigations is approved as requested aligned with PT Leukocyte alkaline phosphatase and PT Leukocyte alkaline phosphatase increased.

CR Number: 2023327001	Implementation Date: 27-Nov-23	Related CR: 2023327001		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Urine vitamin C</i>	Approved as Requested	Proposed LLT	
To PT	<i>Vitamin C</i>		<i>Urine vitamin C</i>	10090471 Current
			To PT	
			<i>Vitamin C</i>	10047620

MSSO Comment: The proposal to add a new LLT Urine vitamin C to PT Vitamin C is approved as requested. Ascorbic acid (vitamin C) is known to interfere with the oxidation reaction of the blood and glucose pad on common urine test strips. Some urine test strips are protected against the interference with iodate, which eliminates ascorbic acid by oxidation. Some test strips include a test for urinary ascorbate. Urine vitamin C will be added as LLT to PT Vitamin C, aligned with Urine vitamin K under Vitamin K.

Supplemental Update Report

CR Number: 2023327002 **Implementation Date:** 27-Nov-23 **Related CR:** 2023327002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>TORCH test</i>	Approved as Requested	Proposed PT <i>TORCH test</i>	10090470
HLT primary	<i>Microbiology and serology tests NEC</i>		HLT primary <i>Microbiology and serology tests NEC</i>	10027530
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT TORCH test to primary HLT Microbiology and serology tests NEC in SOC Investigations is approved as requested. TORCH test, alternatively named TORCH screening, helps to identify a group of infections transmitted from mother to the baby either via placenta or during delivery. Torch is the acronym for Toxoplasmosis, Others (including syphilis, HIV, varicella, listeriosis, enteroviruses, parvovirus B19), Rubella, Cytomegalovirus, and Herpes simplex virus.

CR Number: 2023327003 **Implementation Date:** 28-Nov-23 **Related CR:** 2023327003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Candida albicans test positive</i>	Approved as Requested	Proposed LLT <i>Candida albicans test positive</i>	10090543 Current
			To PT <i>Candida test positive</i>	10070451

MSSO Comment: The proposal to add a new term Candida albicans test positive is approved as requested. Candida albicans is a fungus found in small amounts, located in the mouth, skin and intestines. Candida albicans test positive will be added as LLT to PT Candida test positive.

CR Number: 2023327004 **Implementation Date:** 28-Nov-23 **Related CR:** 2023327004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Candida tropicalis test positive</i>	Approved as Requested	Proposed LLT <i>Candida tropicalis test positive</i>	10090544 Current
			To PT <i>Candida test positive</i>	10070451

MSSO Comment: The proposal to add a new term Candida tropicalis test positive is approved as requested. Candida tropicalis is a species of yeast in the genus Candida. It is a common pathogen in neutropenic hosts, in whom it may spread through the bloodstream to peripheral organs. Candida tropicalis test positive will be added as an LLT to PT Candida test positive.

Supplemental Update Report

CR Number: 2023327005 **Implementation Date:** 29-Nov-23 **Related CR:** 2023327005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Pyroglutamic acid test</i>	Approved Not as Requested	Proposed LLT <i>Pyroglutamic acid test</i>	10090575 Current
HLT primary	<i>Protein analyses NEC</i>		To PT <i>Pyroglutamate test</i>	10090571
SOC primary	<i>Investigations</i>			

MSSO Comment: The proposal to add a new PT Pyroglutamic acid test to primary HLT Protein analyses NEC in SOC Investigations is approved but not as requested. Elevated values of Pyroglutamic acid may be due to supplementation with glutathione or N-acetyl cysteine, result from a genetic disorder, metabolic effects of certain antibiotics, or intake of certain infant formulas. Pyroglutamic acid test will be added as LLT under a new PT Pyroglutamate test, which will be added to HLT Protein analyses NEC, as the non qualified name of existing PT Pyroglutamate increased.

CR Number: 202333133 **Implementation Date:** 29-Nov-23 **Related CR:** 2023327005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Pyroglutamate test</i>	Approved as Requested	Proposed PT <i>Pyroglutamate test</i>	10090571
HLT primary	<i>Protein analyses NEC</i>		HLT primary <i>Protein analyses NEC</i>	10036998
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO Comment:

CR Number: 2023327006 **Implementation Date:** 29-Nov-23 **Related CR:** 2023327006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Peripheral nerve block prolonged</i>	Approved as Requested	Proposed PT <i>Peripheral nerve block prolonged</i>	10090572
HLT primary	<i>Anaesthetic and allied procedural complications</i>		HLT primary <i>Anaesthetic and allied procedural complications</i>	10080709
SOC primary	<i>Injury, poisoning and procedural complications</i>		SOC primary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new PT Peripheral nerve block prolonged to primary HLT Anaesthetic and allied procedural complications in SOC Injury, poisoning and procedural complications is approved as requested. Complications of peripheral nerve blocks are fortunately rare, but can be devastating for both the patient and the anaesthesiologist.

Supplemental Update Report

CR Number: 2023327007 **Implementation Date:** 29-Nov-23 **Related CR:** 2023327007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Retrolubar block</i>	Approved Not as Requested	Proposed LLT <i>Retrolubar block</i>	10090574 Current
HLT primary	<i>Anaesthesia and allied procedures</i>		To PT <i>Anaesthetic ophthalmic procedure</i>	10082763
SOC primary	<i>Surgical and medical procedures</i>			

MSSO Comment: The proposal to add a new PT Retrolubar block to primary HLT Anaesthesia and allied procedures in SOC Surgical and medical procedures is approved but not as requested. Retrolubar block is type of regional anesthetic nerve block used in intraocular surgery. In this technique, local anesthetic is injected into the retrolubar space, providing sensory anesthesia of the cornea, uvea, and conjunctiva by blocking the ciliary nerves. Retrolubar block will be added as LLT to PT Anaesthetic ophthalmic procedure.

CR Number: 2023327008 **Implementation Date:** 29-Nov-23 **Related CR:** 2023327008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Oxford Scale</i>	Approved Not as Requested	Proposed LLT <i>Oxford muscle scale</i>	10090576 Current
HLT primary	<i>Physical examination procedures and organ system status</i>		To PT <i>Muscle strength test</i>	10090570
SOC primary	<i>Investigations</i>			

MSSO Comment: The proposal to add a new PT Oxford Scale to primary HLT Physical examination procedures and organ system status in SOC Investigations is approved but not as requested. The Oxford Muscle Scale is a numerical rating scale used to quantify the power or strength produced by the contraction of a muscle. The proposed term will be modified for greater clarity to Oxford muscle scale and added as LLT to a new PT Muscle strength test which will be added in a related change to HLT Physical examination procedures and organ system status.

CR Number: 202333132 **Implementation Date:** 29-Nov-23 **Related CR:** 2023327008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Muscle strength test</i>	Approved as Requested	Proposed PT <i>Muscle strength test</i>	10090570
HLT primary	<i>Physical examination procedures and organ system status</i>		HLT primary <i>Physical examination procedures and organ system status</i>	10071941
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2023327009 **Implementation Date:** 29-Nov-23 **Related CR:** 2023327009

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Numerical rating scale	Approved Not as Requested	Proposed LLT	
HLT primary	Physical examination procedures and organ system status		Numeric pain rating scale	10090573 Current
SOC primary	Investigations		To PT Pain assessment	10050533

MSSO Comment: The proposal to add a new PT Numerical rating scale to primary HLT Physical examination procedures and organ system status in SOC Investigations is approved but not as requested. The numeric rating scale is one of the most commonly used pain scales in medicine frequently administered verbally to the patient and usually represented in a horizontal line with an eleven point numeric range. The proposed term will be modified for greater clarity and added as the LLT Numeric pain rating scale to PT Pain assessment.

CR Number: 2023328000 **Implementation Date:** 28-Nov-23 **Related CR:** 2023328000

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Measured glomerular filtration rate	Approved as Requested	Proposed LLT	
			Measured glomerular filtration rate	10090549 Current
			To PT Glomerular filtration rate	10018355

MSSO Comment: The proposal to add a new term Measured glomerular filtration rate is approved as requested. Measured Glomerular Filtration Rate is a clinical parameter used to assess the rate at which the glomeruli in the kidneys filter the blood to form urine. Measured glomerular filtration rate will be added as LLT to PT Glomerular filtration rate.

CR Number: 2023328001 **Implementation Date:** 28-Nov-23 **Related CR:** 2023328001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Gordon's syndrome,familial hyperkalemic hypertension	Approved Not as Requested	Proposed LLT	
			Familial hyperkalemic hypertension	10090551 Current
			To PT Pseudohypoaldosteronism	10080593

MSSO Comment: The proposal to add a new term Gordon's syndrome,familial hyperkalemic hypertension is approved but not as requested. Familial Hyperkalemic Hypertension (FHHT) syndrome, also known as Pseudohypoaldosteronism type II, is a very rare genetic form of hypertension associated with hyperkalemia and hyperchloremic metabolic acidosis, low renin and a normal GFR. The requested term will be modified and added as a sub-concept LLT Familial hyperkalemic hypertension to PT Pseudohypoaldosteronism. In a related change, the British English spelled counterpart LLT Familial hyperkalaemic hypertension will also be added to PT Pseudohypoaldosteronism. Furthermore, LLT Gordon syndrome will be made non-current due to the ambiguity of the eponym.

Supplemental Update Report

CR Number: 2023332314	Implementation Date: 28-Nov-23	Related CR: 2023328001		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Familial hyperkalaemic hypertension</i>	Approved as Requested	Proposed LLT	
To PT	<i>Pseudohypoaldosteronism</i>		<i>Familial hyperkalaemic hypertension</i>	10090553 Current
			To PT	
			<i>Pseudohypoaldosteronism</i>	10080593

MSSO
Comment:

CR Number: 2023332315	Implementation Date: 28-Nov-23	Related CR: 2023328001		
<u>Change Requested</u>	Change Status of LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
LLT to change	<i>Gordon syndrome</i>	Approved as Requested	LLT to change	
Status	<i>Non-current</i>		<i>Gordon syndrome</i>	10083951 Non-Current
			Status	
			<i>Non-current</i>	

MSSO
Comment:

CR Number: 2023328002	Implementation Date: 28-Nov-23	Related CR: 2023328002		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Acute myocardial infarction type 4c</i>	Approved as Requested	Proposed LLT	
			<i>Acute myocardial infarction type 4c</i>	10090548 Current
			To PT	
			<i>Acute myocardial infarction</i>	10000891

MSSO
Comment: The proposal to add a new term Acute myocardial infarction type 4c is approved as requested. Type 4C myocardial infarction is a special type of myocardial infarction related to restenosis without thrombosis. Acute myocardial infarction type 4c will be added as LLT to PT Acute myocardial infarction.

Supplemental Update Report

CR Number: 2023328003	Implementation Date: 28-Nov-23	Related CR: 2023328003		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Partial tendon rupture</i>	Approved as Requested	Proposed LLT <i>Partial tendon rupture</i>	10090550 Current
			To PT <i>Tendon rupture</i>	10043248

MSSO Comment: The proposal to add a new term Partial tendon rupture is approved as requested. A partial tendon rupture occurs when only a portion of the tendon is torn or damaged, rather than a complete break. Partial tendon rupture will be added as LLT under PT Tendon rupture.

