# Common Terminology Criteria for Adverse Events (CTCAE) v6.0 (MedDRA 28.0)

Published July 22, 2025

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National Institutes of Health
U.S. Department of Health and Human Services

#### Introduction

The NCI Common Terminology Criteria for Adverse Events is a descriptive terminology which can be utilized for Adverse Event (AE) reporting. A grading (severity) scale is provided for each AE term.

Please note: CTCAE incorporates elements of the MedDRA terminology. For further details on MedDRA refer to the MedDRA MSSO Web site (https://www.meddra.org/).

**SOC:** CTCAE terms are grouped by MedDRA Primary System Organ Class (SOC), the highest level of the MedDRA hierarchy. Within each SOC, AEs are listed and accompanied by descriptions of severity (Grade).

**CTCAE Term:** An Adverse Event (AE) is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may <u>not</u> be considered related to the medical treatment or procedure. An AE is a term that is a unique representation of a specific event used for medical documentation and scientific analyses. Each CTCAE v6.0 term is a MedDRA v28.0 LLT (Lowest Level Term).

**Definition:** A brief Definition is provided to clarify the meaning of each AE term. A single dash (-) indicates a Definition is not available.

**Navigational Note:** A Navigational Note is used to assist the reporter in choosing a correct AE. It may list other AEs that should be considered in addition to <u>or</u> in place of the AE in question. Navigational notes appear immediately following the term definition.

**Grade:** Grade refers to the severity of the AE. The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline:

**Grade 1** Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.

**Grade 2** Moderate; minimal, local or noninvasive intervention indicated; limiting instrumental ADL or mild/moderate impact on ageappropriate normal daily activity (pediatric)\*.

**Grade 3** Severe or medically significant but not immediately lifethreatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)\*\*.

**Grade 4** Life-threatening consequences; urgent intervention indicated.

**Grade 5** Death related to AE.

A semi-colon (;) indicates 'or' within the description of the grade. A grade is to be assigned when a clinical finding/situation fulfills *any* of the conditions separated by a semicolon in the grade descriptions.

A single dash (-) indicates a Grade is not available. Not all Grades are appropriate for all AEs, including Grade 5 (Death).

## **Activities of Daily Living (ADL):**

\*Instrumental ADL refers to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.

\*\*Self-care ADL refers to bathing, dressing and undressing, feeding self, using the toilet, taking medications.

#### **Pediatric Activities of Daily Living (ADL):**

\*Mild/moderate impact on age-appropriate normal daily activity.

\*\*Severe impact on age-appropriate normal daily activity.

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# **Blood and lymphatic system disorders**

#### Anemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Hemoglobin (Hgb) <lln -<="" td=""><td>Hgb &lt;10.0 - 8.0 g/dL; &lt;6.2 -</td><td>Hgb &lt;8.0 g/dL; &lt;4.9 mmol/L;</td><td>Life-threatening</td><td>Death</td></lln>	Hgb <10.0 - 8.0 g/dL; <6.2 -	Hgb <8.0 g/dL; <4.9 mmol/L;	Life-threatening	Death
10.0 g/dL; <lln -="" 6.2="" l;<="" mmol="" td=""><td>4.9 mmol/L; &lt;100 - 80 g/L</td><td>&lt;80 g/L; transfusion indicated</td><td>consequences; urgent</td><td></td></lln>	4.9 mmol/L; <100 - 80 g/L	<80 g/L; transfusion indicated	consequences; urgent	
<lln -="" 100="" g="" l<="" td=""><td></td><td></td><td>intervention indicated</td><td></td></lln>			intervention indicated	

**Definition:** A disorder characterized by a reduction in the amount of hemoglobin in 100 ml of blood. Signs and symptoms of anemia may include pallor of the skin and mucous membranes, shortness of breath, palpitations of the heart, soft systolic murmurs, lethargy, and fatigability.

**Navigational Note: -**

#### Aplastic anemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Use of growth factor	Severe or medically	Life-threatening	Death
	indicated; transfusion	significant but not	consequences; urgent	
	indicated	immediately life-threatening;	intervention indicated	
		hospitalization or		
		prolongation of existing		
		hospitalization indicated		

**Definition:** A disorder characterized by the inability of the bone marrow to make enough new blood cells.

**Navigational Note:** Do not report individual cell count decreases in addition to this term.

# Blood and lymphatic system disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition: -**

Navigational Note: -

# Bone marrow hypocellular

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mildly hypocellular or <=25%	Moderately hypocellular or	Severely hypocellular or >50 -	Aplastic persistent for longer	Death
reduction from normal	>25 - <50% reduction from	<=75% reduction cellularity	than 2 weeks	
cellularity for age	normal cellularity for age	from normal for age		

**Definition:** A disorder characterized by the inability of the bone marrow to produce hematopoietic elements.

**Navigational Note:** Consider Blood and lymphatic system disorders: Anemia, Thrombocytopenia, and/or Investigations: Neutrophil count decreased if bone marrow hypocellularity is not seen.

#### Disseminated intravascular coagulation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Laboratory findings with no	Laboratory findings and	Life-threatening	Death
	bleeding	bleeding	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by systemic pathological activation of blood clotting mechanisms which results in clot formation throughout the body. There is an increase in the risk of hemorrhage as the body is depleted of platelets and coagulation factors.

### Eosinophilia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN and >Baseline	-	Steroids initiated	-	-

**Definition:** A disorder characterized by laboratory test results that indicate an increased number of eosinophils in the blood.

**Navigational Note: -**

## Febrile neutropenia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	ANC <1000/mm3 with a	Life-threatening	Death
		single temperature of >38.3	consequences; urgent	
		degrees C (101 degrees F) or	intervention indicated	
		a sustained temperature of		
		>=38 degrees C (100.4		
		degrees F) for more than one		
		hour		

**Definition:** A disorder characterized by an ANC <1000/mm3 and a single temperature of >38.3 degrees C (101 degrees F) or a sustained temperature of >=38 degrees C (100.4 degrees F) for more than one hour.

Navigational Note: -

#### Hemolysis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Laboratory evidence of	Evidence of hemolysis and	Transfusion or medical	Life-threatening	Death
hemolysis only (e.g., direct	>=2 g decrease in	intervention indicated (e.g.,	consequences; urgent	
antiglobulin test; DAT;	hemoglobin	steroids)	intervention indicated	
Coombs'; schistocytes;				
decreased haptoglobin)				

**Definition:** A disorder characterized by laboratory test results that indicate widespread erythrocyte cell membrane destruction.

## Hemolytic anemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<10% drop in Hgb from last	<=2 units of PRBCs	>2 units of PRBCs per day	Life-threatening	Death
assessment; intervention not	transfused per day	indicated	consequences; urgent	
indicated			intervention indicated	

**Definition:** Anemia resulting from hemolysis.

**Navigational Note: -**

# Hemolytic uremic syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-		Laboratory findings with	Life-threatening	Death
		clinical consequences (e.g.,	consequences, (e.g., CNS	
		renal insufficiency, petechiae)	hemorrhage or	
			thrombosis/embolism or	
			renal failure)	

**Definition:** A disorder characterized by a form of thrombotic microangiopathy with renal failure, hemolytic anemia, and severe thrombocytopenia when the etiology is due to infections with shiga-toxin producing bacteria, such as E coli O157:H7.

Navigational Note: -

# Leukocytosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	>100,000/mm3	Clinical manifestations of	Death
			leucostasis; urgent	
			intervention indicated	

**Definition:** A disorder characterized by laboratory test results that indicate an increased number of white blood cells in the blood.

Navigational Note: Do not use for increases due to growth factors, steroids, or leukemias.

## Lymph node pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in a lymph node.

Navigational Note: Record final diagnosis/cause once determined.

#### Lymphopenia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	-	-	-	-

**Definition:** A finding based on laboratory test results that indicate a decrease in number of lymphocytes in a blood specimen.

Navigational Note: -

## Methemoglobinemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	>ULN	Requiring urgent intervention	Life-threatening	Death
			consequences	

**Definition:** A disorder characterized by laboratory test results that indicate increased methemoglobin in the blood.

Navigational Note: -

# Thrombocytopenia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<lln -="" -<="" 75,000="" <lln="" mm3;="" td=""><td>&lt;75,000 - 50,000/mm3; &lt;75.0</td><td>&lt;50,000 - 10,000/mm3; &lt;50.0</td><td>&lt;10,000/mm3; 10.0 x 10^9/L;</td><td>Death</td></lln>	<75,000 - 50,000/mm3; <75.0	<50,000 - 10,000/mm3; <50.0	<10,000/mm3; 10.0 x 10^9/L;	Death
75.0 x 10^9/L	- 50.0 x 10^9/L	- 10.0 x 10^9/L; transfusion	life-threatening	
		indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by a decrease in number of platelets in a blood specimen.

# **Thrombocytosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	-	-	-	-

**Definition:** A finding based on laboratory test results that indicate an increase in number of platelets in a blood specimen.

**Navigational Note: -**

#### Thrombotic microangiopathy

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Outpatient intervention	Transfusion or IV	Life-threatening	Death
	indicated (e.g., modification	intervention indicated	consequences	
	of immunosuppression)			

**Definition:** A disorder characterized by a form of thrombotic microangiopathy with laboratory findings that indicate hemolytic anemia, severe thrombocytopenia, and renal insufficiency/failure.

**Navigational Note: -**

# Thrombotic thrombocytopenic purpura

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Laboratory findings with	Life-threatening	Death
		clinical consequences (e.g.,	consequences, (e.g., CNS	
		renal insufficiency, petechiae)	hemorrhage or	
			thrombosis/embolism or	
			renal failure)	

**Definition:** A disorder characterized by a deficiency of ADAMTS13 and the presence of microangiopathic hemolytic anemia, thrombocytopenic purpura, fever, renal abnormalities and neurological abnormalities such as seizures, hemiplegia, and visual disturbances. It is an acute or subacute condition.

#### **Aortic valve disease**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic valvular	Asymptomatic; moderate	Symptomatic; severe	Life-threatening	Death
thickening with or without	regurgitation or stenosis by	regurgitation or stenosis by	consequences; urgent	
mild valvular regurgitation or	imaging	imaging; symptoms	intervention indicated (e.g.,	
stenosis by imaging		controlled with medical	valve replacement,	
		intervention	valvuloplasty)	

**Definition:** A disorder characterized by a defect in aortic valve function or structure.

**Navigational Note: -**

#### **Asystole**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Intervention indicated; device	Life-threatening	Death
		(e.g., pacemaker)	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by a dysrhythmia without cardiac electrical activity. Typically, this is accompanied by cessation of the pumping function of the heart.

Navigational Note: -

#### **Atrial fibrillation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention	Non-urgent medical	Symptomatic, urgent	Life-threatening	Death
not indicated	intervention indicated;	intervention indicated; device	consequences	
	electrical cardioversion	(e.g., pacemaker); ablation;		
		new onset		

**Definition:** A disorder characterized by a dysrhythmia without discernible P waves and an irregular ventricular response due to multiple reentry circuits. The rhythm disturbance originates above the ventricles.

#### **Atrial flutter**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention	Non-urgent medical	Symptomatic, urgent	Life-threatening	Death
not indicated	intervention indicated	intervention indicated; device	consequences	
		(e.g., pacemaker); ablation		

**Definition:** A disorder characterized by a dysrhythmia with organized rhythmic atrial contractions with a rate of 200-300 beats per minute. The rhythm disturbance originates in the atria.

**Navigational Note: -**

#### Atrioventricular block complete

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Non-urgent intervention	Symptomatic and	Life-threatening	Death
	indicated	incompletely controlled	consequences; urgent	
		medically, or controlled with	intervention indicated	
		device (e.g., pacemaker); new		
		onset		

**Definition:** A disorder characterized by a dysrhythmia with complete failure of atrial electrical impulse conduction through the AV node to the ventricles.

Navigational Note: -

#### Atrioventricular block first degree

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention	Non-urgent intervention	-	1	-
not indicated	indicated			

**Definition:** A disorder characterized by a dysrhythmia with a delay in the time required for the conduction of an electrical impulse through the atrioventricular (AV) node beyond 0.2 seconds; prolongation of the PR interval greater than 200 milliseconds.

# **Cardiac arrest**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	Life-threatening	Death
			consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by cessation of the pumping function of the heart.

**Navigational Note: -**

# Cardiac disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

Definition: -

#### Chest pain - cardiac

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; pain on	Pain at rest; cardiac	-	-
	exertion; hemodynamically	catheterization; new onset		
	stable; limiting instrumental	cardiac chest pain; unstable		
	ADL or mild/moderate	angina; limiting self-care ADL		
	impact on age-appropriate	or severe impact on age-		
	normal daily activity	appropriate normal daily		
	(pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by substernal discomfort due to insufficient myocardial oxygenation e.g., angina pectoris.

Navigational Note: Consider Cardiac disorders: Myocardial infarction. Record final diagnosis/cause once determined.

#### **Heart failure**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; no initiation	Outpatient initiation or	Hospitalization indicated	Requiring inotropic support,	Death
or intensification of	intensification of treatment		mechanical circulatory	
treatment			support, or consideration of	
			cardiac transplantation	

**Definition:** A disorder characterized by the inability of the heart to pump blood at an adequate volume to meet tissue metabolic requirements, or, the ability to do so only at an elevation in the filling pressure.

Navigational Note: If asymptomatic, consider Cardiac disorders: Left ventricular dysfunction.

#### Left ventricular dysfunction

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Left ventricular ejection	LVEF 40 - 49% <b>AND</b> one or	New LVEF reduction to <40%	-	-
fraction (LVEF) ≥50% <b>AND</b>	more of the following:			
one or more of the following:	1) LVEF reduction by ≥10%			
1) New relative decline in	2) New relative decline in GLS			
Global Longitudinal Strain	>15% from baseline			
(GLS) >15% from baseline	3) New rise in cardiac			
2) New rise in cardiac	biomarkers			
biomarkers				

**Definition:** A disorder characterized by an **ASYMPTOMATIC** abnormality of cardiac function.

Navigational Note: If symptomatic, consider Cardiac disorders: Heart failure.

#### Mitral valve disease

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic valvular	Asymptomatic; moderate	Symptomatic; severe	Life-threatening	Death
thickening with or without	regurgitation or stenosis by	regurgitation or stenosis by	consequences; urgent	
mild valvular regurgitation or	imaging	imaging; symptoms	intervention indicated (e.g.,	
stenosis by imaging		controlled with medical	valve replacement,	
		intervention	valvuloplasty)	

**Definition:** A disorder characterized by a defect in mitral valve function or structure.

Navigational Note: -

# Mobitz (type) II atrioventricular block

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention	Symptomatic; medical	Symptomatic and	Life-threatening	Death
not indicated	intervention indicated	incompletely controlled	consequences; urgent	
		medically, or require a device	intervention indicated	
		(e.g., pacemaker)		

**Definition:** A disorder characterized by a dysrhythmia with relatively constant PR interval prior to the block of an atrial impulse. This is the result of intermittent failure of atrial electrical impulse conduction through the atrioventricular (AV) node to the ventricles.

