

Common Terminology Criteria for Adverse Events (CTCAE) v3.0

March 31, 2003, Publish Date: June 10, 2003

Notice of Modifications

The table below details the revisions made to the CTCAE v3.0 since its initial publication on March 31, 2003 through June 10, 2003. The revisions include minor editorial corrections and adjustments to Grade 5 definitions for several Adverse Events. The only significant change is the inclusion of 'Euphoria' under Mood alteration – *Select* in the NEUROLOGY. This was an omission of an AE term that existed in CTC v2.0 and is included in CTCAE v3.0.

To differentiate the two timeframes, the revisions made between March 31 and April 16, 2003 are shaded, while the revisions made between April 17 and June 10, 2003 have no shading.

Please note that the CTCAE v3.0 document now includes the Publish Date of June 10, 2003. The previous CTCAE v3.0 documents published on March 31st and April 16th are obsolete and should no longer be used.

Revision to	Revision Description
Quick Reference page: First sentence under Navigation Note	From: A 'NAVIGATION NOTE' indicates the location of a CTCAE term... To: A 'NAVIGATION Note' indicates the location of an AE term...
Quick Reference page: Third paragraph under Grades	From: An "Em dash" (—) indicates a grade not available To: An 'Em dash' (—) indicates a grade not available.
ALLERGY/IMMUNOLOGY, Page 1 Autoimmune reaction ALSO CONSIDER	From: Hemolysis; To: Hemolysis (e.g., immune hemolytic anemia, drug-related hemolysis);
AUDITORY/EAR, Page 2 AE Name	From: Hearing {patients with/without baseline audiogram and enrolled in a monitoring program} To: Hearing: patients with/without baseline audiogram and enrolled in a monitoring program
AUDITORY/EAR, Page 2 AE Name	From: Hearing {patients without baseline audiogram and not enrolled in a monitoring program} To: Hearing: patients without baseline audiogram and not enrolled in a monitoring program
AUDITORY/EAR, Page 2 Short Name	From: Otitis To: Otitis, middle
AUDITORY/EAR, Page 2 Otitis, external ear (non-infectious) ALSO CONSIDER	From: Hearing {patients with/without baseline audiogram and enrolled in a monitoring program} ¹ ; Hearing {patients without baseline audiogram and not enrolled in a monitoring program} ¹ . To: Hearing: patients with/without baseline audiogram and enrolled in a monitoring program ¹ ; Hearing: patients without baseline audiogram and not enrolled in a monitoring program ¹ .

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Revision to	Revision Description
AUDITORY/EAR, Page 3 Tinnitus ALSO CONSIDER	From: Hearing {patients with/without baseline audiogram and enrolled in a monitoring program} ¹ ; Hearing {patients without baseline audiogram and not enrolled in a monitoring program} ¹ . To: Hearing: patients with/without baseline audiogram and enrolled in a monitoring program ¹ ; Hearing: patients without baseline audiogram and not enrolled in a monitoring program ¹ .
CARDIAC ARRHYTHMIA, Page 5 Conduction abnormality/atrioventricular heart block – <i>Select</i> : AV Block-Second degree Mobitz Typell	From: AV Block-Second degree Mobitz Typell To: AV Block-Second degree Mobitz Type II
CARDIAC ARRHYTHMIA, Page 6 Supra-ordinate term	From: Ventricular arrhythmia – <i>Select</i> To: Ventricular arrhythmia – <i>Select</i> :
CARDIAC ARRHYTHMIA, Page 6 Short Name	From: Ventricular arrhythmia To: Ventricular arrhythmia – <i>Select</i>
CARDIAC GENERAL, Page 7 Cardiac ischemia/infarction	Moved to its alphabetical placement within the category.
CARDIAC GENERAL, Page 7 Cardiac ischemia/infarction, Grade 5	From: — To: Death
CONSTITUTIONAL SYMPTOMS, Page 11 AE Name	From: Fatigue (lethargy, malaise, asthenia) To: Fatigue (asthenia, lethargy, malaise)
CONSTITUTIONAL SYMPTOMS, Page 11 Obesity, Grade 5	From: Death To: —
CONSTITUTIONAL SYMPTOMS, Page 11 Odor (patient odor), Grade 5	From: Death To: —
CONSTITUTIONAL SYMPTOMS, Page 12 Weight gain, Grade 5	From: Death To: —
CONSTITUTIONAL SYMPTOMS, Page 12 Short Name	From: Weight Loss To: Weight loss
DERMATOLOGY/SKIN, Page 14 Injection site reaction/extravasation changes, Grade 5	From: Death To: —
DERMATOLOGY/SKIN, Page 15 Rash: hand-foot skin reaction, Grade 5	From: Death To: —
DERMATOLOGY/SKIN, Page 16 Urticaria (hives, welts, wheals), Grade 5	From: Death To: —
ENDOCRINE, Page 17 Gynecomastia	The listing for Gynecomastia was changed to the following NAVIGATION NOTE: Gynecomastia is graded in the SEXUAL/REPRODUCTIVE FUNCTION CATEGORY.