CR Number: 2023328004	Implementation Date: 28-Nov-23	Related CR: 2023328004		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Calcium score test /cardiac calcium score test</i>	Approved Not as Requested	Proposed LLT <i>Cardiac calcium score</i>	10090546 Current
			To PT <i>Computerised tomogram heart</i>	10088901

MSSO Comment: The proposal to add a new term Calcium score test /cardiac calcium score test is approved but not as requested. A cardiac calcium score test is a non-invasive imaging test that measures the amount of calcium deposits in the coronary arteries of the heart. Cardiac calcium score, which is a synonym of LLT Coronary calcium scan and will be added as an LLT to PT Computerised tomogram heart.

CR Number: 2023328005	Implementation Date: 28-Nov-23	Related CR: 2023328005		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Exogenous steroid usage</i>	Rejected		

MSSO Comment: The proposal to add a new term Exogenous steroid usage is not approved. The requested term can be represented by existing PT Steroid therapy.

Supplemental Update Report

CR Number: 2023328006	Implementation Date: 28-Nov-23	Related CR: 2023328006	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New Term			<u>MedDRA Code #</u>
Proposed Term <i>HAS-BLED score</i>		Approved as Requested	Proposed LLT <i>HAS-BLED score</i> 10090552 Current
			To PT <i>Bleeding risk assessment</i> 10090545

MSSO Comment: The proposal to add a new term HAS-BLED score is approved as requested. The HAS-BLED score (Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly) Score is used for predicting the bleeding risk in anticoagulated patients with atrial fibrillation. HAS-BLED score will be added as LLT to a new PT Bleeding risk assessment. In a related change, new PT Bleeding risk assessment will be added under HLT Coagulation and bleeding analyses.

CR Number: 2023332316	Implementation Date: 28-Nov-23	Related CR: 2023328006	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New PT			<u>MedDRA Code #</u>
Proposed PT <i>Bleeding risk assessment</i>		Approved as Requested	Proposed PT <i>Bleeding risk assessment</i> 10090545
HLT primary <i>Coagulation and bleeding analyses</i>			HLT primary <i>Coagulation and bleeding analyses</i> 10009728
SOC primary <i>Investigations</i>			SOC primary <i>Investigations</i> 10022891

MSSO Comment:

CR Number: 2023328007	Implementation Date: 28-Nov-23	Related CR: 2023328007	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>
Add a New Term			<u>MedDRA Code #</u>
Proposed Term <i>Organic sleep disorder</i>		Approved as Requested	Proposed LLT <i>Organic sleep disorder</i> 10090547 Current
			To PT <i>Sleep disorder due to a general medical condition</i> 10063910

MSSO Comment: The proposal to add a new term Organic sleep disorder is approved as requested. Organic sleep disorder will be added as a synonym LLT to PT Sleep disorder due to a general medical condition.

Supplemental Update Report

CR Number: 2023330000 Implementation Date: 29-Nov-23 Related CR: 2023330000

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Cyst of septum pellucidum</i>	Approved Not as Requested	Proposed LLT <i>Septum pellucidum cyst</i>	10090577 Current
			To PT <i>Congenital cerebral cyst</i>	10054954

MSSO Comment: The proposal to add a new LLT Cyst of septum pellucidum is approved but not as requested. A septum pellucidum cyst is defined as a congenital cystic structure between the lateral ventricles, whose walls exhibit lateral bowing and are 10 mm apart or greater. The requested term will be added in the natural word order as LLT Septum pellucidum cyst to PT Congenital cerebral cyst.

CR Number: 2023331015 Implementation Date: 29-Nov-23 Related CR: 2023331015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Instillation site abscess</i>	Approved as Requested	Proposed PT <i>Instillation site abscess</i>	10073602
From HLT	<i>Application site reactions</i>		From HLT <i>Application site reactions</i>	10003057
To HLT	<i>Instillation site reactions</i>		To HLT <i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site abscess from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. "Instillation site" PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331016 Implementation Date: 29-Nov-23 Related CR: 2023331016

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Instillation site anaesthesia</i>	Approved as Requested	Proposed PT <i>Instillation site anaesthesia</i>	10073603
From HLT	<i>Application site reactions</i>		From HLT <i>Application site reactions</i>	10003057
To HLT	<i>Instillation site reactions</i>		To HLT <i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site anaesthesia from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. "Instillation site" PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

Supplemental Update Report

CR Number: 2023331017 Implementation Date: 29-Nov-23 Related CR: 2023331017

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site atrophy</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site atrophy</i>	10073604
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site atrophy from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331018 Implementation Date: 29-Nov-23 Related CR: 2023331018

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site bruise</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site bruise</i>	10073630
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site bruise from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

Supplemental Update Report

CR Number: 2023331019 Implementation Date: 29-Nov-23 Related CR: 2023331019

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site burn</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site burn</i>	10073605
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site burn from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. "Instillation site" PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331020 Implementation Date: 29-Nov-23 Related CR: 2023331020

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site coldness</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site coldness</i>	10063769
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site coldness from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. "Instillation site" PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331021 Implementation Date: 29-Nov-23 Related CR: 2023331021

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site complication</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site complication</i>	10071163
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site complication from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331022 Implementation Date: 29-Nov-23 Related CR: 2023331022

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site discharge</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site discharge</i>	10073606
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site discharge from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331023 Implementation Date: 29-Nov-23 Related CR: 2023331023

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site discolouration</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site discolouration</i>	10073607
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site discolouration from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331024 Implementation Date: 29-Nov-23 Related CR: 2023331024

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site discomfort</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site discomfort</i>	10065652
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site discomfort from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331025 Implementation Date: 29-Nov-23 Related CR: 2023331025

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site dryness</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site dryness</i>	10063772
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site dryness from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331026 Implementation Date: 29-Nov-23 Related CR: 2023331026

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site erosion</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site erosion</i>	10073608
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site erosion from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331027 Implementation Date: 29-Nov-23 Related CR: 2023331027

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site erythema</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site erythema</i>	10063762
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site erythema from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331028 Implementation Date: 29-Nov-23 Related CR: 2023331028

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site exfoliation</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site exfoliation</i>	10073601
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site exfoliation from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331029 Implementation Date: 29-Nov-23 Related CR: 2023331029

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Instillation site foreign body sensation</i>	Approved as Requested	Proposed PT <i>Instillation site foreign body sensation</i>	10063771
From HLT	<i>Application site reactions</i>		From HLT <i>Application site reactions</i>	10003057
To HLT	<i>Instillation site reactions</i>		To HLT <i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site foreign body sensation from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. "Instillation site" PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331030 Implementation Date: 29-Nov-23 Related CR: 2023331030

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Instillation site haematoma</i>	Approved as Requested	Proposed PT <i>Instillation site haematoma</i>	10073609
From HLT	<i>Application site reactions</i>		From HLT <i>Application site reactions</i>	10003057
To HLT	<i>Instillation site reactions</i>		To HLT <i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site haematoma from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. "Instillation site" PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331031 Implementation Date: 29-Nov-23 Related CR: 2023331031

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Instillation site haemorrhage</i>	Approved as Requested	Proposed PT <i>Instillation site haemorrhage</i>	10073610
From HLT	<i>Application site reactions</i>		From HLT	
To HLT	<i>Instillation site reactions</i>		<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site haemorrhage from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331032 Implementation Date: 29-Nov-23 Related CR: 2023331032

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Instillation site hyperaesthesia</i>	Approved as Requested	Proposed PT <i>Instillation site hyperaesthesia</i>	10073611
From HLT	<i>Application site reactions</i>		From HLT	
To HLT	<i>Instillation site reactions</i>		<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site hyperaesthesia from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331033 Implementation Date: 29-Nov-23 Related CR: 2023331033

<u>Change Requested</u>	Link (move) a PT to another HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site hypersensitivity</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site hypersensitivity</i>	10073612
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site hypersensitivity from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331034 Implementation Date: 29-Nov-23 Related CR: 2023331034

<u>Change Requested</u>	Link (move) a PT to another HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site hypoaesthesia</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site hypoaesthesia</i>	10074587
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site hypoaesthesia from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331035 Implementation Date: 29-Nov-23 Related CR: 2023331035

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site induration</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site induration</i>	10073613
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site induration from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331036 Implementation Date: 29-Nov-23 Related CR: 2023331036

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site infection</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site infection</i>	10073614
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site infection from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331037 Implementation Date: 29-Nov-23 Related CR: 2023331037

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Instillation site inflammation</i>	Approved as Requested	Proposed PT <i>Instillation site inflammation</i>	10073615
From HLT	<i>Application site reactions</i>		From HLT	
To HLT	<i>Instillation site reactions</i>		<i>Application site reactions</i>	10003057
			To HLT <i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site inflammation from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331038 Implementation Date: 29-Nov-23 Related CR: 2023331038

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Instillation site irritation</i>	Approved as Requested	Proposed PT <i>Instillation site irritation</i>	10055117
From HLT	<i>Application site reactions</i>		From HLT	
To HLT	<i>Instillation site reactions</i>		<i>Application site reactions</i>	10003057
			To HLT <i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site irritation from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331039 Implementation Date: 29-Nov-23 Related CR: 2023331039

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site lacrimation</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site lacrimation</i>	10065653
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site lacrimation from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331040 Implementation Date: 29-Nov-23 Related CR: 2023331040

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site necrosis</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site necrosis</i>	10073616
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site necrosis from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331041 Implementation Date: 29-Nov-23 Related CR: 2023331041

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site nodule</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site nodule</i>	10073617
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site nodule from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. "Instillation site" PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331042 Implementation Date: 29-Nov-23 Related CR: 2023331042

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site odour</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site odour</i>	10073618
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site odour from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. "Instillation site" PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331043 Implementation Date: 29-Nov-23 Related CR: 2023331043

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site oedema</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site oedema</i>	10073619
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site oedema from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331044 Implementation Date: 29-Nov-23 Related CR: 2023331044

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site pain</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site pain</i>	10022459
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site pain from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331045 Implementation Date: 29-Nov-23 Related CR: 2023331045

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Instillation site papules</i>	Approved as Requested	Proposed PT <i>Instillation site papules</i>	10073620
From HLT	<i>Application site reactions</i>		From HLT <i>Application site reactions</i>	10003057
To HLT	<i>Instillation site reactions</i>		To HLT <i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site papules from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331046 Implementation Date: 29-Nov-23 Related CR: 2023331046

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Instillation site paraesthesia</i>	Approved as Requested	Proposed PT <i>Instillation site paraesthesia</i>	10073558
From HLT	<i>Application site reactions</i>		From HLT <i>Application site reactions</i>	10003057
To HLT	<i>Instillation site reactions</i>		To HLT <i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site paraesthesia from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331047 Implementation Date: 29-Nov-23 Related CR: 2023331047

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site pruritus</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site pruritus</i>	10063763
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site pruritus from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331048 Implementation Date: 29-Nov-23 Related CR: 2023331048

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site pustules</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site pustules</i>	10073621
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site pustules from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331049 Implementation Date: 29-Nov-23 Related CR: 2023331049

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site rash</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site rash</i>	10073622
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site rash from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331050 Implementation Date: 29-Nov-23 Related CR: 2023331050

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site reaction</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site reaction</i>	10063765
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site reaction from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331051 Implementation Date: 29-Nov-23 Related CR: 2023331051