# Mobitz type I

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention	Symptomatic; medical	Symptomatic and	Life-threatening	Death
not indicated	intervention indicated	incompletely controlled	consequences; urgent	
		medically, or controlled with	intervention indicated	
		device (e.g., pacemaker)		

**Definition:** A disorder characterized by a dysrhythmia with a progressively lengthening PR interval prior to the blocking of an atrial impulse. This is the result of intermittent failure of atrial electrical impulse conduction through the atrioventricular (AV) node to the ventricles.

# **Myocardial infarction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Asymptomatic; imaging or	Hemodynamically stable	Life-threatening	Death
	ECG features consistent with	<b>AND</b> detection of a rise	consequences;	
	myocardial infarction which	and/or fall of Cardiac	hemodynamically <b>UN</b> stable	
	may be of uncertain age	troponin values with at least	<b>AND</b> detection of a rise	
		1 value above the 99th	and/or fall of Cardiac	
		percentile URL <b>AND</b> at least 1	troponin values with at least	
		of the following:	1 value above the 99th	
		1) Symptoms of myocardial	percentile URL <b>AND</b> at least 1	
		ischemia;	of the following:	
		2) New ischemic ECG	1) Symptoms of myocardial	
		changes;	ischemia;	
		3) Development of	2) New ischemic ECG	
		pathological Q waves;	changes;	
		4) Imaging evidence of new	3) Development of	
		loss of viable myocardium or	pathological Q waves;	
		new regional wall motion	4) Imaging evidence of new	
		abnormality in a pattern	loss of viable myocardium or	
		consistent with an ischemic	new regional wall motion	
		etiology;	abnormality in a pattern	
		5) Identification of a coronary	consistent with an ischemic	
		thrombus by angiography	etiology;	
			5) Identification of a coronary	
			thrombus by angiography	

**Definition:** A disorder characterized by gross necrosis of the myocardium; this is due to an interruption of blood supply to the area. **Navigational Note:** -

#### **Myocarditis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic with Lab or	Symptoms with moderate	Severe with symptoms at rest	Life-threatening	Death
ECG findings only	activity or exertion	or with minimal activity or	consequences; urgent	
		exertion; intervention	intervention indicated (e.g.,	
		indicated; new onset of	continuous IV therapy or	
		symptoms	mechanical hemodynamic	
			support); hemodynamically	
			unstable requiring non-	
			invasive or invasive	
			ventilation; complete or high	
			grade AV block; significant	
			ventricular arrhythmia	

**Definition:** A disorder characterized by inflammation of the muscle tissue of the heart.

**Navigational Note: -**

# **Palpitations**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Intervention indicated	-	-	-
not indicated				

**Definition:** A disorder characterized by an unpleasant sensation of irregular and/or forceful beating of the heart.

Navigational Note: Record final diagnosis/cause once determined.

#### Paroxysmal atrial tachycardia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention	Non-urgent medical	Symptomatic, urgent	Life-threatening	Death
not indicated	intervention indicated	intervention indicated;	consequences; incompletely	
		ablation	controlled medically;	
			cardioversion indicated	

**Definition:** A disorder characterized by a dysrhythmia with abrupt onset and sudden termination of atrial contractions with a rate of 150-250 beats per minute. The rhythm disturbance originates in the atria.

#### Pericardial effusion

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Asymptomatic effusion size	Effusion with physiologic	Life-threatening	Death
	small to moderate	consequences	consequences;	
			hospitalization	

**Definition:** A disorder characterized by fluid collection within the pericardial sac, usually due to inflammation.

Navigational Note: Consider Cardiac disorders: Pericardial tamponade, Pericarditis.

# Pericardial tamponade

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	Life-threatening	Death
			consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an increase in intrapericardial pressure due to the collection of blood or fluid in the pericardium. **Navigational Note:** Consider Cardiac disorders: Pericarditis.

#### **Pericarditis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, ECG or	Symptomatic pericarditis	Pericarditis with physiologic	Life-threatening	Death
physical findings (e.g., rub)	(e.g., chest pain)	consequences (e.g.,	consequences; urgent	
consistent with pericarditis		pericardial constriction)	intervention indicated	

**Definition:** A disorder characterized by irritation to the layers of the pericardium (the protective sac around the heart).

Navigational Note: -

#### Pulmonary valve disease

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic valvular	Asymptomatic; moderate	Symptomatic; severe	Life-threatening	Death
thickening with or without	regurgitation or stenosis by	regurgitation or stenosis by	consequences; urgent	
mild valvular regurgitation or	imaging	imaging; symptoms	intervention indicated (e.g.,	
stenosis by imaging		controlled with medical	valve replacement,	
		intervention	valvuloplasty)	

**Definition:** A disorder characterized by a defect in pulmonary valve function or structure.

#### Sick sinus syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention	Symptomatic, intervention	Symptomatic, intervention	Life-threatening	Death
not indicated	not indicated; change in	indicated	consequences; urgent	
	medication initiated		intervention indicated	

**Definition:** A disorder characterized by a dysrhythmia with alternating periods of bradycardia and atrial tachycardia accompanied by syncope, fatigue and dizziness.

**Navigational Note: -**

#### Sinus bradycardia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention	Symptomatic, intervention	Symptomatic, intervention	Life-threatening	Death
not indicated	not indicated; change in	indicated	consequences; urgent	
	medication initiated		intervention indicated	

**Definition:** A disorder characterized by a dysrhythmia with a heart rate less than 60 beats per minute that originates in the sinus node. **Navigational Note:** -

# Sinus tachycardia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention not indicated	Symptomatic; non-urgent medical intervention indicated	Urgent medical intervention indicated	-	-

**Definition:** A disorder characterized by a dysrhythmia with a heart rate greater than 100 beats per minute that originates in the sinus node.

**Navigational Note:** Record final diagnosis/cause once determined.

## Supraventricular tachycardia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention	Non-urgent medical	Symptomatic, urgent	Life-threatening	Death
not indicated	intervention indicated	intervention indicated	consequences	

**Definition:** A disorder characterized by a dysrhythmia with a heart rate greater than 100 beats per minute that originates above the ventricles.

#### Tricuspid valve disease

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic valvular	Asymptomatic; moderate	Symptomatic; severe	Life-threatening	Death
thickening with or without	regurgitation or stenosis by	regurgitation or stenosis;	consequences; urgent	
mild valvular regurgitation or	imaging	symptoms controlled with	intervention indicated (e.g.,	
stenosis		medical intervention	valve replacement,	
			valvuloplasty)	

**Definition:** A disorder characterized by a defect in tricuspid valve function or structure.

**Navigational Note: -**

# Ventricular arrhythmia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention	Non-urgent medical	Urgent intervention indicated	Life-threatening	Death
not indicated	intervention indicated		consequences;	
			hemodynamic compromise	

**Definition:** A disorder characterized by a dysrhythmia that originates in the ventricles.

**Navigational Note: -**

#### **Ventricular fibrillation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	Life-threatening	Death
			consequences;	
			hemodynamic compromise	

**Definition:** A disorder characterized by a dysrhythmia without discernible QRS complexes due to rapid repetitive excitation of myocardial fibers without coordinated contraction of the ventricles.

# Ventricular tachycardia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Non-urgent medical	Symptomatic, urgent	Life-threatening	Death
	intervention indicated	intervention indicated	consequences;	
			hemodynamic compromise	

**Definition:** A disorder characterized by a dysrhythmia with a heart rate greater than 100 beats per minute that originates distal to the bundle of His.

# **Congenital, familial and genetic disorders**

# Congenital, familial and genetic disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

Definition: -

# Ear and labyrinth disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

Definition: -

Navigational Note: -

# Ear pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the ear.

Navigational Note: Record final diagnosis/cause once determined.

# External ear pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the external ear region.

**Navigational Note:** Record final diagnosis/cause once determined.

#### **Hearing impaired**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Adult: Subjective change in	Adult: Hearing loss not	Adult: Hearing loss requiring	Adult: Nonservicable	-
hearing in the absence of	requiring hearing aid;	hearing aid; intervention	hearing; decrease in hearing	
documented hearing loss;	intervention not indicated;	indicated; limiting self-care	to profound bilateral loss	
threshold shift of 15 - 25 dB	limiting instrumental ADL;	ADL; threshold shift of >25	(absolute threshold >80 dB	
averaged at 2 contiguous test	threshold shift of >25 dB	dB averaged at 3 contiguous	HL at 2 kHz and above);	
frequencies in at least one	averaged at 2 contiguous test	test frequencies in at least	Pediatric: Audiologic	
ear (on a 1, 2, 4, 3, 6, and 8	frequencies in at least one	one ear(on a 1, 2, 3, 4, 6, and	indication for cochlear	
kHz audiogram);	ear (on a 1, 2, 3, 4, 6, and 8	8 kHz audiogram);	implant; >40 dB HL (i.e., 45	
<b>Pediatric</b> (on a 1, 2, 3, 4, 6,	kHz audiogram);	<b>Pediatric</b> (on a 1, 2, 3, 4, 6,	dB HL or more); SNHL at 2	
and 8 kHz audiogram):	<b>Pediatric</b> (on a 1, 2, 3, 4, 6,	and 8 kHz audiogram):	kHz and above	
Threshold shift >20 dB	and 8 kHz audiogram):	Hearing loss sufficient to		
hearing loss (HL) (i.e., 25 dB	Threshold shift >20 dB at 4	indicate therapeutic		
HL or greater); sensorineural	kHz in at least one ear;	intervention, including		
hearing loss (SNHL) above 4	mild/moderate impact on	hearing aids; threshold shift		
kHz (i.e., 6 or 8 kHz) in at	age-appropriate normal daily	>20 dB at 2 to <4 kHz in at		
least one ear	activity	least one ear; severe impact		
		on age-appropriate normal		
		daily activity		

**Definition:** A disorder characterized by partial or complete loss of the ability to detect or understand sounds resulting from damage to ear structures.

**Navigational Note: -**

#### Middle ear inflammation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Serous otitis	Serous otitis, medical	Mastoiditis; necrosis of canal	Life-threatening	Death
	intervention indicated	soft tissue or bone	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by inflammation (physiologic response to irritation), swelling and redness to the middle ear. **Navigational Note:** -

#### **Tinnitus**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
not indicated	instrumental ADL or	self-care ADL or severe		
	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by noise in the ears, such as ringing, buzzing, roaring or clicking.

**Navigational Note: -**

## Vertigo

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
	instrumental ADL or	self-care ADL or severe		
	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by a sensation as if the external world were revolving around the patient (objective vertigo) or as if he himself were revolving in space (subjective vertigo).

**Navigational Note: -**

#### Vestibular disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Symptomatic; limiting	Severe symptoms; limiting	-	-
	instrumental ADL or	self-care ADL or severe		
	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by dizziness, imbalance, nausea, and vision problems.

# Adrenal insufficiency

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Moderate symptoms;	Severe symptoms;	Life-threatening	Death
diagnostic observations only;	medical intervention	hospitalization indicated	consequences; urgent	
intervention not indicated	indicated		intervention indicated	

**Definition:** A disorder characterized by the adrenal cortex not producing enough of the hormone cortisol and in some cases, the hormone aldosterone. It may be due to a disorder of the adrenal cortex as in Addison's disease or primary adrenal insufficiency.

Navigational Note: -

# Cushingoid

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Severe symptoms, medical	-	-
not indicated	medical intervention	intervention or		
	indicated	hospitalization indicated		

**Definition:** A disorder characterized by signs and symptoms that resemble Cushing's disease or syndrome: buffalo hump obesity, striations, adiposity, hypertension, diabetes, and osteoporosis, usually due to exogenous corticosteroids.

Navigational Note: -

#### **Delayed puberty**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	No breast development by	No breast development by	-	-
	age 13 yrs for females; testes	age 14 yrs for females; no		
	volume of <3 cc or no Tanner	increase in testes volume or		
	Stage 2 development by age	no Tanner Stage 2 by age 16		
	14.5 yrs for males	yrs for males; hormone		
		replacement indicated		

**Definition:** A disorder characterized by unusually late sexual maturity.

# **Endocrine disorders - Other, specify**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** -

**Navigational Note: -**

# Hyperparathyroidism

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention	-	-	-
The marcacea	indicated			

**Definition:** A disorder characterized by an increase in production of parathyroid hormone by the parathyroid glands. This results in hypercalcemia (abnormally high levels of calcium in the blood).

# Hyperthyroidism

Grade 2	Grade 3	Grade 4	Grade 5
Symptomatic; thyroid suppression therapy ndicated; limiting nstrumental ADL or mild/moderate impact on age-appropriate normal daily	Severe symptoms; hospitalization indicated; limiting self-care ADL or severe impact on age- appropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death
n n	mptomatic; thyroid uppression therapy dicated; limiting strumental ADL or ild/moderate impact on	mptomatic; thyroid uppression therapy dicated; limiting strumental ADL or sild/moderate impact on ge-appropriate normal daily symptomatic; thyroid Severe symptoms; hospitalization indicated; limiting self-care ADL or severe impact on age- appropriate normal daily activity (pediatric)	/mptomatic; thyroid Severe symptoms; Life-threatening consequences; urgent intervention indicated strumental ADL or appropriate normal daily activity (pediatric)

**Definition:** A disorder characterized by excessive levels of thyroid hormone in the body. Common causes include an overactive thyroid gland or thyroid hormone overdose.

**Navigational Note: -**

# Hypogonadism

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by a decrease in production of sex hormones from the gonads.

# Hypoparathyroidism

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Moderate symptoms;	Severe symptoms; medical	Life-threatening	Death
diagnostic observations only;	medical intervention	intervention or	consequences; urgent	
intervention not indicated	indicated	hospitalization indicated	intervention indicated	

**Definition:** A disorder characterized by a decrease in production of parathyroid hormone by the parathyroid glands.

Navigational Note: -

# **Hypophysitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by inflammation and cellular infiltration of the pituitary gland.

## Hypopituitarism

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; limiting self-care ADL or severe impact on ageappropriate normal daily	Life-threatening consequences; urgent intervention indicated	Death
		activity (pediatric)		

**Definition:** A disorder characterized by a decrease in production of hormones from the pituitary gland.

**Navigational Note:** Consider Endocrine disorders: Hypophysitis.

# Hypothyroidism

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; thyroid	Severe symptoms;	Life-threatening	Death
diagnostic observations only;	replacement initiated;	hospitalization indicated;	consequences; urgent	
intervention not indicated	increase in current thyroid	limiting self-care ADL or	intervention indicated	
	replacement therapy; limiting	severe impact on age-		
	instrumental ADL or	appropriate normal daily		
	mild/moderate impact on	activity (pediatric)		
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by a decrease in production of thyroid hormone by the thyroid gland.

