

Appendix 4. TOXICITY SCALE (CTC-NCIC CRITERIA)

Recommendations for Grading of Acute and Subacute Toxicity, Version Dec 1994 (revised)

GRADE	0	1	2	3	4
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ALLERGY					
AL LER Allergy	none	transient rash, fever < 38°C, 100.4°F	urticaria, fever = 38°C, 100.4°F, mild bronchospasm	serum sickness, bronchospasm, req parenteral meds	anaphylaxis
Fever felt to be caused by <u>drug allergy</u> should be coded as ALLERGY (AL LER). <u>Non allergic</u> drug fever (eg. as from biologics) should be coded under FLU-LIKE SYMPTOMS (FL FEV). If fever is due to <u>infection</u> , code INFECTION only (IN FEC or IN NEU). NB: Protocols requiring detailed reporting of hypersensitivity reactions, will include a Hypersensitivity Reaction module.					
AL OTH other *	none	mild	moderate	severe	life threatening

BLOOD/BONE MARROW (SI UNITS)						
BL WBC White Blood Count (WBC)	≥ 4.0	10 ⁹ /l	3.0 - 3.9	2.0 - 2.9	1.0 - 1.9	< 1.0
BL PLT Platelets	WNL	10 ⁹ /l	75.0 - normal	50.0 - 74.9	25.0 - 49.9	< 25.0
BL HGB Hemoglobin (Hgb)	WNL	g/l	100 - normal	80 - 99	65 - 79	< 65
BL GRA granulocytes (i.e neut + bands)	≥ 2.0	10 ⁹ /l	1.5 - 1.9	1.0 - 1.4	0.5 - 0.9	< 0.5
BL LYM Lymphocytes	≥ 2.0	10 ⁹ /l	1.5 - 1.9	1.0 - 1.4	0.5 - 0.9	< 0.5
BL HEM Hemorrhage resulting from thrombocytopenia (clinical)	none		mild, no transfusion (includes bruise/hematoma, petechiae)	gross, 1 - 2 units transfusion per episode	gross, 3 - 4 units transfusion per episode	massive, > 4 units transfusion per episode
BL OTH Other *	none		mild	moderate	severe	life threatening

CANCER RELATED SYMPTOMS						
CA DEA Death from malignant disease within 30 days of treatment * (grade = 5)	-		-	-	-	-
CA PAI Cancer pain *	none		pain, but no treatment req	pain controlled with non-opioids	pain controlled with opioids	uncontrollable pain
CA SEC Second malignancy *	none		-	-	present	-
CA OTH Other *	none		mild	moderate	severe	life threatening

CARDIOVASCULAR						
CD ART Arterial * (non myocardial)	none		-	-	transient events (eg. transient ischemic attack)	permanent event (eg. cerebral vascular accident)
CD VEN Venous *	none		superficial (excludes IV site reaction → code SK LTO)	deep vein thrombosis not req anticoagulant therapy	deep vein thrombosis req anticoagulant therapy	pulmonary embolism
CD DYS Dysrhythmias	none		asymptomatic, transient, req no therapy	recurrent or persistent, req no therapy	req therapy	req monitoring, or hypotension, or ventricular tachycardia, or fibrillation
CD EDE Edema * (eg. peripheral edema)	none		1+ or dependent in evening only	2+ or dependent throughout day	3+	4+, generalized anasarca