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site scab</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site scab</i>	10073623
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site scab from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331052 Implementation Date: 29-Nov-23 Related CR: 2023331052

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Instillation site swelling</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site swelling</i>	10073624
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site swelling from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331053 Implementation Date: 29-Nov-23 Related CR: 2023331053

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Instillation site thrombosis</i>	Approved as Requested	Proposed PT <i>Instillation site thrombosis</i>	10073625
From HLT	<i>Application site reactions</i>		From HLT <i>Application site reactions</i>	10003057
To HLT	<i>Instillation site reactions</i>		To HLT <i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site thrombosis from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331054 Implementation Date: 29-Nov-23 Related CR: 2023331054

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Instillation site ulcer</i>	Approved as Requested	Proposed PT <i>Instillation site ulcer</i>	10073626
From HLT	<i>Application site reactions</i>		From HLT <i>Application site reactions</i>	10003057
To HLT	<i>Instillation site reactions</i>		To HLT <i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site ulcer from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331055 Implementation Date: 29-Nov-23 Related CR: 2023331055

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Instillation site urticaria</i>	Approved as Requested	Proposed PT <i>Instillation site urticaria</i>	10073627
From HLT	<i>Application site reactions</i>		From HLT <i>Application site reactions</i>	10003057
To HLT	<i>Instillation site reactions</i>		To HLT <i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site urticaria from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023331056 Implementation Date: 29-Nov-23 Related CR: 2023331056

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Instillation site vesicles</i>	Approved as Requested	Proposed PT <i>Instillation site vesicles</i>	10073628
From HLT	<i>Application site reactions</i>		From HLT <i>Application site reactions</i>	10003057
To HLT	<i>Instillation site reactions</i>		To HLT <i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site vesicles from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. “Instillation site” PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

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CR Number: 2023331057 Implementation Date: 29-Nov-23 Related CR: 2023331057

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Instillation site warmth</i>	Approved as Requested	Proposed PT	
From HLT	<i>Application site reactions</i>		<i>Instillation site warmth</i>	10073629
To HLT	<i>Instillation site reactions</i>		From HLT	
			<i>Application site reactions</i>	10003057
			To HLT	
			<i>Instillation site reactions</i>	10090509

MSSO Comment: The proposal to move the PT Instillation site warmth from HLT Application site reactions to HLT Instillation site reactions is approved as requested. This PT is being moved based on the decision made to split HLT Application and instillation site reactions into two separate HLTs – HLT Application site reactions and HLT Instillation site reactions to improve analysis and assist with the differentiation between products which are applied such as ointments from those being instilled such as eye drops. "Instillation site" PTs are being moved to new HLT Instillation site reactions. See batch # 10117501, change request # 2023144056.

CR Number: 2023332000 Implementation Date: 30-Nov-23 Related CR: 2023332000

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Obesity class I</i>	Approved as Requested	Proposed LLT	
			<i>Obesity class I</i>	10090593 Current
			To PT	
			<i>Obesity</i>	10029883

MSSO Comment: The proposal to add a new LLT Obesity class I is approved as requested. Obesity is frequently subdivided into categories: Class I refers to BMI of 30 to < 35. Obesity class I will be added as LLT to PT Obesity.

CR Number: 2023332001 Implementation Date: 30-Nov-23 Related CR: 2023332001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Obesity class II</i>	Approved as Requested	Proposed LLT	
			<i>Obesity class II</i>	10090594 Current
			To PT	
			<i>Obesity</i>	10029883

MSSO Comment: The proposal to add a new LLT Obesity class II is approved as requested. Obesity is frequently subdivided into categories: Class II refers to BMI of 35 to < 40. Obesity class II will be added as LLT to PT Obesity.

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CR Number: 2023332002 Implementation Date: 30-Nov-23 Related CR: 2023332002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Obesity class III</i>	Approved as Requested	Proposed LLT <i>Obesity class III</i>	10090595 Current
			To PT <i>Obesity</i>	10029883

MSSO Comment: The proposal to add a new LLT Obesity class III is approved as requested. Obesity is frequently subdivided into categories: Class III refers to BMI of 40 or higher. Obesity class III will be added as LLT to PT Obesity

CR Number: 2023332003 Implementation Date: 30-Nov-23 Related CR: 2023332003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Multiple acyl-coenzyme A dehydrogenase deficiency</i>	Approved Not as Requested	Proposed PT <i>Multiple acyl-coenzyme A dehydrogenase deficiency</i>	10090590
			HLT primary <i>Inborn errors of lipid metabolism</i>	10059674
			SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Lipid metabolism and deposit disorders NEC</i>	10024581
			SOC secondary <i>Metabolism and nutrition disorders</i>	10027433

MSSO Comment: The proposal to add a new LLT Multiple acyl-coenzyme A dehydrogenase deficiency is approved but not as requested. Multiple acyl-coenzyme A dehydrogenase deficiency (MADD) represents a clinical spectrum in which presentations can be divided into type I (neonatal onset with congenital anomalies), type II (neonatal onset without congenital anomalies), and type III (late onset). Many affected individuals die in the newborn period despite metabolic treatment. In those who survive the neonatal period, recurrent metabolic decompensation resembling Reye syndrome and the development of hypertrophic cardiomyopathy can occur. Congenital anomalies may include dysmorphic facial features, large cystic kidneys, hypospadias and chordee in males, and neuronal migration defects (heterotopias) on brain MRI. Multiple acyl-coenzyme A dehydrogenase deficiency will be added as PT to primary HLT Inborn errors of lipid metabolism, secondary HLT Lipid metabolism and deposit disorders NEC and secondary HLT Myopathies.

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CR Number: 2023334158		Implementation Date: 30-Nov-23	Related CR: 2023332003	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Multiple acyl-coenzyme A dehydrogenase deficiency</i>	Approved as Requested	Proposed PT <i>Multiple acyl-coenzyme A dehydrogenase deficiency</i>	10090590
To HLT	<i>Myopathies</i>		To HLT <i>Myopathies</i>	10028640

MSSO
Comment:

CR Number: 2023332004		Implementation Date: 30-Nov-23	Related CR: 2023332004	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Odontophobia</i>	Approved Not as Requested	Proposed PT <i>Odontophobia</i>	10090592
			HLT primary <i>Fear symptoms and phobic disorders (incl social phobia)</i>	10068299
			SOC primary <i>Psychiatric disorders</i>	10037175

MSSO
Comment: The proposal to add a new LLT Odontophobia is approved but not as requested. Odontophobia is an intense and irrational fear of dental treatment. This fear can be triggered by a variety of factors, including a past negative experience with dental treatment, the fear of pain or discomfort, or a fear of loss of control. Odontophobia will be added as PT to HLT Fear symptoms and phobic disorders (incl social phobia).

CR Number: 2023332005		Implementation Date: 30-Nov-23	Related CR: 2023332005	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Inappropriate dose prescribed</i>	Approved as Requested	Proposed LLT <i>Inappropriate dose prescribed</i>	10090596 Current
			To PT <i>Product prescribing issue</i>	10080459

MSSO
Comment: The proposal to add a new LLT Inappropriate dose prescribed is approved as requested. Inappropriate dose prescribed will be added as LLT to PT Product prescribing issue for instances where it is not reported whether intentionally or as an error.

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CR Number: 2023332006		Implementation Date: 30-Nov-23	Related CR: 2023332006	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Remaining symptoms</i>	Approved Not as Requested	Proposed PT <i>Residual symptom</i>	10090591
			HLT primary <i>General signs and symptoms NEC</i>	10018072
			SOC primary <i>General disorders and administration site conditions</i>	10018065

MSSO Comment: The proposal to add a new LLT Remaining symptoms is approved but not as requested. The proposed term will be modified and added as PT Residual symptom to HLT General signs and symptoms NEC.

CR Number: 2023332007		Implementation Date: 06-Dec-23	Related CR: 2023332007	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Link (move) an LLT to another PT <i>Muscular rheumatism</i>	Approved After Suspension	Proposed LLT <i>Muscular rheumatism</i>	10028363 Current
From PT	<i>Fibromyalgia</i>		From PT <i>Fibromyalgia</i>	10048439
To PT	<i>Polymyalgia rheumatica</i>		To PT <i>Polymyalgia rheumatica</i>	10036099

MSSO Comment: The proposal to move the LLT Muscular rheumatism from PT Fibromyalgia to PT Polymyalgia rheumatica is approved as requested after suspension for better alignment. Muscular rheumatism can be considered as lay synonym of Polymyalgia rheumatica.

CR Number: 2023332008		Implementation Date: 30-Nov-23	Related CR: 2023332008	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Apoplexy of the left/right ovary</i>	Approved Not as Requested	Proposed LLT <i>Ovarian apoplexy</i>	10090597 Current
			To PT <i>Ovarian haemorrhage</i>	10065741

MSSO Comment: The proposal to add a new term Apoplexy of the left/right ovary is approved but not as requested. Ovarian apoplexy is a sudden rupture in the ovary, commonly at the site of a cyst, accompanied by hemorrhage in the ovarian tissue and/or intraperitoneal bleeding. The proposed term will be modified for greater clarification and avoidance of laterality specifications and added as LLT Ovarian apoplexy to PT Ovarian haemorrhage.

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CR Number: 2023332009	Implementation Date: 01-Dec-23	Related CR: 2023332009	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Chimeric Transition Syndrome</i>	Approved Not as Requested	Proposed LLT <i>Chimeric transition syndrome</i>
			To PT <i>Engraftment syndrome</i>
			10090612 Current
			10050684

MSSO Comment: The proposal to add a new term Chimeric Transition Syndrome is approved but not as requested. Engraftment syndrome is a well-known complication that is found to be associated with Hematopoietic stem cell transplantation (Auto-HSCT and Allo-HSCT) that is manifested through a set of clinically significant signs and symptoms. An engraftment syndrome-like condition termed chimeric transition syndrome also may occur after transplants. Proposed term will be modified for MedDRA capitalization conventions and added as subconcept LLT Chimeric transition syndrome under PT Engraftment syndrome.

CR Number: 2023332010	Implementation Date: 30-Nov-23	Related CR: 2023332010	
<u>Change Requested</u>	Link (move) a PT to another HLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed PT	<i>Magnetic resonance imaging neck normal</i>	Approved as Requested	Proposed PT <i>Magnetic resonance imaging neck normal</i>
From HLT	<i>Cardiac imaging procedures</i>		10090466
To HLT	<i>Musculoskeletal and soft tissue imaging procedures</i>		From HLT <i>Cardiac imaging procedures</i>
			10007574
			To HLT <i>Musculoskeletal and soft tissue imaging procedures</i>
			10028386

MSSO Comment: The proposal to move the PT Magnetic resonance imaging neck normal from HLT Cardiac imaging procedures to HLT Musculoskeletal and soft tissue imaging procedures is approved as requested. PT Magnetic resonance imaging neck normal will be moved from HLT Cardiac imaging procedures to HLT Musculoskeletal and soft tissue imaging procedures, to be aligned with PT Magnetic resonance imaging neck abnormal.

