

## MedDRA Version 17.0 Complex Changes

The following decisions have been made for the implementation of each set of complex changes for MedDRA Version 17.0. All MedDRA user comments submitted via e-mail to the MSSO were evaluated by the MSSO's International Medical Officers before making a decision on these requests.

### MedDRA User Submitted Requests:

#### 1. Add a new HLT *Exserohilum infections* to HLGT *Fungal infectious disorders*

**Submitter rationale:** Adding this HLT would provide a grouping of several terms related to exserohilum infections with a public health impact.

**Additional Terminology Impact:** Based upon a review by the MSSO, the following PTs would be moved under new HLT *Exserohilum infections* if this change were implemented:

- PT *Exserohilum infection*
- PT *Meningitis exserohilum*

**Implementation Status:** This proposal will be implemented as requested. Although typically a rare infection, this pathogen has been associated with medicinal product contamination and thus is clinically significant and warrants its own grouping term to facilitate analysis.

#### 2. Add new HLT *Off label uses* to HLGT *Therapeutic procedures and supportive care NEC*

**Submitter rationale:** The new EU legislation extends the definition of an adverse drug reaction to include use inside and outside of the terms of the marketing authorisation. Therefore there is a need to code and aggregate cases of 'off label use' where this has been reported and to specify the type of 'off label use' more precisely. Additional PTs are required to provide this specificity of coding.

**MSSO Note:** If this change were implemented, any PT and LLTs added or moved under the proposed HLT *Off label uses* would have to be carefully considered in

order to make clear distinctions between the concepts of off label use, misuse, medication errors, and intentional vs unintentional use. See section 3.16 of the *MedDRA Term Selection: Points to Consider* document.

**Implementation Status:** This proposal will continue to be suspended. Based on user feedback, there was no clear consensus on whether to implement this proposed change. The MSSO will continue to solicit feedback from regulators and industry on this issue.

### **3. Replace HLGT *Coagulopathies and bleeding diatheses (excl thrombocytopenic)* with new HLGT *Coagulopathies and bleeding diatheses***

**Submitter rationale:** The submitter is working in the ITP (idiopathic thrombocytopenic purpura) studies where the majority of AEs are easy bruising , worsening Petechia ,and Ecchymoses. As pathophysiology, the bleeding events are due to thrombocytopenia. Proposal: Add new HLGT *Coagulopathies and bleeding diatheses* with the following HLTs under it - HLT *Bleeding tendencies*, HLT *Coagulation factor deficiencies*, HLT *Coagulopathies* and HLT *Purpuras (excl thrombocytopenic)*. The PT *Purpura* should be under the HLT *Bleeding tendencies* . Removing the exclusion criteria stated in parenthesis will broaden the scope of the HLGT and the limitation of excluding thrombocytopenia related bleeding concepts.

**Terminology Impact:** If approved, the HLTs under HLGT *Coagulopathies and bleeding diatheses (excl thrombocytopenic)* would move under new HLGT *Coagulopathies and bleeding diatheses*. HLGT *Coagulopathies and bleeding diatheses (excl thrombocytopenic)* would be removed.

**Implementation Status:** This proposal will be not be implemented. The proposed HLGT *Coagulopathies and bleeding diatheses* is too broad and would encompass a broad range of terms relating to diagnoses, signs, and symptoms of bleeding, regardless of etiology. The MSSO prefers to keep the existing hierarchy which separates out those terms relating solely to coagulation and bleeding diatheses.

### **4. Add new HLT *Product operational issues* to HLGT *Product quality issues***

**Submitter rationale:** Currently, MedDRA does not have adequate terms available to code reports associated with cosmetics that are difficult to remove. The closest term available is LLT *Device difficult to remove*, however cosmetics are not regulated as devices and therefore the use of this term would be misleading. We recommend to add the HLT *Product operational issues* (similar to the HLT *Device operational issues NEC*) in order to capture reports of products that are intended for

application but are difficult to remove. For example, reports of a consumer who applies mascara and has a difficult time removing the product, which results in an injury, could potentially be coded to terms mapping to the HLT, such as Product difficult remove.

