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