CR Number: 2023332011	Implementation Date: 30-Nov-23	Related CR: 2023332011	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Mastocytic colitis</i>	Approved as Requested	Proposed LLT <i>Mastocytic colitis</i>
			To PT <i>Mastocytic enterocolitis</i>
			10090589 Current
			10071282

MSSO Comment: The proposal to add a new term Mastocytic colitis is approved as requested. Mastocytic enterocolitis is a disease of the colon, or large intestine that is caused by an increased number of mast cells in the lining of the colon. It is characterized by dense mast cell infiltrate within the mucosa of the gastrointestinal tract. Mastocytic colitis will be added as sub-concept LLT under PT Mastocytic enterocolitis.

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CR Number: 2023332012	Implementation Date: 30-Nov-23	Related CR: 2023332012		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Axillary swelling</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Axillary swelling is not approved. The MSSO considers proposed term as imprecise. There are a number of axillary terms in MedDRA that may meet your coding needs.

CR Number: 2023332295	Implementation Date: 30-Nov-23	Related CR: 2023332295		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Benign rectal neoplasm</i>	Approved as Requested	Proposed LLT <i>Benign rectal neoplasm</i> To PT <i>Benign anorectal neoplasm</i>	10090587 Current 10060992

MSSO Comment: The proposal to add a new term Benign rectal neoplasm is approved as requested. Benign rectal neoplasm will be added as a sub-concept LLT to PT Benign anorectal neoplasm.

CR Number: 2023332296	Implementation Date: 30-Nov-23	Related CR: 2023332296		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Prostate waterjet ablation</i>	Approved as Requested	Proposed LLT <i>Prostate waterjet ablation</i> To PT <i>Transurethral prostatectomy</i>	10090588 Current 10044445

MSSO Comment: The proposal to add a new LLT Prostate waterjet ablation is approved as requested. Transurethral waterjet ablation is a minimally invasive, water based surgical therapy that combines image guidance and robotics to remove prostatic tissue. Prostate waterjet ablation will be added as an LLT to PT Transurethral prostatectomy. In a related change, PT Water vapour thermal therapy will be demoted under PT Transurethral prostatectomy as a sub-concept LLT.

Supplemental Update Report

CR Number: 2023334157	Implementation Date: 30-Nov-23	Related CR: 2023332296	
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>
PT to merge	<i>Water vapour thermal therapy</i>	Approved as Requested	PT to merge
To PT	<i>Transurethral prostatectomy</i>		<i>Water vapour thermal therapy</i>
			10086771 Current
			To PT
			<i>Transurethral prostatectomy</i>
			10044445

MSSO
Comment:

CR Number: 2023332297	Implementation Date: 01-Dec-23	Related CR: 2023332297	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Maggots in Wound</i>	Approved Not as Requested	Proposed LLT
			<i>Maggot wound infestation</i>
			10090615 Current
			To PT
			<i>Myiasis</i>
			10028586

MSSO Comment: The proposal to add a new LLT Maggots in Wound is approved but not as requested. Maggots are the larval stage of flies. The proposed term will be modified for clarity and added as LLT Maggot wound infestation to PT Myiasis.

CR Number: 2023332298	Implementation Date: 01-Dec-23	Related CR: 2023332298	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Prosthesis site discomfort</i>	Approved as Requested	Proposed LLT
			<i>Prosthesis site discomfort</i>
			10090616 Current
			To PT
			<i>Medical device site discomfort</i>
			10076101

MSSO Comment: The proposal to add a new LLT Prosthesis site discomfort is approved as requested. Protheses can lead to discomfort due to several reasons including pressure, friction, moisture or alignment issues. Prosthesis site discomfort will be added as LLT to PT Medical device site discomfort.

Supplemental Update Report

CR Number: 2023332299 Implementation Date: 01-Dec-23 Related CR: 2023332299

<u>Change Requested</u>	Change Status of LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
LLT to change	<i>Elevated venous pressure during dialysis</i>	Approved Not as Requested	Proposed PT	
Status	<i>current</i>		<i>Elevated prepump venous pressure during dialysis</i>	10090613
			HLT primary	
			<i>Dialysis related complications</i>	10071945
			SOC primary	
			<i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to change status of LLT Elevated venous pressure during dialysis to current is approved but not as requested. Existing LLT Elevated venous pressure during dialysis is non-current because of the ambiguity as it may refer to prepump related or a patient systemic venous pressure. However, a new term PT Elevated prepump venous pressure during dialysis will be added to HLT Dialysis related complications to represent the concept.

CR Number: 2023332300 Implementation Date: 01-Dec-23 Related CR: 2023332300

<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Elevated negative arterial pressure (in dialysis)</i>	Approved Not as Requested	Proposed PT	
			<i>Excessive prepump negative arterial pressure during dialysis</i>	10090614
			HLT primary	
			<i>Dialysis related complications</i>	10071945
			SOC primary	
			<i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new LLT Elevated negative arterial pressure (in dialysis) is approved but not as requested. Monitoring arterial pressure is crucial during dialysis to ensure that blood flow rates are within the prescribed range and that the procedure is effective. Excessive prepump negative arterial pressure is a signal that there may be an issue affecting the blood flow on the arterial side of the circuit. The requested term will be modified for clarity and added as PT Excessive prepump negative arterial pressure during dialysis to HLT Dialysis related complications.

Supplemental Update Report

CR Number: 2023332301	Implementation Date: 30-Nov-23	Related CR: 2023332301		
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Takatsuki syndrome</i>	Approved as Requested	Proposed LLT <i>Takatsuki syndrome</i>	10090598 Current
			To PT <i>POEMS syndrome</i>	10053869

MSSO Comment: The proposal to add a new term Takatsuki syndrome is approved as requested. POEMS syndrome, also known as osteosclerotic myeloma, Takatsuki syndrome, and Crow-Fukase syndrome, is a rare paraneoplastic syndrome due to an underlying plasma cell disorder. Takatsuki syndrome will be added as synonym LLT to PT POEMS syndrome.

CR Number: 2023332317	Implementation Date: 04-Dec-23	Related CR: 2023332317		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Obstetric paralysis</i>	Approved Not as Requested	Proposed LLT <i>Obstetric brachial plexus paralysis</i>	10090620 Current
To PT	<i>Injury to brachial plexus due to birth trauma</i>		To PT <i>Injury to brachial plexus due to birth trauma</i>	10022158

MSSO Comment: The proposal to add a new LLT Obstetric paralysis to PT Injury to brachial plexus due to birth trauma is approved but not as requested. The proposed term will be modified for clarity and will be added as synonym LLT Obstetric brachial plexus paralysis to PT Injury to brachial plexus due to birth trauma.

CR Number: 2023332318	Implementation Date: 04-Dec-23	Related CR: 2023332318		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Obstetric palsy</i>	Rejected		
To PT	<i>Injury to brachial plexus due to birth trauma</i>			

MSSO Comment: The proposal to add a new LLT Obstetric palsy to PT Injury to brachial plexus due to birth trauma is not approved. The requested term can be represented by newly added LLT Obstetric brachial plexus paralysis added in change request 2023332317.

Supplemental Update Report

CR Number: 2023332319 Implementation Date: 04-Dec-23 Related CR: 2023332319

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Add a New PT <i>Blastocystis test positive</i>	Approved as Requested	Proposed PT <i>Blastocystis test positive</i>	10090619
			HLT primary <i>Parasite identification and serology</i>	10033903
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Blastocystis test positive is approved as requested. Modern blastocystis testing is mainly based on molecular detection methods. Routine stool microscopy along with culture in Jones' medium could serve as an alternative detection tool in resource-poor diagnostic laboratory settings. Blastocystis test positive will be added as PT to the HLT Parasite identification and serology to represent the positive result of existing PT Blastocystis test.

CR Number: 2023333099 Implementation Date: 05-Dec-23 Related CR: 2023333099

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Vaccine exposed to high temperature administered</i>	Approved Not as Requested	Proposed PT <i>Product with quality issue administered</i>	10090630
			HLT primary <i>Product administration errors and issues</i>	10079147
			SOC primary <i>Injury, poisoning and procedural complications</i>	10022117
			HLT secondary <i>Product quality issues NEC</i>	10069324
			SOC secondary <i>Product issues</i>	10077536

MSSO Comment: The proposal to add a new LLT Vaccine exposed to high temperature administered is approved but not as requested. The requested term is a combination concept of a storage and an administration error. The MSSO refrains from adding further combination terms. However, a new PT Product with quality issue administered, under primary HLT Product administration errors and issues and to secondary HLT Product quality issues NEC, will be added which may be used to represent the scenario in combination with LLT Product storage error temperature too high. In a related change, LLT Out of specification product use will be moved from PT Poor quality product administered to new PT Product with quality issue administered for better alignment.

Supplemental Update Report

CR Number: 2023339005 Implementation Date: 05-Dec-23 Related CR: 2023333099

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Link (move) an LLT to another PT <i>Out of specification product use</i>	Approved as Requested	Proposed LLT <i>Out of specification product use</i>	10083420 Current
From PT	<i>Poor quality product administered</i>		From PT <i>Poor quality product administered</i>	10081478
To PT	<i>Product with quality issue administered</i>		To PT <i>Product with quality issue administered</i>	10090630

MSSO
Comment:

CR Number: 2023333100 Implementation Date: 05-Dec-23 Related CR: 2023333100

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>Vaccine exposed to low temperature administered</i>	Rejected		

MSSO
Comment: The proposal to add a new LLT Vaccine exposed to low temperature administered is not approved. The requested term is a combination concept of a storage and an administration error. The MSSO refrains from adding further combination terms. See change request 2023333099 for the addition of the new PT Product with quality issue administered, which may be used to represent the scenario in combination with LLT Product storage error temperature too low.

CR Number: 2023333129 Implementation Date: 01-Dec-23 Related CR: 2023333129

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Add a New LLT <i>HyperCKemia</i>	Rejected		
To PT	<i>Blood creatine phosphokinase increased</i>			

MSSO
Comment: The proposal to add a new LLT HyperCKemia to PT Blood creatine phosphokinase increased is not approved. HyperCKemia rarely is used as a synonym of blood creatine phosphokinase increased. However, if your report of hyperCKemia indicates a rare congenital/familial disease characterized by elevated levels of an enzyme called creatine kinase in the blood, then resubmit with references indicating as such.

Supplemental Update Report

CR Number: 2023333130	Implementation Date: 01-Dec-23	Related CR: 2023333130	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed PT	<i>Aphantasia</i>	Approved as Requested	Proposed PT <i>Aphantasia</i> 10090610 HLT primary <i>Cortical dysfunction NEC</i> 10011168 SOC primary <i>Nervous system disorders</i> 10029205 HLT secondary <i>Specific cognitive ability disturbances</i> 10041427 SOC secondary <i>Psychiatric disorders</i> 10037175

MSSO Comment: The proposal to add a new PT Aphantasia is approved as requested. Aphantasia is the inability to form mental images of real or imaginary people, places, or things. PT Aphantasia will be added under primary HLT Cortical dysfunction NEC and secondary HLT Specific cognitive ability disturbances.

CR Number: 2023333131	Implementation Date: 01-Dec-23	Related CR: 2023333131	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed LLT	<i>Fat transfer</i>	Approved as Requested	Proposed LLT <i>Fat transfer</i> 10090611 Current
To PT	<i>Lipoinjection</i>		To PT <i>Lipoinjection</i> 10072153

MSSO Comment: The proposal to add a new LLT Fat transfer to PT Lipoinjection is approved as requested. Fat transfer will be added as synonym LLT to existing LLT Lipotransfer under PT Lipoinjection.

