

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

March 31, 2003, Publish Date: August 9, 2006

Notice of Modifications

The table below details the revisions made to the CTCAE v3.0 since its initial publication on March 31, 2003 through August 9, 2006. 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 CATEGORY and 'Blood' under the General subcategory within the INFECTION CATEGORY for the following Supra-ordinate terms:

- Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils – *Select*
- Infection with normal ANC or Grade 1 or 2 neutrophils – *Select*
- Infection with unknown ANC – *Select*

The **Publish Date** column indicates the CTCAE document Publish Date in which the revision occurred.

Please note that the CTCAE v3.0 document now includes the Publish Date of August 9, 2006. The previous CTCAE v3.0 documents published on March 31, April 16, June 10, and December 12, 2003 are obsolete and should no longer be used.

Publish Date	Revision to	Revision Description
April 16, 2003	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...
April 16, 2003	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.
June 10, 2003	ALLERGY/IMMUNOLOGY, Page 1 Autoimmune reaction ALSO CONSIDER	From: Hemolysis; To: Hemolysis (e.g., immune hemolytic anemia, drug-related hemolysis);
April 16, 2003	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
April 16, 2003	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
April 16, 2003	AUDITORY/EAR, Page 2 Short Name	From: Otitis To: Otitis, middle

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June 10, 2003	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 .
June 10, 2003	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 .
December 12, 2003	BLOOD/BONE MARROW, Page 4 Myelodysplasia Grade 3	From: Abnormal marrow cytogenetics (marrow blasts <5%) To: Abnormal marrow cytogenetics (marrow blasts ≤5%)
April 16, 2003	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
April 16, 2003	CARDIAC ARRHYTHMIA, Page 6 Supra-ordinate term	From: Ventricular arrhythmia – <i>Select</i> To: Ventricular arrhythmia – <i>Select</i> :
April 16, 2003	CARDIAC ARRHYTHMIA, Page 6 Short Name	From: Ventricular arrhythmia To: Ventricular arrhythmia – <i>Select</i>
June 10, 2003	CARDIAC GENERAL, Page 7 Cardiac ischemia/infarction	Moved to its alphabetical placement within the category.
June 10, 2003	CARDIAC GENERAL, Page 7 Cardiac ischemia/infarction, Grade 5	From: — To: Death
December 12, 2003	CARDIAC GENERAL, Page 7 Hypertension Grade 2, both Adult and Pediatric criteria	From: Recurrent or persistent (>24 hrs)... To: Recurrent or persistent (≥24 hrs)...
June 10, 2003	CONSTITUTIONAL SYMPTOMS, Page 11 AE Name	From: Fatigue (lethargy, malaise, asthenia) To: Fatigue (asthenia, lethargy, malaise)
December 12, 2003	CONSTITUTIONAL SYMPTOMS, Page 11 Obesity, Grade 4	From: BMI >40 kg/m ² To: BMI ≥40 kg/m ²
April 16, 2003	CONSTITUTIONAL SYMPTOMS, Page 11 Obesity, Grade 5	From: Death To: —
April 16, 2003	CONSTITUTIONAL SYMPTOMS, Page 11 Odor (patient odor), Grade 5	From: Death To: —
December 12, 2003	CONSTITUTIONAL SYMPTOMS, Page 11 Rigors/chills, Grade 2	From: Moderate, narcotics incidedated To: Moderate, narcotics indicated

