

Parameter Level Summary of Changes for the Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 2.0

The *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 2.0* contains a number of parameter level (i.e., adverse event) severity grading criteria changes detailed below when compared with the *Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Event, Version 1.0* – December 2004 (Clarification dated August 2009). In addition, the Instructions for Use section has been expanded.

Major Clinical Conditions Category Changes

Cardiovascular Section

- Hypertension: age qualifiers
- Hypertension, < 18 years of age: Grades 1-4

Dermatologic Section

- Hyperpigmentation: Grades 1-2
- Hypopigmentation: Grades 1-2
- Rash: Grades 1-2

Endocrine and Metabolic Section

- Gynecomastia: Grades 1-3
- Hyperthyroidism: Grade 1
- Hypothyroidism: Grade 1
- Lipoatrophy: Grades 1-3
- Lipohypertrophy: Grades 1-3

Gastrointestinal Section

- Ascites: Grade 3
- Diarrhea:
 - ≥ 1 year of age: Grade 3
 - < 1 year of age: Grade 4
- Nausea: to Grade 3

Musculoskeletal Section

- Osteoporosis: age qualifiers
- Osteoporosis:
 - ≥ 30 years of age: Grades 1 and 3 only
 - < 30 years of age: Grades 1-3
- Osteoporosis: footnote added

Neurologic Section

- Developmental Delay: age qualifiers
- New Onset Seizure:
 - ≥ 18 years of age: Grades 2-4
 - < 18 years of age: Grades 1-4
- Pre-existing Seizure: Grades 2-4
- Syncope: Grades 1-3

Psychiatric Section

- Insomnia: Grades 1-4

Respiratory Section

- Acute Bronchospasm: Grades 1-4
- Dyspnea or Respiratory Distress: age qualifiers removed

Systemic Section

- Fever: Grades 1-4
- Pain: footnote added

Site Reactions to Injections and Infusions Category Changes

- Injection Site Pain or Tenderness: Grade 2
- Injection Site Erythema or Redness: Grades 1-4
- Injection Site Erythema or Redness: footnote added
- Injection Site Induration or Swelling: Grades 1-4

Laboratory Values Category Changes

Chemistries Section

- Amylase (Pancreatic) or Amylase (Total), High: Grades 2-3
- Total Bilirubin, High: age qualifiers (*see also Appendix A*)
- Total Bilirubin, High, all age qualifiers: Grades 1-4 (*see also Appendix A*)
- Cardiac Troponin I, High: Grade 4
- Triglycerides, Fasting, High: Grades 1-4
- Phosphate, Low, > 14 years of age: Grades 1-3

Hematology Section

- Absolute CD4+ Count, Low: age qualifiers
- Absolute Lymphocyte Count, Low: age qualifiers
- Absolute Neutrophil Count (ANC), Low, > 7 days of age: Grades 1-4
- Hemoglobin, Low: age qualifiers
- Hemoglobin, Low: footnote added
- Hemoglobin, Low, all age qualifiers: Grades 1-4
- WBC, Decreased: age qualifiers added
- WBC, Decreased:
 - > 7 days of age: Grades 1-4
 - ≤ 7 days of age: Grades 1-4

Urinalysis Section

- Hematuria: Grades 3-4
- Proteinuria: Grades 2-3

Changes Made Throughout the Document

- Added “High” or “Low” and “Increased” or “Decreased” qualifiers in the Laboratory Values categories
- The terms “No symptoms” are used instead of “asymptomatic”; the term “symptoms” is used instead of “symptomatic”
- Definitions and explanations are included as footers
- The term “AND/OR” is used instead of “AND” and “OR”
- Unit ranges now use greater and less than signs; slight rounding was performed, if needed
- Removed the qualifiers “Adult” and “Pediatric” from parameters