CR Number: 2023333136	Implementation Date: 06-Dec-23	Related CR: 2023333136	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u> <u>MedDRA Code #</u>
Proposed LLT	<i>Fibrositis</i>	Rejected	
From PT	<i>Fibromyalgia</i>		
HLT primary	<i>Muscle infections and inflammations</i>		

MSSO Comment: The proposal to promote the LLT Fibrositis from PT Fibromyalgia to primary HLT Muscle infections and inflammations in SOC Musculoskeletal and connective tissue disorders is not approved. Based on international literature search fibrositis most often is used synonymously to fibromyalgia. It is only found in outdated literature articles as an independent concept.

Supplemental Update Report

CR Number: 2023333137 Implementation Date: 06-Dec-23 Related CR: 2023333137

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Fibromyositis</i>	Rejected		
From PT	<i>Fibromyalgia</i>			
To PT	<i>Fibrositis</i>			

MSSO Comment: The proposal to move the LLT Fibromyositis from PT Fibromyalgia to PT Fibrositis is not approved since LLT Fibrositis was not promoted in change request 2023333136.

CR Number: 2023333138 Implementation Date: 06-Dec-23 Related CR: 2023333138

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Muscular rheumatism</i>	Rejected		
From PT	<i>Fibromyalgia</i>			
To PT	<i>Fibrositis</i>			

MSSO Comment: The proposal to move the LLT Muscular rheumatism from PT Fibromyalgia to PT Fibrositis is not approved. Muscular rheumatism has been moved in change request 2023332007 to PT Polymyalgia rheumatica.

CR Number: 2023334001 Implementation Date: 06-Dec-23 Related CR: 2023334001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>15q13.3 microdeletion syndrome</i>	Approved Not as Requested	Proposed PT	
			<i>15q13.3 microdeletion syndrome</i>	10090652
			HLT primary	
			<i>Chromosomal abnormalities NEC</i>	10008805
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Intellectual disabilities</i>	10077548
			SOC secondary	
			<i>Nervous system disorders</i>	10029205

MSSO Comment: The proposal to add a new LLT 15q13.3 microdeletion syndrome is approved but not as requested. 15q13.3 microdeletion syndrome has a variable phenotype with manifestations including mild to severe intellectual disabilities, seizures/epilepsy, behavioral abnormalities, autism, schizophrenia, hypotonia, and visual impairment. 15q13.3 microdeletion syndrome will be added as a PT with a primary link to HLT Chromosomal abnormalities NEC and to secondary HLT Intellectual disabilities. In a related change, the primary HLT for PT 1p36 deletion syndrome will be changed from HLT Musculoskeletal disorders congenital NEC to HLT Chromosomal abnormalities NEC for consistent alignment of similar concepts.

Supplemental Update Report

CR Number: 2023340005 Implementation Date: 06-Dec-23 Related CR: 2023334001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>1p36 deletion syndrome</i>	Approved as Requested	Proposed PT	
From HLT	<i>Musculoskeletal disorders congenital NEC</i>		<i>1p36 deletion syndrome</i>	10082398
To HLT	<i>Chromosomal abnormalities NEC</i>		From HLT	
			<i>Musculoskeletal disorders congenital NEC</i>	10029513
			To HLT	
			<i>Chromosomal abnormalities NEC</i>	10008805

MSSO
Comment:

CR Number: 2023334002 Implementation Date: 06-Dec-23 Related CR: 2023334002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Adult-onset foveomacular vitelliform dystrophy (AOFVD)</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Adult-onset foveomacular vitelliform dystrophy (AOFVD) is not approved. The proposed term can be represented by existing LLT Adult-onset vitelliform macular dystrophy.

CR Number: 2023334003 Implementation Date: 06-Dec-23 Related CR: 2023334003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>TOPAZ Coblation Therapy</i>	Rejected		

MSSO Comment: The proposal to add a new LLT TOPAZ Coblation Therapy is not approved. Since MedDRA rules do not allow addition of trade names, the proposed term can be represented with the LLT Microdebridatation controlled ablation, added in change request 2023116003.

Supplemental Update Report

CR Number: 2023334004 Implementation Date: 06-Dec-23 Related CR: 2023334004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Tortuous esophagus</i>	Approved as Requested	Proposed LLT <i>Tortuous esophagus</i>	10090655 Current
			To PT <i>Tortuous oesophagus</i>	10090653

MSSO Comment: The proposal to add a new LLT Tortuous esophagus is approved as requested. A tortuous esophagus consists in sigmoid shape of the esophagus through the chest towards the gastroenteric junction and is frequently associated to dilatation. It is a frequent image finding of achalasia, but also of other esophageal disorders such as gastroesophageal reflux disease, hiatal hernia or the esophageal pathology associated to connective tissue disorders. Tortuous esophagus will be added as an LLT to a new PT Tortuous oesophagus representing the British spelling of the term, which will be added, in a related change to the HLT Oesophageal disorders NEC.

CR Number: 2023340006 Implementation Date: 06-Dec-23 Related CR: 2023334004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Tortuous oesophagus</i>	Approved as Requested	Proposed PT <i>Tortuous oesophagus</i>	10090653
HLT primary	<i>Oesophageal disorders NEC</i>		HLT primary <i>Oesophageal disorders NEC</i>	10030168
SOC primary	<i>Gastrointestinal disorders</i>		SOC primary <i>Gastrointestinal disorders</i>	10017947

MSSO Comment:

CR Number: 2023334005 Implementation Date: 06-Dec-23 Related CR: 2023334005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Proximal Femoral Nailing System</i>	Approved Not as Requested	Proposed LLT <i>Intramedullary femoral nailing</i>	10090654 Current
			To PT <i>Internal fixation of fracture</i>	10022576

MSSO Comment: The proposal to add a new LLT Proximal Femoral Nailing System is approved but not as requested. Proximal Femoral Nailing System is an advanced fixation system for proximal femur fractures. The proposed term will be modified to Intramedullary femoral nailing, most widely used in medical literature, and added as an LLT to PT Internal fixation of fracture.

Supplemental Update Report

CR Number: 2023334064 Implementation Date: 04-Dec-23 Related CR: 2023334064

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Kidney Essence deficiency</i>	Rejected		

MSSO Comment: The proposal to add a new term Kidney Essence deficiency is not approved. Kidney Essence (Jing 精) Deficiency usually involves Deficiency of Kidney Yin and, to some extent, Kidney Yang. Its signs manifest in relation to growth, development, reproduction, sexuality, bones, marrow, the brain, teeth, memory and hair. The requested term is used in Traditional Chinese Medicine (TCM). TCM concepts are not in the scope of MedDRA.

CR Number: 2023334065 Implementation Date: 04-Dec-23 Related CR: 2023334065

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Intermingled Phlegm and Blood Stasis Syndrome</i>	Rejected		

MSSO Comment: The proposal to add a new term Intermingled Phlegm and Blood Stasis Syndrome is not approved. Phlegm and blood stasis syndrome (PBSS) is one of the main syndromes in coronary heart disease (CHD). Syndromes of Chinese medicine (CM) are lack of quantitative and easy-implementation diagnosis standards. Intermingled Phlegm and Blood Stasis Syndrome is a concept used in Traditional Chinese Medicine and as such not in the scope of MedDRA.

CR Number: 2023334066 Implementation Date: 04-Dec-23 Related CR: 2023334066

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Anergia</i>	Approved Not as Requested	LLT to change <i>Anergy</i> Status <i>Current</i>	10051225 Non-Current

MSSO Comment: The proposal to add a new term Anergia is approved but not as requested. Anergy in immunology is defined as absence of the normal immune response to a particular antigen or allergen. The status of the non-current LLT Anergy will be changed to current (under PT Decreased immune responsiveness) to represent the requested term.

Supplemental Update Report

CR Number: 2023334067

Implementation Date: 04-Dec-23

Related CR: 2023334067

[Change Requested](#)

Add a New Term

[Final Disposition](#)

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Proposed Term *Gonadectomy*

Rejected

MSSO Comment: The proposal to add a new term Gonadectomy is not approved. Gonadectomy refers to the surgical removal of an ovary or testis and as such is not acceptable to be added to MedDRA as it does not represent a single concept. Furthermore, this expression most often is only used in veterinary medicine.

CR Number: 2023334068

Implementation Date: 04-Dec-23

Related CR: 2023334068

[Change Requested](#)

Add a New Term

[Final Disposition](#)

[Final Placement](#)

[MedDRA
Code #](#)

Proposed Term *Genetic disorder*

Rejected

MSSO Comment: The proposal to add a new term Genetic disorder is not approved. A genetic disorder is a health problem caused by one or more abnormalities in the genome. It can be caused by a mutation in a single gene (monogenic) or multiple genes (polygenic) or by a chromosomal abnormality. The requested term is too broad and unspecific.

CR Number: 2023334069

Implementation Date: 04-Dec-23

Related CR: 2023334069

[Change Requested](#)

Add a New Term

[Final Disposition](#)

[Final Placement](#)

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Code #](#)

Proposed Term *Zuckerkindl tubercle*

Rejected

MSSO Comment: The proposal to add a new term Zuckerkindl tubercle is not approved. The Zuckerkindl tubercle is a residue from the embryological development of the thyroid gland and represents as such a normal structure. Normal anatomical structures are out of scope of MedDRA.

Supplemental Update Report

CR Number: 2023334070 **Implementation Date:** 05-Dec-23 **Related CR:** 2023334070

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Checkpoint inhibitor-related pneumonitis	Rejected		

MSSO Comment: The proposal to add a new term Checkpoint inhibitor-related pneumonitis is not approved. The requested term represents a drug-induced concept which the MSSO generally refrains from adding to the terminology.

CR Number: 2023334071 **Implementation Date:** 05-Dec-23 **Related CR:** 2023334071

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Immune checkpoint inhibitors	Rejected		

MSSO Comment: The proposal to add a new term Immune checkpoint inhibitors is not approved. MSSO does not include drug names and classes as this is out of scope of the terminology.

CR Number: 2023334072 **Implementation Date:** 04-Dec-23 **Related CR:** 2023334072

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Generalised pustular psoriasis	Approved as Requested	Proposed PT Generalised pustular psoriasis	10090621
			HLT primary Psoriatic conditions	10065874
			SOC primary Skin and subcutaneous tissue disorders	10040785
			HLT secondary Immune and associated conditions NEC	10027682
			SOC secondary Immune system disorders	10021428

MSSO Comment: The proposal to add a new PT Generalised pustular psoriasis is approved as requested. The most severe, generalized form of pustular psoriasis which is chronic, relapsing psoriasis and characterized by vesicles or pustules is called generalised pustular psoriasis. Generalised pustular psoriasis will be added as a PT to primary HLT Psoriatic conditions and to secondary HLT Immune and associated conditions NEC. In a related change, the American English counterpart, LLT Generalized pustular psoriasis will also be added under PT Generalised pustular psoriasis.