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ENDOCRINE, Page 17 Short Name	From: Masculinization To: Masculinization of female
ENDOCRINE, Page 17 Neuroendocrine: gonadotropin secretion abnormality, Grade 5	From: Death To: —
ENDOCRINE, Page 17 Neuroendocrine: growth hormone secretion abnormality, Grade 5	From: Death To: —
ENDOCRINE, Page 18 Parathyroid function, low (hypoparathyroidism), Grade 5	From: Death To: —
GASTROINTESTINAL, Page 20 Dental: teeth, Grade 5	From: Death To: —
GASTROINTESTINAL, Page 20 Dental: teeth development, Grade 5	From: Death To: —
GASTROINTESTINAL, Page 20 Distension/bloating, abdominal, Grade 5	From: Death To: —
GASTROINTESTINAL, Page 21 Dry mouth/salivary gland (xerostomia), Grade 5	From: Death To: —
GASTROINTESTINAL, Page 23 Ileus, GI (functional obstruction of bowel, i.e., neuroconstipation), ALSO CONSIDER	From: Constipation; Nausea; Obstruction – Select in the GASTROINTESTINAL ; Vomiting. To: Constipation; Nausea; Obstruction, GI – <i>Select</i> ; Vomiting.
GASTROINTESTINAL, Page 23 Incontinence, anal Grade 1	From: Requires occasional use of pads required To: Occasional use of pads required
GASTROINTESTINAL, Page 23 Incontinence, anal Grade 2	From: Requires daily use of pads required To: Daily use of pads required
GASTROINTESTINAL, Page 24 Mucositis/stomatitis (clinical exam) – <i>Select</i> : Grade 2 and 3	From: pseudomebranes To: pseudomembranes
GASTROINTESTINAL, Page 25 Necrosis, GI – <i>Select</i> Grade 3	From: Inability to alimnt adequatety by GI tract, To: Inability to alimnt adequately by GI tract
GASTROINTESTINAL, Page 25 Obstruction, GI – <i>Select</i> Grade 3	From: Symptomatic and severely altered GI function; To: Symptomatic and severely altered GI function
GASTROINTESTINAL, Page 27 Stricture/stenosis (including anastomotic), GI – <i>Select</i> Grade 3	From: Symptomatic and severely altered GI function; To: Symptomatic and severely altered GI function