**Navigational Note:** Consider Endocrine disorders: Hypophysitis.

# **Precocious puberty**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Physical signs of puberty with	Physical signs and	-	-	-
no biochemical markers for	biochemical markers of			
females <8 years and males	puberty for females <8 years			
<9 years	and males <9 years			

**Definition:** A disorder characterized by unusually early development of secondary sexual features; the onset of sexual maturation begins usually before age 8 for girls and before age 9 for boys.

Navigational Note: -

# **Testosterone deficiency**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; mild	Replacement therapy	-	-	-
symptoms with no	initiated			
intervention indicated				

**Definition:** A disorder characterized by low testosterone.

**Navigational Note: -**

# **Thyroiditis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Medical intervention	Hospitalization indicated	Life-threatening	Death
	indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by inflammation or destruction of the thyroid gland.

**Navigational Note: -**

#### Virilization

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	-	-	-
not indicated	medical intervention			
	indicated			

**Definition:** A disorder characterized by inappropriate masculinization occurring in a female or prepubertal male.

#### **Blurred vision**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Intervention not indicated	Symptomatic; moderate	Symptomatic with marked	Best corrected visual acuity	-
	decrease in visual acuity	decrease in visual acuity	of 20/200 or worse in the	
	(best corrected visual acuity	(best corrected visual acuity	affected eye	
	20/40 and better or 3 lines or	worse than 20/40 or more		
	less decreased vision from	than 3 lines of decreased		
	known baseline); limiting	vision from known baseline,		
	instrumental ADL or	up to 20/200); limiting self-		
	mild/moderate impact on	care ADL or severe impact on		
	age-appropriate normal daily	age-appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by visual perception of unclear or fuzzy images.

Navigational Note: Consider: Eye disorders: Uveitis.

#### Cataract

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
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 or mild/moderate impact on age-appropriate normal daily	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 selfcare ADL or severe impact on age-appropriate normal daily activity (pediatric)	Best corrected visual acuity of 20/200 or worse in the affected eye	-
	activity (pediatric)	(2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2		

**Definition:** A disorder characterized by partial or complete opacity of the crystalline lens of one or both eyes. This results in a decrease in visual acuity and eventual blindness if untreated.

#### Corneal ulcer

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Corneal ulcer without	Perforation in the affected	-
		perforation in the affected	eye	
		eye		

**Definition:** A disorder characterized by an area of epithelial tissue loss on the surface of the cornea. It is associated with inflammatory cells in the cornea and anterior chamber.

**Navigational Note: -**

# Decreased night vision

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Symptomatic but not limiting	Moderate decrease in visual	Marked decrease in visual	Best corrected visual acuity	-
ADL	acuity (best corrected visual	acuity (best corrected visual	of 20/200 or worse in the	
	acuity 20/40 and better or 3	acuity worse than 20/40 or	affected eye	
	lines or less decreased vision	more than 3 lines of		
	from known baseline);	decreased vision from known		
	limiting instrumental ADL or	baseline, up to 20/200);		
	mild/moderate impact on	limiting self-care ADL or		
	age-appropriate normal daily	severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by an inability to see clearly in dim light.

#### Dry eye

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Clinical or diagnostic	Symptomatic; moderate	Symptomatic with marked	-	-
observations only; symptoms	decrease in visual acuity	decrease in visual acuity		
relieved by lubricants	(best corrected visual acuity	(best corrected visual acuity		
	20/40 and better or 3 lines or	worse than 20/40 or more		
	less decreased vision from	than 3 lines of decreased		
	known baseline)	vision from known baseline,		
		up to 20/200); limiting self-		
		care ADL or severe impact on		
		age-appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by dryness of the cornea and conjunctiva.

**Navigational Note:** If corneal ulcer is present, grade under Eye disorders: Corneal ulcer. If related to syndromes not present in CTCAE (ex. Sjogren's syndrome, etc.), report as Other, specify in the most representative SOC.

# Extraocular muscle paresis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Unilateral paresis without	Bilateral paresis or unilateral	Bilateral paresis requiring	-
diagnostic observations only	double vision	paresis causing double vision	head turning to see beyond	
		in peripheral gaze, but not in	central 60 degrees or double	
		central gaze	vision in central gaze	

**Definition:** A disorder characterized by incomplete paralysis of an extraocular muscle.

# Eye disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Sight-threatening	-
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; best corrected	immediately sight-	intervention indicated; best	
intervention not indicated;	visual acuity 20/40 and better	threatening; decrease in	corrected visual acuity of	
no change in vision	or 3 lines or less decreased	visual acuity (best corrected	20/200 or worse in the	
	vision from known baseline;	visual acuity worse than	affected eye	
	limiting instrumental ADL or	20/40 or more than 3 lines of		
	mild/moderate impact on	decreased vision from known		
	age-appropriate normal daily	baseline, up to 20/200);		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** -

**Navigational Note: -**

# Eye pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the eye.

**Navigational Note:** Record final diagnosis/cause once determined.

## **Eyelid function disorder**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Clinical or diagnostic	Symptomatic; nonoperative	Operative intervention	-	-
observations only;	intervention indicated;	indicated requiring		
intervention not indicated	limiting instrumental ADL or	hospitalization; limiting self-		
	mild/moderate impact on	care ADL or severe impact on		
	age-appropriate normal daily	age-appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by impaired eyelid function.

**Navigational Note: -**

# Flashing lights

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Symptomatic	Limiting instrumental ADL or	Limiting self-care ADL or	-	-
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by a sudden or brief burst of light.

Navigational Note: Consider Eye disorders: Retinal tear, Retinal detachment.

### **Floaters**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Symptomatic	Limiting instrumental ADL or	Limiting self-care ADL or	-	-
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by an individual seeing spots before their eyes. The spots are shadows of opaque cell fragments in the vitreous humor or lens.

Navigational Note: Consider Eye disorders: Retinal tear, Retinal detachment.

## Glaucoma

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Less than 8 mmHg of	Topical medication indicated	EIOP causing visual field	Visual field deficit within the	-
elevated intraocular pressure		deficits	central 10 degrees of the	
(EIOP); no visual field deficit			visual field in the affected eye	

**Definition:** A disorder characterized by an increase in pressure in the eyeball due to obstruction of the aqueous humor outflow.

Navigational Note: -

## Keratitis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; moderate	Symptomatic with marked	Perforation; best corrected	-
diagnostic observations only;	decrease in visual acuity	decrease in visual acuity	visual acuity of 20/200 or	
intervention not indicated	(best corrected visual acuity	(best corrected visual acuity	worse in the affected eye	
	20/40 and better or 3 lines or	worse than 20/40 or more		
	less decreased vision from	than 3 lines of decreased		
	known baseline)	vision from known baseline,		
		up to 20/200); corneal ulcer;		
		limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by inflammation to the cornea of the eye.

**Navigational Note:** Consider Eye disorders: Corneal ulcer.

# **Optic nerve disorder**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Moderate decrease in visual	Marked decrease in visual	Best corrected visual acuity	-
diagnostic observations only	acuity (best corrected visual	acuity (best corrected visual	of 20/200 or worse in the	
	acuity 20/40 and better or 3	acuity worse than 20/40 or	affected eye	
	lines or less decreased vision	more than 3 lines of		
	from known baseline)	decreased vision from known		
		baseline, up to 20/200)		

**Definition:** A disorder characterized by involvement of the optic nerve (second cranial nerve).

**Navigational Note: -**

# Papilledema

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; no visual field	Symptomatic; moderate	Symptomatic with marked	Best corrected visual acuity	-
deficit	decrease in visual acuity	decrease in visual acuity	of 20/200 or worse in the	
	(best corrected visual acuity	(best corrected visual acuity	affected eye	
	20/40 and better or 3 lines or	worse than 20/40 or more		
	less decreased vision from	than 3 lines of decreased		
	known baseline)	vision from known baseline,		
		up to 20/200)		

**Definition:** A disorder characterized by swelling around the optic disc.

Navigational Note: Record final diagnosis/cause once determined.

### Periorbital edema

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Soft or non-pitting	Indurated or pitting edema;	Edema associated with visual	-	-
, -	topical intervention indicated	disturbance; increased		
		intraocular pressure,		
		glaucoma or retinal		
		hemorrhage; diuretics		
		indicated; operative		
		intervention indicated		

**Definition:** A disorder characterized by swelling due to an excessive accumulation of fluid around the orbits of the face.

Navigational Note: Record final diagnosis/cause once determined.

# Photophobia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Symptomatic	Limiting instrumental ADL or	Limiting self-care ADL or	-	-
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by fear and avoidance of light.

**Navigational Note: -**

#### **Retinal detachment**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Macular sparing	Macula-off rhegmatogenous	-
		rhegmatogenous	retinal detachment	
		detachment		

**Definition:** A disorder characterized by the separation of the inner retina layers from the underlying pigment epithelium.

#### **Retinal tear**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
No retinal detachment and	No retinal detachment and	-	-	-
treatment not indicated	treatment indicated			

**Definition:** A disorder characterized by a small laceration of the retina. Symptoms include flashes and floaters.

Navigational Note: If retinal detachment is present, grade under Eye disorders: Retinal detachment.

#### Retinal vascular disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Retinal vascular disorder	Retinal vascular disorder with	-	-
	without neovascularization	neovascularization		

**Definition:** A disorder characterized by pathological retinal blood vessels that adversely affects vision.

Navigational Note: If vitreous hemorrhage is present, report under Eye disorders: Vitreous hemorrhage.

## Retinopathy

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; moderate	Symptomatic with marked	Best corrected visual acuity	-
diagnostic observations only	decrease in visual acuity	decrease in visual acuity	of 20/200 or worse in the	
	(best corrected visual acuity	(best corrected visual acuity	affected eye	
	20/40 and better or 3 lines or	worse than 20/40 or more		
	less decreased vision from	than 3 lines of decreased		
	known baseline); limiting	vision from known baseline,		
	instrumental ADL or	up to 20/200); limiting self-		
	mild/moderate impact on	care ADL or severe impact on		
	age-appropriate normal daily	age-appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder involving the retina.

Navigational Note: If vitreous hemorrhage is present, report under Eye disorders: Vitreous hemorrhage.

### Scleral disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
No change in vision from	Symptomatic; moderate	Symptomatic with marked	Best corrected visual acuity	-
baseline	decrease in visual acuity	decrease in visual acuity	of 20/200 or worse in the	
	(best corrected visual acuity	(best corrected visual acuity	affected eye	
	20/40 and better or 3 lines or	worse than 20/40 or more		
	less decreased vision from	than 3 lines of decreased		
	known baseline); limiting	vision from known baseline,		
	instrumental ADL or	up to 20/200); limiting self-		
	mild/moderate impact on	care ADL or severe impact on		
	age-appropriate normal daily	age-appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by involvement of the sclera of the eye.

**Navigational Note: -**

## **Uveitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Anterior uveitis with trace	Anterior uveitis with 1+ or 2+	Anterior uveitis with 3+ or	Best corrected visual acuity	-
cells	cells	greater cells; intermediate	of 20/200 or worse in the	
		posterior or pan-uveitis	affected eye	

**Definition:** A disorder characterized by inflammation to the uvea of the eye.

**Navigational Note: -**

## Vision decreased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate decrease in visual	Marked decrease in visual	Best corrected visual acuity	-
	acuity (best corrected visual	acuity (best corrected visual	of 20/200 or worse in the	
	acuity 20/40 and better or 3	acuity worse than 20/40 or	affected eye	
	lines or less decreased vision	more than 3 lines of	-	
	from known baseline)	decreased vision from known		
		baseline, up to 20/200)		

**Definition:** A disorder characterized by a decrease in visual acuity.

Navigational Note: If etiology is known, use a more specific CTCAE term. Consider: Eye disorders: Uveitis

# Vitreous hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Intervention not indicated	Symptomatic; moderate	Symptomatic with marked	Best corrected visual acuity	-
	decrease in visual acuity	decrease in visual acuity	of 20/200 or worse in the	
	(best corrected visual acuity	(best corrected visual acuity	affected eye	
	20/40 and better or 3 lines or	worse than 20/40 or more		
	less decreased vision from	than 3 lines of decreased		
	known baseline); limiting	vision from known baseline,		
	instrumental ADL or	up to 20/200); vitrectomy		
	mild/moderate impact on	indicated; limiting self-care		
	age-appropriate normal daily	ADL or severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by bleeding into the vitreous humor.

Navigational Note: -

# Watering eyes

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Intervention not indicated	Symptomatic; moderate	Marked decrease in visual	Best corrected visual acuity	-
	decrease in visual acuity	acuity (best corrected visual	of 20/200 or worse in the	
	(best corrected visual acuity	acuity worse than 20/40 or	affected eye	
	20/40 and better or 3 lines or	more than 3 lines of	-	
	less decreased vision from	decreased vision from known		
	known baseline)	baseline, up to 20/200)		

**Definition:** A disorder characterized by excessive tearing in the eyes; it can be caused by overproduction of tears or impaired drainage of the tear duct.

#### **Abdominal distension**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; limiting	Severe discomfort; limiting	-	-
diagnostic observations only;	instrumental ADL or	self-care ADL or severe		
intervention not indicated	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by swelling of the abdomen.

**Navigational Note: -**

# **Abdominal pain**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the abdominal region.

Navigational Note: Record final diagnosis/cause once determined.

# **Anal fissure**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic	Invasive intervention	-	-
		indicated		

**Definition:** A disorder characterized by a tear in the lining of the anus.

#### **Anal fistula**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the opening in the anal canal to the perianal skin.

Navigational Note: -

#### **Anal mucositis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate symptoms;	Severe symptoms; limiting	-	-
symptoms; intervention not	medical intervention	self-care ADL or severe		
indicated	indicated; limiting	impact on age-appropriate		
	instrumental ADL or	normal daily activity		
	mild/moderate impact on	(pediatric)		
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by ulceration or inflammation of the mucous membrane of the anus.

**Navigational Note:** Report Grade 4 and 5 as Gastrointestinal disorders: Anal ulcer.

### **Anal necrosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	TPN or hospitalization indicated; invasive	Life-threatening consequences; urgent	Death
		intervention indicated	operative intervention	
			indicated	

**Definition:** A disorder characterized by a necrotic process occurring in the anal region.

# **Anal pain**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the anal region.

Navigational Note: Record final diagnosis/cause once determined.

#### **Anal stenosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Symptomatic and severely	Life-threatening	Death
diagnostic observations only;	function	altered GI function; non-	consequences; urgent	
intervention not indicated		emergent operative	operative intervention	
		intervention indicated; TPN	indicated	
		or hospitalization indicated		

**Definition:** A disorder characterized by a narrowing of the lumen of the anal canal.

**Navigational Note: -**

### **Anal ulcer**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function	TPN indicated; elective	consequences; urgent	
intervention not indicated		invasive intervention	operative intervention	
		indicated	indicated	

**Definition:** A disorder characterized by a circumscribed, erosive lesion on the mucosal surface of the anal canal.

#### **Ascites**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; medical	Severe symptoms; catheter	Life-threatening	Death
diagnostic observations only;	intervention or paracentesis	placement indicated	consequences; urgent	
intervention not indicated	indicated		operative intervention	
			indicated	

**Definition:** A disorder characterized by accumulation of serous or hemorrhagic fluid in the peritoneal cavity.

Navigational Note: Record final diagnosis/cause once determined.