Supplemental Update Report

CR Number: 2023338013	Implementation Date: 04-Dec-23	Related CR: 2023334072		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Generalized pustular psoriasis</i>	Approved as Requested	Proposed LLT	
To PT	<i>Generalised pustular psoriasis</i>		<i>Generalized pustular psoriasis</i>	10090623 Current
			To PT	
			<i>Generalised pustular psoriasis</i>	10090621

MSSO
Comment:

CR Number: 2023334073	Implementation Date: 04-Dec-23	Related CR: 2023334073		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Generalised pustular psoriasis flare</i>	Approved as Requested	Proposed LLT	
To PT	<i>Generalised pustular psoriasis</i>		<i>Generalised pustular psoriasis flare</i>	10090622 Current
			To PT	
			<i>Generalised pustular psoriasis</i>	10090621

MSSO
Comment: The proposal to add a new LLT Generalised pustular psoriasis flare to PT Generalised pustular psoriasis is approved as requested. Generalized pustular psoriasis is a severe and potentially life threatening condition, characterised by flares. In a related change, the American English counterpart LLT Generalized pustular psoriasis flare will also be added under PT Generalised pustular psoriasis.

CR Number: 2023338014	Implementation Date: 04-Dec-23	Related CR: 2023334073		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Generalized pustular psoriasis flare</i>	Approved as Requested	Proposed LLT	
To PT	<i>Generalised pustular psoriasis</i>		<i>Generalized pustular psoriasis flare</i>	10090624 Current
			To PT	
			<i>Generalised pustular psoriasis</i>	10090621

MSSO
Comment:

Supplemental Update Report

CR Number: 2023334093		Implementation Date: 04-Dec-23	Related CR: 2023334093	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Product strength mixup</i>	Approved Not as Requested	Proposed PT <i>Product strength confusion</i>	10090626
			HLT primary <i>Product confusion errors and issues</i>	10079148
			SOC primary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new term Product strength mixup is approved but not as requested. Strength confusion can happen if products are available in different strengths. The requested term will be modified for clarity and consistency with related terms and added as PT Product strength confusion to HLT Product confusion errors and issues.

CR Number: 2023334094		Implementation Date: 04-Dec-23	Related CR: 2023334094	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Basal bolus insulin mixup</i>	Approved Not as Requested	Proposed LLT <i>Basal-bolus regimen confusion</i>	10090627 Current
			To PT <i>Product regimen confusion</i>	10090625

MSSO Comment: The proposal to add a new term Basal bolus insulin mixup is approved but not as requested. Basal-bolus regimen refers to products belonging to the same drug class but are given as different types. Confusion of bolus/basal may lead to severe consequences. The proposed term will be modified and added as LLT Basal-bolus regimen confusion to PT Product regimen confusion which will be added to HLT Product confusion errors and issues in a related change.

CR Number: 2023338015		Implementation Date: 04-Dec-23	Related CR: 2023334094	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Product regimen confusion</i>	Approved as Requested	Proposed PT <i>Product regimen confusion</i>	10090625
HLT primary	<i>Product confusion errors and issues</i>		HLT primary <i>Product confusion errors and issues</i>	10079148
SOC primary	<i>Injury, poisoning and procedural complications</i>		SOC primary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment:

Supplemental Update Report

CR Number: 2023334095 **Implementation Date:** 04-Dec-23 **Related CR:** 2023334095

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Bolus basal insulin mixup</i>	Rejected		

MSSO Comment: The proposal to add a new term Bolus basal insulin mixup is not approved. It is not possible to represent the direction of every scenario. Therefore, the term added in change request 2023334094 is sufficient to represent the concept.

CR Number: 2023334096 **Implementation Date:** 04-Dec-23 **Related CR:** 2023334096

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Product mixup</i>	Rejected		

MSSO Comment: The proposal to add a new term Product mixup is not approved. The requested term is represented by LLT/PT Product confusion.

CR Number: 2023334097 **Implementation Date:** 05-Dec-23 **Related CR:** 2023334097

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Term to modify	<i>Infected socket</i>	Approved Not as Requested	LLT to change <i>Infected socket</i>	10089354 Non-Current
Replacement term	<i>Tooth socket infection</i>		Status <i>Non-current</i>	

MSSO Comment: The proposal to rename PT/LLT Infected socket to Tooth socket infection is approved but not as requested. As socket does not only refer to teeth but can also refer to other locations, e.g. eye socket, the LLT Infected socket will be made non-current. In a related change, new LLT Tooth socket infection will be added under PT Alveolar osteitis.

Supplemental Update Report

CR Number: 2023339006 **Implementation Date:** 05-Dec-23 **Related CR:** 2023334097

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Tooth socket infection</i>	Approved as Requested	Proposed LLT	
To PT	<i>Alveolar osteitis</i>		<i>Tooth socket infection</i>	10090635 Current
			To PT	
			<i>Alveolar osteitis</i>	10066995

MSSO
Comment:

CR Number: 2023334098 **Implementation Date:** 05-Dec-23 **Related CR:** 2023334098

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>T-cell ratio decreased</i>	Rejected		
To PT	<i>CD4/CD8 ratio decreased</i>			

MSSO The proposal to add a new LLT T-cell ratio decreased to PT CD4/CD8 ratio decreased is not approved. T-cell relations are not limited to CD4/CD8 - see e.g. CD25/CD69. Thus, adding
Comment: the unspecific T-cell ratio decreased as LLT to PT CD4/CD8 ratio decreased is incorrect.

CR Number: 2023334099 **Implementation Date:** 05-Dec-23 **Related CR:** 2023334099

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>T-cell ratio increased</i>	Rejected		
To PT	<i>CD4/CD8 ratio increased</i>			

MSSO The proposal to add a new LLT T-cell ratio increased to PT CD4/CD8 ratio increased is not approved. T-cell relations are not limited to CD4/CD8 - see e.g. CD25/CD69. Thus, adding
Comment: the unspecific T-cell ratio increased as LLT to PT CD4/CD8 ratio increased is incorrect.

Supplemental Update Report

CR Number: 2023334100		Implementation Date: 05-Dec-23	Related CR: 2023334100	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Atherogenic index of plasma increased</i>	Approved as Requested	Proposed PT <i>Atherogenic index of plasma increased</i>	10090631
			HLT primary <i>Cholesterol analyses</i>	10008651
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Atherogenic index of plasma increased is approved as requested. The atherogenic index of plasma (AIP) is a numerical lipid index that is used to assess the risk of atherosclerosis and cardiovascular disease. Atherogenic index of plasma increased will be added as a PT to HLT Cholesterol analyses. In a related change, LLT Atherogenic index of plasma high will also be added to new PT Atherogenic index of plasma increased.

CR Number: 2023339007		Implementation Date: 05-Dec-23	Related CR: 2023334100	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Atherogenic index of plasma high</i>	Approved as Requested	Proposed LLT <i>Atherogenic index of plasma high</i>	10090636 Current
To PT	<i>Atherogenic index of plasma increased</i>		To PT <i>Atherogenic index of plasma increased</i>	10090631

MSSO Comment:

CR Number: 2023334101		Implementation Date: 05-Dec-23	Related CR: 2023334101	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Atherogenic index of plasma decreased</i>	Approved as Requested	Proposed PT <i>Atherogenic index of plasma decreased</i>	10090633
			HLT primary <i>Cholesterol analyses</i>	10008651
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Atherogenic index of plasma decreased is approved as requested. The atherogenic index of plasma (AIP) is a numerical lipid index that is used to assess the risk of atherosclerosis and cardiovascular disease. Atherogenic index of plasma decreased will be added as a PT to HLT Cholesterol analyses. In a related change, LLT Atherogenic index of plasma low will also be added to new PT Atherogenic index of plasma decreased.

Supplemental Update Report

CR Number: 2023339008		Implementation Date: 05-Dec-23	Related CR: 2023334101	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Atherogenic index of plasma low</i>	Approved as Requested	Proposed LLT	
To PT	<i>Atherogenic index of plasma decreased</i>		<i>Atherogenic index of plasma low</i>	10090637 Current
			To PT	
			<i>Atherogenic index of plasma decreased</i>	10090633

MSSO
Comment:

CR Number: 2023334102		Implementation Date: 05-Dec-23	Related CR: 2023334102	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Atherogenic index of plasma abnormal</i>	Approved as Requested	Proposed PT	
			<i>Atherogenic index of plasma abnormal</i>	10090632
			HLT primary	
			<i>Cholesterol analyses</i>	10008651
			SOC primary	
			<i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Atherogenic index of plasma abnormal is approved as requested. The atherogenic index of plasma (AIP) is a numerical lipid index that is used to assess the risk of atherosclerosis and cardiovascular disease. PT Atherogenic index of plasma abnormal will be added to HLT Cholesterol analyses.

CR Number: 2023334103		Implementation Date: 05-Dec-23	Related CR: 2023334103	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Noninfective posterior uveitis</i>	Approved as Requested	Proposed LLT	
To PT	<i>Noninfective chorioretinitis</i>		<i>Noninfective posterior uveitis</i>	10090634 Current
			To PT	
			<i>Noninfective chorioretinitis</i>	10074696

MSSO Comment: The proposal to add a new LLT Noninfective posterior uveitis to PT Noninfective chorioretinitis is approved as requested. Noninfective posterior uveitis refers to a form of uveitis, specifically affecting the posterior segment of the eye. The posterior segment includes the choroid, retina, and optic nerve. Noninfective posterior uveitis will be added as sub-concept LLT to PT Noninfective chorioretinitis.

Supplemental Update Report

CR Number: 2023334104 Implementation Date: 05-Dec-23 Related CR: 2023334104

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Mirror writing</i>	Approved as Requested	Proposed LLT	
To PT	<i>Dysgraphia</i>		<i>Mirror writing</i>	10090639 Current
			To PT	
			<i>Dysgraphia</i>	10058319

MSSO The proposal to add a new LLT Mirror writing to PT Dysgraphia is approved as requested. Mirror writing is unusual handwriting, in which the writing is in the opposite direction to normal, with reversed letters that can be effortlessly read using a mirror.
Comment:

CR Number: 2023334105 Implementation Date: 05-Dec-23 Related CR: 2023334105

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Hemorrhagic pancreatic cyst</i>	Approved Not as Requested	Proposed LLT	
			<i>Hemorrhagic pancreatic cyst</i>	10090641 Current
			To PT	
			<i>Haemorrhagic pancreatic cyst</i>	10090638

MSSO The proposal to add a new PT Hemorrhagic pancreatic cyst is approved but not as requested. Intracystic hemorrhages are one of the most common complications during the puncture of a pancreatic cyst for diagnosis or in the process of cyst ablation. Contrary wise to pancreatic pseudocyst ruptures, these cyst hemorrhages are generally self-limited and mild. Hemorrhagic pancreatic cyst will be added as LLT under a new PT Haemorrhagic pancreatic cyst representing the British spelling of the concept, which will be added with a primary link to HLT Cystic pancreatic disorders and secondary links to HLT Gastrointestinal haemorrhages, to HLT Gastrointestinal neoplasms benign NEC and to secondary HLT Gastrointestinal and hepatobiliary procedural complications.
Comment:

Supplemental Update Report

CR Number: 2023339009 Implementation Date: 05-Dec-23 Related CR: 2023334105

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Haemorrhagic pancreatic cyst	Approved as Requested	Proposed PT	
HLT primary	Cystic pancreatic disorders		Haemorrhagic pancreatic cyst	10090638
SOC primary	Gastrointestinal disorders		HLT primary	
			Cystic pancreatic disorders	10011774
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Gastrointestinal haemorrhages	10052742
			SOC secondary	
			Vascular disorders	10047065

