

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

**Addendum 2
Male Genital Grading Table for Use in Microbicide Studies**

INDIVIDUAL SIGNS/SYMPTOMS (Specify Area: Penis, Scrotum, or Perineum)				
PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE-THREATENING
PAIN AND TENDERNESS (specify location)				
*Note - if both pain and tenderness are present, only report the one with the most severe grade				
Pain* ¹	Pain causing no or minimal interference with usual social & functional activities	Pain causing greater than minimal interference with usual social & functional activities or the need for non-narcotic medication	Pain causing inability to perform usual social & functional activities or the need for narcotic medication	Disabling pain causing inability to perform basic self-care functions OR hospitalization (other than emergency room visit) indicated
Tenderness* ¹	Mild tenderness	Moderate tenderness	Severe tenderness	NA
OTHER GENITAL SYMPTOMS				
Genital itching	Itching causing no, mild, or moderate interference with daily activities	Itching causing inability to perform usual social & functional activities; may require intervention such as antihistamine or bathing to provide relief	NA	NA
Genital erythema	Erythema covering < 50% of surface	Erythema covering ≥ 50% of surface	NA	NA
Genital edema	Mild, non-pitting edema	Moderate, 1-2+ pitting edema	3+ pitting edema, severe enough to require urinary drainage or weeping edema ± skin breakdown	NA
Genital lesions (blisters, ulcerations, pustules, or scaling/peeling)	No treatment indicated	Treatment indicated	Severe epithelial disruption with hospitalization indicated	NA
Genital rash	Rash covering < 50% of surface	Rash covering ≥ 50% of surface	Skin breakdown	NA
Genital bruising, petechiae, or ecchymoses	Covering < 50% of surface	Covering ≥ 50% of surface	NA	NA

¹ If pain or tenderness is included in the grading of another category (e.g., Balantis), it should not be graded again in the pain or tenderness category.

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PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE-THREATENING
Genital abrasions or lacerations	Small superficial disruptions	Small disruptions extending through the mucosa or large superficial disruptions, hospitalization not indicated	Large disruptions extending through the mucosa, hospitalization indicated	Lacerations extending into the peritoneal cavity, bladder, or rectum
Palpable or visible genital mass, new or increased in size (papule or nodule)	New mass or increased size of known mass with no or minimal symptoms	New mass or increased size of known mass with moderate symptoms	Mass causing severe symptoms or impacting bladder/bowel function	Mass requiring hospitalization; malignancy
Urethral discharge	Small amount white or clear	Purulent discharge, any amount	NA	NA
URINARY SYMPTOMS				
Urinary frequency	Up to 2 times participant's normal frequency	> 2 times participant's normal frequency	NA	NA
Hematuria	Minimal or microscopic, no intervention indicated (beyond evaluation for infection)	Gross blood in urine or medical intervention/evaluation indicated (beyond evaluation for infection)	Persistent bleeding with transfusion or intervention indicated to obtain hemostasis (endoscopy, interventional radiology, or operative)	Profuse hemorrhage with shock or orthostatic dizziness
Dysuria	Mild	Moderate	Inability to void due to pain	NA

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COMPOSITE SIGNS/SYMPTOMS (Use instead of individual categories if 2 or more signs/symptoms are present)				
PARAMETER	GRADE 1 MILD (Use if all signs/ symptoms would individually be Grade 0 or 1)	GRADE 2 MODERATE (Use if one or more signs/symptoms would individually be Grade 2 and all others Grade 0 or 1)	GRADE 3 SEVERE (Use if one or more signs/symptoms would individually be Grade 3)	GRADE 4 POTENTIALLY LIFE-THREATENING
NO ORGANISM IDENTIFIED BUT INADEQUATE TESTING PERFORMED				
Urethritis (urinary frequency, dysuria, urethral discharge)	Mild signs/symptoms	Moderate signs/symptoms	Severe signs/symptoms	NA
Balanitis (inflammation of the glans or shaft of the penis including rash, scaling/peeling, erythema, edema, pain and tenderness)	Mild signs/symptoms	Moderate signs/symptoms	Severe signs/symptoms	NA
Prostatitis (urinary symptoms plus tenderness of prostate on exam)	Mild signs/symptoms	Moderate signs/symptoms	Severe signs/symptoms	NA
Genital dermatitis (including "jock itch") (itching, pain, erythema, edema, rash, tenderness, or other lesions)	Mild signs/symptoms	Moderate signs/symptoms	Severe signs/symptoms	NA
NO ORGANISM IDENTIFIED AFTER APPROPRIATE TESTING PERFORMED				
Urethritis (urinary frequency, dysuria, urethral discharge)	Mild signs/symptoms	Moderate signs/symptoms	Severe signs/symptoms	NA
Balanitis (inflammation of the glans or shaft of the penis including rash, scaling/peeling, erythema, edema, pain and tenderness)	Mild signs/symptoms	Moderate signs/symptoms	Severe signs/symptoms	NA