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GASTROINTESTINAL, Page 27 Typhlitis (cecal inflammation) ALSO CONSIDER	Alphabetized the listing: From: Colitis; Ileus, GI (functional obstruction of bowel, i.e., neuroconstipation); Hemorrhage, GI – Select. To: Colitis; Hemorrhage, GI – Select; Ileus, GI (functional obstruction of bowel, i.e., neuroconstipation).
GASTROINTESTINAL, Page 28 Ulcer, GI – Select ALSO CONSIDER	From: Hemorrhage, GI – Select; Ulcer. To: Hemorrhage, GI – Select.
GROWTH AND DEVELOPMENT, Page 29 Bone growth: limb length discrepancy, Grade 4	From: Disabling; epiphysidesis To: Disabling; epiphysiodesis
HEMORRHAGE/BLEEDING, Page 31 Hemorrhage, GI – <i>Select</i> : Appendix	Deleted 'Appendix' as it is a duplicate of 'Cecum/appendix'
HEMORRHAGE/BLEEDING, Page 32 Petechiae/purpura (hemorrhage/bleeding into skin or mucosa), Grade 5	From: Death To: —
HEMORRHAGE/BLEEDING, Page 32 Hemorrhage, pulmonary/upper respiratory – <i>Select</i> REMARK	From: Transfusion implies pRBC To: Transfusion implies pRBC.
HEPATOBIILIARY/PANCREAS, Page 34 NAVIGATION NOTE	From: "...GI – Select in GASTROINTESTINAL CATEGORY. To: "...GI – Select in the GASTROINTESTINAL CATEGORY.
HEPATOBIILIARY/PANCREAS, Page 34 Liver dysfunction/failure (clinical) ALSO CONSIDER	From: Bilirubin To: Bilirubin (hyperbilirubinemia)
INFECTION, Page 36 Viral hepatitis ALSO CONSIDER	From: Bilirubin To: Bilirubin (hyperbilirubinemia)
INFECTION, Page 37 INFECTION – <i>Select</i> : AUDITORY/HEARING subheading	From: AUDITORY/ HEARING To: AUDITORY/ EAR
INFECTION, Page 37 INFECTION – <i>Select</i> : DERMATOLOGY/SKIN subheading	From: Skin (cellulites) To: Skin (cellulitis)
INFECTION, Page 37 INFECTION – <i>Select</i> : GASTROINTESTINAL subheading – Oral	Deleted 'Oral' as it is a duplicate of 'Oral cavity-gums (gingivitis)'
LYMPHATICS, Page 38 Dermal change lymphedema, phlebolymphe ma , Grade 5	From: Death To: —
LYMPHATICS, Page 39 Lymphedema-related fibrosis, Grade 5	From: Death To: —

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LYMPHATICS, Page 39 Lymphocele, Grade 5	From: Death To: —
LYMPHATICS, Page 39 Phlebolympathic cording, Grade 5	From: Death To: —
METABOLIC/LABORATORY, Page 40 Alkaline phosphatase, Grade 5	From: Death To: —
METABOLIC/LABORATORY, Page 40 ALT, SGPT (serum glutamic pyruvic transaminase), Grade 5	From: Death To: —
METABOLIC/LABORATORY, Page 40 Amylase, Grade 5	From: Death To: —
METABOLIC/LABORATORY, Page 40 AST, SGOT (serum glutamic oxaloacetic transaminase), Grade 5	From: Death To: —
METABOLIC/LABORATORY, Page 40 Bilirubin (hyperbilirubinemia), Grade 5	From: Death To: —
METABOLIC/LABORATORY, Page 40 Calcium, serum-low (hypocalcemia) Grades 1, 2, 3, and 4	The separation of Ionized calcium was moved from the Adverse Event name column and placed within each grade definition.
METABOLIC/LABORATORY, Page 41 Calcium, serum-high (hypercalcemia) Grades 1, 2, 3, and 4	The separation of Ionized calcium was moved from the Adverse Event name column and placed within each grade definition.
METABOLIC/LABORATORY, Page 41 GGT (γ -Glutamyl transpeptidase), Grade 5	From: Death To: —
METABOLIC/LABORATORY, Page 41 Lipase, Grade 5	From: Death To: —
MUSCULOSKELETAL/SOFT TISSUE, Page 43 Extremity-lower (gait/walking) ALSO CONSIDER	From: Ataxia To: Ataxia (incoordination)
MUSCULOSKELETAL/SOFT TISSUE, Page 44 Fibrosis-deep connective tissue, Grade 5	From: — To: Death
MUSCULOSKELETAL/SOFT TISSUE, Page 44 Fibrosis-deep connective tissue, ALSO CONSIDER	From: Induration/fibrosis skin To: Induration/fibrosis (skin and subcutaneous tissue)