MSSO
Comment:

CR Number: 2023339010 Implementation Date: 05-Dec-23 Related CR: 2023334105

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Haemorrhagic pancreatic cyst	Approved as Requested	Proposed PT	
To HLT	Gastrointestinal neoplasms benign NEC		Haemorrhagic pancreatic cyst	10090638
			To HLT	
			Gastrointestinal neoplasms benign NEC	10017989

MSSO
Comment:

Supplemental Update Report

CR Number: 2023339011	Implementation Date: 05-Dec-23	Related CR: 2023334105	MedDRA Code #
Change Requested	Link a PT to a HLT	Final Disposition	Final Placement
Proposed PT	<i>Haemorrhagic pancreatic cyst</i>	Approved as Requested	Proposed PT
To HLT	<i>Gastrointestinal and hepatobiliary procedural complications</i>		<i>Haemorrhagic pancreatic cyst</i> 10090638
			To HLT
			<i>Gastrointestinal and hepatobiliary procedural complications</i> 10017927

MSSO
Comment:

CR Number: 2023334106	Implementation Date: 05-Dec-23	Related CR: 2023334106	MedDRA Code #
Change Requested	Add a New LLT	Final Disposition	Final Placement
Proposed LLT	<i>Branch atheromatous disease</i>	Approved as Requested	Proposed LLT
To PT	<i>Ischaemic stroke</i>		<i>Branch atheromatous disease</i> 10090640 Current
			To PT
			<i>Ischaemic stroke</i> 10061256

MSSO
Comment: The proposal to add a new LLT Branch atheromatous disease to PT Ischaemic stroke is approved as requested. Branch atheromatous disease is a subtype of ischemic stroke caused by proximal atherosclerosis mainly of perforating arteries, but also of paramedian pontine artery, long insular artery and others. Early neurological deterioration and recurrent stereotyped transient ischemic attacks are typical clinical manifestations.

CR Number: 2023334165	Implementation Date: 05-Dec-23	Related CR: 2023334165	MedDRA Code #
Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement
Proposed LLT	<i>Coryza</i>	Rejected	
From PT	<i>Rhinitis</i>		
To PT	<i>Rhinorrhoea</i>		

MSSO
Comment: The proposal to move the LLT Coryza from PT Rhinitis to PT Rhinorrhoea is not approved. Rhinitis, also known as coryza, is irritation and inflammation of the mucous membrane inside the nose. Dorland's Medical Dictionary defines it as 'acute rhinitis'. Common symptoms are a stuffy nose, runny nose, sneezing, and post-nasal drip. Therefore, Coryza is best placed as synonym LLT to PT Rhinitis. Rhinorrhea, runny nose, can have other causes such as allergies, exposure to cold temperatures, cocaine abuse, or drug withdrawal etc.

Supplemental Update Report

CR Number: 2023334166		Implementation Date: 05-Dec-23	Related CR: 2023334166	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Chikungunya serology test</i>	Approved as Requested	Proposed LLT <i>Chikungunya serology test</i>	10090647 Current
			To PT <i>Chikungunya test</i>	10090644

MSSO Comment: The proposal to add a new LLT Chikungunya serology test is approved as requested. Chikungunya can only be definitively diagnosed by a blood test. Tests such as reverse transcriptase–polymerase chain reaction (RT–PCR) can detect the virus directly in blood samples collected during the first week of illness. Chikungunya serology test will be added as LLT to a new broad PT Chikungunya test which will be added in a related change to HLT Virus identification and serology.

CR Number: 2023339014		Implementation Date: 05-Dec-23	Related CR: 2023334166	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Chikungunya test</i>	Approved as Requested	Proposed PT <i>Chikungunya test</i>	10090644
HLT primary	<i>Virus identification and serology</i>		HLT primary <i>Virus identification and serology</i>	10047490
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO Comment:

CR Number: 2023334167		Implementation Date: 05-Dec-23	Related CR: 2023334167	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Chikungunya antibodies IgM and IgG test</i>	Approved Not as Requested	Proposed LLT <i>Chikungunya antibody test</i>	10090648 Current
HLT primary	<i>Virus identification and serology</i>		To PT <i>Chikungunya test</i>	10090644
SOC primary	<i>Investigations</i>			

MSSO Comment: The proposal to add a new PT Chikungunya antibodies IgM and IgG test to primary HLT Virus identification and serology in SOC Investigations is approved but not as requested. Antibody test detect the immune response to chikungunya virus infection. The antibody levels are typically detectable by the first week after illness onset and can still be detected for about 2 months. The requested term will be modified and added as an LLT Chikungunya antibody test to new PT Chikungunya test, added in change request 2023334166.

Supplemental Update Report

CR Number:	2023334168	Implementation Date:	05-Dec-23	Related CR:	2023334168	MedDRA Code #
Change Requested	Add a New LLT	Final Disposition		Final Placement		
Proposed LLT	<i>Chikungunya PCR test</i>	Approved as Requested		Proposed LLT <i>Chikungunya PCR test</i>		10090649 Current
				To PT <i>Chikungunya test</i>		10090644

MSSO Comment: The proposal to add a new LLT Chikungunya PCR test is approved as requested. Chikungunya can only be definitively diagnosed by a blood test. Tests such as reverse transcriptase–polymerase chain reaction (RT–PCR) can detect the virus directly in blood samples collected during the first week of illness. Chikungunya PCR test will be added as LLT to new PT Chikungunya test, added in change request 2023334166.

CR Number:	2023334169	Implementation Date:	05-Dec-23	Related CR:	2023334169	MedDRA Code #
Change Requested	Add a New PT	Final Disposition		Final Placement		
Proposed PT	<i>Chikungunya virus detection test</i>	Approved Not as Requested		Proposed LLT <i>Chikungunya virus detection test</i>		10090646 Current
HLT primary	<i>Virus identification and serology</i>			To PT <i>Chikungunya test</i>		10090644
SOC primary	<i>Investigations</i>					

MSSO Comment: The proposal to add a new PT Chikungunya virus detection test to primary HLT Virus identification and serology in SOC Investigations is approved but not as requested. Chikungunya virus detection test will be added as LLT to the new broad PT Chikungunya test, added in change request 2023334166.

CR Number:	2023334170	Implementation Date:	05-Dec-23	Related CR:	2023334170	MedDRA Code #
Change Requested	Add a New PT	Final Disposition		Final Placement		
Proposed PT	<i>Chikungunya immunisation</i>	Approved as Requested		Proposed PT <i>Chikungunya immunisation</i>		10090645
HLT primary	<i>Immunisations</i>			HLT primary <i>Immunisations</i>		10021431
SOC primary	<i>Surgical and medical procedures</i>			SOC primary <i>Surgical and medical procedures</i>		10042613

MSSO Comment: The proposal to add a new PT Chikungunya immunisation to primary HLT Immunisations in SOC Surgical and medical procedures is approved as requested. The first chikungunya vaccine has recently been approved by FDA and is under review for a Rapid assessment for marketing-authorisation application in the EU/EMA. In a related change, the American counterpart LLT Chikungunya immunization will also be added to the new PT Chikungunya immunisation

Supplemental Update Report

CR Number: 2023339015 **Implementation Date:** 05-Dec-23 **Related CR:** 2023334170

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Chikungunya immunization</i>	Approved as Requested	Proposed LLT	
To PT	<i>Chikungunya immunisation</i>		<i>Chikungunya immunization</i>	10090650 Current
			To PT	
			<i>Chikungunya immunisation</i>	10090645

MSSO
Comment:

CR Number: 2023334171 **Implementation Date:** 05-Dec-23 **Related CR:** 2023334171

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Ascitic tap</i>	Rejected		

MSSO The proposal to add a new term Ascitic tap is not approved. The proposed term is a colloquial synonym of existing LLT Ascites drainage and does provide meaningful translation into all
Comment: MedDRA languages.

CR Number: 2023334172 **Implementation Date:** 05-Dec-23 **Related CR:** 2023334172

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Whole body CT scan or Full-body CT scan</i>	Rejected		

MSSO The proposal to add a new term Whole body CT scan or Full-body CT scan is not approved. The proposed concept is represented by existing LLT Whole body CAT.
Comment:

Supplemental Update Report

CR Number: 2023334173	Implementation Date: 05-Dec-23	Related CR: 2023334173		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>Plasmacytomas removal</i>	Rejected		

MSSO Comment: The proposal to add a new term Plasmacytomas removal is not approved. "Removal" for plasmacytoma is not a valid single concept. Treatment options include therapy, surgery, and chemotherapy. Furthermore, MedDRA cannot provide for all possible haematological pathologies an corresponding removal/treatment counterpart. Please consider the broad LLT Malignant neoplasm removal for your needs.

CR Number: 2023334174	Implementation Date: 05-Dec-23	Related CR: 2023334174		
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Thoracoabdominal CT scan</i>	Approved as Requested	Proposed LLT <i>Thoracoabdominal CT scan</i>	10090628 Current
			To PT <i>Computerised tomogram abdomen</i>	10053876

MSSO Comment: The proposal to add a new LLT Thoracoabdominal CT scan is approved as requested. Thoracoabdominal CT scan stands for a computerized broad exploration of both thoracic and abdominal cavities, which is particularly helpful in cases of extensive trauma or in disseminated conditions such as multiple embolization events. Thoracoabdominal CT scan will be added as a sub-concept LLT of PT Computerised tomogram abdomen.

CR Number: 2023334175	Implementation Date: 05-Dec-23	Related CR: 2023334175		
Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	<i>ALK NEGATIVE ANAPLASTIC LARGE-CELL LYMPHOMA</i>	Approved Not as Requested	Proposed LLT <i>ALK negative anaplastic large-cell lymphoma</i>	10090629 Current
			To PT <i>Anaplastic large cell lymphoma T- and null-cell types</i>	10002227

MSSO Comment: The proposal to add a new term ALK NEGATIVE ANAPLASTIC LARGE-CELL LYMPHOMA is approved but not as requested. ALK- anaplastic large cell lymphoma (ALK- ALCL) is a rare subtype of CD30+ large T-cell lymphoma that typically affects older adults and has a poor prognosis. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as the LLT ALK negative anaplastic large-cell lymphoma to PT Anaplastic large cell lymphoma T- and null-cell types. In a related change, PT Anaplastic large-cell lymphoma will be demoted under PT Anaplastic large cell lymphoma T- and null-cell types. Anaplastic large cell lymphomas (ALCL)s are a group of mature T-cell lymphoma.

Supplemental Update Report

CR Number: 2023339004 Implementation Date: 05-Dec-23 Related CR: 2023334175

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Anaplastic large-cell lymphoma</i>	Approved as Requested	PT to merge	
To PT	<i>Anaplastic large cell lymphoma T- and null-cell types</i>		<i>Anaplastic large-cell lymphoma</i>	10073478 Current
			To PT	
			<i>Anaplastic large cell lymphoma T- and null-cell types</i>	10002227

MSSO
Comment:

CR Number: 2023334176 Implementation Date: 05-Dec-23 Related CR: 2023334176

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Hyposalivation</i>	Rejected		

MSSO Comment: The proposal to add a new term Hyposalivation is not approved. The requested term can be represented by existing LLT Salivary hyposecretion. However, in a related change, PT Aptyalism will be swapped with LLT Salivary hyposecretion to have the more commonly used expression on PT level.