### **Belching**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Increase from baseline	Intervention initiated	-	-	-
	(including over the counter			
	medications)			

**Definition:** To expel gas noisily from the mouth.

Navigational Note: Synonym: Burping

# **Bloating**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
No change in bowel function or oral intake	Symptomatic, decreased oral intake; change in bowel	-	-	-
	function			

**Definition:** A disorder characterized by subject-reported feeling of uncomfortable fullness of the abdomen.

Navigational Note: -

# Cecal hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the cecum.

### Cheilitis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Clinical or diagnostic	Moderate symptoms; limiting	Severe symptoms;	-	-
observations only;	instrumental ADL or	intervention indicated;		
intervention not indicated	mild/moderate impact on	limiting self-care ADL or		
	age-appropriate normal daily	severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by inflammation of the lip.

**Navigational Note: -**

# Chylous ascites

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; medical	Severe symptoms; elective	Life-threatening	Death
diagnostic observations only;	intervention indicated (e.g.,	operative intervention	consequences; urgent	
intervention not indicated	fat-restricted diet);	indicated	operative intervention	
	paracentesis or tube		indicated	
	drainage indicated			

**Definition:** A disorder characterized by accumulation of milky fluid in the peritoneal cavity.

**Navigational Note: -**

# **Colitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Abdominal pain; mucus or	Severe abdominal pain;	Life-threatening	Death
diagnostic observations only;	blood in stool	peritoneal signs	consequences; urgent	
intervention not indicated			intervention indicated	

**Definition:** A disorder characterized by inflammation of the colon.

#### Colonic fistula

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the large intestine and another organ or anatomic site.

**Navigational Note: -**

#### **Colonic obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Hospitalization indicated;	Life-threatening	Death
diagnostic observations only;	function	invasive intervention	consequences; urgent	
intervention not indicated		indicated	operative intervention	
			indicated	

**Definition:** A disorder characterized by blockage of the normal flow of the intestinal contents in the colon.

**Navigational Note: -**

# **Colonic perforation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Invasive intervention not	Invasive intervention	Life-threatening	Death
	indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by a rupture in the colonic wall.

Navigational Note: Consider Gastrointestinal disorders: Colitis.

#### **Colonic stenosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function	tube feeding or	consequences; urgent	
intervention not indicated		hospitalization indicated;	operative intervention	
		elective operative	indicated	
		intervention indicated		

**Definition:** A disorder characterized by a narrowing of the lumen of the colon.

**Navigational Note: -**

#### Colonic ulcer

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function	TPN indicated; elective	consequences; urgent	
intervention not indicated		invasive intervention	operative intervention	
		indicated	indicated	

**Definition:** A disorder characterized by a circumscribed, erosive lesion on the mucosal surface of the colon.

**Navigational Note: -**

# Constipation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema	Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Obstipation with manual evacuation indicated; limiting self-care ADL or severe impact on age-appropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A disorder characterized by irregular and infrequent or difficult evacuation of the bowels.

### **Dental caries**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
One or more dental caries,	Dental caries involving the	Dental caries resulting in	-	-
not involving the root	root	pulpitis or periapical abscess		
		or resulting in tooth loss		

**Definition:** A disorder characterized by the decay of a tooth, in which it becomes softened, discolored and/or porous.

Navigational Note: -

### Diarrhea

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Change in consistency or	Increase of 4 - 6 stools per	Increase of >=7 stools per	Life-threatening	Death
frequency	day over baseline; moderate	day over baseline;	consequences; urgent	
	increase in ostomy output compared to baseline; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric); change in consistency or frequency AND limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity	hospitalization indicated; severe increase in ostomy output compared to baseline; requires IV intervention; limiting self-care ADL or severe impact on age- appropriate normal daily activity (pediatric)	intervention indicated	
	(pediatric)			

**Definition:** A disorder characterized by an increase in frequency and/or loose or watery bowel movements.

**Navigational Note:** Consider Gastrointestinal disorders: Colitis, Enterocolitis.

## **Dry mouth**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Symptomatic (e.g., dry or	Moderate symptoms; oral	Inability to adequately	-	-
thick saliva) without	intake alterations (e.g.,	aliment orally; tube feeding		
significant dietary alteration;	copious water, other	or TPN indicated;		
unstimulated saliva flow >0.2	lubricants, diet limited to	unstimulated saliva <0.1		
ml/min	purees and/or soft, moist	ml/min		
	foods); unstimulated saliva			
	0.1 to 0.2 ml/min			

**Definition:** A disorder characterized by reduced salivary flow in the oral cavity.

**Navigational Note:** If related to syndromes not present in CTCAE (ex. Sjogren's syndrome, etc.), report as Other, specify in the most representative SOC.

### **Duodenal fistula**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the duodenum and another organ or anatomic site. **Navigational Note:** -

## **Duodenal hemorrhage**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the duodenum. **Navigational Note:** Consider Gastrointestinal disorders: Enterocolitis.

#### **Duodenal obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Hospitalization indicated;	Life-threatening	Death
diagnostic observations only;	function	invasive intervention	consequences; urgent	
intervention not indicated		indicated	operative intervention	
			indicated	

**Definition:** A disorder characterized by blockage of the normal flow of stomach contents through the duodenum.

**Navigational Note: -**

## **Duodenal perforation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Invasive intervention not	Invasive intervention	Life-threatening	Death
	indicated	indicated	consequences; urgent	
			operative intervention	
			indicated	

**Definition:** A disorder characterized by a rupture in the duodenal wall. **Navigational Note:** Consider Gastrointestinal disorders: Enterocolitis.

### **Duodenal stenosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function	tube feeding or	consequences; urgent	
intervention not indicated		hospitalization indicated;	operative intervention	
		elective operative	indicated	
		intervention indicated		

**Definition:** A disorder characterized by a narrowing of the lumen of the duodenum.

#### **Duodenal ulcer**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Severely altered GI function; TPN indicated; elective invasive intervention indicated; limiting self-care ADL or severe impact on age- appropriate normal daily activity (pediatric)	Life-threatening consequences; urgent operative intervention indicated	Death

**Definition:** A disorder characterized by a circumscribed, erosive lesion on the mucosal surface of the duodenal wall.

**Navigational Note: -**

## Dyspepsia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Severe symptoms; operative	-	-
not indicated	medical intervention	intervention indicated		
	indicated			

**Definition:** A disorder characterized by an uncomfortable, often painful feeling in the stomach, resulting from impaired digestion.

Symptoms include burning stomach, bloating, heartburn, nausea and vomiting.

Navigational Note: Consider Gastrointestinal disorders: Gastritis, Gastroparesis.

# Dysphagia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Symptomatic, able to eat regular diet	Symptomatic and altered eating/swallowing	Severely altered eating/swallowing; tube feeding, TPN, or	Life-threatening consequences; urgent intervention indicated	Death
		hospitalization indicated		

**Definition:** A disorder characterized by difficulty in swallowing.

#### **Enterocolitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Abdominal pain; mucus or	Severe or persistent	Life-threatening	Death
diagnostic observations only;	blood in stool	abdominal pain; fever; ileus;	consequences; urgent	
intervention not indicated		peritoneal signs	intervention indicated	

**Definition:** A disorder characterized by inflammation of the small and large intestines.

**Navigational Note:** If reporting a known abnormality of the colon, use Gastrointestinal disorders: Colitis. If reporting a documented infection, use Infections and infestations: Enterocolitis infectious.

#### **Enterovesical fistula**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the urinary bladder and the intestine.

Navigational Note: -

# Esophageal fistula

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the esophagus and another organ or anatomic site.

**Navigational Note: -**

# Esophageal hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the esophagus.

## **Esophageal necrosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Inability to aliment	Life-threatening	Death
		adequately by Gl tract;	consequences; urgent	
		invasive intervention	operative intervention	
		indicated	indicated	

**Definition:** A disorder characterized by a necrotic process occurring in the esophageal wall.

**Navigational Note: -**

# **Esophageal obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Hospitalization indicated;	Life-threatening	Death
diagnostic observations only;	function; limiting	invasive intervention	consequences; urgent	
intervention not indicated	instrumental ADL or	indicated; limiting self care	intervention indicated	
	mild/moderate impact on	ADL or severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by blockage of the normal flow of the contents in the esophagus.

**Navigational Note: -**

# Esophageal pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the esophageal region.

**Navigational Note:** Record final diagnosis/cause once determined.

## **Esophageal perforation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Invasive intervention not	Invasive intervention	Life-threatening	Death
	indicated	indicated	consequences; urgent	
			operative intervention	
			indicated	

**Definition:** A disorder characterized by a rupture in the wall of the esophagus.

Navigational Note: -

## **Esophageal stenosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function	tube feeding or	consequences; urgent	
intervention not indicated		hospitalization indicated;	operative intervention	
		elective operative	indicated	
		intervention indicated		

**Definition:** A disorder characterized by a narrowing of the lumen of the esophagus.

**Navigational Note: -**

# Esophageal ulcer

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function; limiting	TPN indicated; elective	consequences; urgent	
intervention not indicated	instrumental ADL or	invasive intervention	operative intervention	
	mild/moderate impact on	indicated; limiting self-care	indicated	
	age-appropriate normal daily	ADL or severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by a circumscribed, erosive lesion on the mucosal surface of the esophageal wall.

# Esophageal varices hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Self-limited; intervention not	Hospitalization	Life-threatening	Death
	indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from esophageal varices.

Navigational Note: -

# **Esophagitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered	Severely altered	Life-threatening	Death
diagnostic observations only;	eating/swallowing; oral	eating/swallowing; tube	consequences; urgent	
intervention not indicated	supplements indicated	feeding, TPN, or	operative intervention	
		hospitalization indicated	indicated	

**Definition:** A disorder characterized by inflammation of the esophageal wall.

**Navigational Note: -**

### **Fecal incontinence**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Occasional use of pads	Daily use of pads required	Severe symptoms; elective	-	-
required		operative intervention		
		indicated		

**Definition:** A disorder characterized by inability to control the escape of stool from the rectum.

**Navigational Note: -**

#### **Flatulence**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate; persistent;	1	-	-
not indicated	psychosocial sequelae			

**Definition:** A disorder characterized by a discharge of excessive gas from the lower GI tract.

#### **Gastric fistula**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the stomach and another organ or anatomic site.

**Navigational Note: -**

# Gastric hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the gastric wall.

Navigational Note: -

### **Gastric necrosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Inability to aliment	Life-threatening	Death
		adequately by Gl tract;	consequences; urgent	
		invasive intervention	operative intervention	
		indicated	indicated	

**Definition:** A disorder characterized by a necrotic process occurring in the gastric wall.

**Navigational Note: -**

## **Gastric perforation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Invasive intervention not	Invasive intervention	Life-threatening	Death
	indicated	indicated	consequences; urgent	
			operative intervention	
			indicated	

**Definition:** A disorder characterized by a rupture in the stomach wall.

#### **Gastric stenosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function	tube feeding or	consequences; urgent	
intervention not indicated		hospitalization indicated;	operative intervention	
		elective operative	indicated	
		intervention indicated		

**Definition:** A disorder characterized by a narrowing of the lumen of the stomach.

**Navigational Note: -**

#### **Gastric ulcer**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function; medical	TPN indicated; elective	consequences; urgent	
intervention not indicated	intervention indicated;	invasive intervention	operative intervention	
	limiting instrumental ADL or	indicated; limiting self-care	indicated	
	mild/moderate impact on	ADL or severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by a circumscribed, erosive lesion on the mucosal surface of the stomach.

Navigational Note: -

# Gastritis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Severely altered eating or	Life-threatening	Death
diagnostic observations only;	function; medical	gastric function; TPN or	consequences; urgent	
intervention not indicated	intervention indicated	hospitalization indicated	operative intervention	
			indicated	

**Definition:** A disorder characterized by inflammation of the stomach.

### Gastroesophageal reflux disease

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Severe symptoms; operative	-	-
not indicated	medical intervention	intervention indicated		
	indicated			

**Definition:** A disorder characterized by reflux of the gastric and/or duodenal contents into the distal esophagus. It is chronic in nature and usually caused by incompetence of the lower esophageal sphincter, and may result in injury to the esophageal mucosal. Symptoms include heartburn and acid indigestion.

Navigational Note: -

## Gastrointestinal disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

Definition: -

**Navigational Note: -**

### **Gastrointestinal fistula**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between any part of the gastrointestinal system and another organ or anatomic site.

### **Gastrointestinal pain**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the gastrointestinal region.

Navigational Note: Consider Gastrointestinal disorders: Colitis, Enterocolitis. Record final diagnosis/cause once determined.

## **Gastroparesis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild nausea, early satiety and	Moderate symptoms; able to	Weight loss >=20% from	Life-threatening	-
bloating, able to maintain	maintain nutrition with	baseline; tube feeding or TPN	consequences; urgent	
caloric intake on regular diet	dietary and lifestyle	indicated; elective operative	intervention indicated	
	modifications; may need	intervention indicated		
	pharmacologic intervention			

**Definition:** A disorder characterized by an incomplete paralysis of the muscles of the stomach wall resulting in delayed emptying of the gastric contents into the small intestine.

Navigational Note: -

## Gingival pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain interfering	Severe pain; inability to	-	-
	with oral intake	aliment orally		

**Definition:** A disorder characterized by a sensation of marked discomfort in the gingival region.

**Navigational Note:** Record final diagnosis/cause once determined.

#### Hematemesis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by the vomiting of blood.

Navigational Note: Record final diagnosis/cause once determined.

#### Hematochezia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by the passage of fresh blood per anus, usually in or with stools.

Navigational Note: Consider Gastrointestinal disorders: Colitis, Enterocolitis, Proctitis; Record final diagnosis/cause once determined.

# Hemorrhoidal hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the hemorrhoids.

Navigational Note: -

### **Hemorrhoids**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; banding or	Severe symptoms; invasive	-	-
diagnostic observations only;	medical intervention	intervention indicated		
intervention not indicated	indicated			

**Definition:** A disorder characterized by the presence of dilated veins in the rectum and surrounding area.

#### lleal fistula

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the ileum and another organ or anatomic site.

Navigational Note: -

# Ileal hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the ileal wall. **Navigational Note:** Consider Gastrointestinal disorders: Enterocolitis.

#### **Ileal obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Hospitalization indicated;	Life-threatening	Death
diagnostic observations only;	function; naso-gastric tube	invasive intervention	consequences; urgent	
intervention not indicated	indicated; limiting	indicated; long intestinal tube	operative intervention	
	instrumental ADL or	indicated; limiting self-care	indicated	
	mild/moderate impact on	ADL or severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by blockage of the normal flow of the intestinal contents in the ileum.