The submitter proposed the following PT be added to proposed HLT *Product operational issues*:

- PT *Product difficult to remove*

**Note:** The MSSO reviewed the request for PT *Product difficult to remove* and added this term under HLT *Product quality issues NEC* for MedDRA Version 17.0

**Implementation Status:** This proposal will be not be implemented. The concept of an operational issue tends to refer to devices and existing HLT *Device operational issues NEC* fulfills this purpose. Additionally, the concept of an operational issue usually does not apply to a medicinal product such as a cream. Therefore, the MSSO considers the proposed PT *Product difficult to remove* to be most appropriately placed under the HLT *Product quality issues NEC*.

## 5. Replace HLGT *Menopause and related conditions* with new HLGT *Menopause related conditions*

**Submitter rationale:** The submitter proposes changing the HLGT *Menopause and related conditions* in SOC *Reproductive system and breast disorders* to HLGT *Menopause related conditions*. The existing name of the HLGT gives the impression that PT *Menopause* is mapped under one of the HLTs under HLGT *Menopause and related conditions*. However, PT *Menopause* is mapped under HLT *Age related issues* in SOC *Social circumstances*. Eliminating the word "and" from HLGT *Menopause and related conditions* provides clarity and more precisely defines the terms that are encompassed within the HLGT.

**Terminology Impact:** If approved, the HLTs under HLGT *Menopause and related conditions* would move under new HLGT *Menopause related conditions*. HLGT *Menopause and related conditions* would be removed.

**Implementation Status:** This proposal will be implemented as requested. The contents of this HLGT *Menopause and related conditions* with its two subordinate HLTs – HLT *Menopausal effects NEC* and HLT *Menopausal effects on the genitourinary tract* relate to conditions associated with menopause and not the state of menopause itself, which is a normal stage of maturation. Therefore, the proposed

*new HLT Menopause related conditions, which replaces HLT Menopause and related conditions, more accurately reflects its contents.*

**6. Link existing HLT *Substance-related disorders* to HLT *Therapeutic and nontherapeutic effects (excl toxicity)***

**Submitter rationale:** PT *Intentional drug misuse* is to be used for all intentional deviations in product usage by patients/ consumers. The current placement only represents one possible causality of related terms and is definitely adequate for conditions like drug abuse etc. For minor deviations in product use, the placement seems to be inadequate and misleading. A linkage to SOC *General disorders and administration site conditions* would allow flexibility and better support safety data representation and analysis.

**Terminology Impact:** If this change were implemented HLT *Substance-related disorders* would have links to two SOC – SOC *Psychiatric disorders* and SOC *General disorders and administration site conditions*.

**MSSO Note:** PT *Intentional drug misuse* was moved to HLT *Therapeutic procedures NEC* in SOC *Surgical and medical procedures* for MedDRA Version 16.1.

**Implementation Status:** This proposal will be not be implemented. Please reference section 3.16 of the MedDRA Term Selection: Points To Consider document – Misuse, Abuse and Addiction. According to the definitions provided, misuse is seen as an intentional use by a patient for a therapeutic purpose and is distinct from the concept of abuse. In MedDRA Version 16.1 PT *Intentional drug misuse* was moved from HLT *Substance-related disorders* in SOC *Psychiatric disorders* to HLT *Therapeutic procedures NEC* in SOC *Surgical and medical procedures*. With this move, the request to provide an additional link for HLT *Substance-related disorders* to HLT *Therapeutic and nontherapeutic effects (excl toxicity)* in SOC *General disorders and administration site conditions* is no longer applicable.

**7. Link HLT *Complications associated with device* to SOC *Injury, poisoning and procedural complications***

**Submitter rationale:** The wording "complications" and the PT content of the HLT *Complications associated with device* indicates harm of the patient that is caused by/ associated with devices. An additional link to SOC *Injury, poisoning and procedural*

*complications* would better represent this background and better support safety data presentation and analysis.

**Terminology Impact:** If this change were implemented, *HLGT Complications associated with device* would have links to two SOCs – *SOC General disorders and administration site conditions* and *SOC Injury, poisoning and procedural complications*.

**Implementation Status:** This proposal will be not be implemented. Linking the *HLGT Complications associated with device* to *SOC Injury, poisoning and procedural complications* would not be appropriate because not all PTs under *HLGT Complications associated with device* represent injury or procedural complications. The addition of links to *SOC Injury, poisoning and procedural complications* for individual PTs under *HLGT Complications associated with device* will be considered.