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April 16, 2003	CONSTITUTIONAL SYMPTOMS, Page 12 Weight gain, Grade 5	From: Death To: —
April 16, 2003	CONSTITUTIONAL SYMPTOMS, Page 12 Short Name	From: Weight Loss To: Weight loss
December 12, 2003	DERMATOLOGY/SKIN, Page 14 AE Name and Short Name	From: Chelitis To: Cheilitis
June 10, 2003	DERMATOLOGY/SKIN, Page 14 Injection site reaction/extravasation changes, Grade 5	From: Death To: —
June 10, 2003	DERMATOLOGY/SKIN, Page 15 Rash: hand-foot skin reaction, Grade 5	From: Death To: —
June 10, 2003	DERMATOLOGY/SKIN, Page 16 Urticaria (hives, welts, wheals), Grade 5	From: Death To: —
June 10, 2003	ENDOCRINE, Page 17 Gynecomastia	The listing for Gynecomastia was changed to the following NAVIGATION NOTE:: Gynecomastia is graded in the SEXUAL/REPRODUCTIVE FUNCTION CATEGORY.
December 12, 2003	ENDOCRINE, Page 17 Hot flashes/flushes Grade 3	From: Interfering with ADL To: Interfering with ADL
December 12, 2003	ENDOCRINE, Page 17 Hot flashes/flushes, Footnote #3	From: ... Hot Flash Studies," <i>Clin Oncol</i> 2001... To: ... Hot Flash Studies," <i>J Clin Oncol</i> 2001...
June 10, 2003	ENDOCRINE, Page 17 Short Name	From: Masculinization To: Masculinization of female
June 10, 2003	ENDOCRINE, Page 17 Neuroendocrine: gonadotropin secretion abnormality, Grade 5	From: Death To: —
June 10, 2003	ENDOCRINE, Page 17 Neuroendocrine: growth hormone secretion abnormality, Grade 5	From: Death To: —
June 10, 2003	ENDOCRINE, Page 18 Parathyroid function, low (hypoparathyroidism), Grade 5	From: Death To: —
June 10, 2003	GASTROINTESTINAL, Page 20 Dental: teeth, Grade 5	From: Death To: —
June 10, 2003	GASTROINTESTINAL, Page 20 Dental: teeth development, Grade 5	From: Death To: —
June 10, 2003	GASTROINTESTINAL, Page 20 Distension/bloating, abdominal, Grade 5	From: Death To: —

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June 10, 2003	GASTROINTESTINAL, Page 21 Dry mouth/salivary gland (xerostomia), Grade 5	From: Death To: —
June 10, 2003	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.
June 10, 2003	GASTROINTESTINAL, Page 23 Incontinence, anal Grade 1	From: Requires occasional use of pads required To: Occasional use of pads required
June 10, 2003	GASTROINTESTINAL, Page 23 Incontinence, anal Grade 2	From: Requires daily use of pads required To: Daily use of pads required
June 10, 2003	GASTROINTESTINAL, Page 24 Mucositis/stomatitis (clinical exam) – <i>Select</i> : Grade 2 and 3	From: pseudomebranes To: pseudomembranes
December 12, 2003	GASTROINTESTINAL, Page 24 Mucositis/stomatitis (functional/symptomatic) – <i>Select</i> : REMARK	REMARK moved to Mucositis/stomatitis (clinical exam)
December 12, 2003	GASTROINTESTINAL, Page 24 Mucositis/stomatitis (functional/symptomatic) – <i>Select</i> : Grade 2, <u>Lower GI sites</u>	From: ... intervention incated but not ... To: ... intervention indicated but not ...
June 10, 2003	GASTROINTESTINAL, Page 25 Necrosis, GI – <i>Select</i> Grade 3	From: Inability to aliment adequately by GI tract; To: Inability to aliment adequately by GI tract
June 10, 2003	GASTROINTESTINAL, Page 25 Obstruction, GI – <i>Select</i> Grade 3	From: Symptomatic and severely altered GI function; To: Symptomatic and severely altered GI function
June 10, 2003	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
June 10, 2003	GASTROINTESTINAL, Page 27 Typhlitis (cecal inflammation) ALSO CONSIDER	Alphabetized the listing: From: Colitis; Ileus, GI (functional obstruction of bowel, i.e., neuroconstipation); Hemorrhage, GI – <i>Select</i> . To: Colitis; Hemorrhage, GI – <i>Select</i> ; Ileus, GI (functional obstruction of bowel, i.e., neuroconstipation).
June 10, 2003	GASTROINTESTINAL, Page 28 Ulcer, GI – <i>Select</i> ALSO CONSIDER	From: Hemorrhage, GI – <i>Select</i> ; Ulcer. To: Hemorrhage, GI – <i>Select</i> .
June 10, 2003	GROWTH AND DEVELOPMENT, Page 29 Bone growth: limb length discrepancy, Grade 4	From: Disabling; epiphysidesis To: Disabling; epiphysiodesis
December 12, 2003	HEMORRHAGE/BLEEDING, Page 30 Hemorrhage, CNS Grade 3	From: ...monitoring, intraventricular thombolysis... To: ...monitoring, intraventricular thrombolysis...