CR Number: 2023339016 Implementation Date: 05-Dec-23 Related CR: 2023334176

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Aptyalism</i>	Approved as Requested	Proposed PT	
With LLT	<i>Salivary hyposecretion</i>		<i>Aptyalism</i>	10003068 Current
			With LLT	
			<i>Salivary hyposecretion</i>	10039425

MSSO
Comment:

Supplemental Update Report

CR Number: 2023335000 Implementation Date: 05-Dec-23 Related CR: 2023335000

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Gastrointestinal mucosal damage	Rejected		

MSSO Comment: The proposal to add a new term Gastrointestinal mucosal damage is not approved. The requested term is a lay and ambiguous expression which may refer to different pathologies within the gastrointestinal tract (e.g. ulcers, erosions, bleedings), dystrophies. Please consider LLT/PT Gastrointestinal mucosal disorder for such unprecise reports if no additional information is available.

CR Number: 2023335001 Implementation Date: 05-Dec-23 Related CR: 2023335001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Bleeding colonic angioectasia	Rejected		

MSSO Comment: The proposal to add a new term Bleeding colonic angioectasia is not approved. The requested term is a combination term with a causal relationship which the MSSO refrains from adding to MedDRA as such combination concepts could lead to overgranularity. LLT Colonic hemorrhage together with a second LLT Colonic angioectasia as underlying cause can be considered to represent this concept.

CR Number: 2023335002 Implementation Date: 05-Dec-23 Related CR: 2023335002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Penile plication	Approved as Requested	Proposed LLT Penile plication	10090643 Current
			To PT Penile curvature repair	10090642

MSSO Comment: The proposal to add a new LLT Penile plication is approved as requested. Penile plication involves tightening the side of the penis opposing the curvature with stitches in order to straighten the penis. This stitching can typically be accomplished through a small incision along the side of the penis. Penile plication will be added as an LLT to a new PT Penile curvature repair, which will be added, in a related change, to HLT Penile therapeutic procedures. Furthermore, LLT Chordee release will be moved from PT Penile repair to the new PT Penile curvature repair for better alignment.

Supplemental Update Report

CR Number: 2023339012	Implementation Date: 05-Dec-23	Related CR: 2023335002		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Penile curvature repair</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Penile therapeutic procedures</i>		<i>Penile curvature repair</i>	10090642
SOC primary	<i>Surgical and medical procedures</i>		HLT primary	
			<i>Penile therapeutic procedures</i>	10034309
			SOC primary	
			<i>Surgical and medical procedures</i>	10042613

MSSO
Comment:

CR Number: 2023339013	Implementation Date: 05-Dec-23	Related CR: 2023335002		
<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Chordee release</i>	Approved as Requested	Proposed LLT	
From PT	<i>Penile repair</i>		<i>Chordee release</i>	10053018 Current
To PT	<i>Penile curvature repair</i>		From PT	
			<i>Penile repair</i>	10052960
			To PT	
			<i>Penile curvature repair</i>	10090642

MSSO
Comment:

CR Number: 2023335003	Implementation Date: 05-Dec-23	Related CR: 2023335003		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Cardiopathy</i>	Rejected		

MSSO The proposal to add a new LLT Cardiopathy is not approved. The proposed term is nonspecific and may be represented by existing LLT/PT Cardiac disorder.
Comment:

Supplemental Update Report

CR Number: 2023335004 Implementation Date: 05-Dec-23 Related CR: 2023335004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Chronic ischemic cardiopathy	Rejected		

MSSO Comment: The proposal to add a new LLT Chronic ischemic cardiopathy is not approved. The proposed term may be represented by LLT Chronic ischemic heart disease, unspecified is under PT Myocardial ischaemia.

CR Number: 2023335812 Implementation Date: 05-Dec-23 Related CR: 2023335812

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Supraventricular bradycardia	Approved as Requested	Proposed PT	
HLT primary	Supraventricular arrhythmias		Supraventricular bradycardia	10090651
SOC primary	Cardiac disorders		HLT primary	
			Supraventricular arrhythmias	10042600
			SOC primary	
			Cardiac disorders	10007541

MSSO Comment: The proposal to add a new PT Supraventricular bradycardia to primary HLT Supraventricular arrhythmias in SOC Cardiac disorders is approved as requested. Rhythm disturbances in the atrium can occur as a result of increased or decreased conduction rate (Supraventricular bradycardia), both of which may potentially compromise cardiac function.

CR Number: 2023335813 Implementation Date: 06-Dec-23 Related CR: 2023335813

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	MARI procedure	Approved Not as Requested	Proposed LLT	
To PT	Cancer surgery		MARI procedure	10090659 Current
			To PT	
			Axillary lymphadenectomy	10068477

MSSO Comment: The proposal to add a new LLT MARI procedure to PT Cancer surgery is approved but not as requested. MARI procedure [marking the axillary lymph node with radioactive iodine (I) seeds] is a new minimal invasive method to assess the pathological response of nodal metastases after neoadjuvant systemic treatment (NST) in patients with breast cancer. Before neoadjuvant chemotherapy, proven tumour-positive axillary lymph nodes are localized using ultrasound-guided insertion of iodine-125-labelled (I-125) seeds. After neoadjuvant chemotherapy, the marked lymph nodes can be removed selectively with the use of a gamma probe. MARI procedure will be added as LLT to the more specific PT Axillary lymphadenectomy. In a related change, LLT Targeted axillary dissection will also be added to PT Axillary lymphadenectomy. Furthermore, the spelled out form of "MARI" will also be added as LLT Marking of axillary lymph node with radioactive iodine seeds to PT Axillary lymphadenectomy.

Supplemental Update Report

CR Number: 2023340008	Implementation Date: 06-Dec-23	Related CR: 2023335813	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Targeted axillary dissection</i>	Approved as Requested	Proposed LLT
To PT	<i>Axillary lymphadenectomy</i>		<i>Targeted axillary dissection</i>
			10090660 Current
			To PT
			<i>Axillary lymphadenectomy</i>
			10068477

MSSO
Comment:

CR Number: 2023340009	Implementation Date: 06-Dec-23	Related CR: 2023335813	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Marking of axillary lymph node with radioactive iodine seeds</i>	Approved as Requested	Proposed LLT
To PT	<i>Axillary lymphadenectomy</i>		<i>Marking of axillary lymph node with radioactive iodine seeds</i>
			10090661 Current
			To PT
			<i>Axillary lymphadenectomy</i>
			10068477

MSSO
Comment:

CR Number: 2023335814	Implementation Date: 06-Dec-23	Related CR: 2023335814	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed Term	<i>Mandibular contouring</i>	Approved Not as Requested	Proposed LLT
			<i>Non-surgical mandibular contouring</i>
			10090657 Current
			To PT
			<i>Facial cosmetic procedure</i>
			10090656

MSSO
Comment: The proposal to add a new term Mandibular contouring is approved but not as requested. Injectables which paralyze the facial muscles are used sometimes as a non-surgical, non-invasive option to slim and contour the jawline. This compares to other procedures, which involve surgically removing part of the muscle or shaving down the jawbone to achieve the same look. Proposed term will be modified for clarity and added as LLT Non-surgical mandibular contouring to PT Facial cosmetic procedure. In a related change, new PT Facial cosmetic procedure will be added under under HLT Facial therapeutic procedures.

Supplemental Update Report

CR Number: 2023340007 Implementation Date: 06-Dec-23 Related CR: 2023335814

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Facial cosmetic procedure</i>	Approved as Requested	Proposed PT <i>Facial cosmetic procedure</i>	10090656
HLT primary	<i>Facial therapeutic procedures</i>		HLT primary <i>Facial therapeutic procedures</i>	10016058
SOC primary	<i>Surgical and medical procedures</i>		SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO
Comment:

CR Number: 2023335815 Implementation Date: 06-Dec-23 Related CR: 2023335815

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Achieve slimmer jaw</i>	Approved Not as Requested	Proposed LLT <i>Non-surgical jawline slimming</i>	10090658 Current
			To PT <i>Facial cosmetic procedure</i>	10090656

MSSO Comment: The proposal to add a new term Achieve slimmer jaw is approved but not as requested. Jawline contouring, mandibular contouring and jawline slimming all aim to alter the jawline and lower face area to give overall balance and symmetry. The cutaneous approach involves injectables to paralyze the muscle to achieve a slimming effect. The proposed term will be modified for clarity and better alignment and added as LLT Non-surgical jawline slimming new PT Facial cosmetic procedure.

CR Number: 2023335816 Implementation Date: 06-Dec-23 Related CR: 2023335816

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Jaw muscles for slimming effect</i>	Rejected		

MSSO Comment: The proposal to add a new term Jaw muscles for slimming effect is not approved. Proposed concept may be represented by LLT Non-surgical jawline slimming (added in change request 2023335815) under new PT Facial cosmetic procedure (added in change request 2023335814).

Supplemental Update Report

CR Number: 2023335817 **Implementation Date:** 06-Dec-23 **Related CR:** 2023335817

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Contouring of the jawline	Rejected		

MSSO Comment: The proposal to add a new term Contouring of the jawline is not approved. The proposed will be modified and added as LLT Non-surgical jawline contouring to new PT Facial cosmetic procedure (added in change request 2023335814).

CR Number: 2023335818 **Implementation Date:** 06-Dec-23 **Related CR:** 2023335818

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Lower facial contour	Rejected		

MSSO Comment: The proposal to add a new term Lower facial contour is not approved. Proposed concept may be represented by LLT Non-surgical jawline contouring (added in change request 2023335817) under new PT Facial cosmetic procedure (added in change request 2023335814).

CR Number: 2023335819 **Implementation Date:** 06-Dec-23 **Related CR:** 2023335819

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Lower face slimming	Rejected		

MSSO Comment: The proposal to add a new term Lower face slimming is not approved. Proposed concept may be represented by LLT Non-surgical jawline slimming (added in change request 2023335815) under new PT Facial cosmetic procedure (added in change request 2023335814).

Supplemental Update Report

CR Number: 2023345002 Implementation Date: 12-Dec-23 Related CR: 2023345002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Documented hypersensitivity to administered product</i>	Approved as Requested	Proposed PT	
From HLT	<i>Product administration errors and issues</i>		<i>Documented hypersensitivity to administered product</i>	10076470
To HLT	<i>Product monitoring errors and issues</i>		From HLT	
			<i>Product administration errors and issues</i>	10079147
			To HLT	
			<i>Product monitoring errors and issues</i>	10079150

MSSO Comment: The proposal to move the PT Documented hypersensitivity to administered product from HLT Product administration errors and issues to HLT Product monitoring errors and issues is approved as requested. Upon review and discussion, the MSSO determined that PT Documented hypersensitivity to administered product is best placed under HLT Product monitoring errors and issues.

CR Number: 2023348001 Implementation Date: 15-Dec-23 Related CR: 2023348001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
LLT to change	<i>Anergy</i>	Approved as Requested	LLT to change	
Status	<i>non-current</i>		<i>Anergy</i>	10051225 Non-Current
			Status	
			<i>non-current</i>	

MSSO Comment: The proposal to change status of LLT Anergy to non-current is approved as requested. After internal review and careful consideration, this term is ambiguous as it can have both contexts (immunological and psychiatric) and should remain non-current.