The following changes are proposed by the MSSO:

**8. Add new HLT *Nervous system autoimmune disorders* to HLG  
*Autoimmune disorders***

**MSSO rationale:** In MedDRA Version 16.0 the MSSO reviewed the placement of autoimmune disorder concepts classified as “systemic”. The review focused on providing additional links, or in some cases reassigning the primary SOC, of existing terms from SOC *Immune system disorders* to a SOC representing the site of manifestation. A total of 56 changes were made based on this review. Several autoimmune terms were added during the proactive review that could be better represented by the presence of an anatomically specific HLT in SOC *Immune system disorders*. Therefore, new HLT *Nervous system autoimmune disorders* is proposed. This HLT corresponds with existing HLT *Hepatic autoimmune disorders*, HLT *Muscular autoimmune disorders* and HLT *Skin autoimmune disorders NEC*, etc.

**Implementation Status:** This proposal will be implemented as requested. Please see the rationale above. The following PTs will be moved under new HLT *Nervous system autoimmune disorders*.

PT <i>Acute disseminated encephalomyelitis</i>	PT <i>Guillain-Barre syndrome</i>	PT <i>Paraneoplastic cerebellar degeneration</i>
PT <i>Acute haemorrhagic leukoencephalitis</i>	PT <i>Leukoencephalomyelitis</i>	PT <i>POEMS syndrome</i>
PT <i>Autoimmune neuropathy</i>	PT <i>Multiple sclerosis</i>	PT <i>Rasmussen encephalitis</i>
PT <i>Chronic inflammatory demyelinating polyradiculoneuropathy</i>	PT <i>Myelitis transverse</i>	PT <i>Stiff person syndrome</i>
PT <i>Concentric sclerosis</i>	PT <i>Neuralgic amyotrophy</i>	PT <i>Susac's syndrome</i>
PT <i>Demyelinating polyneuropathy</i>	PT <i>Neuromyelitis optica</i>	PT <i>Toxic oil syndrome</i>
PT <i>Encephalitis allergic</i>	PT <i>Optic neuritis</i>	
PT <i>Encephalitis autoimmune</i>	PT <i>Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection</i>	

9. **Add a New HLT *Plasma cell myelomas* to HLGT *Plasma cell neoplasms***

**Merge exiting HLT *Multiple myelomas* to new HLT *Plasma cell myelomas***

**MSSO rationale:** "Multiple myeloma" is now called "plasma cell myeloma" in the WHO classification.

**Terminology Impact:** New HLT *Plasma cell myelomas* would be added under existing HLGT *Plasma cell neoplasms*. The PTs under HLT *Multiple myelomas* would reside under new HLT *Plasma cell myelomas*. Existing HLT *Multiple myelomas* would be removed as a result of the merge if these changes were implemented.

**Implementation Status:** This proposal will be implemented as requested. Please see the rationale above.

10. **Replace HLT *Central nervous system aneurysms* with new HLT *Central nervous system aneurysms and dissections* in HLGT *Central nervous system vascular disorders***

**MSSO Rationale:** The addition of PT *Intracranial artery dissection* in MedDRA Version 16.1 under HLT *Central nervous system aneurysms* makes the HLT name unsuitable. Replacing HLT *Central nervous system aneurysms* with new HLT *Central nervous system aneurysms and dissections* will broaden the scope of the existing HLT *Central nervous system aneurysms*. Three PTs under HLT *Central nervous system aneurysms* – PT *Carotid artery dissection*, PT *Intracranial artery dissection* and PT *Vertebral artery dissection* would be better represented by the new HLT *Central nervous system aneurysms and dissections*.

**Implementation Status:** This proposal will be implemented as requested. Please see the rationale above.

11. **Add new HLT *Bone and joint injuries NEC* to HLGT *Bone and joint injuries***

**MSSO rationale:** The rationale for this proposed change is that many of the PTs under HLT *Limb injuries NEC (incl traumatic amputation)* are not necessarily "limb" issues such as PT *Bursa injury*, PT *Cartilage injury*, PT *Joint injury*, PT *Synovial rupture* and PT *Traumatic arthritis*, PT *Traumatic arthropathy*, PT *Traumatic arthrosis* and PT *Joint hyperextension*. The new HLT *Bone and joint*

*injuries NEC* would have a broader scope and will better represent all the non-limb/non-extremity terms.

**Implementation Status:** This proposal will be implemented as requested. Please see the rationale above. In a related change, the MSSO will merge existing HLT *Limb injuries NEC (incl traumatic amputation)* under new HLT *Bone and joint injuries NEC*.