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April 16, 2003	HEMORRHAGE/BLEEDING, Page 31 Hemorrhage, GI – <i>Select</i> : Appendix	Deleted 'Appendix' as it is a duplicate of 'Cecum/appendix'
June 10, 2003	HEMORRHAGE/BLEEDING, Page 32 Petechiae/purpura (hemorrhage/bleeding into skin or mucosa), Grade 5	From: Death To: —
June 10, 2003	HEMORRHAGE/BLEEDING, Page 32 Hemorrhage, pulmonary/upper respiratory – <i>Select</i> REMARK	From: Transfusion implies pRBC To: Transfusion implies pRBC.
June 10, 2003	HEPATOBIILIARY/PANCREAS, Page 34 NAVIGATION NOTE	From: "...GI – Select in GASTROINTESTINAL CATEGORY. To: "...GI – Select in the GASTROINTESTINAL CATEGORY.
June 10, 2003	HEPATOBIILIARY/PANCREAS, Page 34 Liver dysfunction/failure (clinical) ALSO CONSIDER	From: Bilirubin To: Bilirubin (hyperbilirubinemia)
August 9, 2006	INFECTION, Page 35 Infection (documented clinically or microbiologically) with Grade 3 or 4 neutrophils (ANC <1.0 x 10 ⁹ /L) – <i>Select</i> Short Name	From: Infection (documented clinically) – Select To: Infection (documented clinically) with Grade 3 or 4 ANC – Select
June 10, 2003	INFECTION, Page 36 Viral hepatitis ALSO CONSIDER	From: Bilirubin To: Bilirubin (hyperbilirubinemia)
April 16, 2003	INFECTION, Page 37 INFECTION – <i>Select</i> : AUDITORY/HEARING subheading	From: AUDITORY/ HEARING To: AUDITORY/ EAR
June 10, 2003	INFECTION, Page 37 INFECTION – <i>Select</i> : DERMATOLOGY/SKIN subheading	From: Skin (cellulites) To: Skin (cellulitis)
April 16, 2003	INFECTION, Page 37 INFECTION – <i>Select</i> : GASTROINTESTINAL subheading – Oral	Deleted 'Oral' as it is a duplicate of 'Oral cavity-gums (gingivitis)'
December 12, 2003	INFECTION, Page 37 INFECTION – <i>Select</i> : GENERAL subheading	Added 'Blood' as a <i>Select AE</i>
June 10, 2003	LYMPHATICS, Page 38 Dermal change lymphedema, phlebolymphe de ma, Grade 5	From: Death To: —
June 10, 2003	LYMPHATICS, Page 39 Lymphedema-related fibrosis, Grade 5	From: Death To: —
June 10, 2003	LYMPHATICS, Page 39 Lymphocele, Grade 5	From: Death To: —
June 10, 2003	LYMPHATICS, Page 39 Phlebolymp h atic cording, Grade 5	From: Death To: —

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June 10, 2003	METABOLIC/LABORATORY, Page 40 Alkaline phosphatase, Grade 5	From: Death To: —
June 10, 2003	METABOLIC/LABORATORY, Page 40 ALT, SGPT (serum glutamic pyruvic transaminase), Grade 5	From: Death To: —
June 10, 2003	METABOLIC/LABORATORY, Page 40 Amylase, Grade 5	From: Death To: —
June 10, 2003	METABOLIC/LABORATORY, Page 40 AST, SGOT (serum glutamic oxaloacetic transaminase), Grade 5	From: Death To: —
June 10, 2003	METABOLIC/LABORATORY, Page 40 Bilirubin (hyperbilirubinemia), Grade 5	From: Death To: —
June 10, 2003	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.
June 10, 2003	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.
December 12, 2003	METABOLIC/LABORATORY, Page 41 AE Name	From: Cholesterol, serum-high (hypercholesteremia) To: Cholesterol, serum-high (hypercholesteremia)
June 10, 2003	METABOLIC/LABORATORY, Page 41 GGT (γ -Glutamyl transpeptidase), Grade 5	From: Death To: —
June 10, 2003	METABOLIC/LABORATORY, Page 41 Lipase, Grade 5	From: Death To: —
June 10, 2003	MUSCULOSKELETAL/SOFT TISSUE, Page 43 Extremity-lower (gait/walking) ALSO CONSIDER	From: Ataxia To: Ataxia (incoordination)
June 10, 2003	MUSCULOSKELETAL/SOFT TISSUE, Page 44 Fibrosis-deep connective tissue, Grade 5	From: — To: Death
June 10, 2003	MUSCULOSKELETAL/SOFT TISSUE, Page 44 Fibrosis-deep connective tissue, ALSO CONSIDER	From: Induration/fibrosis skin To: Induration/fibrosis (skin and subcutaneous tissue)
June 10, 2003	MUSCULOSKELETAL/SOFT TISSUE, Page 44 Fibrosis-deep connective tissue, ALSO CONSIDER	From: Neuropathy-motor; Neuropathy-sensory To: Neuropathy: motor; Neuropathy: sensory
April 16, 2003	MUSCULOSKELETAL/SOFT TISSUE, Page 44 AE Name	From: Local complication-device/prosthesis-related To: Local complication – device/prosthesis-related

