

Supplemental Update Report

CR Number: 2023248001

Implementation Date: 26-Oct-23

Related CR: 2023248001

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT *Drug-induced liver injury*

Approved as Requested

Proposed PT

Drug-induced liver injury

10072268

To SMQ *Hepatitis, non-infectious (SMQ)*

To SMQ

Hepatitis, non-infectious (SMQ)

20000010

Term scope *Narrow*

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

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA
Code #

Proposed PT *Suspected drug-induced liver injury*

Approved as Requested

Proposed PT

Suspected drug-induced liver injury

10088572

To SMQ *Hepatitis, non-infectious (SMQ)*

To SMQ

Hepatitis, non-infectious (SMQ)

20000010

Term scope *Narrow*

Term scope

Narrow

Term_category

A

Term_weight

0

MSSO
Comment:

Supplemental Update Report

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.

CR Number: 2023296006 **Implementation Date:** 01-Nov-23 **Related CR:** 2023296006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Proposed Term	Canthus squamous cell carcinoma	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.

Supplemental Update Report

CR Number: 2023297012		Implementation Date: 01-Nov-23	Related CR: 2023297012	
Change Requested	Add a New Term	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	Add a New Term	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.				

CR Number: 2023298001		Implementation Date: 01-Nov-23	Related CR: 2023298001	
Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Vomiting post radiotherapy</i>	Approved as Requested	Proposed LLT <i>Vomiting post radiotherapy</i>	10057591 Current
From PT	<i>Vomiting</i>		From PT <i>Vomiting</i>	10047700
To PT	<i>Procedural vomiting</i>		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.				

Supplemental Update Report

CR Number: 2023298002		Implementation Date: 01-Nov-23	Related CR: 2023298002		
Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
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.

CR Number: 2023298003		Implementation Date: 01-Nov-23	Related CR: 2023298003		
Change Requested	Add a New Term	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.

Supplemental Update Report

CR Number: 2023305005		Implementation Date: 01-Nov-23	Related CR: 2023298003	
Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Penile haemangioma	Approved as Requested	Proposed PT	
To HLT	Vascular neoplasms		Penile haemangioma	10090393
			To HLT	
			Vascular neoplasms	10057189
MSSO Comment:				

CR Number: 2023305006		Implementation Date: 01-Nov-23	Related CR: 2023298003	
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Penile hemangioma	Approved as Requested	Proposed LLT	
To PT	Penile haemangioma		Penile hemangioma	10090394 Current
			To PT	
			Penile haemangioma	10090393
MSSO Comment:				

Supplemental Update Report

CR Number: 2023298008

Implementation Date: 01-Nov-23

Related CR: 2023298008

Change Requested

Add a New PT

Final Disposition

Final Placement

MedDRA
Code #

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.

CR Number: 2023305001

Implementation Date: 01-Nov-23

Related CR: 2023298008

Change Requested

Link a PT to a HLT

Final Disposition

Final Placement

MedDRA
Code #

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:

Supplemental Update Report

CR Number: 2023298009		Implementation Date: 01-Nov-23	Related CR: 2023298009	
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
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	
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
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.				

CR Number: 2023305002		Implementation Date: 01-Nov-23	Related CR: 2023298010	
Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	<i>Scrotectomy</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Testicular and scrotal therapeutic procedures</i>		<i>Scrotectomy</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:				

Supplemental Update Report

CR Number: 2023298011

Implementation Date: 01-Nov-23

Related CR: 2023298011

Change Requested

Add a New PT

Final Disposition

Final Placement

MedDRA
Code #

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.

CR Number: 2023305003

Implementation Date: 01-Nov-23

Related CR: 2023298011

Change Requested

Link a PT to a HLT

Final Disposition

Final Placement

MedDRA
Code #

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:

Supplemental Update Report

CR Number: 2023298012		Implementation Date: 01-Nov-23	Related CR: 2023298012	
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Disruptive behavior</i>	Approved Not as Requested	Proposed LLT	10090386 Current
To PT	<i>Abnormal behaviour</i>		<i>Disruptive behavior</i>	
			To PT	10077244
			<i>Defiant behaviour</i>	
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	
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	<i>Disruptive behaviour</i>	Approved as Requested	Proposed LLT	10090389 Current
To PT	<i>Defiant behaviour</i>		<i>Disruptive behaviour</i>	
			To PT	10077244
			<i>Defiant behaviour</i>	
MSSO Comment:				

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	<i>Cobalt allergy</i>	Approved as Requested	Proposed LLT	10090388 Current
To PT	<i>Allergy to metals</i>		<i>Cobalt allergy</i>	
			To PT	10066414
			<i>Allergy to metals</i>	
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.				

Supplemental Update Report

CR Number: 2023298014		Implementation Date: 01-Nov-23	Related CR: 2023298014		MedDRA Code #
Change Requested	Add a New LLT	Final Disposition	Final Placement		
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.

CR Number: 2023299012		Implementation Date: 01-Nov-23	Related CR: 2023299012		MedDRA Code #
Change Requested	Add a New LLT	Final Disposition	Final Placement		
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.

CR Number: 2023299013		Implementation Date: 01-Nov-23	Related CR: 2023299013		MedDRA Code #
Change Requested	Add a New LLT	Final Disposition	Final Placement		
Proposed LLT	Removal of scrotum	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 Scrotoectomy in change request 2023298010.

Supplemental Update Report

CR Number: 2023299014		Implementation Date: 01-Nov-23	Related CR: 2023299014	
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Corporal injury	Approved Not as Requested	Proposed PT Corporal injury	10090390
			HLT primary Criminal activity	10011391
			SOC primary Social circumstances	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	
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Sugar allergy	Rejected		
To PT	Food allergy			

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.

CR Number: 2023300002		Implementation Date: 01-Nov-23	Related CR: 2023300002	
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Sugar intolerance	Approved as Requested	Proposed LLT Sugar intolerance	10090398 Current
			To PT Carbohydrate intolerance	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.

Supplemental Update Report

CR Number: 2023300003	Implementation Date: 01-Nov-23	Related CR: 2023300003	MedDRA Code #
Change Requested	Add a New LLT	Final Disposition	Final Placement
Proposed LLT	EDEMAWEAR	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	MedDRA Code #
Change Requested	Add a New LLT	Final Disposition	Final Placement
Proposed LLT	Striated muscle autoantibody test	Approved Not as Requested	Proposed PT
			Striated muscle autoantibody test
			10090397
			HLT primary
			Autoimmunity analyses
			10003828
			SOC primary
			Investigations
			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	
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Gastrointestinal immunotoxicity	Approved Not as Requested	Proposed PT	
			Immune-mediated gastrointestinal disorder	10090395
			HLT primary	
			Gastrointestinal inflammatory disorders NEC	10017921
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Immune and associated conditions NEC	10027682
			SOC secondary	
			Immune system disorders	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	
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Potential immunotoxic pneumopathy	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	
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Immune-mediated renal toxicity	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	
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	HMG CoA reductase antibodies serum	Approved Not as Requested	Proposed PT HMG CoA reductase antibody test	10090396
			HLT primary Autoimmunity analyses	10003828
			SOC primary Investigations	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	
Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	Post herpetic pruritus	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	
Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	Foreign body ear lobe	Approved Not as Requested	Proposed LLT Foreign body ear lobe	10090399 Current
			To PT Foreign body in ear	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.
