



Guidelines for grading Baseline Abnormalities

Several studies within SWOG require the listing of baseline abnormalities along with their grade. This can be problematic if the CTCAE term includes baseline in the description of the grade, or a change or addition in medication. In an effort to assist sites with these questions, the following guidelines are being provided. These guidelines are only to be used during screening or prior to registration, not during treatment. If your site has other standards you use, this is fine also.

Recording grades for Adverse Events from Previous treatment:

If an eligibility question asks that all adverse events from previous treatment be ≤ 1 , you would **not** use these criteria to grade conditions caused by previous treatment. You would use the CTCAE as written, utilizing the baseline from before the previous treatment was initiated.

Baseline Abnormality: Any abnormal assessment (e.g. physical findings, subjective complaint, or diagnostic test abnormality) identified as part of the routine pre-study work-up for which a CTCAE term exists.

A patient’s diagnosis (e.g. Lung Cancer, diabetes, asthma) is not a CTCAE term and should not be provided as a baseline abnormality.

1) When the term *Baseline* is part of the definition for the grade:

Drop the *baseline* term from the definition. For example:

CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4
Creatinine increased	>ULN - 1.5 x ULN	>1.5 - 3.0 x baseline; >1.5 - 3.0 x ULN	>3.0 x baseline; >3.0 - 6.0 x ULN	>6.0 x ULN
Definition: A finding based on laboratory test results that indicate increased levels of creatinine in a biological specimen.				
Navigational Note: Also consider Renal and urinary disorders: Acute kidney injury				

For Liver Function Tests:

Alanine aminotransferase increased	>ULN - 3.0 x ULN if baseline was normal; 1.5 - 3.0 x baseline if baseline was abnormal	>3.0 - 5.0 x ULN if baseline was normal; >3.0 - 5.0 x baseline if baseline was abnormal	>5.0 - 20.0 x ULN if baseline was normal; >5.0 - 20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal
Definition: A finding based on laboratory test results that indicate an increase in the level of alanine aminotransferase (ALT or SGPT) in the blood specimen.				
Navigational Note: Also consider Hepatobiliary disorders: Hepatic failure				

For Hyperglycemia:

Hyperglycemia	Abnormal glucose above baseline with no medical intervention	Change in daily management from baseline for a diabetic; oral antidiabetic agent initiated; workup for diabetes	Insulin therapy initiated; hospitalization indicated	Life-threatening consequences; urgent intervention indicated
---------------	--	---	--	--

Exception – Diarrhea; the current stools per day becomes the baseline, so Diarrhea would be graded as 0. Unless the patient received prior cancer treatment, then you would grade as specified in the CTCAE, with the baseline from the previous treatment.

Diarrhea Grade the baseline stools per day as grade 0, if no prior treatment.	Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline	Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL	Increase of ≥ 7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self care ADL	Life-threatening consequences; urgent intervention indicated
--	--	--	---	--



Guidelines for grading Baseline Abnormalities

- 2) If a patient takes medication for a pre-existing condition, such as HTN, GERD, Hypokalemia etc., and the condition is under control (meaning there are no signs or symptoms), it should not be reported as a baseline abnormality.
- 3) When there are several descriptions for a particular grade (the semi colon indicates 'or'), only utilize the first example and drop the reference to baseline. For example:

Hypertension	Adult: Systolic BP 120 - 139 mm Hg or diastolic BP 80 - 89 mm Hg;	Adult: Systolic BP 140 - 159 mm Hg or diastolic BP 90 - 99 mm Hg if previously WNL; change in baseline medical intervention indicated; recurrent or persistent (>=24 hrs); symptomatic increase by >20 mm Hg (diastolic) or to >140/90 mm Hg; monotherapy indicated initiated;	Adult: Systolic BP >=160 mm Hg or diastolic BP >=100 mm Hg; medical intervention indicated; more than one drug or more intensive therapy than previously used indicated;	Adult and Pediatric: Life-threatening consequences (e.g., malignant hypertension, transient or permanent neurologic deficit, hypertensive crisis); urgent intervention indicated
Cataract	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline); glare symptoms affecting instrumental ADL	Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self care ADL	Best corrected visual acuity of 20/200 or worse in the affected eye

- 4) If the description only refers to baseline in grade 1, just having the condition would be grade 1. For Example:

Belching	Increase from baseline Condition present	Intervention initiated (including over the counter medications)	-	-
----------	---	---	---	---

5) Weight Gain or Loss.

This should not be reported as a baseline abnormality because this will be determined based on the weight just prior to the administration of the first treatment.

For questions contact: gamail@swog.org