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June 10, 2003	MUSCULOSKELETAL/SOFT TISSUE, Page 45 Muscle weakness, generalized or specific area (not due to neuropathy) – <i>Select</i> : Extremity-upper, -lower	Alphabetized the following <i>Select AEs</i> : From: – Extremity-upper – Extremity-lower To: – Extremity-lower – Extremity-upper
June 10, 2003	MUSCULOSKELETAL/SOFT TISSUE, Page 45 Myositis (inflammation/damage of muscle) ALSO CONSIDER	From: CPK To: CPK (creatine phosphokinase)
June 10, 2003	MUSCULOSKELETAL/SOFT TISSUE, Page 46 Seroma, Grade 5	From: Death To: —
April 16, 2003	MUSCULOSKELETAL/SOFT TISSUE, Page 46 Soft tissue necrosis – <i>Select</i> : Head	Added 'Head' as a <i>Select AE</i>
June 10, 2003	MUSCULOSKELETAL/SOFT TISSUE, Page 46 Soft tissue necrosis – <i>Select</i> : Extremity-upper, -lower	Alphabetized the following <i>Select AEs</i> : From: – Extremity-upper – Extremity-lower To: – Extremity-lower – Extremity-upper
June 10, 2003	MUSCULOSKELETAL/SOFT TISSUE, Page 46 NAVIGATION NOTE	From: “Wound non-infectious is graded Wound complication...” To: “Wound non-infectious is graded as Wound complication...”
June 10, 2003	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 ³ /L) – <i>Select</i> ; Infection with normal ANC or Grade 1 or 2 neutrophils – <i>Select</i> ; Infection with unknown ANC – <i>Select</i> .
June 10, 2003	NEUROLOGY, Page 48 Dizziness, Grade 5	From: Death To: —
June 10, 2003	NEUROLOGY, Page 48 Dizziness, ALSO CONSIDER	From: Neuropathy-cranial – <i>Select</i> To: Neuropathy: cranial – <i>Select</i>
April 16, 2003	NEUROLOGY, Page 48 AE Name	From: Extrapyrmidal/involuntary movement/restlessness/ tremor To: Extrapyrmidal/involuntary movement/restlessness
June 10, 2003	NEUROLOGY, Page 49 Leukoencephalopathy (radiographic findings), Grade 5	From: Death To: —
April 16, 2003	NEUROLOGY, Page 49 Mood alteration – <i>Select</i> : Euphoria	Added 'Euphoria' as a <i>Select AE</i>
April 16, 2003	NEUROLOGY, Page 50 Phrenic nerve dysfunction, Grade 3	From: Significant dysfunction; intervention indicated (e.g., diaphragmatic ilacation) To: Significant dysfunction; intervention indicated (e.g., diaphragmatic plication)

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June 10, 2003	NEUROLOGY, Page 51 NAVIGATION NOTE: Taste alteration	Moved to its alphabetical placement within the category.
April 16, 2003	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.
June 10, 2003	OCULAR/VISUAL, Page 52 Dry eye syndrome, Grade 5	From: Death To: —
June 10, 2003	NEUROLOGY, Page 52 NAVIGATION NOTE: Ocular muscle weakness	Moved to its alphabetical placement within the category.
June 10, 2003	OCULAR/VISUAL, Page 52 Eyelid dysfunction, Grade 5	From: Death To: —
June 10, 2003	OCULAR/VISUAL, Page 52 Eyelid dysfunction, REMARK	From: eythema To: erythema
June 10, 2003	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.
June 10, 2003	OCULAR/VISUAL, Page 52 Keratitis (corneal inflammation/corneal ulceration), Grade 5	From: Death To: —
April 16, 2003	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
June 10, 2003	OCULAR/VISUAL, Page 52 Night blindness (nyctalopia), Grade 5	From: Death To: —
June 10, 2003	OCULAR/VISUAL, Page 53 Nystagmus, Grade 5	From: Death To: —
June 10, 2003	OCULAR/VISUAL, Page 53 AE Name and Short Name	From: Ocular surface diseases To: Ocular surface disease
June 10, 2003	OCULAR/VISUAL, Page 53 Ocular surface disease, Grade 5	From: Death To: —
June 10, 2003	OCULAR/VISUAL, Page 53 Ophthalmoplegia/diplopia (double vision), Grade 5	From: Death To: —