## **Ileal perforation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Invasive intervention not	Invasive intervention	Life-threatening	Death
	indicated	indicated	consequences; urgent	
			operative intervention	
			indicated	

**Definition:** A disorder characterized by a rupture in the ileal wall.

Navigational Note: Consider Gastrointestinal disorders: Enterocolitis.

### **Ileal stenosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function	tube feeding or	consequences; urgent	
intervention not indicated		hospitalization indicated;	operative intervention	
		elective operative	indicated	
		intervention indicated		

**Definition:** A disorder characterized by a narrowing of the lumen of the ileum.

**Navigational Note: -**

## lleal ulcer

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function	TPN indicated; elective	consequences; urgent	
intervention not indicated		invasive intervention	operative intervention	
		indicated	indicated	

**Definition:** A disorder characterized by a circumscribed, erosive lesion on the mucosal surface of the ileum.

#### **Ileus**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic and radiologic	Symptomatic; altered GI	Severely altered GI function;	Life-threatening	Death
observations only	function; bowel rest	TPN indicated; tube	consequences; urgent	
	indicated	placement indicated	intervention indicated	

**Definition:** A disorder characterized by failure of the ileum to transport intestinal contents.

Navigational Note: -

### Intra-abdominal hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms;	Hospitalization	Life-threatening	Death
	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding in the abdominal cavity.

**Navigational Note: -**

## Jejunal fistula

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the jejunum and another organ or anatomic site.

Navigational Note: -

# Jejunal hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the jejunal wall. **Navigational Note:** Consider Gastrointestinal disorders: Enterocolitis.

## Jejunal obstruction

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Hospitalization indicated;	Life-threatening	Death
diagnostic observations only;	function; limiting	invasive intervention	consequences; urgent	
intervention not indicated	instrumental ADL or	indicated; limiting self care	operative intervention	
	mild/moderate impact on	ADL or severe impact on age-	indicated	
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by blockage of the normal flow of the intestinal contents in the jejunum.

**Navigational Note: -**

# Jejunal perforation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Invasive intervention not	Invasive intervention	Life-threatening	Death
	indicated	indicated	consequences; urgent	
			operative intervention	
			indicated	

**Definition:** A disorder characterized by a rupture in the jejunal wall. **Navigational Note:** Consider Gastrointestinal disorders: Enterocolitis.

# Jejunal stenosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function	tube feeding or	consequences; urgent	
intervention not indicated		hospitalization indicated;	operative intervention	
		elective operative	indicated	
		intervention indicated		

**Definition:** A disorder characterized by a narrowing of the lumen of the jejunum.

### Jejunal ulcer

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function	TPN indicated; elective	consequences; urgent	
intervention not indicated		invasive intervention	operative intervention	
		indicated	indicated	

**Definition:** A disorder characterized by a circumscribed, erosive lesion on the mucosal surface of the jejunum.

Navigational Note: -

# Lip pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort of the lip.

Navigational Note: Record final diagnosis/cause once determined.

## Malabsorption

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Altered diet; oral intervention	Inability to aliment	Life-threatening	Death
	indicated	adequately; TPN indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by inadequate absorption of nutrients in the small intestine. Symptoms include abdominal marked discomfort, bloating and diarrhea.

#### Melena

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by black, tarry stools.

Navigational Note: Record final diagnosis/cause once determined.

#### **Mucositis oral**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate pain or ulcer that	Severe pain; interfering with	Life-threatening	Death
symptoms; intervention not	does not interfere with oral	oral intake	consequences; urgent	
indicated	intake; modified diet		intervention indicated	
	indicated			

**Definition:** A disorder characterized by ulceration or inflammation of the oral mucosal.

**Navigational Note: -**

#### Nausea

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Loss of appetite without	Oral intake decreased	Inadequate oral caloric or	-	-
alteration in eating habits	without significant weight	fluid intake; tube feeding,		
	loss, dehydration or	TPN, or hospitalization		
	malnutrition; IV intervention	indicated		
	indicated			

**Definition:** A disorder characterized by a queasy sensation and/or the urge to vomit.

**Navigational Note:** Consider Gastrointestinal disorders: Enterocolitis, Gastritis and/or Endocrine disorders: Adrenal insufficiency, Hypophysitis.

### **Obstruction gastric**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Hospitalization indicated;	Life-threatening	Death
diagnostic observations only;	function; limiting	invasive intervention	consequences; urgent	
intervention not indicated	instrumental ADL or	indicated; limiting self care	operative intervention	
	mild/moderate impact on	ADL or severe impact on age-	indicated	
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by blockage of the normal flow of the contents in the stomach.

**Navigational Note: -**

# Oral cavity fistula

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the oral cavity and another organ or anatomic site.

**Navigational Note: -**

## Oral dysesthesia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild discomfort; not	Moderate pain; interfering	Disabling pain; tube feeding	-	-
interfering with oral intake	with oral intake	or TPN indicated		

**Definition:** A disorder characterized by a burning or tingling sensation on the lips, tongue or entire mouth.

Navigational Note: -

## Oral hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the mouth.

### Oral pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the mouth, tongue or lips.

Navigational Note: Record final diagnosis/cause once determined.

#### Pancreatic duct stenosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function	tube feeding or	consequences; urgent	
intervention not indicated		hospitalization indicated;	operative intervention	
		elective operative	indicated	
		intervention indicated		

**Definition:** A disorder characterized by a narrowing of the lumen of the pancreatic duct.

**Navigational Note: -**

### Pancreatic fistula

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the pancreas and another organ or anatomic site.

### Pancreatic hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the pancreas.

Navigational Note: -

# Pancreatic insufficiency

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic and	Increase in stool frequency,	Sequelae of absorption	-	-
pancreatic enzymes <lln< td=""><td>bulk, or odor; steatorrhea</td><td>deficiency</td><td></td><td></td></lln<>	bulk, or odor; steatorrhea	deficiency		

**Definition:** A disorder characterized by impaired exocrine pancreatic function usually associated with decreased pancreatic exocrine enzymes production.

**Navigational Note: -**

#### **Pancreatic necrosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Tube feeding or TPN	Life-threatening	Death
		indicated; invasive	consequences; urgent	
		intervention indicated	operative intervention	
			indicated	

**Definition:** A disorder characterized by a necrotic process occurring in the pancreas.

**Navigational Note: -**

#### **Pancreatitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Radiologic findings only	Severe pain; vomiting;	Life-threatening	Death
		medical intervention	consequences; urgent	
		indicated (e.g., analgesia,	intervention indicated	
		nutritional support)		

**Definition:** A disorder characterized by inflammation of the pancreas with no documented pancreas infection.

#### Periodontal disease

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Gingival recession or	Moderate gingival recession	Spontaneous bleeding;	-	-
gingivitis; limited bleeding on	or gingivitis; multiple sites of	severe bone loss with or		
probing; mild local bone loss	bleeding on probing;	without tooth loss;		
	moderate bone loss	osteonecrosis of maxilla or		
		mandible		

**Definition:** A disorder in the gingival tissue around the teeth.

Navigational Note: -

#### Peritoneal necrosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Tube feeding or TPN	Life-threatening	Death
		indicated; invasive	consequences; urgent	
		intervention indicated	operative intervention	
			indicated	

**Definition:** A disorder characterized by a necrotic process occurring in the peritoneum.

**Navigational Note: -**

# **Proctitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Rectal discomfort, intervention not indicated	Symptomatic (e.g., rectal discomfort, passing blood or mucus); fecal urgency or stool incontinence; medical intervention indicated; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Severe symptoms; limiting self-care ADL or severe impact on age-appropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A disorder characterized by inflammation of the rectum.

**Navigational Note:** Consider Gastrointestinal disorders: Fecal incontinence.

#### **Rectal fissure**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic	Invasive intervention	-	-
		indicated		

**Definition:** A disorder characterized by a tear in the lining of the rectum.

**Navigational Note: -**

#### **Rectal fistula**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the rectum and another organ or anatomic site.

**Navigational Note: -**

#### **Rectal mucositis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate symptoms;	Severe symptoms; limiting	Life-threatening	Death
symptoms; intervention not	medical intervention	self-care ADL or severe	consequences; urgent	
indicated	indicated; limiting	impact on age-appropriate	operative intervention	
	instrumental ADL or	normal daily activity	indicated	
	mild/moderate impact on	(pediatric)		
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by ulceration or inflammation of the mucous membrane of the rectum.

#### **Rectal necrosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Tube feeding or TPN	Life-threatening	Death
		indicated; invasive	consequences; urgent	
		intervention indicated	operative intervention	
			indicated	

**Definition:** A disorder characterized by a necrotic process occurring in the rectal wall.

**Navigational Note: -**

### **Rectal obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Hospitalization indicated;	Life-threatening	Death
diagnostic observations only;	function; limiting	invasive intervention	consequences; urgent	
intervention not indicated	instrumental ADL or	indicated; limiting self care	operative intervention	
	mild/moderate impact on	ADL or severe impact on age-	indicated	
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by blockage of the normal flow of the intestinal contents in the rectum.

Navigational Note: -

# **Rectal pain**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the rectal region.

**Navigational Note:** Record final diagnosis/cause once determined.

# **Rectal perforation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Invasive intervention not	Invasive intervention	Life-threatening	Death
	indicated	indicated	consequences; urgent	
			operative intervention	
			indicated	

**Definition:** A disorder characterized by a rupture in the rectal wall.

**Navigational Note: -**

### **Rectal stenosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function	tube feeding or	consequences; urgent	
intervention not indicated		hospitalization indicated;	operative intervention	
		elective operative	indicated	
		intervention indicated		

**Definition:** A disorder characterized by a narrowing of the lumen of the rectum.

**Navigational Note: -**

### **Rectal ulcer**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function (e.g., altered dietary	TPN indicated; elective	consequences; urgent	
intervention not indicated	habits, vomiting, diarrhea)	invasive intervention	operative intervention	
		indicated	indicated	

**Definition:** A disorder characterized by a circumscribed, erosive lesion on the mucosal surface of the rectum.

# Retroperitoneal hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Self-limited; intervention	Hospitalization	Life-threatening	Death
	indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the retroperitoneal area.

**Navigational Note: -**

# Salivary duct inflammation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Slightly thickened saliva;	Thick, ropy, sticky saliva;	Acute salivary gland necrosis;	Life-threatening	Death
slightly altered taste (e.g.,	markedly altered taste;	severe secretion-induced	consequences; urgent	
metallic)	alteration in diet indicated;	symptoms (e.g., thick	intervention indicated	
	secretion-induced symptoms;	saliva/oral secretions or		
	limiting instrumental ADL or	gagging); tube feeding or TPN		
	mild/moderate impact on	indicated; limiting self-care		
	age-appropriate normal daily	ADL or severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by inflammation of the salivary duct.

**Navigational Note: -**

# Salivary gland fistula

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between a salivary gland and another organ or anatomic site. **Navigational Note:** -

#### **Small intestinal mucositis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate symptoms;	Severe pain; interfering with	Life-threatening	Death
symptoms; intervention not	medical intervention	oral intake; tube feeding, TPN	consequences; urgent	
indicated	indicated; limiting	or hospitalization indicated;	intervention indicated	
	instrumental ADL or	limiting self-care ADL or		
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by ulceration or inflammation of the mucous membrane of the small intestine.

Navigational Note: -

#### **Small intestinal obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Hospitalization indicated;	Life-threatening	Death
diagnostic observations only;	function; limiting	invasive intervention	consequences; urgent	
intervention not indicated	instrumental ADL or	indicated; limiting self care	operative intervention	
	mild/moderate impact on	ADL or severe impact on age-	indicated	
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by blockage of the normal flow of the intestinal contents of the small intestine.

Navigational Note: -

# **Small intestinal perforation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Invasive intervention not	Invasive intervention	Life-threatening	Death
	indicated	indicated	consequences; urgent	
			operative intervention	
			indicated	

**Definition:** A disorder characterized by a rupture in the small intestine wall.

**Navigational Note:** Consider Gastrointestinal disorders: Enterocolitis.

#### **Small intestinal stenosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Symptomatic and severely	Life-threatening	Death
diagnostic observations only;	function	altered GI function; tube	consequences; urgent	
intervention not indicated		feeding, TPN or	operative intervention	
		hospitalization indicated;	indicated	
		non-emergent operative		
		intervention indicated		

**Definition:** A disorder characterized by a narrowing of the lumen of the small intestine.

**Navigational Note: -**

### Small intestine ulcer

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function; limiting	TPN indicated; elective	consequences; urgent	
intervention not indicated	instrumental ADL or	invasive intervention	operative intervention	
	mild/moderate impact on	indicated; limiting self-care	indicated	
	age-appropriate normal daily	ADL or severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by a circumscribed, erosive lesion on the mucosal surface of the small intestine.

**Navigational Note: -**

# Stomach pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the stomach.

**Navigational Note:** Record final diagnosis/cause once determined.

# Tooth development disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; hypoplasia of	Impairment correctable with	Maldevelopment with	-	-
tooth or enamel	oral surgery	impairment not surgically		
		correctable; limiting self-care		
		ADL or severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by a pathological process of the teeth occurring during tooth development.

Navigational Note: -

### **Tooth discoloration**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Surface stains	-	-	-	-

**Definition:** A disorder characterized by a change in tooth hue or tint.

**Navigational Note: -**

### Toothache

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the tooth.

### **Typhlitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Symptomatic (e.g.,	Life-threatening	Death
		abdominal pain, fever,	consequences; urgent	
		change in bowel habits with	operative intervention	
		ileus); peritoneal signs	indicated	

**Definition:** A disorder characterized by necrotizing enterocolitis in neutropenic patients. Also referred to as neutropenic enterocolitis, ileocecal syndrome, or cecitis.

**Navigational Note:** Includes Clostridioides difficile (c. diff, c. difficile). Also report Investigations: Neutrophil count decreased; Also consider Infections and infestations: Cecal infection.

# Upper gastrointestinal hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the upper gastrointestinal tract (oral cavity, pharynx, esophagus, and stomach). **Navigational Note:** -

### Visceral arterial ischemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Brief (<24 hrs) episode of	Prolonged (>=24 hrs) or	Life-threatening	Death
	ischemia managed medically	recurring symptoms and/or	consequences; evidence of	
	and without permanent	invasive intervention	end organ damage; urgent	
	deficit	indicated	operative intervention	
			indicated	

**Definition:** A disorder characterized by a decrease in blood supply due to narrowing or blockage of a visceral (mesenteric) artery. **Navigational Note:** -

# **Vomiting**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Intervention not indicated	Initiation of outpatient IV	Initiation of tube feeding, or	Life-threatening	Death
	hydration; medical	TPN; hospitalization	consequences	
	intervention indicated	indicated		

**Definition:** A disorder characterized by the reflexive act of ejecting the contents of the stomach through the mouth. **Navigational Note:** Consider Gastrointestinal disorders: Enterocolitis, Gastritis and/or Endocrine disorders: Adrenal insufficiency, Hypophysitis.

