



## Selected Grading Events: DAIDS Criteria, Version 2.0, November, 2014<sup>1</sup>

### General

PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE- THREATENING
<b>Clinical adverse event <u>NOT</u> identified elsewhere in the grading table</b>	Mild symptoms causing no or minimal interference with usual social & functional activities with intervention not indicated	Moderate symptoms causing greater than minimal interference with usual social & functional activities with intervention indicated	Severe symptoms causing inability to perform usual social & functional activities with intervention or hospitalization indicated	Potentially life-threatening symptoms causing inability to perform basic self-care functions with intervention indicated to prevent permanent impairment, persistent disability, or death

### Cardiovascular

PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE- THREATENING
<b>Arrhythmia</b> (by ECG or physical examination) <i>Specify type, if applicable</i>	No symptoms <u>AND</u> no intervention indicated	No symptoms <u>AND</u> non-urgent intervention indicated	Non-life-threatening symptoms <u>AND</u> non-urgent intervention indicated	Life-threatening arrhythmia <u>OR</u> urgent intervention indicated
<b>Prolonged QTc Interval</b>	0.45 to 0.47 seconds	> 0.47 to 0.50 seconds	> 0.50 seconds <u>OR</u> ≥ 0.06 seconds above baseline	Life-threatening consequences (e.g., Torsade de Pointes, other associated serious ventricular dysrhythmia)

<sup>1</sup> Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health US Department of Health and Human Services. *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events*, Version 2.0, November 2014. [http://rsc.tech-res.com/Document/safetyandpharmacovigilance/DAIDS\\_AE\\_Grading\\_Table\\_v2\\_NOV2014.pdf](http://rsc.tech-res.com/Document/safetyandpharmacovigilance/DAIDS_AE_Grading_Table_v2_NOV2014.pdf).



Dermatologic

PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE-THREATENING
<b>Hyperpigmentation</b>	Slight or localized causing no or minimal interference with usual social & functional activities	Marked or generalized causing greater than minimal interference with usual social & functional activities	NA	NA
<b>Rash</b> <i>Specify type, if applicable</i>	Localized rash	Diffuse rash <u>OR</u> target lesions	Diffuse rash <u>AND</u> vesicles or limited number of bullae or superficial ulcerations of mucous membrane limited to one site	Extensive or generalized bullous lesions <u>OR</u> ulceration of mucous membrane involving two or more distinct mucosal sites <u>OR</u> Stevens-Johnson syndrome <u>OR</u> toxic epidermal necrolysis

Endocrine

PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE-THREATENING
<b>Hypothyroidism</b>	No symptoms <u>AND</u> abnormal laboratory value	Symptoms causing greater than minimal interference with usual social & functional activities <u>OR</u> thyroid replacement therapy indicated	Symptoms causing inability to perform usual social & functional activities <u>OR</u> uncontrolled despite treatment modification	Life-threatening consequences (e.g., myxedema coma)



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Gastrointestinal

PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE- THREATENING
<b>Diarrhea</b> ≥ 1 year of age	Transient or intermittent episodes of unformed stools <u>OR</u> increase of ≤ 3 stools over baseline per 24-hour period	Persistent episodes of unformed to watery stools <u>OR</u> increase of 4 to 6 stools over baseline per 24-hour period	Increase of ≥ 7 stools per 24-hour period <u>OR</u> IV fluid replacement indicated	Life-threatening consequences (e.g., hypotensive shock)
<b>Nausea</b>	Transient (< 24 hours) or intermittent AND no or minimal interference with oral intake	Persistent nausea resulting in decreased oral intake for 24 to 48 hours	Persistent nausea resulting in minimal oral intake for > 48 hours OR rehydration indicated (e.g., IV fluids)	Life-threatening consequences (e.g., hypotensive shock)
<b>Pancreatitis</b>	NA	Symptoms with hospitalization not indicated	Symptoms with hospitalization indicated	Life-threatening consequences (e.g., circulatory failure, hemorrhage, sepsis)
<b>Vomiting</b>	Transient or intermittent AND no or minimal interference with oral intake	Frequent episodes with no or mild dehydration	Persistent vomiting resulting in orthostatic hypotension OR aggressive rehydration indicated (e.g., IV fluids)	Life-threatening consequences (e.g., hypotensive shock)



Musculoskeletal

PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE- THREATENING
<b>Arthralgia</b>	Joint pain causing no or minimal interference with usual social & functional activities	Joint pain causing greater than minimal interference with usual social & functional activities	Joint pain causing inability to perform usual social & functional activities	Disabling joint pain causing inability to perform basic self-care functions

Neurological

PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE- THREATENING
<b>Neurosensory Alteration</b> (includes paresthesia and painful neuropathy) <i>Specify type, if applicable</i>	Minimal paresthesia causing no or minimal interference with usual social & functional activities <b>OR</b> no symptoms with sensory alteration on examination	Sensory alteration or paresthesia causing greater than minimal interference with usual social & functional activities	Sensory alteration or paresthesia causing inability to perform usual social & functional activities	Disabling sensory alteration or paresthesia causing inability to perform basic self-care functions
<b>Seizures</b> <b>New Onset Seizure</b> ≥ 18 years of age	NA	NA	1 to 3 seizures	Prolonged and repetitive seizures (e.g., status epilepticus) <b>OR</b> difficult to control (e.g., refractory epilepsy)