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June 10, 2003	OCULAR/VISUAL, Page 53 Optic disc edema, Grade 5	From: Death To: —	
June 10, 2003	OCULAR/VISUAL, Page 53 Proptosis/enophthalmos, Grade 5	From: Death To: —	
June 10, 2003	OCULAR/VISUAL, Page 53 Retinal detachment, Grade 5	From: Death To: —	
June 10, 2003	OCULAR/VISUAL, Page 53 Retinopathy, Grade 5	From: Death To: —	
June 10, 2003	OCULAR/VISUAL, Page 54 Scleral necrosis/melt, Grade 5 OCULAR/VISUAL	From: Death To: —	
June 10, 2003	OCULAR/VISUAL, Page 54 Uveitis, Grade 5	From: Death To: —	
June 10, 2003	OCULAR/VISUAL, Page 54 Short Name	From: Blurred V ision To: Blurred v ision	
June 10, 2003	OCULAR/VISUAL, Page 54 Short Name	From: V ision-flashing lights To: Flashing lights	
June 10, 2003	OCULAR/VISUAL, Page 54 Vision-flashing lights/floaters, Grade 5	From: Death To: —	
June 10, 2003	OCULAR/VISUAL, Page 54 Vitreous hemorrhage, Grade 5	From: Death To: —	
June 10, 2003	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;
June 10, 2003	PAIN, Page 55 PAIN – <i>Select</i> , Grade 5	From: Death To: —	
June 10, 2003	PAIN, Page 55 PAIN – <i>Other</i> (Specify, ___), Grade 2 and 3	Grade 2 From: Moderate pain; To: Moderate pain;	Grade 3 From: Severe pain; To: Severe pain;
June 10, 2003	PAIN, Page 55 PAIN – <i>Other</i> (Specify, ___), Grade 5	From: Death To: —	
April 16, 2003	PAIN, Page 55 PAIN – <i>Select</i> : AUDITORY/HEARING subheading	From: AUDITORY/ H EARING To: AUDITORY/ E AR	
April 16, 2003	PAIN, Page 55 PAIN – <i>Select</i> : AUDITORY/EAR subheading – Ear/external	From: E ar/ e xternal To: E xternal e ar	

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April 16, 2003	PAIN, Page 55 PAIN – <i>Select</i> : AUDITORY/EAR subheading – Ear/middle	From: Ear/middle To: Middle ear
June 10, 2003	PULMONARY/UPPER RESPIRATORY, Page 56 Bronchospasm, wheezing ALSO CONSIDER	From: Allergic reaction/hypersensitivity reaction To: Allergic reaction/hypersensitivity (including drug fever)
June 10, 2003	PULMONARY/UPPER RESPIRATORY, Page 56 Cough, Grade 5	From: Death To: —
June 10, 2003	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> .
June 10, 2003	PULMONARY/UPPER RESPIRATORY, Page 57 Dyspnea (shortness of breath) ALSO CONSIDER	From: Neuropathy-motor To: Neuropathy: motor
June 10, 2003	PULMONARY/UPPER RESPIRATORY, Page 57 Hiccoughs (hiccups, singultus), Grade 5	From: Death To: —
April 16, 2003	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
June 10, 2003	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)
April 16, 2003	PULMONARY/UPPER RESPIRATORY, Page 58 Pneumonitis/pulmonary infiltrates, Grade 3	From: Symptomatic, interfering with ADL; O2 indicated To: Symptomatic, interfering with ADL; O ₂ indicated
June 10, 2003	PULMONARY/UPPER RESPIRATORY, Page 58 Pneumonitis/pulmonary infiltrates ALSO CONSIDER	From: Dyspnea To: Dyspnea (shortness of breath)
April 16, 2003	PULMONARY/UPPER RESPIRATORY, Page 59 Short Name	From: Pulmonary fibrosis (radiographic changes) To: Pulmonary fibrosis
June 10, 2003	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> .
April 16, 2003	RENAL/GENITOURINARY, Page 60 Short Name	From: Incontinence To: Incontinence, urinary