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PARAMETER	GRADE 1 MILD (Use if all signs/ symptoms would individually be Grade 0 or 1)	GRADE 2 MODERATE (Use if one or more signs/symptoms would individually be Grade 2 and all others Grade 0 or 1)	GRADE 3 SEVERE (Use if one or more signs/symptoms would individually be Grade 3)	GRADE 4 POTENTIALLY LIFE-THREATENING
Prostatitis (urinary symptoms plus tenderness of prostate on exam)	Mild signs/symptoms	Moderate signs/symptoms	Severe signs/symptoms	NA
Genital dermatitis (including "jock itch") (itching, pain, erythema, edema, rash, tenderness, or other lesions)	Mild signs/symptoms	Moderate signs/symptoms	Severe signs/symptoms	NA

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INFECTIONS AND DYSPLASIA				
PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE-THREATENING
GENITOURINARY INFECTIONS				
Condyloma	Mild or no interference with daily function	Moderate interference with daily function	Severe interference with daily function or secondary infection or surgery needed	NA
Genital herpes	Characteristic ulcerative or vesicular lesions confirmed by culture, PCR, Tzanck prep or other diagnostic test of lesion or previous type-specific serology, covering < 10% of genitalia	Same criteria as mild but covering 10 - < 50% of genitalia	Same criteria as mild but covering ≥ 50% of genitalia	Symptoms of significant systemic involvement such as encephalitis, hepatitis
Candida ²	Positive culture, wet mount, or other laboratory test for yeast, with mild symptoms	Positive culture, wet mount, or other laboratory test for yeast, with moderate to severe symptoms	NA	NA
Trichomonas	NA	Positive wet mount, culture, PCR, or other licensed test, showing <i>T. vaginalis</i> , regardless of symptoms	NA	NA
Chlamydia	NA	Positive culture or other diagnostic test for Chlamydia, asymptomatic or with urethritis only	Positive test for Chlamydia with prostatitis	NA

² Consider absence of symptoms regardless of candida test results as normal.

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PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE-THREATENING
Gonorrhea	NA	Positive culture or other diagnostic test for Gonorrhea, asymptomatic or with urethritis only	Positive test for Gonorrhea with prostatitis	NA
Syphilis ³	NA	Syphilis diagnosed by a positive treponemal test along with a positive non-treponemal test and no previous treatment or a four-fold rise in titer on the non-treponemal test after previous treatment regardless of symptoms or non-oral lesions positive by darkfield exam for treponemes	Criteria for Grade 2 Syphilis in the presence of neurologic symptoms or a positive CSF VDRL or FTA-ABS	NA
Urinary tract infection (by urinalysis and urine culture)	5-10 WBC/hpf on urinalysis with a negative culture per protocol definition (with or without symptoms)	>10 WBC/hpf on urinalysis or a positive culture per protocol definition (with or without symptoms)	Pyelonephritis	Urosepsis
GENITAL DYSPLASIA				
Epithelial dysplasia or malignancy (by biopsy)	Intraepithelial Neoplasia 1 (IN1)	Intraepithelial Neoplasia 2 (IN2)	Carcinoma in situ (CIS)	Invasive carcinoma

³ Consider negative treponemal or non-treponemal test or both positive with known treatment and stable titers (< 4 fold increase) as normal.

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