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MUSCULOSKELETAL/SOFT TISSUE, Page 44 Fibrosis-deep connective tissue, ALSO CONSIDER	From: Neuropathy-motor; Neuropathy-sensory To: Neuropathy: motor; Neuropathy: sensory
MUSCULOSKELETAL/SOFT TISSUE, Page 44 AE Name	From: Local complication-device/prosthesis-related To: Local complication – device/prosthesis-related
MUSCULOSKELETAL/SOFT TISSUE, Page 45 Muscle weakness, generalized or specific area (not due to neuropathy) – <i>Select</i> : Extremity-upper, -lower	Alphabetized the following Select AEs: From: – Extremity-upper – Extremity-lower To: – Extremity-lower – Extremity-upper
MUSCULOSKELETAL/SOFT TISSUE, Page 45 Myositis (inflammation/damage of muscle) ALSO CONSIDER	From: CPK To: CPK (creatine phosphokinase)
MUSCULOSKELETAL/SOFT TISSUE, Page 46 Seroma, Grade 5	From: Death To: —
MUSCULOSKELETAL/SOFT TISSUE, Page 46 Soft tissue necrosis – <i>Select</i> : Head	Added 'Head' as a Select AE
MUSCULOSKELETAL/SOFT TISSUE, Page 46 Soft tissue necrosis – <i>Select</i> : Extremity- upper, -lower	Alphabetized the following Select AEs: From: – Extremity-upper – Extremity-lower To: – Extremity-lower – Extremity-upper
MUSCULOSKELETAL/SOFT TISSUE, Page 46 NAVIGATION NOTE	From: "Wound non-infectious is graded Wound complication..." To: "Wound non-infectious is graded as Wound complication..."
NEUROLOGY, Page 47 Arachnoiditis/meningismus/radiculitis ALSO CONSIDER	From: Infection – <i>Select</i> . To: Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils (ANC <1.0 x 10 ⁹ /L) – <i>Select</i> ; Infection with normal ANC or Grade 1 or 2 neutrophils – <i>Select</i> ; Infection with unknown ANC – <i>Select</i> .
NEUROLOGY, Page 48 Dizziness, Grade 5	From: Death To: —
NEUROLOGY, Page 48 Dizziness, ALSO CONSIDER	From: Neuropathy-cranial – Select To: Neuropathy: cranial – Select
NEUROLOGY, Page 48 AE Name	From: Extrapyr amidal /involuntary movement/ restlessness / tremor To: Extrapyr amidal /involuntary movement/restlessness

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NEUROLOGY, Page 49 Leukoencephalopathy (radiographic findings), Grade 5	From: Death To: —
NEUROLOGY, Page 49 Mood alteration – <i>Select</i> : Euphoria	Added 'Euphoria' as a Select AE
NEUROLOGY, Page 50 Phrenic nerve dysfunction, Grade 3	From: Significant dysfunction; intervention indicated (e.g., diaphragmatic nlacation) To: Significant dysfunction; intervention indicated (e.g., diaphragmatic plication)
NEUROLOGY, Page 51 NAVIGATION NOTE: Taste alteration	Moved to its alphabetical placement within the category.
NEUROLOGY, Page 51 NAVIGATION NOTE	From: Taste alteration (CN VII, IX) is graded as Taste alteration (dysgeusia) in the GASTROINTESTINAL CATEGORY To: Taste alteration (CN VII, IX) is graded as Taste alteration (dysgeusia) in the GASTROINTESTINAL CATEGORY.
OCULAR/VISUAL, Page 52 Dry eye syndrome, Grade 5	From: Death To: —
NEUROLOGY, Page 52 NAVIGATION NOTE: Ocular muscle weakness	Moved to its alphabetical placement within the category.
OCULAR/VISUAL, Page 52 Eyelid dysfunction, Grade 5	From: Death To: —
OCULAR/VISUAL, Page 52 Eyelid dysfunction, REMARK	From: eythema To: erythema
OCULAR/VISUAL, Page 52 Eyelid dysfunction, REMARK	Alphabetized the listing: From: Eyelid dysfunction includes madarosis, erythema, thickening, telangiectasis, trichiasis, canalicular stenosis, symblepharon, ectropion, and entropion. To: Eyelid dysfunction includes canalicular stenosis, ectropion, entropion, erythema, madarosis, symblepharon, telangiectasis, thickening, and trichiasis.
OCULAR/VISUAL, Page 52 Keratitis (corneal inflammation/corneal ulceration), Grade 5	From: Death To: —
OCULAR/VISUAL, Page 52 Keratitis (corneal inflammation/corneal ulceration), Grade 3	From: symptomatic and interfering with adl; operative intervention indicated To: Symptomatic and interfering with ADL ; operative intervention indicated
OCULAR/VISUAL, Page 52 Night blindness (nyctalopia), Grade 5	From: Death To: —
OCULAR/VISUAL, Page 53 Nystagmus, Grade 5	From: Death To: —

