

# Implemented MedDRA Version 23.0 Complex Changes

(November 2019)

## MedDRA User Proposed Requests:

### 1. Merge HLT *Oral soft tissue pain and paraesthesia* to HLT *Oral soft tissue signs and symptoms*

**Justification:** Please consider merging HLT *Oral soft tissue pain and paraesthesia* into HLT *Oral soft tissue signs and symptoms* to group related concepts. Paraesthesia oral is separated from the related "aesthesia" concepts of Hypoaesthesia oral, Oral dysaesthesia, and Oral hyperaesthesia. Similarly, Lip pain and Oral pain, are separated from the related concepts of Lip discomfort and Oral discomfort.

**Terminology Impact:** If approved, HLT *Oral soft tissue pain and paraesthesia* would be removed and the underlying PTs would move under HLT *Oral soft tissue signs and symptoms*.

**Implementation Status:** This request will be approved as requested. Merging HLT *Oral soft tissue pain and paraesthesia* to HLT *Oral soft tissue signs and symptoms* groups related PTs (such as oral "aesthesia", and lip and oral pain and discomfort concepts) together to facilitate coding and analysis.

### 2. Add new HLT *Gastrointestinal injuries* To HLT *Injuries NEC*

**Justification:** Please create an HLT *Gastrointestinal injuries* to rectify the placement of non-abdominal foreign body terms, such as LLT *Foreign body in mouth* in the HLT *Abdominal injuries NEC*. The mouth is not part of the abdomen, it should not be in an abdominal HLT.

**Terminology Impact:** If approved, following PTs would move under the new HLT:

- PT *Colon injury*

- PT *Foreign body in gastrointestinal tract*
- PT *Gastrointestinal injury*
- PT *Gastrointestinal organ contusion*
- PT *Pancreatic contusion*
- PT *Pancreatic duct rupture*
- PT *Pancreatic injury*
- PT *Traumatic pancreatitis*

**MSSO Note:** As an alternative to creating a new HLT, consider replacing HLT *Abdominal injuries NEC* with HLT *Abdominal and gastrointestinal injuries NEC*. This would broaden the scope of the HLT and accurately represent the underlying terms.

**Implementation Status:** This request will be approved, but not as requested. New HLT *Abdominal and gastrointestinal injuries NEC* will be added to HLGT *Injuries NEC* and existing HLT *Abdominal injuries NEC* will be merged to new HLT *Abdominal and gastrointestinal injuries NEC*. These actions broaden the scope of the HLT *Abdominal and gastrointestinal injuries NEC* and more accurately represent the underlying terms.

Additionally, PTs will be moved from HLT *Site specific injuries NEC* to new HLT *Abdominal and gastrointestinal injuries NEC*. Below is an example of PT moves.

- PT *Anal injury*
- PT *Gingival injury*
- PT *Lip injury*
- PT *Oesophageal injury*
- PT *Oral contusion*
- PT *Palate injury*
- PT *Tongue injury*
- PT *Tooth injury*

## **MSSO Proposed Requests:**

1. **Merge existing HLT *Accelerated and malignant hypertension* to existing HLT *Vascular hypertensive disorders NEC***

**MSSO Rationale:** This change would group all vascular hypertension concepts under one single HLT for analysis purposes instead of having the few PTs under HLT *Accelerated and malignant hypertension* grouped separately.

**Terminology Impact:** If approved, HLT *Accelerated and malignant hypertension* would be removed and the underlying PTs would move under HLT *Vascular hypertensive disorders NEC*.

**Implementation Status:** Based on MedDRA user feedback, this request will not be approved. The more clinically significant accelerated and malignant hypertension concepts warrant remaining under HLT *Accelerated and malignant hypertension* rather than consolidating them under the non-specific HLT *Vascular hypertensive disorders NEC*.