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CD FUN Function	none	asymptomatic, decline of resting ejection fraction of $\geq 10\%$ but $< 20\%$ of baseline value	asymptomatic, decline of resting ejection fraction by $> 20\%$ of baseline value	mild CHF, responsive to therapy	severe or refractory CHF
CD HBP Hypertension	none or no change	asymptomatic, transient increase by $> 20\text{mm Hg}$ (D) or to $> 150/100$ if previously WNL. No therapy req	recurrent or persistent increase by $> 20\text{mm Hg}$ (D) or to $> 150/100$ if previously WNL. No therapy req	req therapy	hypertensive crisis
CD LBP Hypotension	none or no change	changes req no therapy (incl. transient orthostatic hypotension)	req fluid replacement or other therapy but no hospitalization	req therapy + hospitalization; resolves within 48hrs of stopping agent	req therapy + hospitalization for $> 48\text{hrs}$ after stopping agent
CD ISC Ischemia (myocardial)	none	non-specific T wave flattening	asymptomatic, ST + T wave changes suggesting ischemia	angina without evidence for infarction	acute myocardial infarction
CD PAI Pain (chest) *	none	pain, but no treatment req	pain controlled with non-opioids	pain controlled with opioids	uncontrollable pain
CD PER Pericardial	none	asymptomatic effusion no intervention req	pericarditis (rub, chest pain, ECG changes)	symptomatic effusion drainage req	tamponade, drainage urgently req; or constrictive pericarditis req surgery
CD TAC Sinus tachycardia *	none	mild	moderate	severe	life threatening
CD OTH Other *	none	mild	moderate	severe	life threatening

COAGULATION

CG FIB Fibrinogen	WNL	0.99 - 0.75 x N	0.74 - 0.50 x N	0.49 - 0.25 x N	≤ 0.24 x N
CG PT Prothrombin time	WNL	1.01 - 1.25 x N	1.26 - 1.50 x N	1.51 - 2.00 x N	> 2.00 x N
CG PTT Partial thromboplastin time	WNL	1.01 - 1.66 x N	1.67 - 2.33 x N	2.34 - 3.00 x N	> 3.00 x N
CG OTH Other *	none	mild	moderate	severe	life threatening

DENTITION (TEETH)

DE DEC Tooth decay*	none	mild	moderate	severe	-
DE PAI Toothache*	none	pain, but no treatment	pain controlled with non-opioids	pain controlled with opioids	uncontrollable pain
DE OTH Other *	none	mild	moderate	severe	life threatening

ENDOCRINE*

EN AME Amenorrhea	no	irregular menses	≥ 3 months	-	-
EN CUS Cushingoid	normal	mild	pronounced	-	-
EN FLA Hot flashes	none	mild or $< 1/\text{day}$	moderate & $\geq 1/\text{day}$	frequent & interferes with normal function	-
EN GYN Gynecomastia	normal	mild	pronounced or painful	-	-
EN IMP Impotence/Libido	normal	decrease in normal function	-	absence of function	-
EN OTH Other	none	mild	moderate	severe	life threatening

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FLU-LIKE SYMPTOMS					
FL FEV fever in absence of infect. * (incl. drug fever)	none	37.1 - 38.0°C 98.7 - 100.4°F	38.1 - 40.0°C 100.5 - 104.0°F	> 40.0°C > 104.0°F for < 24 hrs	> 40.0°C (104.0°F) for > 24 hrs or fever accompanied by hypotension
	Fever felt to be caused by <u>drug allergy</u> should be coded as ALLERGY (AL LER). <u>Non-allergic</u> drug fever (eg. as from biologics) should be coded under FLU-LIKE SYMPTOMS (FL FEV). If fever is due to <u>infection</u> , code INFECTION only (IN FEC or IN NEU).				
FL HAY Hayfever* (includes sneezing, nasal stuffiness, post-nasal drip)	none	mild	moderate	severe	-
FL JOI Arthralgia* (joint pain)	none	mild	moderate	severe	-
FL LET Lethargy* (fatigue, malaise)	none	mild, fall of 1 level in perf. status	moderate, fall of 2 levels in perf. status	severe, fall of 3 levels in perf. status	-
FL MYA Myalgia* (muscle ache)	none	mild	moderate	severe	-
FL RIG Rigors/Chills* (Gr 3 incl cyanosis)	none	mild or brief	pronounced or /and prolonged	cyanosis	-
FL SWE Sweating* (diaphoresis)	none	mild	moderate	severe	-
FL OTH Other*	none	mild	moderate	severe	life threatening

