

## **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**

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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