**12. Add new HLT *Connective tissue disorders NEC* to HLGT *Connective tissue disorders (excl congenital)***

**Merge existing HLT *Connective tissue disorders (excl LE)* to HLT *Connective tissue disorders NEC***

**MSSO rationale:** Several of the PT concepts under HLT *Connective tissue disorders (excl LE)* such as PT *Overlap syndrome*, PT *Undifferentiated connective tissue disease*, PT *Mixed connective tissue disease*, PT *Collagen disorder* and PT *Connective tissue disorder* are associated with development of lupus erythematosus during the course of these disease processes. Since the name of the HLT *Connective tissue disorders (excl LE)* excludes disease conditions associated with lupus erythematosus, the existing placement of the PTs listed above is not optimal. The new HLT *Connective tissue disorders NEC* will remove this restriction and broaden the scope for future placements.

**Terminology Impact:** The PTs under HLT *Connective tissue disorders (excl LE)* would reside under new HLT *Connective tissue disorders NEC*. Existing HLT *Connective tissue disorders (excl LE)* would be removed as a result of the merge if these changes were implemented.

**Implementation Status:** This proposal will be implemented as requested. Please see the rationale above.

**13. Add new HLT *Burkholderia infections* to HLGT *Bacterial infectious disorders***

**MSSO Rationale:** *Burkholderia* is an important pathogen in the cystic fibrosis population and people with immunocompromised status. In recent times *Burkholderia* has been implicated in mortality and morbidity in immunocompromised population, homosexual population and patients with cystic fibrosis. Therefore, it is appropriate to provide a separate HLT for this genus.



**Terminology Impact:** Based upon a review by the MSSO, the following PTs would move to new HLT *Burkholderia infections* if this change were implemented.

- PT *Burkholderia cepacia complex infection*
- PT *Burkholderia cepacia complex sepsis*
- PT *Burkholderia gladioli infection*
- PT *Burkholderia infection*
- PT *Burkholderia mallei infection*
- PT *Burkholderia pseudomallei infection*

**Implementation Status:** This proposal will be implemented as requested. Please see the rationale above.

#### **14. Merge HLT *Colonic neoplasms malignant* under HLT *Colorectal neoplasms malignant***

**MSSO Rationale:** Merging HLT *Colonic neoplasms malignant* under HLT *Colorectal neoplasms malignant* will combine overlapping concepts and prevent signal dispersion.

**Terminology Impact:** The PTs under HLT *Colonic neoplasms malignant* would reside under HLT *Colorectal neoplasms malignant*. Existing HLT *Colonic neoplasms malignant* would be removed as a result of the merge if these changes were implemented.

**Implementation Status:** This proposal will be implemented as requested. The MSSO will merge HLT *Colonic neoplasms malignant* under HLT *Colorectal neoplasms malignant*. In addition, HLT *Rectal neoplasms malignant* will be merged under HLT *Colorectal neoplasms malignant*. Colonic and rectal malignant neoplasms share common pathological characteristics. HLT *Anal canal neoplasms malignant* will remain as a separate HLT since the pathological characteristics of these neoplasms are distinct from malignant colorectal neoplasms.

**15. Add new HLT *Transplantation complications* to HLGT *Procedural related injuries and complications NEC***

**MSSO Rationale:** A new HLT *Transplantation complications* in SOC *Injury, poisoning and procedural complications* would allow a more precise grouping for several concepts now under HLT *Non-site specific procedural complications* or other site specific HLTs under HLGT *Procedural related injuries and complications NEC* in SOC *Injury, poisoning and procedural complications*.

**Terminology Impact:** Based on an MSSO review, the following is an example of PTs that would move from HLT *Non-site specific procedural complications* to the new HLT *Transplantation complications* if this change were implemented.

**Implementation Status:** This proposal will be implemented as requested. Please see the rationale above. The following PTs will move under new HLT *Transplantation complications*.