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GASTROINTESTINAL					
GI ANO Anorexia*	none	mild	moderate	severe	dehydration
GI APP Appetite increased*	none	mild	moderate	-	-
GI ASC Ascites (non malignant)*	none	mild	moderate	severe	life threatening
GI DIA Diarrhea	none	increase of 2 - 3 stools per day ; or mild increase of loose watery colostomy output compared to pre-trt	increase of 4 - 6 stools per day, or nocturnal stools; or moderate increase in loose watery colostomy output compared to pre-trt	increase of 7 - 9 stools per day, or incontinence, malabsorption; or severe increase in loose watery colostomy output compared with pre-trt	increase of ≥ 10 stools per day, or grossly bloody diarrhea, or grossly bloody colostomy output or loose watery colostomy output req parenteral support; dehydration
GI DPH Esophagitis/dysphagia/odynophagia* (incl recall reaction)	none	dys.or odyn. not req trt, or painless ulcers on esophagoscopy	dys. or odyn. req trt	dys. or odyn. lasting > 14 days despite trt	dys. or odyn. with 10% loss of body wt, dehydration, hosp. req
GI DRY Mouth, nose dryness*	none	mild	moderate	severe	-
GI FIS Fistula* (intestinal, esophageal, rectal)	none	-	-	req intervention	req operation
GI GAS Flatulence*	none	mild	moderate	severe	-
GI HEA Heartburn* (incl. dyspepsia)	none	mild	moderate	severe	-
GI HEM Gastrointestinal bleeding *	none	mild, no transfusion	gross, 1 - 2 units transfusion per episode	gross, 3 - 4 units transfusion per episode	massive > 4 units transfusion per episode
Bleeding resulting from thrombocytopenia should be coded under BL HEM, not GI					

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GI NAU Nausea	none	able to eat reasonable intake	intake significantly decreased but can eat	no significant intake	-
GI OBS Small bowel obstruction*	no	-	intermittent, no intervention	req intervention	req operation
GI PAI Gastrointestinal pain/cramping* (incl. rectal pain)	none	pain, but no treatment req	pain controlled with non-opioids	pain controlled with opioids	uncontrollable pain
GI PRO Proctitis (rectal)	none	perianal itch, hemorrhoids	tenesmus or ulcerations relieved with therapy, anal fissure	tenesmus or ulcerations or other symptoms not relieved with therapy	mucosal necrosis with hemorrhage or other life threatening proctitis
GI STO Stomatitis/ oral	none	painless ulcers, erythema, or mild soreness	painful erythema, edema, or ulcers, but can eat	painful erythema, edema, or ulcers, and cannot eat	mucosal necrosis and/or req parenteral or enteral support, dehydration
GI TAS Taste, sense of smell altered*	none	mild	moderate	severe	-
GI ULC Gastritis/ulcer*	none	antacid	req vigorous medical management or non-surgical trt	uncontrolled by medical management; req surgery for GI ulceration	perforation or bleeding
GI VOM Vomiting	none	1 episode in 24hrs	2 - 5 episodes in 24hrs	6 - 10 episodes in 24hrs	> 10 episodes in 24hrs or req parenteral support, dehydration
GI OTH Other*	none	mild	moderate	severe	life threatening

GENITO-URINARY					
GU BLA Bladder changes*	none	light epithelial atrophy, or minor telangiectasia	generalized telangiectasia	severe generalized telangiectasia (often with petechiae) or reduction in bladder capacity (< 15 ml)	necrosis, or contracted bladder (capacity < 100 ml), or fibrosis
GU CRE Creatinine	WNL	< 1.5 x N	1.5 - 3.0 x N	3.1 - 6.0 x N	> 6.0 x N
GU CYS Cystitis* (non bacterial)	none	mild symptoms, req no intervention	symptoms relieved completely with ther.	symptoms not relieved despite therapy	severe (life threatening) cystitis
Urinary tract infection should be coded under infection not GU					
GU FIS Fistula* (vaginal, vesicovaginal)	none	-	-	req intervention	req operation
GU FRE Frequency*	none	freq of urination or nocturia twice pre-trt habit	freq of urination or nocturia < hourly	freq with urgency and nocturia ≥ hourly	-
GU HEM Hematuria, bleeding per vagina	negative	micro only	gross, no clots	gross + clots	req transfusion
Bleeding resulting from thrombocytopenia should be coded under BL HEM not GU.					
GU INC Incontinence*	none	mild	moderate	severe	-
GU OBS Ureteral obstruction*	none	unilateral, no surgery	bilateral, no surgery req	not complete bilateral, but stents, nephrostomy tubes or surgery req	complete bilateral obstruction
GU PAI Genito-urinary pain * (eg : dysuria, dysmenorrhea, dyspareunia)	none	pain, but no treatment req	pain controlled with non-opioids	pain controlled with opioids	uncontrollable pain