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OCULAR/VISUAL, Page 53 AE Name and Short Name	From: Ocular surface disease To: Ocular surface disease	
OCULAR/VISUAL, Page 53 Ocular surface disease, Grade 5	From: Death To: —	
OCULAR/VISUAL, Page 53 Ophthalmoplegia/diplopia (double vision), Grade 5	From: Death To: —	
OCULAR/VISUAL, Page 53 Optic disc edema, Grade 5	From: Death To: —	
OCULAR/VISUAL, Page 53 Proptosis/enophthalmos, Grade 5	From: Death To: —	
OCULAR/VISUAL, Page 53 Retinal detachment, Grade 5	From: Death To: —	
OCULAR/VISUAL, Page 53 Retinopathy, Grade 5	From: Death To: —	
OCULAR/VISUAL, Page 54 Scleral necrosis/melt, Grade 5 OCULAR/VISUAL	From: Death To: —	
OCULAR/VISUAL, Page 54 Uveitis, Grade 5	From: Death To: —	
OCULAR/VISUAL, Page 54 Short Name	From: Blurred Vision To: Blurred vision	
OCULAR/VISUAL, Page 54 Short Name	From: Vision -flashing lights To: Flashing lights	
OCULAR/VISUAL, Page 54 Vision-flashing lights/floaters, Grade 5	From: Death To: —	
OCULAR/VISUAL, Page 54 Vitreous hemorrhage, Grade 5	From: Death To: —	
PAIN, Page 55 PAIN – <i>Select</i> , Grade 2 and 3	Grade 2 From: Moderate pain; To: Moderate pain;	Grade 3 From: Severe pain; To: Severe pain;
PAIN, Page 55 PAIN – <i>Select</i> , Grade 5	From: Death To: —	

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PAIN, Page 55 PAIN – Other (Specify, ___), Grade 2 and 3	Grade 2 From: Moderate pain; To: Moderate pain;	Grade 3 From: Severe pain; To: Severe pain;
PAIN, Page 55 PAIN – Other (Specify, ___), Grade 5	From: Death To: —	
PAIN, Page 55 PAIN – <i>Select</i> : AUDITORY/HEARING subheading	From: AUDITORY/HEARING To: AUDITORY/EAR	
PAIN, Page 55 PAIN – <i>Select</i> : AUDITORY/EAR subheading – Ear/external	From: Ear/external To: External ear	
PAIN, Page 55 PAIN – <i>Select</i> : AUDITORY/EAR subheading – Ear/middle	From: Ear/middle To: Middle ear	
PULMONARY/UPPER RESPIRATORY, Page 56 Bronchospasm, wheezing ALSO CONSIDER	From: Allergic reaction/hypersensitivity reaction To: Allergic reaction/hypersensitivity (including drug fever)	
PULMONARY/UPPER RESPIRATORY, Page 56 Cough, Grade 5	From: Death To: —	
PULMONARY/UPPER RESPIRATORY, Page 56 Atelectasis ALSO CONSIDER	From: Infection – <i>Select</i> . To: Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils (ANC <1.0 x 10 ⁹ /L) – <i>Select</i> ; Infection with normal ANC or Grade 1 or 2 neutrophils – <i>Select</i> ; Infection with unknown ANC – <i>Select</i> .	
PULMONARY/UPPER RESPIRATORY, Page 57 Dyspnea (shortness of breath) ALSO CONSIDER	From: Neuropathy-motor To: Neuropathy: motor	
PULMONARY/UPPER RESPIRATORY, Page 57 Hiccoughs (hiccups, singultus), Grade 5	From: Death To: —	
PULMONARY/UPPER RESPIRATORY, Page 57 Hypoxia, Grade 2	From: Decreased O ₂ saturation with exercise (e.g., pulse ox <88%); intermittent supplemental oxygen To: Decreased O ₂ saturation with exercise (e.g., pulse oximeter <88%); intermittent supplemental oxygen	
PULMONARY/UPPER RESPIRATORY, Page 58 Pleural effusion (non-malignant), Grade 4	From: Life-threatening (e.g., causing hemodynamic instability or ventilatory support) indicated To: Life-threatening (e.g., causing hemodynamic instability or ventilatory support) indicated	
PULMONARY/UPPER RESPIRATORY, Page 58 Pneumonitis/pulmonary infiltrates, Grade 3	From: Symptomatic, interfering with ADL; O ₂ indicated To: Symptomatic, interfering with ADL; O ₂ indicated	