# **General disorders and administration site conditions**

#### Chills

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild sensation of cold;	Moderate tremor of the	Severe or prolonged, not	-	-
shivering; chattering of teeth	entire body; narcotics	responsive to narcotics		
	indicated			

**Definition:** A disorder characterized by a sensation of cold that often marks a physiologic response to sweating after a fever.

**Navigational Note:** Consider Injury, poisoning and procedural complications: Infusion related reaction.

#### **Death neonatal**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	Neonatal loss of life	-

**Definition:** Newborn death occurring during the first 28 days after birth.

**Navigational Note: -**

#### **Death NOS**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	-	Death

**Definition:** Death that cannot be attributed to a CTCAE term associated with Grade 5.

Navigational Note: If death is due to an AE (ex., Cardiac disorders: Cardiac arrest), report as a Grade 5 event under that AE.

### **Disease progression**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	-	Death

**Definition:** Death due to disease progression that cannot be attributed to a CTCAE term associated with Grade 5.

Navigational Note: If death is due to an AE (ex., Cardiac disorders: Cardiac arrest), report as a Grade 5 event under that AE.

#### Edema face

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized edema	Moderate localized edema;	Severe swelling; limiting self-	-	-
	limiting instrumental ADL or	care ADL or severe impact on		
	mild/moderate impact on	age-appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by swelling due to excessive fluid accumulation in facial area tissues.

Navigational Note: Record final diagnosis/cause once determined.

# Facial pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the face.

Navigational Note: Record final diagnosis/cause once determined.

# **Fatigue**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Fatigue relieved by rest	Fatigue not relieved by rest;	Fatigue not relieved by rest,	-	-
	limiting instrumental ADL or	limiting self-care ADL or		
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by a state of generalized weakness with a pronounced inability to summon sufficient energy to accomplish daily activities.

Navigational Note: Record final diagnosis/cause once determined.

#### **Fever**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
38.0 - 39.0 degrees C (100.4 -	>39.0 - 40.0 degrees C (102.3	>40.0 degrees C (>104.0	>40.0 degrees C (>104.0	Death
102.2 degrees F)	- 104.0 degrees F)	degrees F) for <=24 hrs	degrees F) for >24 hrs	

**Definition:** A disorder characterized by elevation of the body's temperature above the upper limit of normal.

Navigational Note: Consider Injury, poisoning and procedural complications: Infusion related reaction.

# Flu like symptoms

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild flu-like symptoms	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
present	instrumental ADL or	self-care ADL or severe		
	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by a group of symptoms similar to those observed in patients with the flu. It includes fever, chills, body aches, malaise, loss of appetite and dry cough.

**Navigational Note:** Synonym: Flu, Influenza; Consider Injury, poisoning and procedural complications: Infusion related reaction.

# **Gait disturbance**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild change in gait (e.g.,	Moderate change in gait (e.g.,	Limiting self-care ADL or	-	-
wide-based, limping or	wide-based, limping or	severe impact on age-		
hobbling)	hobbling); assistive device	appropriate normal daily		
	indicated; limiting	activity (pediatric)		
	instrumental ADL or			
	mild/moderate impact on			
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by walking difficulties.

# General disorders and administration site conditions - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** -

**Navigational Note: -**

#### Generalized edema

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Noted on exam; 1+ pitting	Oral therapy initiated;	Interferes with self-care ADL	Life-threatening	-
edema	interfering with instrumental	or severe impact on age-	consequences	
	ADLs or mild/moderate	appropriate normal daily		
	impact on age-appropriate	activity (pediatric);		
	normal daily activity	intravenous IV therapy		
	(pediatric)	indicated; skin breakdown		

**Definition:** A disorder characterized by fluid accumulation in the tissues of the body including the skin.

Navigational Note: Record final diagnosis/cause once determined.

### Hypothermia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	35 - >32 degrees C; 95 - >89.6	32 - >28 degrees C; 89.6 -	<=28 degrees C; 82.4 degrees	Death
	degrees F	>82.4 degrees F	F; life-threatening	
			consequences (e.g., coma,	
			hypotension, pulmonary	
			edema, acidemia, ventricular	
			fibrillation)	

**Definition:** A disorder characterized by an abnormally low body temperature. Treatment is required when the body temperature is 35C (95F) or below.

**Navigational Note: -**

#### Infusion site extravasation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Painless edema	Erythema with associated	Ulceration or necrosis; severe	Life-threatening	Death
	symptoms (e.g., edema, pain,	tissue damage; operative	consequences; urgent	
	induration, phlebitis)	intervention indicated	intervention indicated	

**Definition:** A disorder characterized by leakage of the infusion into the surrounding tissue. Signs and symptoms may include induration, erythema, swelling, burning sensation and marked discomfort at the infusion site.

**Navigational Note: -**

# Injection site reaction

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Tenderness with or without	Pain; lipodystrophy; edema;	Ulceration or necrosis; severe	Life-threatening	Death
associated symptoms (e.g.,	phlebitis	tissue damage; operative	consequences; urgent	
warmth, erythema, itching)		intervention indicated	intervention indicated	

**Definition:** A disorder characterized by an intense adverse reaction (usually immunologic) developing at the site of an injection. **Navigational Note:** -

#### Localized edema

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized to dependent	Moderate localized edema	Severe localized edema and	-	-
areas, no disability or	and intervention indicated;	intervention indicated;		
functional impairment	limiting instrumental ADL or	limiting self-care ADL or		
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by swelling due to excessive fluid accumulation at a specific anatomic site.

**Navigational Note:** Prior to using this term consider specific edema areas and/or causes: Cardiac disorders: Heart failure; General disorders and administration site conditions: Edema face, Peripheral edema; Nervous system disorders: Edema cerebral; Respiratory, thoracic and mediastinal disorders: Laryngeal edema, Pulmonary edema; Eye disorders: Periorbital edema; Vascular disorders: Lymphedema. Record final diagnosis/cause once determined.

#### Malaise

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Uneasiness or lack of well	Uneasiness or lack of well	Uneasiness or lack of well	-	-
being	being limiting instrumental	being limiting self-care ADL		
	ADL or mild/moderate	or severe impact on age-		
	impact on age-appropriate	appropriate normal daily		
	normal daily activity	activity (pediatric)		
	(pediatric)			

**Definition:** A disorder characterized by a feeling of general discomfort or uneasiness, an out-of-sorts feeling.

### Multi-organ failure

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Shock with azotemia and	Life-threatening	Death
		acid-base disturbances;	consequences (e.g.,	
		significant coagulation	vasopressor dependent and	
		abnormalities	oliguric or anuric or ischemic	
			colitis or lactic acidosis)	

**Definition:** A disorder characterized by progressive deterioration of the lungs, liver, kidney and clotting mechanisms.

Navigational Note: -

# Non-cardiac chest pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the chest unrelated to a heart disorder.

Navigational Note: Record final diagnosis/cause once determined.

#### Pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by the sensation of marked discomfort, distress or agony.

**Navigational Note:** Prior to using this term consider using a specific body part pain term found throughout the CTCAE (over 40 different pain terms). Record final diagnosis/cause once determined.

### Peripheral edema

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Swelling or obscuration of anatomic architecture on close inspection	Readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily	Gross deviation from normal anatomic contour; limiting self-care ADL or severe impact on age-appropriate normal daily activity (pediatric)	-	-
	obliteration of skin folds; readily apparent deviation from normal anatomic contour; limiting instrumental ADL or mild/moderate impact on	self-care ADL or severe impact on age-appropriate normal daily activity		

**Definition:** A disorder characterized by swelling due to excessive fluid accumulation in the body periphery.

Navigational Note: Consider Cardiac disorders: Heart failure; Record final diagnosis/cause once determined.

### **Pneumatosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Moderate symptoms;	Severe symptoms; operative	Life-threatening	Death
diagnostic observations only;	medical intervention	intervention indicated	consequences; urgent	
intervention not indicated	indicated		operative intervention	
			indicated	

**Definition:** A finding of gas in the bowel wall.

Navigational Note: -

#### Sudden death NOS

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	-	Death

**Definition:** An unexpected death that cannot be attributed to a CTCAE term associated with Grade 5.

Navigational Note: If death is due to an AE (ex., Cardiac disorders: Cardiac arrest), report as a Grade 5 event under that AE.

# Vaccination site lymphadenopathy

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Local lymph node	Localized ulceration;	-	-	-
enlargement	generalized lymph node			
	enlargement			

**Definition:** A disorder characterized by lymph node enlargement after vaccination.

### **Bile duct stenosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered Gl	Severely altered GI function;	Life-threatening	Death
diagnostic observations only;	function; IV fluids indicated	invasive intervention	consequences; urgent	
intervention not indicated	<24 hrs	indicated	operative intervention	
			indicated	

**Definition:** A disorder characterized by a narrowing of the lumen of the bile duct.

**Navigational Note: -**

# **Biliary fistula**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the bile ducts and another organ or anatomic site.

**Navigational Note: -**

# **Biliary obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Symptomatic and severely	Life-threatening	Death
diagnostic observations only;	function; IV fluids indicated	altered GI function;	consequences; urgent	
intervention not indicated	<24 hrs	hospitalization indicated;	operative intervention	
		non-emergent operative	indicated	
		intervention indicated		

**Definition:** A disorder characterized by blockage of the normal flow of the normal flow of bile.

# **Budd-Chiari syndrome**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Medical management	Severe or medically	Life-threatening	Death
	indicated	significant but not	consequences; moderate to	
		immediately life-threatening;	severe encephalopathy;	
		hospitalization or	coma	
		prolongation of existing		
		hospitalization indicated;		
		asterixis; mild		
		encephalopathy		

**Definition:** A disorder characterized by occlusion of the hepatic veins and typically presents with abdominal pain, ascites and hepatomegaly.

Navigational Note: -

# Cholecystitis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Symptomatic; medical	Severe symptoms; invasive	Life-threatening	Death
	intervention indicated	intervention indicated	consequences; urgent	
			operative intervention	
			indicated	

**Definition:** A disorder characterized by inflammation involving the gallbladder. It may be associated with the presence of gallstones. **Navigational Note:** -

# Gallbladder fistula

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the gallbladder and another organ or anatomic site. **Navigational Note:** -

#### Gallbladder necrosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	Life-threatening	Death
			consequences; urgent	
			invasive intervention	
			indicated	

**Definition:** A disorder characterized by a necrotic process occurring in the gallbladder.

**Navigational Note: -**

### **Gallbladder obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; altered GI	Symptomatic and severely	Life-threatening	Death
diagnostic observations only;	function; IV fluids indicated	altered GI function;	consequences; urgent	
intervention not indicated	<24 hrs	hospitalization indicated;	operative intervention	
		non-emergent operative	indicated	
		intervention indicated		

**Definition:** A disorder characterized by blockage of the normal flow of the contents of the gallbladder.

**Navigational Note: -**

# Gallbladder pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the gallbladder region.

**Navigational Note:** Record final diagnosis/cause once determined.

# **Gallbladder perforation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	Life-threatening	Death
			consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by a rupture in the gallbladder wall.

Navigational Note: -

# **Hepatic failure**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Asterixis; mild	Life-threatening	Death
		encephalopathy; drug-	consequences; moderate to	
		induced liver injury (DILI);	severe encephalopathy;	
		limiting self-care ADL or	coma	
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by the inability of the liver to metabolize chemicals in the body. Laboratory test results reveal abnormal plasma levels of ammonia, bilirubin, lactic dehydrogenase, alkaline phosphatase, aminotransferase, and/or prolongation of prothrombin time (INR.) Drug-induced liver injury (DILI) as defined by Hy's Law.

**Navigational Note: -**

# Hepatic hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the liver.

# **Hepatic necrosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	Life-threatening	Death
			consequences; urgent	
			invasive intervention	
			indicated	

**Definition:** A disorder characterized by a necrotic process occurring in the hepatic parenchyma.

**Navigational Note: -**

# Hepatic pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the liver region.

Navigational Note: Record final diagnosis/cause once determined.

# **Hepatitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms;	Symptomatic liver	Life-threatening	Death
	medical intervention	dysfunction; compensated	consequences; severe	
	indicated	cirrhosis; hospitalization or	decompensated liver	
		prolongation of existing	function (e.g., coagulopathy,	
		hospitalization indicated	encephalopathy, coma)	

**Definition:** A disorder characterized by inflammation of the liver.

**Navigational Note:** Consider Infections and infestations: Hepatitis viral, Hepatobiliary disorders: Hepatic failure. Report Autoimmune hepatitis under Hepatobiliary disorders: Other, specify.

# Hepatobiliary disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** -

Navigational Note: -

### Perforation bile duct

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Invasive intervention	Life-threatening	Death
		indicated	consequences; urgent	
			operative intervention	
			indicated	

**Definition:** A disorder characterized by a rupture in the wall of the extrahepatic or intrahepatic bile duct. **Navigational Note:** -

# **Portal hypertension**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Decreased portal vein flow	Reversal/retrograde portal	Life-threatening	Death
		vein flow; associated with	consequences; urgent	
		varices and/or ascites	intervention indicated	

**Definition:** A disorder characterized by an increase in blood pressure in the portal venous system.

### Portal vein thrombosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Intervention not indicated	Medical intervention	Life-threatening	Death
		indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by the formation of a thrombus (blood clot) in the portal vein.

Navigational Note: -

# Sinusoidal obstruction syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Blood bilirubin 2 - 5 mg/dL;	Blood bilirubin >5 mg/dL;	Life-threatening	Death
	minor interventions required	coagulation modifier	consequences (e.g.,	
	(i.e., blood product, diuretic,	indicated (e.g., defibrotide);	ventilatory support, dialysis,	
	oxygen)	reversal of flow on	plasmapheresis, peritoneal	
		ultrasound	drainage)	

**Definition:** A disorder characterized by severe hepatic injury as a result of the blood vessels of the liver becoming inflamed and/or blocked.

# **Allergic reaction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Systemic intervention not	Oral intervention indicated	Bronchospasm;	Life-threatening	Death
indicated		hospitalization indicated for	consequences; urgent	
		clinical sequelae; IV	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an adverse general response from exposure to an allergen.

**Navigational Note:** If related to infusion, consider Injury, poisoning and procedural complications: Infusion related reaction. If related to immunization, consider Injury, poisoning and procedural complications: Systemic post-immunization reaction. Do not report both.

# **Anaphylaxis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Symptomatic bronchospasm,	Life-threatening	Death
		with or without urticaria;	consequences; urgent	
		parenteral intervention	intervention indicated	
		indicated; allergy-related		
		edema/angioedema;		
		hypotension		

**Definition:** A disorder characterized by an acute inflammatory reaction resulting from the release of histamine and histamine-like substances from mast cells, causing a hypersensitivity immune response. Clinically, it presents with breathing difficulty, dizziness, hypotension, cyanosis and loss of consciousness and may lead to death.