HLGT	HLT	PT	LLT	Notes
Procedural related injuries and complications NEC				
	<a href="#">Transplantation complications</a>			
		Acute graft versus host disease		Moved from HLT <i>Non-site specific procedural complications</i>
		Acute graft versus host disease in intestine		Moved from HLT <i>Gastrointestinal and hepatobiliary procedural complications</i>
		Acute graft versus host disease in liver		Moved from HLT <i>Gastrointestinal and hepatobiliary procedural complications</i>
		Acute graft versus host disease in skin		Moved from HLT <i>Skin procedural complications</i>
		Arteriovenous graft site abscess		Moved from HLT <i>Cardiac and vascular procedural complications</i>
		Arteriovenous graft		Moved from HLT

HLGT	HLT	PT	LLT	Notes
		aneurysm		<i>Cardiac and vascular procedural complications</i>
		Arteriovenous graft site haematoma		Moved from HLT <i>Cardiac and vascular procedural complications</i>
		Arteriovenous graft site haemorrhage		Moved from HLT <i>Cardiac and vascular procedural complications</i>
		Arteriovenous graft site infection		Moved from HLT <i>Cardiac and vascular procedural complications</i>
		Blood stem cell transplant failure		Moved from HLT <i>Site specific procedural complications NEC</i>
		Bone graft lysis		Moved from HLT <i>Musculoskeletal procedural complications</i>
		Bone marrow harvest failure		Moved from HLT <i>Site specific procedural complications NEC</i>
		Chronic graft versus host disease		Moved from HLT <i>Non-site specific procedural complications</i>
		Chronic graft versus host disease in intestine		Moved from HLT <i>Gastrointestinal and hepatobiliary procedural complications</i>
		Chronic graft versus host disease in liver		Moved from HLT <i>Gastrointestinal and hepatobiliary procedural complications</i>
		Chronic graft versus host disease in skin		Moved from HLT <i>Skin procedural complications</i>
		Complications of bone marrow transplant		Moved from HLT <i>Non-site specific procedural complications</i>

 New  
 Existing

<b>HLGT</b>	<b>HLT</b>	<b>PT</b>	<b>LLT</b>	<b>Notes</b>
		Complications of intestinal transplant		Moved from HLT <i>Gastrointestinal and hepatobiliary procedural complications</i>
		Complications of limb reattachment surgery		Moved from HLT <i>Musculoskeletal procedural complications</i>
		Complications of transplant surgery		Moved from HLT <i>Non-site specific procedural complications</i>
		Complications of transplanted heart		Moved from HLT <i>Cardiac and vascular procedural complications</i>
		Complications of transplanted kidney		Moved from HLT <i>Urinary tract procedural complications</i>
		Complications of transplanted liver		Moved from HLT <i>Gastrointestinal and hepatobiliary procedural complications</i>
		Complications of transplanted lung		Moved from HLT <i>Respiratory tract and thoracic cavity procedural complications</i>
		Complications of transplanted pancreas		Moved from HLT <i>Gastrointestinal and hepatobiliary procedural complications</i>
		Delayed engraftment		Moved from HLT <i>Non-site specific procedural complications</i>
		Donor site complication		Moved from HLT <i>Non-site specific procedural complications</i>
		Engraft failure		Moved from HLT <i>Site specific procedural complications</i> <i>NEC</i>

<b>HLGT</b>	<b>HLT</b>	<b>PT</b>	<b>LLT</b>	<b>Notes</b>
		Engraftment syndrome		Moved from HLT <i>Non-site specific procedural complications</i>
		Graft complication		Moved from HLT <i>Non-site specific procedural complications</i>
		Graft delamination		Moved from HLT <i>Musculoskeletal procedural complications</i>
		Graft dysfunction		Moved from HLT <i>Non-site specific procedural complications</i>
		Graft haemorrhage		Moved from HLT <i>Non-site specific procedural complications</i>
		Graft infection		Moved from HLT <i>Non-site specific procedural complications</i>
		Graft ischaemia		Moved from HLT <i>Non-site specific procedural complications</i>
		Graft loss		Moved from HLT <i>Non-site specific procedural complications</i>
		Graft overgrowth		Moved from HLT <i>Non-site specific procedural complications</i>
		Graft thrombosis		Moved from HLT <i>Non-site specific procedural complications</i>
		Graft versus host disease		Moved from HLT <i>Non-site specific procedural complications</i>
		Graft versus host disease in intestine		Moved from HLT <i>Gastrointestinal and hepatobiliary procedural complications</i>
		Graft versus host disease in liver		Moved from HLT <i>Gastrointestinal and hepatobiliary procedural complications</i>

