

High 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 changes detailed below when compared with the *Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 1.0* – December 2004 (Clarification dated August 2009). In addition, an introduction has been added, and the Glossary and Acronym and Instructions for Use sections have been expanded.

Section Heading Changes

Deleted

- Infection (and the one parameter [*see Parameters Removed*])
- Genitourinary (and three of the four parameters [*see Parameters Removed*])
- Ocular/Visual (moved the two parameters to Sensory [*see New below*])

Renamed

- Injection Site Reactions to Site Reactions to Injections and Infusions
- Skin – Dermatological to Dermatologic

New

- Pregnancy, Puerperium, and Perinatal
- Psychiatric
- Sensory (incorporates Ocular/Visual parameters)
- Urinary (incorporates one parameter [*see Parameters Modified*] in the former Genitourinary heading)

Parameter (i.e., Adverse Event) Groupings Created

- Amylase-related laboratory values (i.e., Pancreatic and Total)
- Blood pressure abnormalities (i.e., Hypertension and Hypotension)
- Lipid disorders (i.e., Fasting Cholesterol, LDL, and Triglycerides)
- Seizures (i.e., New Onset Seizure and Pre-existing Seizure)

Parameters Modified

- Abnormal Fat Accumulation changed to Lipohypertrophy
- Bone Mineral Loss changed to Osteoporosis
- Hemoglobin categorized by age and sex
- Injection Site Reactions categorized by age, erythema or redness, and induration or swelling
- Insomnia moved to the new section heading called Psychiatric Conditions
- Unintentional Weight Loss changed to Weight Loss
- Urinary Tract Obstruction moved to the new section heading called Urinary
- Uveitis moved to the new section heading called Sensory
- Visual Changes moved to the new section heading called Sensory
- Vertigo moved to the new section heading called Sensory
- WBC, decreased categorized by age

Parameters Added

Cardiovascular Section

- Heart Failure

Dermatologic Section

- Bruising
- Cellulitis
- Petechiae

Gastrointestinal Section

- Bloating or Distention
- Gastrointestinal Bleeding
- Perforation (colon or rectum)
- Rectal Discharge

Musculoskeletal Section

- Osteopenia

Pregnancy, Puerperium, and Perinatal Section

- Fetal Death or Stillbirth
- Preterm Delivery
- Spontaneous Abortion or Miscarriage

Psychiatric Section

- Psychiatric Disorders
- Suicidal Ideation or Attempt

Sensory Section

- Hearing Loss
- Tinnitus

Systemic Section

- Cytokine Release Syndrome
- Serum Sickness
- Underweight

Chemistries Section

- Direct Bilirubin, High
- Calcium (ionized), High and Low
- Creatinine Clearance or eGFR, Low

Urinalysis Section

- Glycosuria

Appendix A

- Total Bilirubin Table for Term and Preterm Neonates

Parameters Removed

Cardiovascular Section

- Pericardial Effusion
- Ventricular Dysfunction
- Vasovagal Episode

Infection Section

- Infection

Neurologic Section

- Alternation in Personality- Behavior or in Mood

Urinary (previously Genitourinary) Section

- Cervicitis (clinical exam)
- Cervicitis (symptoms)
- Inter-menstrual Bleeding
- Vulvovaginitis (clinical exam)
- Vulvovaginitis (symptoms)

Chemistries Section

- Cardiac Troponin T

Urinalysis Section

- Proteinuria, 24 hour collection