

DIVISION OF AIDS TABLE FOR GRADING THE SEVERITY OF ADULT AND PEDIATRIC ADVERSE EVENTS

**Addendum 3 Rectal Grading Table for Use in Microbicide Studies**

Clarification dated May 2012

<b>PARAMETER</b>	<b>GRADE 1 Mild</b>	<b>GRADE 2 Moderate</b>	<b>GRADE 3 Severe</b>	<b>GRADE 4 Potentially Life- threatening</b>
<b>Anal</b>				
Bruising (in absence of thrombocytopenia)	≤25% of perianal tissue	>25% of perianal tissue	NA	NA
Hemorrhoids	No symptoms or symptoms not requiring medical intervention	Symptomatic with medical intervention indicated	Symptoms causing inability to perform usual social & functional activities with surgical intervention indicated	NA
Anorectal pruritis	Itching localized AND relieved spontaneously or with ≤ 48 hours treatment	Itching requiring > 48 hours treatment	Symptoms causing inability to perform usual social & functional activities	NA
Anal edema	≤25% of perianal tissue with edema	>25% of perianal tissue w/ edema	NA	NA
Anal erythema	≤25% of perianal tissue with erythema	>25% of perianal tissue erythema	NA	NA
Epithelial disruption, NOS (e.g abrasions)	≤25% of circumference small superficial disruptions	>25% of circumference small superficial disruptions	Symptoms causing inability to perform usual social & functional activities	NA
Anal Fissure	Superficial fissure	Deep fissure	Symptoms causing inability to perform usual social & functional activities	NA

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Incontinence	NA	Incontinence with or without the need for medical treatment or use of a pad	Symptoms causing inability to perform usual social & functional activities, operative intervention indicated	Bowel diversion indicated
External anal condyloma (new onset or increased size/extent)	New lesions covering ≤25% of perianal tissue	New lesions covering >25% of perianal tissue	Lesions causing obstruction with surgical intervention indicated	NA
Internal anal condyloma (new onset or increased size/extent)	New lesions covering ≤25% of circumference	New lesions covering >25% of circumference	Lesions causing obstruction with surgical intervention indicated	NA
Anal intraepithelial neoplasia (by biopsy)	AIN1	AIN2	AIN3/CIS	Anal squamous carcinoma
Anal cytology (when anal biopsy not available)	ASCUS/LSIL	HSIL	CIS	Anal squamous carcinoma
<b>Colorectal</b>				
Colitis, confirmed	No symptoms, regardless of pathologic or radiographic evidence of inflammation	Abdominal pain; mucus or blood in stool	Abdominal pain, fever, change in bowel habits with ileus; peritoneal signs	Life threatening consequences (e.g., perforation, bleeding, ischemia, necrosis, toxic megacolon)

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Constipation	Occasional or intermittent symptoms, occasional use of stool softeners, laxatives, dietary modifications, or enema	Persistent symptoms with regular use of laxatives or enemas indicated	Symptoms causing inability to perform usual social & functional activities	Life threatening consequences (e.g., obstruction, toxic megacolon)
Diarrhea	Transient or intermittent episodes of unformed stools OR Increase of $\leq 3$ stools over baseline per 24-hour period	Persistent episodes of unformed to watery stools OR Increase of 4 – 6 stools over baseline per 24-hour period	Bloody diarrhea OR Increase of $\geq 7$ stools per 24-hour period OR IV fluid replacement indicated	Life-threatening consequences (e.g., hypotensive shock)
Discharge	Visible discharge	Discharge requiring the use of pads	NA	NA
Distension or bloating	Symptoms causing no or minimal interference with usual social & functional activities	Symptoms causing greater than minimal interference with usual social & functional activities	Symptoms causing inability to perform usual social & functional activities	NA

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Flatulence	Symptoms causing no or minimal interference with usual social & functional activities	Symptoms causing greater than minimal interference with usual social & functional activities	NA	NA
Urgency +/- incontinence	Symptoms causing no or minimal interference with usual social & functional activities	Symptoms causing greater than minimal interference with usual social & functional activities	Symptoms causing inability to perform usual social & functional activities	NA
Hematochezia (rectal bleeding)	Mild-intermittent without transfusion	Persistent without transfusion	Requiring transfusion	Life-threatening consequences
Endoscopic colorectal mucosal abnormality	Minimal small superficial disruptions of the mucosa	Moderate superficial and/or scattered deep disruption(s) of the mucosa	Severe extensive deep disruption(s) of the mucosa	NA
Tenesmus	Symptoms causing no or minimal interference with usual social & functional activities	Symptoms causing greater than minimal interference with usual social & functional activities	Symptoms causing inability to perform usual social & functional activities	NA

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Proctalgia	Symptoms causing no or minimal interference with usual social & functional activities	Symptoms causing greater than minimal interference with usual social & functional activities	Symptoms causing inability to perform usual social & functional activities and/or fecal incontinence	NA
Painful defecation	Symptoms causing no or minimal interference with usual social & functional activities	Symptoms causing greater than minimal interference with usual social & functional activities	Symptoms causing inability to perform usual social & functional activities	NA
Perforation, colon/rectum	NA	NA	Medical/surgical intervention indicated	Life-threatening consequences
<b>Other GI Events</b>				
GI Bleed	Mild not requiring intervention other than iron supplement	Moderate requiring endoscopic intervention	Requiring transfusion	Life-threatening consequences
Melena, confirmed	NA	No transfusion required	Requiring transfusion	Life-threatening consequences
Abscess, indicate site	Perianal abscess with fluctuance	Abscess that is draining or needs incision and drainage	Abscess that requires more severe surgical intervention	Necrotizing fasciitis from abscess

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Fistulae, indicate site	Dry fistulae	Draining fistulae	Fistulae requiring medical/surgical intervention	Life-threatening consequences
Abdominal Pain	Pain causing no or minimal interference with usual social & or functional activities	Pain causing greater than minimal interference with usual social & or functional activities	Pain causing inability to perform usual social & or functional activities	Disabling pain causing inability to perform basic self-care OR Hospitalization (other than emergency room visit) indicated
<b>STIs</b>				
HSV	Present but no treatment required	Treatment required	Complicated disease requiring medical/surgical intervention	NA
Chlamydia	NA	Treatment required	Complicated disease requiring medical/surgical intervention	NA
Syphilis	NA	Treatment required	Complicated disease requiring medical/surgical intervention	NA
Gonorrhea	NA	Treatment required	Complicated disease requiring medical/surgical intervention	NA
Lymphogranuloma venereum	NA	Treatment required	Complicated disease requiring medical/surgical intervention	NA