<b>HLGT</b>	<b>HLT</b>	<b>PT</b>	<b>LLT</b>	<b>Notes</b>
		Graft versus host disease in lung		Moved from HLT <i>Respiratory tract and thoracic cavity procedural complications</i>
		Graft versus host disease in skin		Moved from HLT <i>Skin procedural complications</i>
		Liver graft loss		Moved from HLT <i>Gastrointestinal and hepatobiliary procedural complications</i>
		Multiple organ transplant rejection		Moved from HLT <i>Non-site specific procedural complications</i>
		Passenger lymphocyte syndrome		Moved from HLT <i>Site specific procedural complications</i> NEC
		Post transplant distal limb syndrome		Moved from HLT <i>Non-site specific procedural complications</i>
		Pre-engraftment immune reaction		Moved from HLT <i>Site specific procedural complications</i> NEC
		Renal graft loss		Moved from HLT <i>Urinary tract procedural complications</i>
		Renal transplant torsion		Moved from HLT <i>Urinary tract procedural complications</i>
		Skin graft contracture		Moved from HLT <i>Skin procedural complications</i>
		Skin graft detachment		Moved from HLT <i>Skin procedural complications</i>
		Skin graft failure		Moved from HLT <i>Skin procedural complications</i>
		Skin graft infection		Moved from HLT <i>Skin procedural complications</i>

HLGT	HLT	PT	LLT	Notes
		Skin graft scar		Moved from HLT <i>Skin procedural complications</i>
		Skin graft scar contracture		Moved from HLT <i>Skin procedural complications</i>
		Transplant abscess		Moved from HLT <i>Non-site specific procedural complications</i>
		Transplant complication		Singular form of HLT Transplantation complications
		Transplant failure		Moved from HLT <i>Non-site specific procedural complications</i>
		Vascular graft occlusion		Moved from HLT <i>Cardiac and vascular procedural complications</i>
		Vascular graft thrombosis		Moved from HLT <i>Cardiac and vascular procedural complications</i>

**16. Add HLT *Stoma site complications* to HLGT *Procedural related injuries and complications NEC***

**MSSO Rationale:** Based on a proactivity request submitted by a MedDRA user to add a set of “stoma site” terms to MedDRA, the MSSO is proposing new HLT *Stoma site complications*. The current hierarchy does not have an appropriate grouping term to add “stoma site” terms.

**Terminology Impact:** Based on an proactivity proposal submitted by a MedDRA user, the following new and existing terms are examples proposed to be included under proposed HLT *Stoma site complications*.

**Implementation Status:** This proposal will be implemented as not as requested. The proposed HLT will be added as HLT *Stoma complications* which is a more inclusive grouping name for the related concepts. The following PTs will be moved, promoted or added under new HLT *Stoma complications*.

HLGT	HLT	PT	LLT	Notes
Procedural related injuries and complications NEC				
	Stoma complications			
		Gastrointestinal stoma complication		Moved from HLT <i>Gastrointestinal and hepatobiliary procedural complications</i>
		Gastrointestinal stoma necrosis		Moved from HLT <i>Gastrointestinal and hepatobiliary procedural complications</i>
		Stoma complication		
		Stoma obstruction		
		Stoma site abscess		Promoted LLT
			Peristomal abscess NOS	
		Stoma site candida		Promoted LLT
		Stoma site discomfort		Promoted LLT
		Stoma site erythema		
			Stoma site redness	Moved from PT <i>Procedural site reaction</i>
		Stoma site haemorrhage		
			Intestinal stoma site bleeding	Moved from PT <i>Post procedural haemorrhage</i>
			Stoma site bleeding	Moved from PT <i>Post procedural haemorrhage</i>
			Stoma site hemorrhage	US spelling
		Stoma site		

 New  
 Existing



HLGT	HLT	PT	LLT	Notes
		hypersensitivity		
		Stoma site hypoesthesia		
			Stoma site hypoesthesia	
			Stoma site numbness	
		Stoma site induration		
		Stoma site infection		Promoted LLT
		Stoma site inflammation		Promoted LLT
		Stoma site irritation		Promoted LLT
		Stoma site ischaemia		
			Stoma site ischemia	US spelling
		Stoma site pain		Promoted LLT
		Stoma site paraesthesia		
			Stoma site paresthesia	US Spelling
		Stoma site phlebitis		
		Stoma site rash		Promoted LLT
		Stoma site reaction		Promoted LLT
		Stoma site thrombosis		
		Stoma site ulcer		
			Stomal ulcer	Moved from PT <i>Anastomotic ulcer</i>
		Stoma site vasculitis		