**Navigational Note:** If related to infusion, consider Injury, poisoning and procedural complications: Infusion related reaction. Do not report both.

#### **Autoimmune disorder**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; serologic or	Evidence of autoimmune	Autoimmune reactions	Life-threatening	Death
other evidence of	reaction involving a non-	involving major organ (e.g.,	consequences; urgent	
autoimmune reaction, with	essential organ or function	colitis, anemia, myocarditis,	intervention indicated	
normal organ function;	(e.g., hypothyroidism)	kidney)		
intervention not indicated				

**Definition:** A disorder characterized by loss of function or tissue destruction of an organ or multiple organs, arising from humoral or cellular immune responses of the individual to his own tissue constituents.

Navigational Note: Prior to using this term consider specific autoimmune AEs.

### Cytokine release syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Fever with or without	Hypotension responding to	Hypotension managed with	Life-threatening	Death
constitutional symptoms	fluids; hypoxia requiring low-	one pressor; hypoxia	consequences; urgent	
	flow nasal cannula or blow-	requiring high-flow nasal	intervention indicated	
	by	cannula, facemask,		
		nonrebreather mask, or		
		Venturi mask		

**Definition:** A disorder characterized by fever, tachypnea, headache, tachycardia, hypotension, rash, and/or hypoxia caused by the release of cytokines.

**Navigational Note:** Consider reporting other organ dysfunctions including neurological toxicities such as: Psychiatric disorders: Confusion, Hallucinations; Nervous system disorders: Dysphasia, Headache, Seizure, Tremor.

#### **Graft versus host disease**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Oral intervention indicated	IV intervention indicated	Life-threatening	Death
			consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by donor cells attacking the recipient's organs.

# Immune system disorders - Other, specify

Grade 2	Grade 3	Grade 4	Grade 5
Moderate; minimal, local or noninvasive intervention indicated; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; limiting self-care ADL or severe impact on ageappropriate normal daily	Life-threatening consequences; urgent intervention indicated	Death
	Moderate; minimal, local or noninvasive intervention indicated; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily	Moderate; minimal, local or noninvasive intervention indicated; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)  Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; limiting self-care ADL or severe impact on age-	Moderate; minimal, local or noninvasive intervention indicated; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)  Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; limiting self-care ADL or severe impact on ageappropriate normal daily

**Definition:** -

Navigational Note: Use for diagnoses not present in CTCAE (ex. Sjogren's syndrome, etc.).

# Secondary hemophagocytic lymphohistiocytosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate symptoms;	Severe or medically	Life-threatening	Death
symptoms; requiring clinical	intervention indicated (e.g.,	significant but not	consequences; urgent	
and/or diagnostic evaluation;	immunosuppressive agents)	immediately life threatening;	intervention indicated	
intervention not indicated		hospitalization or		
		prolongation of existing		
		hospitalization indicated		

**Definition:** A disorder characterized by the development of a pathological and biochemical hyperinflammatory syndrome characterized by fever, cytopenias, hyperferritinemia, coagulopathy, hypofibrinogenemia and/or transaminitis and is attributable to therapy.

### Serum sickness

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Clinical or diagnostic	Moderate arthralgia; fever,	Severe arthralgia or arthritis;	Life-threatening	Death
observations only;	rash, urticaria, antihistamines	extensive rash; steroids or IV	consequences; pressor or	
intervention not indicated	indicated	fluids indicated	ventilatory support indicated	

**Definition:** A disorder characterized by a delayed-type hypersensitivity reaction to foreign proteins derived from an animal serum. It occurs approximately six to twenty-one days following the administration of the foreign antigen. Symptoms include fever, arthralgias, myalgias, skin eruptions, lymphadenopathy, chest marked discomfort and dyspnea.

#### **Abdominal infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the abdominal cavity.

**Navigational Note: -**

# **Anorectal infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized, local intervention	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
indicated	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the anal area and the rectum.

**Navigational Note: -**

# **Appendicitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	IV antibiotic, antifungal, or	Life-threatening	Death
		antiviral intervention	consequences; urgent	
		indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by acute inflammation to the vermiform appendix caused by a pathogenic agent.

# **Appendicitis perforated**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Medical intervention	Life-threatening	Death
		indicated; operative	consequences; urgent	
		intervention indicated	intervention indicated	

**Definition:** A disorder characterized by acute inflammation to the vermiform appendix caused by a pathogenic agent with gangrenous changes resulting in the rupture of the appendiceal wall. The appendiceal wall rupture causes the release of inflammatory and bacterial contents from the appendiceal lumen into the abdominal cavity.

**Navigational Note: -**

#### **Arteritis infective**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	IV antibiotic, antifungal, or	Life-threatening	Death
		antiviral intervention	consequences; urgent	
		indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving an artery.

**Navigational Note: -**

# **Aseptic meningitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Steroid therapy indicated;	Life-threatening	Death
		severe changes in mental	consequences; urgent	
		status; self-limited seizure	intervention indicated	
		activity; neurologic		
		abnormalities		

**Definition:** A disorder characterized by an inflammatory process of the meninges of the brain and/or spinal cord.

**Navigational Note:** Consider Infections and infestations: Meningitis.

#### **Bacteremia**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Blood culture positive with	1	-	-
	no signs or symptoms			

**Definition:** A disorder characterized by the presence of bacteria in the blood stream.

Navigational Note: Grade 2 with hospitalization is acceptable; Consider Infections and infestations: Sepsis (Grades 3, 4 & 5).

# **Biliary tract infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the biliary tract.

**Navigational Note: -**

### **Bladder infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the bladder.

**Navigational Note: -**

### **Bone infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the bones.

#### **Breast infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Local infection with	IV antibiotic, antifungal, or	Life-threatening	Death
	moderate symptoms; oral	antiviral intervention	consequences; urgent	
	intervention indicated (e.g.,	indicated; severe infection;	intervention indicated	
	antibiotic, antifungal, or	axillary adenitis		
	antiviral)			

**Definition:** A disorder characterized by an infectious process involving the breast.

**Navigational Note: -**

### **Bronchial infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms; oral	IV antibiotic, antifungal, or	Life-threatening	Death
	intervention indicated (e.g.,	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the bronchi.

**Navigational Note: -**

# Candidiasis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; local	Oral intervention indicated	IV antifungal intervention	Life-threatening	Death
symptom management	(e.g., antifungal)	indicated	consequences	
indicated				

**Definition:** A disorder characterized by a fungal infection caused by candida.

Navigational Note: If recovered in bloodstream report as Infections and infestations: Fungemia.

#### **Catheter related infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; local intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated; oral intervention	antiviral intervention	consequences; urgent	
	indicated (e.g., antibiotic,	indicated; invasive	intervention indicated	
	antifungal, or antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process that involves a catheter or port.

**Navigational Note:** If related to a device other than a catheter or port, use Infections and infestations: Device related infection.

### **Cecal infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; oral intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., antibiotic,	antiviral intervention	consequences; urgent	
	antifungal, or antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the cecum.

**Navigational Note: -**

### **Cervicitis infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; local intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., topical	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the uterine cervix.

# Conjunctivitis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Symptomatic; moderate	Symptomatic with marked	Best corrected visual acuity	-
symptoms; intervention not	decrease in visual acuity	decrease in visual acuity	of 20/200 or worse in the	
indicated	(best corrected visual acuity	(best corrected visual acuity	affected eye	
	20/40 and better or 3 lines or	worse than 20/40 or more		
	less decreased vision from	than 3 lines of decreased		
	known baseline)	vision from known baseline,		
		up to 20/200); limiting self-		
		care ADL or severe impact on		
		age-appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by inflammation, swelling and redness to the conjunctiva of the eye.

**Navigational Note:** Consider Infections and infestations: Conjunctivitis infective if caused by infection.

# **Conjunctivitis infective**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; local intervention	IV antibiotic, antifungal, or	Life-threatening	-
	indicated (e.g., topical	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the conjunctiva. Clinical manifestations include pink or red color in the eyes.

Navigational Note: -

### **Corneal infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; local intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., topical	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the cornea.

#### **Cranial nerve infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	IV antibiotic, antifungal, or	Life-threatening	Death
		antiviral intervention	consequences; urgent	
		indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving a cranial nerve.

Navigational Note: -

### Cytomegalovirus infection reactivation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate symptoms;	Severe or medically	Life-threatening	Death
symptoms; clinical or	medical intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated	immediately life-threatening;	intervention indicated;	
intervention not indicated		hospitalization or	blindness	
		prolongation of existing		
		hospitalization indicated; IV		
		intervention indicated		

**Definition:** A disorder characterized by the reactivation of cytomegalovirus (CMV).

Navigational Note: Synonym: CMV

#### **Device related infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
	(e.g., antibiotic, antifungal)	antiviral intervention	consequences; urgent	
		indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the use of a medical device.

**Navigational Note:** If related to a catheter or port, use Infections and infestations: Catheter related infection.

#### **Duodenal infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms;	IV antibiotic, antifungal, or	Life-threatening	Death
	medical intervention	antiviral intervention	consequences; urgent	
	indicated (e.g., oral	indicated; invasive	intervention indicated	
	antibiotics)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the duodenum.

Navigational Note: -

### **Encephalitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	IV antibiotic, antifungal, or	Life-threatening	Death
		antiviral intervention	consequences; urgent	
		indicated; steroid therapy	intervention indicated	
		indicated; severe changes in		
		mental status; self-limited		
		seizure activity; neurologic		
		abnormalities		

**Definition:** A disorder characterized by an infectious or inflammatory process involving the brain tissue.

**Navigational Note: -**

### **Encephalomyelitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	IV antibiotic, antifungal, or	Life-threatening	Death
		antiviral intervention	consequences; urgent	
		indicated; steroid therapy	intervention indicated	
		indicated; severe changes in		
		mental status; self-limited		
		seizure activity; neurologic		
		abnormalities		

**Definition:** A disorder characterized by an infectious or inflammatory process involving the brain and spinal cord tissues.

#### **Endocarditis infective**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	IV antibiotic, antifungal, or	Life-threatening	Death
		antiviral intervention	consequences; urgent	
		indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the endocardial layer of the heart. **Navigational Note:** -

### **Endophthalmitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Local intervention indicated	Systemic intervention;	Best corrected visual acuity	-
		hospitalization indicated	of 20/200 or worse in the	
			affected eye	

**Definition:** A disorder characterized by an infectious process involving the internal structures of the eye. **Navigational Note:** -

#### **Enterocolitis infectious**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Passage of >3 unformed	IV antibiotic, antifungal, or	Life-threatening	Death
	stools per 24 hrs or duration	antiviral intervention	consequences; urgent	
	of illness >48 hrs; moderate	indicated; invasive	intervention indicated	
	abdominal pain; oral	intervention indicated;		
	intervention indicated (e.g.,	profuse watery diarrhea with		
	antibiotic, antifungal, or	signs of hypovolemia; bloody		
	antiviral)	diarrhea; fever; severe		
		abdominal pain;		
		hospitalization indicated		

**Definition:** A disorder characterized by an infectious process involving the small and/or large intestines.

**Navigational Note:** Includes Clostridioides difficile (c. diff, c. difficile). Consider Gastrointestinal disorders: Typhlitis, Infections and infestations: Cecal infection.

### **Epstein-Barr virus infection reactivation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate symptoms;	Severe or medically	Life-threatening	Death
symptoms; clinical or	medical intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated	immediately life-threatening;	intervention indicated	
intervention not indicated		hospitalization or		
		prolongation of existing		
		hospitalization indicated; IV		
		intervention indicated		

**Definition:** A disorder characterized by the reactivation of Epstein-Barr virus (EBV).

Navigational Note: Synonym: EBV

# **Esophageal infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Local intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
	(e.g., oral antibiotic,	antiviral intervention	consequences; urgent	
	antifungal, antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the esophagus.

Navigational Note: -

### **Eye infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; local intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., topical	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated;	
	antiviral)	intervention indicated	enucleation	

**Definition:** A disorder characterized by an infectious process involving the eye.

### **Folliculitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
No intervention indicated	Topical intervention initiated	Systemic intervention	-	-
		indicated		

**Definition:** A disorder characterized by inflammation or infection of the hair follicles.

**Navigational Note: -**

# Fungemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms;	Severe or medically	-	-
	medical intervention	significant but not		
	indicated	immediately life-threatening;		
		hospitalization or		
		prolongation of existing		
		hospitalization indicated		

**Definition:** A disorder characterized by the presence of fungus in the blood stream.

Navigational Note: -

#### **Gallbladder infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the gallbladder.

### **Gum infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Local therapy indicated	Moderate symptoms; oral	IV antibiotic, antifungal, or	Life-threatening	Death
(swish and swallow)	intervention indicated (e.g.,	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the gums.

Navigational Note: -

# **Hepatic infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms; oral	IV antibiotic, antifungal, or	Life-threatening	Death
	intervention indicated (e.g.,	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the liver.

Navigational Note: -

# **Hepatitis B reactivation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild symptoms; clinical or	Moderate symptoms; medical intervention	Severe or medically significant but not	Life-threatening consequences; urgent	Death
diagnostic observations only; intervention not indicated	indicated	immediately life-threatening; hospitalization or	intervention indicated; severe decompensated liver	
		prolongation of existing hospitalization indicated; IV	function (e.g., coagulopathy, encephalopathy, coma)	
		intervention indicated		

**Definition:** A disorder characterized by the reactivation of hepatitis B virus.

### **Hepatitis viral**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention	Moderate symptoms;	Symptomatic liver	Life-threatening	Death
not indicated	medical intervention	dysfunction; fibrosis by	consequences; severe	
	indicated	biopsy; compensated	decompensated liver	
		cirrhosis; hospitalization or	function (e.g., coagulopathy,	
		prolongation of existing	encephalopathy, coma)	
		hospitalization indicated		

**Definition:** A disorder characterized by a viral pathologic process involving the liver parenchyma.

**Navigational Note: -**

# Herpes simplex reactivation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate symptoms;	Severe or medically	Life-threatening	Death
symptoms; clinical or	medical intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated	immediately life-threatening;	intervention indicated	
intervention not indicated		hospitalization or		
		prolongation of existing		
		hospitalization indicated; IV		
		intervention indicated		

**Definition:** A disorder characterized by the reactivation of Herpes simplex virus.

# Infections and infestations - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; limiting self-care ADL or severe impact on ageappropriate normal daily	Life-threatening consequences; urgent intervention indicated	Death
		activity (pediatric)		

**Definition:** -

Navigational Note: -

# Infective myositis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; local intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., topical	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the skeletal muscles.

