

**DIVISION OF AIDS TABLE FOR GRADING THE SEVERITY OF
ADULT AND PEDIATRIC ADVERSE EVENTS
PUBLISH DATE: DECEMBER 2004**

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

INDIVIDUAL SIGNS/SYMPTOMS				
PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE-THREATENING
ANAL				
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	Symptomatic, interfering with usual social & functional activities, operative intervention indicated	Life-threatening consequences
Anorectal pruritis	Itching localized AND relieved spontaneously or with ≤ 48 hours treatment	Itching requiring > 48 hours treatment	Generalized itching causing inability to perform usual social & functional activities	NA
Anal edema	≤ 25% of perianal tissue with edema	> 25% of perianal tissue with edema	> 25% of perianal tissue with severe edema	NA
Anal erythema	≤ 25% of perianal tissue with erythema	> 25% of perianal tissue with erythema	NA	NA
Epithelial disruption, NOS (e.g., abrasions)	Small superficial disruptions	Large epithelial disruptions	Large epithelial disruptions interfering with usual social & functional activities	NA
Anal fissure	Superficial fissure	Deep fissure	Deep fissure interfering with usual social & functional activities	NA
Incontinence without urgency	NA	Use of pad required	Interfering with usual social & functional activities, operative intervention indicated	Permanent bowel diversion indicated
External anal condyloma (new onset or increased size/extent)	New lesions covering < 25% of perianal tissue	New lesions covering 25-75% of perianal tissue	New lesions covering > 75% of perianal tissue	NA
Internal anal condyloma (new onset or increased size/extent)	New lesions covering < 25% of circumference	New lesions covering 25-75% of circumference	New lesions covering > 75% of circumference	NA
Anal intraepithelial neoplasia (by biopsy)	AIN1	AIN2	AIN3	Invasive squamous carcinoma of the anus

NOTE: For protocols utilizing this Addendum, when the same parameter appears in both this Rectal Grading Table and the main DAIDS AE Grading Table, use the grading scheme in this table.

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COLORECTAL				
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)
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 interfering with daily activities; obstipation with manual evacuation indicated	Life threatening consequences (e.g., obstruction, toxic megacolon)
Diarrhea	Increase in liquidity or decrease in consistency of stool (increase of < 4 stools per day over normal pattern)	Increase in liquidity or decrease in consistency of stool (increase of 4-6 stools per day over normal pattern)	Increase in liquidity or decrease in consistency of stool (increase of > 6 stools per day over normal pattern) with incontinence and/or dehydration	Life-threatening dehydration
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	Symptoms causing inability to perform basic self-care functions
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	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

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Proctitis, confirmed	Increased stool frequency, occasional blood-streaked stools or rectal discomfort not requiring medication	Increased stool frequency, bleeding, mucus discharge, or rectal discomfort requiring medication	Increased stool frequency/diarrhea requiring parenteral support; rectal bleeding requiring transfusion; or persistent mucus discharge, necessitating pads	Perforation, bleeding or necrosis and/or other life-threatening complication requiring surgical intervention (e.g., colostomy)
Hematochezia	Mild-intermittent without transfusion	Persistent without transfusion	Requiring transfusion	Life-threatening consequences
Mucosal disruption, NOS	Scattered small superficial disruptions	> 25% of visual field displaying multiple aphthae or single large ulcer	Diffuse disruptions of the mucosa	Life-threatening consequences
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 and/or fecal incontinence	NA
Proctalgia Fugax	NA	Pain causing greater than minimal interference with usual social & functional activities	Pain causing inability to perform usual social & functional activities	Disabling pain causing inability to perform basic self-care OR Hospitalization (other than emergency room visit) indicated
Perforation, colon/rectum	NA	NA	Medical intervention indicated	Life-threatening consequences
OTHER GI EVENTS				
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 draining	Abscess that requires more severe surgical intervention	Necrotizing fasciitis from abscess
Fistulae, indicate site	Dry fistulae	Draining fistulae	Fistulae requiring medical intervention	Life-threatening consequences

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Pain, indicate location (abdomen, rectum, anus, perineum, other [specify])	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
Nausea ¹	Transient (< 24 hours) or intermittent nausea with no or minimal interference with oral intake	Persistent nausea resulting in decreased oral intake for 24-48 hours	Persistent nausea resulting in minimal oral intake for > 48 hours OR aggressive rehydration indicated (e.g., IV fluids)	Life-threatening consequences (e.g., hypotensive shock)
Vomiting ¹	Transient or intermittent vomiting with no or minimal interference with oral intake	Frequent episodes of vomiting 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)
STIs				
HSV	Present, but no treatment required	Treatment required	NA	NA
Chlamydia	NA	Treatment required	NA	NA
Syphilis	NA	Treatment required	NA	NA
Gonorrhea	NA	Treatment required	NA	NA
Lymphogranuloma venereum	NA	Treatment required	NA	NA

¹ The grading scheme for this parameter is the same as the one listed in the main DAIDS AE Grading Table.

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