2. The MSSO proposes the following complex changes to improve the placement of gene concepts in MedDRA:

- Replace HLT *Chromosomal abnormalities and abnormal gene carriers* with new HLT *Chromosomal abnormalities, gene alterations, and gene variants* in SOC *Congenital, familial and genetic disorders*
- Add new HLT *Gene mutations and other alterations* to new HLT *Chromosomal abnormalities, gene alterations, and gene variants*
- Merge HLT *Acquired gene mutations and other alterations* to new HLT *Gene mutations and other alterations*
- Move appropriate gene mutation PTs under HLT *Gene mutations and other alterations*
- Add new HLT *Genetic polymorphisms* to HLT *Chromosomal abnormalities, gene alterations, and gene variants*
- Move appropriate genetic polymorphism terms from HLT *Acquired gene mutations and alterations* to new HLT *Genetic polymorphisms*

**Justification:** Grouping all gene conditions and alterations such as overexpressions, rearrangements and mutations together, regardless of whether they are congenital or acquired, would better organize these concepts in MedDRA. SOC *Congenital, familial and genetic disorders* is the appropriate place for grouping these concepts since it covers genetic disorders. The changes would also separate chromosomal concepts from gene concepts. Similarly, separating out the genetic polymorphisms, which are considered gene variants rather than gene alterations, would aid in coding and retrieval of these concepts.

**Terminology Impact:** If approved, existing HLT *Chromosomal abnormalities and abnormal gene carriers* would be removed and the underlying HLTs would move under new HLT *Chromosomal abnormalities, gene alterations, and gene variants*. Existing HLT *Acquired gene mutations and other alterations* would be removed and replaced with new HLT *Gene mutations and other alterations*.

Examples of gene mutation PTs that would move under new HLT *Gene mutations and other alterations* include: PT *Gene mutation*, PT *DNA mismatch repair protein gene mutation*, and PT *PAPSS2 gene mutation*.

Examples of genetic polymorphism PTs that would move under HLT *Genetic polymorphisms* include: PT *CYP1A2 polymorphism*, PT *Endothelial protein C receptor polymorphism*, and PT *Interleukin 28B polymorphism*.

**Implementation status:** This request will be approved, but not as requested. Proposed HLT *Gene mutations and other alterations* will be added as HLT *Gene mutations and other alterations NEC*. The rest of the proposed changes will be implemented as proposed. Grouping all gene conditions and alterations such as overexpressions, rearrangements and mutations together, regardless of whether they are congenital or acquired, better organizes these concepts in MedDRA. These changes also separate chromosomal concepts from gene concepts. Similarly, separating out the genetic polymorphisms, which are considered gene variants rather than gene alterations, would aid in coding and retrieval of these concepts. Modifications to the wording of the MedDRA Introductory Guide will be made to explain that SOC *Congenital, familial and genetic disorders* is intended to cover gene concepts, whether they are acquired or congenital.

Below are examples of PTs that will move as a result of these changes:

PT Moved	From HLT	In SOC	To HLT	In SOC
Acquired chromosomal abnormality	Acquired gene mutations and other alterations	General disorders and administration site conditions	Chromosomal abnormalities NEC	Congenital, familial and genetic disorders
Acquired gene mutation	Acquired gene mutations and other alterations	General disorders and administration site conditions	Gene mutations and other alterations NEC	Congenital, familial and genetic disorders
Acquired mitochondrial DNA deletion	Acquired gene mutations and other alterations	General disorders and administration site conditions	Genetic mitochondrial abnormalities NEC	Congenital, familial and genetic disorders
Fatal familial insomnia	Autosomal chromosomal abnormalities	Congenital, familial and genetic disorders	Gene mutations and other alterations NEC	Congenital, familial and genetic disorders
Gene mutation	Chromosomal abnormalities NEC	Congenital, familial and genetic disorders	Gene mutations and other alterations NEC	Congenital, familial and genetic disorders
Hereditary angioedema	Congenital disorders NEC	Congenital, familial and genetic disorders	Gene mutations and other alterations NEC	Congenital, familial and genetic disorders
Li-Fraumeni syndrome	Abnormal gene carriers	Congenital, familial and genetic disorders	Gene mutations and other alterations NEC	Congenital, familial and genetic disorders
Mismatch repair cancer syndrome	Abnormal gene carriers	Congenital, familial and genetic disorders	Gene mutations and other alterations NEC	Congenital, familial and genetic disorders
NAT1 polymorphism	Acquired gene mutations and other alterations	General disorders and administration site conditions	Genetic polymorphisms	Congenital, familial and genetic disorders
Phakomatosis	Congenital disorders NEC	Congenital, familial and genetic disorders	Gene mutations and other alterations NEC	Congenital, familial and genetic disorders