Psychiatric

PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE- THREATENING
<p><b>Psychiatric Disorders</b> (includes anxiety, depression, mania, and psychosis) <i>Specify disorder</i></p>	<p>Symptoms with intervention not indicated <u>OR</u> behavior causing no or minimal interference with usual social &amp; functional activities</p>	<p>Symptoms with intervention indicated <u>OR</u> behavior causing greater than minimal interference with usual social &amp; functional activities</p>	<p>Symptoms with hospitalization indicated <u>OR</u> behavior causing inability to perform usual social &amp; functional activities</p>	<p>Threatens harm to self or others <u>OR</u> acute psychosis <u>OR</u> behavior causing inability to perform basic self-care functions</p>
<p><b>Suicidal Ideation or Attempt</b> <i>Report only one</i></p>	<p>Preoccupied with thoughts of death <u>AND</u> no wish to kill oneself</p>	<p>Preoccupied with thoughts of death <u>AND</u> wish to kill oneself with no specific plan or intent</p>	<p>Thoughts of killing oneself with partial or complete plans but no attempt to do so <u>OR</u> hospitalization indicated</p>	<p>Suicide attempted</p>



Sensory

PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE- THREATENING
<b>Hearing Loss</b> ≥ 12 years of age	NA	Hearing aid or intervention not indicated	Hearing aid or intervention indicated	Profound bilateral hearing loss (> 80 dB at 2 kHz and above) OR non-serviceable hearing (i.e., >50 dB audiogram and <50% speech discrimination)
<b>Visual Changes</b> (assessed from baseline)	Visual changes causing no or minimal interference with usual social & functional activities	Visual changes causing greater than minimal interference with usual social & functional activities	Visual changes causing inability to perform usual social & functional activities	Disabling visual loss in affected eye(s)

Systemic

PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE- THREATENING
<b>Weight Loss</b> (excludes postpartum weight loss)	NA	5 to < 9% loss in body weight from baseline	≥ 9 to < 20% loss in body weight from baseline	≥ 20% loss in body weight from baseline OR aggressive intervention indicated (e.g., tube feeding, total parenteral nutrition)



Lab values: chemistries

PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE- THREATENING
<b>ALT or SGPT, High</b> <i>Report only one</i>	1.25 to < 2.5 x ULN	2.5 to < 5.0 x ULN	5.0 to < 10.0 x ULN	≥ 10.0 x ULN
<b>Amylase (Pancreatic) or Amylase (Total), High</b> <i>Report only one</i>	1.1 to < 1.5 x ULN	1.5 to < 3.0 x ULN	3.0 to < 5.0 x ULN	≥ 5.0 x ULN
<b>AST or SGOT, High</b> <i>Report only one</i>	1.25 to < 2.5 x ULN	2.5 to < 5.0 x ULN	5.0 to < 10.0 x ULN	≥ 10.0 x ULN
<b>Total Bilirubin, High</b> > 28 days of age	1.1 to < 1.6 x ULN	1.6 to < 2.6 x ULN	2.6 to < 5.0 x ULN	≥ 5.0 x ULN
<b>Creatinine, High</b>	1.1 to 1.3 x ULN	> 1.3 to 1.8 x ULN OR increase of > 0.3 mg/dL above baseline	> 1.8 to < 3.5 x ULN OR increase of 1.5 to < 2.0 x above baseline	≥ 3.5 x ULN OR increase of ≥ 2.0 x above baseline
<b>Lipase, High</b>	1.1 to < 1.5 x ULN	1.5 to < 3.0 x ULN	3.0 to < 5.0 x ULN	≥ 5.0 x ULN
<b>Potassium, Low</b> (mEq/L; mmol/L)	3.0 to < 3.4 3.0 to < 3.4	2.5 to < 3.0 2.5 to < 3.0	2.0 to < 2.5 2.0 to < 2.5	< 2.0 < 2.0





Lab values: hematology

PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE- THREATENING
<b>Hemoglobin<sup>2</sup> Low</b> (g/dL; mmol/L) <sup>18</sup> ≥ 13 years of age (male only)	10.0 to 10.9 6.19 to 6.76	9.0 to < 10.0 5.57 to < 6.19	7.0 to < 9.0 4.34 to < 5.57	< 7.0 < 4.34
≥ 13 years of age (female only)	9.5 to 10.4 5.88 to 6.48	8.5 to < 9.5 5.25 to < 5.88	6.5 to < 8.5 4.03 to < 5.25	< 6.5 < 4.03
<b>Platelets, Decreased</b> (cells/mm <sup>3</sup> ; cells/L)	100,000 to < 124,999 100.000 x 10 <sup>9</sup> to < 124.999 x 10 <sup>9</sup>	50,000 to < 100,000 50.000 x 10 <sup>9</sup> to < 100.000 x 10 <sup>9</sup>	25,000 to < 50,000 25.000 x 10 <sup>9</sup> to < 50.000 x 10 <sup>9</sup>	< 25,000 < 25.000 x 10 <sup>9</sup>
<b>WBC, Decreased</b> (cells/mm <sup>3</sup> ; cells/L)  > 7 days of age	2,000 to 2,499 2.000 x 10 <sup>9</sup> to 2.499 x 10 <sup>9</sup>	1,500 to 1,999 1.500 x 10 <sup>9</sup> to 1.999 x 10 <sup>9</sup>	1,000 to 1,499 1.000 x 10 <sup>9</sup> to 1.499 x 10 <sup>9</sup>	< 1,000 < 1.000 x 10 <sup>9</sup>

<sup>2</sup> Male and female sex is defined as sex at birth.