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GU PRT Proteinuria	no change	1 + or < 0.3 g/% or < 3 g/l	2 - 3 + or 0.3 - 1.0 g/% or 3 - 10 g/l	4 + or > 1.0 g/% or > 10 g/l	nephrotic syndrome
GU VAG Vaginitis* (+/- vaginal discharge) (non-infectious)	none	mild, no trt req	moderate, relieved with trt	severe, not relieved with trt	life threatening
GU OTH Other*	none	mild	moderate	severe	life-threatening

HEPATIC

HP ALK Alk. Phos or 5' nucleotidase	within normal limits (WNL)	≤ 2.5 x N (Normal)	2.6 - 5.0 x N	5.1-20.0 x N	> 20 x N
HP ALT Transaminase SGPT (ALT)	WNL	≤ 2.5 x N (Normal)	2.6 - 5.0 x N	5.1-20.0 x N	> 20 x N
HP AST Transaminase SGOT (AST)	WNL	≤ 2.5 x N (Normal)	2.6 - 5.0 x N	5.1 - 20.0 x N	> 20 x N
HP BIL Bilirubin	WNL	-	< 1.5 x N	1.5 - 3.0 x N	> 3.0 x N
HP CLI Liver (clinical)	no change from baseline	-	-	precoma	hepatic coma
HP LDH LDH*	WNL	≤ 2.5 x N (Normal)	2.6 - 5.0 x N	5.1 - 20.0 x N	> 20 x N
HP OTH Other*	none	mild	moderate	severe	life-threatening
Viral Hepatitis should be coded as infection rather than liver toxicity.					

INFECTION

IN FEC Infection	none	mild, no active therapy	moderate, localized infection, active therapy req	severe systemic infection, req parenteral trt, specify site	life threatening sepsis, specify site
IN NEU Febrile Neutropenia* Absolute granulocyt count < 1.0 x 10 ⁹ /l, fever ≥ 38.5 °C treated with (or ought to have been treated with) IV antibiotics	none	-	-	present	-
Fever felt to be caused by <u>drug allergy</u> should be coded as ALLERGY (AL LER). <u>Non-allergy drug fever</u> (eg. as from biologics) should be coded under FLU-LIKE SYMPTOMS (FL FEV). If fever is due to <u>infection</u> , code INFECTION only (IN FEC or IN NEU).					

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METABOLIC (SI UNITS)					
MT AMY Amylase	WNL	< 1.5 x N	1.5 - 2.0 x N	2.1 - 5.0 x N	> 5.1 x N
MT HCA Hypercalcemia	< 2.64 mmol/l	2.64 - 2.88	2.89 - 3.12	3.13 - 3.37	> 3.37
MT LCA Hypocalcemia	> 2.10 mmol/l	2.10 - 1.93	1.92 - 1.74	1.73 - 1.51	≤ 1.50
MT HGL Hyperglycemia	< 6.44 mmol/l	6.44 - 8.90	8.91 - 13.8	13.9 - 27.8	> 27.8 or ketoacidosis
MT LGL hypoglycemia	> 3.55 mmol/l	3.03 - 3.55	2.19 - 3.02	1.66 - 2.18	< 1.66
MT LKA Hypokalemia*	no change or > 3.5 mmol/l	3.1 - 3.5	2.6 - 3.0	2.1 - 2.5	≤ 2.0
MT LMA Hypomagnesemia	> 0.70 mmol/l	0.70 - 0.58	0.57 - 0.38	0.37 - 0.30	≤ 0.29
MT LNA Hyponatremia*	no change or >135 mmol/l	131 - 135	126 - 130	121 - 125	≤ 120
MT OTH Other*	none	mild	moderate	severe	life threatening