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June 10, 2003	RENAL/GENITOURINARY, Page 60 Incontinence, urinary, Grade 5	From: Death To: —
June 10, 2003	RENAL/GENITOURINARY, Page 62 Urinary electrolyte wasting (e.g., Fanconi's syndrome, renal tubular acidosis), Grade 5	From: Death To: —
June 10, 2003	RENAL/GENITOURINARY, Page 62 Urinary electrolyte wasting (e.g., Fanconi's syndrome, renal tubular acidosis), ALSO CONSIDER	From: Acidosis To: Acidosis (metabolic or respiratory)
June 10, 2003	RENAL/GENITOURINARY, Page 62 Urinary retention (including neurogenic bladder), REMARK	REMARK added: The etiology of retention (if known) is graded as Obstruction, GU – Select; Stricture/stenosis (including anastomotic), GU – Select.
June 10, 2003	RENAL/GENITOURINARY, Page 62 Urinary retention (including neurogenic bladder), ALSO CONSIDER	From: The etiology of retention (if known) is graded as Obstruction, GU – Select; Stricture/stenosis (including anastomotic), GU – Select. To: Obstruction, GU – Select; Stricture/stenosis (including anastomotic), GU – Select.
June 10, 2003	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
June 10, 2003	SEXUAL/REPRODUCTIVE FUNCTION, Page 65 Vaginitis (not due to infection), Grade 5	From: Death To: —
June 10, 2003	SURGERY/INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure:</i> AUDITORY/HEARING subheading	From: AUDITORY/HEARING To: AUDITORY/EAR
June 10, 2003	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.
June 10, 2003	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.
June 10, 2003	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.
June 10, 2003	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.
June 10, 2003	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.
June 10, 2003	SURGERY/INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure:</i> HEPATOBIILIARY/ PANCREAS subheading – Pancreas	Moved to its alphabetical placement within the grouping.

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June 10, 2003	SURGERY/INTRA-OPERATIVE INJURY, Page 67 Intra-operative injury – <i>Select Organ or Structure</i> : MUSCULOSKELETAL subheading –Extremity- upper, -lower	Alphabetized the following <i>Select AEs</i> : From: – Extremity-upper – Extremity-lower To: – Extremity-lower – Extremity-upper	
June 10, 2003	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.	
June 10, 2003	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
April 16, 2003	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.'	
April 16, 2003	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	
June 10, 2003	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.	
June 10, 2003	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).	
June 10, 2003	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	
June 10, 2003	SYNDROMES, Page 68 Flu-like syndrome	Moved to its alphabetical placement within the category.	
April 16, 2003	SYNDROMES, Page 69 Short Name	From: Retinoic acid syndrome To: "Retinoic acid syndrome"	

Publish Date	Revision to	Revision Description
June 10, 2003	SYNDROMES, Page 69 Syndromes – Other (Specify, ___), Grade 5	From: To: Death
June 10, 2003	VASCULAR, Page 70 Phlebitis (including superficial thrombosis), Grade 5	From: Death To: —
June 10, 2003	VASCULAR, Page 70 Portal vein flow, Grade 5	From: Death To: —
June 10, 2003	VASCULAR, Page 70 Thrombosis/embolism (vascular access-related), Grade 2	From: Deep vein thrombosis ₇ 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
April 16, 2003	VASCULAR, Page 70 Short Name	From: Thrombosis/embolism To: Thrombosis/ thrombus /embolism
June 10, 2003	VASCULAR, Page 70 Thrombosis/thrombus/embolism, Grade 2	From: Deep vein thrombosis ₇ 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
April 16, 2003	VASCULAR, Page 70 Vessel injury-artery – <i>Select</i> : Lower extremity	Deleted 'Lower extremity' as it is a duplicate of 'Extremity-lower'
June 10, 2003	VASCULAR, Page 71 Vessel injury-vein – <i>Select</i> : Extremity-upper, -lower	Alphabetized the following <i>Select</i> AEs: From: – Extremity-upper – Extremity-lower To: – Extremity-lower – Extremity-upper