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PULMONARY/UPPER RESPIRATORY, Page 58 Pneumonitis/pulmonary infiltrates ALSO CONSIDER	From: Dyspnea To: Dyspnea (shortness of breath)
PULMONARY/UPPER RESPIRATORY, Page 59 Short Name	From: Pulmonary fibrosis (radiographic changes) To: Pulmonary fibrosis
RENAL/GENITOURINARY, Page 60 Cystitis ALSO CONSIDER	From: Infection – <i>Select</i> . To: Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils (ANC <1.0 x 10 ⁹ /L) – <i>Select</i> ; Infection with normal ANC or Grade 1 or 2 neutrophils – <i>Select</i> ; Infection with unknown ANC – <i>Select</i> .
RENAL/GENITOURINARY, Page 60 Short Name	From: Incontinence To: Incontinence, urinary
RENAL/GENITOURINARY, Page 60 Incontinence, urinary, Grade 5	From: Death To: —
RENAL/GENITOURINARY, Page 62 Urinary electrolyte wasting (e.g., Fanconi's syndrome, renal tubular acidosis), Grade 5	From: Death To: —
RENAL/GENITOURINARY, Page 62 Urinary electrolyte wasting (e.g., Fanconi's syndrome, renal tubular acidosis), ALSO CONSIDER	From: Acidosis To: Acidosis (metabolic or respiratory)
RENAL/GENITOURINARY, Page 62 Urinary retention (including neurogenic bladder), REMARK	REMARK added: The etiology of retention (if known) is graded as Obstruction, GU – <i>Select</i> ; Stricture/stenosis (including anastomotic), GU – <i>Select</i> .
RENAL/GENITOURINARY, Page 62 Urinary retention (including neurogenic bladder), ALSO CONSIDER	From: The etiology of retention (if known) is graded as Obstruction, GU – <i>Select</i> ; Stricture/stenosis (including anastomotic), GU – <i>Select</i> . To: Obstruction, GU – <i>Select</i> ; Stricture/stenosis (including anastomotic), GU – <i>Select</i> .
SEXUAL/REPRODUCTIVE FUNCTION, Page 65 Vaginal mucositis, Grade 4	From: Tissue necrosis; significant spontaneous bleeding; life-threatening consequences To: Tissue necrosis; significant spontaneous bleeding; life-threatening consequences
SEXUAL/REPRODUCTIVE FUNCTION, Page 65 Vaginitis (not due to infection), Grade 5	From: Death To: —
SURGERY/INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure</i> : AUDITORY/HEARING subheading	From: AUDITORY/HEARING To: AUDITORY/EAR