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NEUROLOGIC					
NE CER Cerebellar	none	slight incoordination, dysdiadochokinesis	intention tremor, dysmetria, slurred speech, nystagmus	locomotor ataxia	cerebellar necrosis
NE CON Constipation	none or no change	mild	moderate	severe, obstipation	ileus > 96 hrs
NE COR Cortical (includes drowsiness)	none	mild somnolence	moderate somnolence	severe somnolence, confusion, disorientation, hallucinations	coma, seizures, toxic psychosis
NE DIZ Dizziness* (includes lightheadedness)	none	mild	moderate	severe (includes fainting)	-
NE EXT Extrapyramidal/ Involuntary movement*	none	mild agitation (includes restlessness)	moderate agitation	torticollis, oculogyric crisis, severe agitation	-
NE HED Headache	none	mild	moderate or severe but transient	unrelenting and severe	-
NE HER Altered hearing	none or no change	asymptomatic hearing loss on audiometry only	tinnitus, symptomatic hearing changes not req hearing aid or trt	hearing loss interfering with function but correctable with hearing aid or trt	hearing changes or deafness not correctable
NE INS Insomnia*	none	mild	moderate	severe	-
NE MOO Mood	no change	mild anxiety or depression	moderate anxiety or depression	severe anxiety or depression	suicidal ideation
NE MOT Motor	none or no change	subjective weakness, no objective findings	mild objective weakness without significant impairment of function	objective weakness with impairment of function	paralysis
NE PAI Neurologic pain* (eg : jaw pain)	none	pain, but no treatment req	pain controlled with non-opioids	pain controlled with opioids	uncontrollable pain
NE PER Personality change*	no change	change, not disruptive to patient or family	disruptive to patient or family	harmful to others or self	psychosis
NE SEN Sensory	none or no change	mild paresthesias, loss of deep tendon reflexes (including tingling)	mild or moderate objective sensory loss, moderate paresthesias	sensory loss or paresthesias that interfere with function	-
NE VIS Vision	none or no change	blurred vision	-	symptomatic subtotal loss of vision	blindness
NE OTH Other * (includes pain)	none	mild	moderate	severe	life-threatening
Code chest pain CD PAI, muscle aches (myalgia) FL MYA, abdominal pain GI PAI, and local pain at IV site SK LTO. For all other types of pain (eg. bone pain), code NE OTH.					

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OCULAR					
OC CAT Cataract *	none	mild	moderate	severe	-
OC CJN Conjunctivis/ Keratitis	none	erythema or chemosis not req steroids or antibiotics	req trt steroids or antibiotics	corneal ulceration or visible opacification	-
OC DRY Dry eye	normal	mild	req artificial tears	severe	req enucleation
OC GLA Glaucoma	no change	-	-	yes	-
OC PAI Eye pain *	none	pain, but no treatment req	pain controlled with non-opioids	pain controlled with opioids	uncontrollable pain
OC TEA Tearing * (watery eyes)	none	mild	moderate	severe	-
OC OTH Other	none	mild	moderate	severe	life threatening

OSSEOUS (BONE)					
OS PAI Bone pain*	none	pain, but no treatment req	pain controlled with non-opioids	pain controlled with opioids	uncontrollable pain
OS OTH Other* (eg. avascular necrosis)	none	mild	moderate	severe	life threatening