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SURGERY//INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure</i> : AUDITORY/HEARING subheading – Outer ear-Pinna	Moved to its alphabetical placement within the grouping.	
SURGERY//INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure</i> : CARDIOVASCULAR subheading – Heart, Spleen	Moved to its alphabetical placement within the grouping.	
SURGERY//INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure</i> : HEAD AND NECK subheading – Neck NOS	Moved to its alphabetical placement within the grouping.	
SURGERY//INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure</i> : GASTROINTESTINAL subheading – Anus	Moved to its alphabetical placement within the grouping.	
SURGERY//INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure</i> : GASTROINTESTINAL subheading – Stoma (GI)	Moved to its alphabetical placement within the grouping.	
SURGERY//INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure</i> : HEPATOBILIARY/ PANCREAS subheading – Pancreas	Moved to its alphabetical placement within the grouping.	
SURGERY//INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure</i> : MUSCULOSKELETAL subheading – Extremity-upper, -lower	Alphabetized the following Select AEs: From: – Extremity-upper – Extremity-lower To: – Extremity-lower – Extremity-upper	
SURGERY//INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure</i> : NEUROLOGY/NERVES subheading	Added CN I (olfactory) within the grouping.	
SURGERY//INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure</i> : NEUROLOGY/NERVES subheading	From: – Nerve-Lingual – Nerve-Lung thoracic – Nerve-recurrent laryngeal – Nerve-peripheral sensory NOS – Nerve-peripheral motor NOS – Nerve-sciatic – Nerve-thoracodorsal – Sacral plexus	To: – Lingual – Lung thoracic – Peripheral motor NOS – Peripheral sensory NOS – Recurrent laryngeal – Sacral plexus – Sciatic – Thoracodorsal

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SURGERY/INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure</i> : NEUROLOGY/NERVES subheading – Brachial Plexus	Deleted duplicate listing of 'Brachial Plexus'
SURGERY/INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure</i> : NEUROLOGY/NERVES subheading – Nerve-lung thoracic	From: Nerve-long thoracic To: Nerve-lung thoracic
SURGERY/INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure</i> : PULMONARY/UPPER RESPIRATORY subheading – Trachea	Moved to its alphabetical placement within the grouping.
SYNDROMES, Page 68 Cytokine release syndrome/acute infusion reaction REMARK, second sentence	From: An Acute infusion reaction may occur with an agent that causes cytokine release (e.g., monoclonal antibodies or other biological agents). To: An acute infusion reaction may occur with an agent that causes cytokine release (e.g., monoclonal antibodies or other biological agents).
SYNDROMES, Page 68 Cytokine release syndrome/acute infusion reaction ALSO CONSIDER	From: Allergic reaction/hypersensitivity reaction (including drug fever); Bronchospasm; Prolonged QTc To: Allergic reaction/hypersensitivity (including drug fever); Bronchospasm, wheezing ; Prolonged QTc interval
SYNDROMES, Page 68 Flu-like syndrome	Moved to its alphabetical placement within the category.
SYNDROMES, Page 69 Short Name	From: Retinoic acid syndrome To: "Retinoic acid syndrome"
SYNDROMES, Page 69 Syndromes – Other (Specify, ___), Grade 5	From: To: Death
VASCULAR, Page 70 Phlebitis (including superficial thrombosis), Grade 5	From: Death To: —
VASCULAR, Page 70 Portal vein flow, Grade 5	From: Death To: —
VASCULAR, Page 70 Thrombosis/embolism (vascular access-related), Grade 2	From: Deep vein thrombosis, or cardiac thrombosis; intervention (e.g., anticoagulation, lysis, filter, invasive procedure) not indicated To: Deep vein thrombosis or cardiac thrombosis; intervention (e.g., anticoagulation, lysis, filter, invasive procedure) not indicated
VASCULAR, Page 70 Short Name	From: Thrombosis/embolism To: Thrombosis/ thrombus /embolism

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VASCULAR, Page 70 Thrombosis/thrombus/embolism, Grade 2	From: Deep vein thrombosis, or cardiac thrombosis; intervention (e.g., anticoagulation, lysis, filter, invasive procedure) not indicated To: Deep vein thrombosis or cardiac thrombosis; intervention (e.g., anticoagulation, lysis, filter, invasive procedure) not indicated
VASCULAR, Page 70 Vessel injury-artery – <i>Select</i> : Lower extremity	Deleted 'Lower extremity' as it is a duplicate of 'Extremity-lower'
VASCULAR, Page 71 Vessel injury-vein – <i>Select</i> : Extremity- upper, -lower	Alphabetized the following Select AEs: From: – Extremity-upper – Extremity-lower To: – Extremity-lower – Extremity-upper

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