PULMONARY					
PU CMD Carbon Monoxide Diffusion Capacity (DLCO)*	> 90% of pretreatment value	decrease to 76 - 90% of pre-trt	decrease to 51 - 75% of pre-trt	decrease to 26 - 50% of pre-trt	decrease to ≤ 25% of pre-trt
PU COU Cough*	none	mild	moderate	severe	-
PU EDE Pulmonary edema*	none	-	out-patient management	in-patient management	req intubation
PU EFF Pleural effusion* (non-malignant)	none	mild	moderate	severe	life threatening
PU FIB Pulmonary fibrosis*	normal	radiographic changes, no symptoms	-	changes with symptoms	-
PU HEM Hemoptysis*	none	mild, no transfusion	gross, 1 - 2 units transfusion per episode	gross, 3 - 4 units transfusion per episode	massive, > 4 units transfusion per episode
	Bleeding resulting from thrombocytopenia should be coded under BL HEM, not PU				
PU HIC Hiccoughs*	none	mild	moderate	severe	-
PU PAI Pulmonary pain*	none	pain, but not treatment req	pain controlled with non-opioids	pain controlled with opioids	uncontrollable pain
PU PNE Pneumonitis* (non-infectious)	normal	radiographic changes, symptoms do not req steroids	steroids req	oxygen req	req assisted ventilation
PU SOB Shortness of breath (dyspnea) (incl wheezing)	none or no change	asymptomatic, with abnormality in PFT's	dyspnea on significant exertion	dyspnea at normal level of activity, apnea without cyanosis	dyspnea at rest, apnea with cyanosis
PU VOI Voice changes* (incl. hoarseness, loss of voice)	none	mild	moderate	severe	-
PU OTH Other*	none	mild	moderate	severe	life-threatening
	Pneumonia should be considered infection and not graded as pulmonary toxicity unless felt to be resultant from pulmonary changes directly induced by treatment				

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SKIN					
SK ALO Alopecia	no loss	mild hair loss	pronounced or total head hair loss	total body hair loss	-
SK CHA Skin changes* (eg. photosensitivity)	none	localized pigmentation changes	generalized pigmentation changes or atrophy	subcut.fibrosis or localized shallow ulceration	generalized ulcerations or necrosis
SK DES Desquamation*	none	dry desquamation	moist desquamation	confluent moist desquamation	-
SK DRY Dry skin*	none	mild	moderate	severe	-
SK FAC Flushing* (eg:-facial)	none	mild	moderate	severe	-
SK HEM Bruising/bleeding	none	mild, no transfusion	gross, 1 - 2 units transfusion per episode	gross, 3 - 4 units transfusion per episode	massive, > 4 units transfusion per episode
Bleeding from thrombocytopenia should be coded under BL HEM, not SK					
SK LTO Local toxicity (reaction at IV site)	none	pain	pain and swelling, with inflammation or phlebitis	ulceration	plastic surgery indicated

SK NAI Nail changes*	none	mild	moderate	severe	-
SK PAI Skin pain* (include sclap pain)	none	pain, but no treatment req	pain controlled with non-opioids	pain controlled with opioids	uncontrollable pain
SK RAS Rash/Itch* (not due to allergy) (includes recall reaction)	none or no change	scattered macular or papular eruption or erythema that is asymptomatic	scattered macular or papular eruption or erythema with pruritus or other associated symptoma	generalized symptomatic macular, papular, or vesicular eruption	exfoliative dermatitis or ulcerating dermatitis
SK OTH Other*	none	mild	moderate	severe	life threatening

WEIGHT					
WT GAI Weight Gain	< 5.0%	5.0 - 9.9%	10.0 - 19.9%	≥ 20.0%	-
WT LOS Weight Loss	< 5.0%	5.0 - 9.9%	10.0 - 19.9%	≥ 20.0%	-

OTHER					
OT OTH Other*	none	mild	moderate	severe	life-threatening
For <u>toxicity which do not have an existing code</u> , but do fit into an existing toxicity category, use "other" variable in the <u>appropriate toxicity category</u> (eg. code sinus tachycardia CARDIOVASCULAR OTHER (CD OTH). Only toxicities which do not fit into <u>existing categories</u> should be coded OTHER OTHER (OT OTH).					