#### Joint infection

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; local intervention	Arthroscopic intervention	Life-threatening	Death
	indicated; oral intervention	indicated (e.g., drainage) or	consequences; urgent	
	indicated (e.g., antibiotic,	arthrotomy (e.g., open	intervention indicated	
	antifungal, or antiviral);	surgical drainage)		
	needle aspiration indicated			
	(single or multiple)			

**Definition:** A disorder characterized by an infectious process involving a joint.

Navigational Note: -

### **Kidney infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the kidney.

**Navigational Note: -**

## Laryngitis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms; oral	IV antibiotic, antifungal, or	Life-threatening	Death
	intervention indicated (e.g.,	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an inflammatory process involving the larynx.

Navigational Note: For symptoms and no intervention, consider Respiratory, thoracic and mediastinal disorders: Hoarseness, Sore throat.

# Lip infection

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized, local intervention	Oral intervention indicated	IV antibiotic, antifungal, or	-	-
indicated	(e.g., antibiotic, antifungal, or	antiviral intervention		
	antiviral)	indicated; invasive		
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the lips.

Navigational Note: -

### Lymph gland infection

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; oral intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., antibiotic,	antiviral intervention	consequences; urgent	
	antifungal, or antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the lymph nodes.

Navigational Note: -

#### **Mediastinal infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	IV antibiotic, antifungal, or	Life-threatening	Death
		antiviral intervention	consequences; urgent	
		indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the mediastinum.

### Meningitis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	IV antibiotic, antifungal, or	Life-threatening	Death
		antiviral intervention	consequences; urgent	
		indicated; steroid therapy	intervention indicated	
		indicated; severe changes in		
		mental status; self-limited		
		seizure activity; neurologic		
		abnormalities		

**Definition:** A disorder characterized by an infectious or inflammatory process of the meninges of the brain and/or spinal cord.

Navigational Note: Consider Infections and infestations: Aseptic meningitis.

### Meningoencephalitis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	IV antibiotic, antifungal, or	Life-threatening	Death
		antiviral intervention	consequences; urgent	
		indicated; steroid therapy	intervention indicated	
		indicated; severe changes in		
		mental status; self-limited		
		seizure activity; neurologic		
		abnormalities		

**Definition:** A disorder characterized by an infectious or inflammatory process involving the meninges and the brain tissue. **Navigational Note:** -

### **Mucosal infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized, local intervention	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
indicated	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving a mucosal surface.

### **Myelitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; mild signs	Moderate weakness or	Severe weakness or sensory	Life-threatening	Death
(e.g., Babinski's reflex or	sensory loss; limiting	loss; limiting self-care ADL or	consequences; urgent	
Lhermitte's sign)	instrumental ADL or	severe impact on age-	intervention indicated	
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by inflammation involving the spinal cord. Symptoms include weakness, paresthesia, sensory loss, marked discomfort and incontinence.

**Navigational Note: -**

#### **Nail infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized, local intervention	Oral intervention indicated	IV antibiotic, antifungal, or	-	-
indicated	(e.g., antibiotic, antifungal, or	antiviral intervention		
	antiviral)	indicated; invasive		
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the nail.

**Navigational Note: -**

#### Otitis externa

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized, local intervention	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
indicated	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the outer ear and ear canal. Contributory factors include excessive water exposure (swimmer's ear infection) and cuts in the ear canal. Symptoms include fullness, itching, swelling and marked discomfort in the ear and ear drainage.

**Navigational Note:** Changes associated with radiation to external ear (pinnae) are graded under Injury, poisoning and procedural complications: Dermatitis radiation.

### Otitis media

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; oral intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., antibiotic,	antiviral intervention	consequences; urgent	
	antifungal, or antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the middle ear.

Navigational Note: -

#### **Ovarian infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; oral intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., antibiotic,	antiviral intervention	consequences; urgent	
	antifungal, or antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the ovary.

Navigational Note: -

#### **Pancreas infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	IV antibiotic, antifungal, or	Life-threatening	Death
		antiviral intervention	consequences; urgent	
		indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the pancreas.

### Paronychia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Nail fold edema or erythema;	Local intervention indicated;	Operative intervention	-	-
disruption of the cuticle	oral intervention indicated	indicated; IV antibiotics		
	(e.g., antibiotic, antifungal,	indicated; limiting self-care		
	antiviral); nail fold edema or	ADL or severe impact on age-		
	erythema with pain;	appropriate normal daily		
	associated with discharge or	activity (pediatric)		
	nail plate separation; limiting			
	instrumental ADL or			
	mild/moderate impact on			
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by an infectious process involving the soft tissues around the nail.

**Navigational Note: -**

#### **Pelvic infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms; oral	IV antibiotic, antifungal, or	Life-threatening	Death
	intervention indicated (e.g.,	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the pelvic cavity.

Navigational Note: -

#### **Penile infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized, local intervention	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
indicated	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the penis.

#### **Periorbital infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; local intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., topical	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process near or around the orbit of the eye.

Navigational Note: -

### Peripheral nerve infection

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; local intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., topical	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the peripheral nerves.

Navigational Note: -

#### **Peritoneal infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	IV antibiotic, antifungal, or	Life-threatening	Death
		antiviral intervention	consequences; urgent	
		indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the peritoneum.

### **Pharyngitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by inflammation of the throat.

Navigational Note: For Grade 1 Consider Respiratory, thoracic and mediastinal disorders: Sore throat.

#### **Phlebitis infective**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized, local intervention	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
indicated	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the vein. Clinical manifestations include erythema, marked discomfort, swelling, and induration along the course of the infected vein.

**Navigational Note: -**

### **Pleural infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the pleura.

#### **Pneumonia**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms; oral	IV antibiotic, antifungal, or	Life-threatening	Death
	intervention indicated (e.g.,	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the lungs, including pneumonia.

**Navigational Note:** Replaces Lung infection as this term is more commonly used. If due to aspiration, consider reporting Respiratory, thoracic and mediastinal disorders: Aspiration

#### **Prostate infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms; oral	IV antibiotic, antifungal, or	Life-threatening	Death
	intervention indicated (e.g.,	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the prostate gland.

**Navigational Note: -**

### Rash pustular

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; local intervention	IV antibiotic, antifungal, or	-	-
	indicated (e.g., topical	antiviral intervention		
	antibiotic, antifungal, or	indicated; invasive		
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by a circumscribed and elevated skin lesion filled with pus. **Navigational Note:** Consider Skin and subcutaneous tissue disorders: Pustular drug eruption.

#### **Rhinitis infective**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; local intervention	-	-	-
	indicated			

**Definition:** A disorder characterized by an infectious process involving the nasal mucosal.

Navigational Note: -

### Salivary gland infection

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms; oral	IV antibiotic, antifungal, or	Life-threatening	Death
	intervention indicated (e.g.,	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the salivary gland.

**Navigational Note: -**

#### **Scrotal infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized, local intervention	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
indicated	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the scrotum.

**Navigational Note: -**

# Sepsis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	IV intervention indicated	Life-threatening	Death
			consequences	

**Definition:** A disorder characterized by the presence of pathogenic microorganisms in the blood stream that cause varying degrees of organ dysfunction due to a dysregulated host response to infection.

Navigational Note: Consider Infections and infestations: Bacteremia (Grade 2).

### **Shingles**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized, local intervention	Local infection with	Severe or medically	Life-threatening	Death
indicated	moderate symptoms; oral	significant but not	consequences; urgent	
	intervention indicated;	immediately life-threatening;	intervention indicated	
	limiting instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated; IV		
	activity (pediatric)	intervention indicated;		
		limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by the reactivation of herpes zoster virus.

Navigational Note: Synonym: Herpes zoster

### **Sinusitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; oral intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., antibiotic,	antiviral intervention	consequences; urgent	
	antifungal, or antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the mucous membranes of the paranasal sinuses.

Navigational Note: -

#### **Skin infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized, local intervention	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
indicated	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the skin such as cellulitis.

### **Small intestine infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms; oral	IV antibiotic, antifungal, or	Life-threatening	Death
	intervention indicated (e.g.,	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the small intestine.

Navigational Note: -

#### Soft tissue infection

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; oral intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., antibiotic,	antiviral intervention	consequences; urgent	
	antifungal, or antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving soft tissues.

**Navigational Note: -**

# **Splenic infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	IV antibiotic, antifungal, or	Life-threatening	Death
		antiviral intervention	consequences; urgent	
		indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the spleen.

#### Stoma site infection

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized, local intervention	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
indicated	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving a stoma (surgically created opening on the surface of the body). **Navigational Note:** -

#### **Tooth infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; local intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., topical	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving a tooth.

Navigational Note: Record final diagnosis/cause once determined.

### **Tracheitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms; oral	IV antibiotic, antifungal, or	Life-threatening	Death
	intervention indicated (e.g.,	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the trachea.

# Upper respiratory infection

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms; oral	IV antibiotic, antifungal, or	Life-threatening	Death
	intervention indicated (e.g.,	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the upper respiratory tract (nose, paranasal sinuses, pharynx, larynx, or trachea).

**Navigational Note: -**

#### **Urethral infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; oral intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., antibiotic,	antiviral intervention	consequences; urgent	
	antifungal, or antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the urethra.

**Navigational Note: -**

### **Urinary tract infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Localized; oral intervention	IV antibiotic, antifungal, or	Life-threatening	Death
	indicated (e.g., antibiotic,	antiviral intervention	consequences; urgent	
	antifungal, or antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the urinary tract, most commonly the bladder and the urethra. **Navigational Note:** -

#### **Uterine infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms; oral	IV antibiotic, antifungal, or	Life-threatening	Death
	intervention indicated (e.g.,	antiviral intervention	consequences; urgent	
	antibiotic, antifungal, or	indicated; invasive	intervention indicated	
	antiviral)	intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the endometrium. It may extend to the myometrium and parametrial tissues.

**Navigational Note: -**

# **Vaginal infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized, local intervention	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
indicated	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the vagina.

**Navigational Note: -**

### Viremia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms;	Severe or medically	-	-
	medical intervention	significant but not		
	indicated	immediately life-threatening;		
		hospitalization or		
		prolongation of existing		
		hospitalization indicated		

**Definition:** A disorder characterized by the presence of a virus in the blood stream.

### **Vulval infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized, local intervention	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
indicated	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the vulva.

Navigational Note: -

#### **Wound infection**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized, local intervention	Oral intervention indicated	IV antibiotic, antifungal, or	Life-threatening	Death
indicated	(e.g., antibiotic, antifungal, or	antiviral intervention	consequences; urgent	
	antiviral)	indicated; invasive	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by an infectious process involving the wound.

# Injury, poisoning and procedural complications

## **Anesthetic complication**

Grade 2	Grade 3	Grade 4	Grade 5
Any anesthesia effects requiring medical intervention for reversal of symptomatic effects and requiring unplanned hospitalization of <24 hours.	Any anesthesia effects requiring medical intervention for reversal of symptomatic effects and requiring unplanned hospitalization of >=24	Anesthesia effects with life- threatening consequences; urgent intervention indicated	Death
	Any anesthesia effects requiring medical intervention for reversal of symptomatic effects and requiring unplanned	Any anesthesia effects requiring medical intervention for reversal of symptomatic effects and requiring unplanned  Any anesthesia effects requiring medical intervention for reversal of symptomatic effects and requiring unplanned	Any anesthesia effects requiring medical intervention for reversal of symptomatic effects and requiring unplanned hospitalization of <24 hours.  Any anesthesia effects requiring medical intervention for reversal of symptomatic effects and requiring unplanned hospitalization of >=24  Anesthesia effects with life- threatening consequences; urgent intervention indicated

**Definition:** A disorder characterized by reactions related to the administration of local or moderate sedation given for a procedure. **Navigational Note:** -

### **Aortic injury**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Operative intervention not	Severe symptoms; repair or	Life-threatening	Death
	indicated	revision indicated; limiting	consequences; evidence of	
		self-care ADL or severe	end organ damage; urgent	
		impact on age-appropriate	operative intervention	
		normal daily activity	indicated	
		(pediatric)		

**Definition:** A finding of damage to the aorta.

### **Arterial injury**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic finding; intervention not indicated	Symptomatic; repair or revision not indicated	Severe symptoms; repair or revision indicated; limiting self-care ADL or severe	Life-threatening consequences; evidence of end organ damage; urgent	Death
		impact on age-appropriate normal daily activity (pediatric)	operative intervention indicated	

**Definition:** A finding of damage to an artery.

**Navigational Note: -**

### Biliary anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic	Symptomatic; medical	Severe symptoms; invasive	Life-threatening	Death
finding; intervention not	intervention indicated	intervention indicated	consequences; urgent	
indicated			operative intervention	
			indicated	

**Definition:** A finding of leakage of bile due to breakdown of a biliary anastomosis (surgical connection of two separate anatomic structures).

**Navigational Note: -**

#### Bladder anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic	Symptomatic; medical	Severe symptoms; invasive	Life-threatening	Death
finding; intervention not indicated	intervention indicated	intervention indicated	consequences; urgent operative intervention	
indicated			indicated	

**Definition:** A finding of leakage of urine due to breakdown of a bladder anastomosis (surgical connection of two separate anatomic structures).

### **Bruising**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Localized or in a dependent	Generalized	-	-	-
area				

**Definition:** A finding of injury of the soft tissues or bone characterized by leakage of blood into surrounding tissues. **Navigational Note:** -

#### Burn

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Minimal symptoms;	Medical intervention;	Moderate to major	Life-threatening	Death
intervention not indicated	minimal debridement	debridement or	consequences	
	indicated	reconstruction indicated		

**Definition:** A finding of impaired integrity to the anatomic site of an adverse thermal reaction. Burns can be caused by exposure to chemicals, direct heat, electricity, flames and radiation. The extent of damage depends on the length and intensity of exposure and time until provision of treatment.

**Navigational Note: -**

#### **Dermatitis radiation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Faint erythema or dry	Moderate to brisk erythema;	Moist desquamation in areas	Life-threatening	Death
desquamation	patchy moist desquamation,	other than skin folds and	consequences; skin necrosis	
	mostly confined to skin folds	creases; bleeding induced by	or ulceration of full thickness	
	and creases; moderate	minor trauma or abrasion	dermis; spontaneous	
	edema		bleeding from involved site;	
			skin graft indicated	

**Definition:** A finding of cutaneous inflammatory reaction occurring as a result of exposure to biologically effective levels of ionizing radiation.

Navigational Note: Synonym: Radiation induced skin toxicities (CTCAE v3.0)

### Esophageal anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic	Symptomatic; medical	Severe symptoms; invasive	Life-threatening	Death
finding; intervention not	intervention indicated	intervention indicated	consequences; urgent	
indicated			operative intervention	
			indicated	

**Definition:** A finding of leakage due to breakdown of an esophageal anastomosis (surgical connection of two separate anatomic structures).

**Navigational Note: -**

#### Fall

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Minor with no resultant	Symptomatic; noninvasive	Hospitalization indicated;	-	-
injuries; intervention not	intervention indicated	invasive intervention		
indicated		indicated		

**Definition:** A finding of sudden movement downward, usually resulting in injury.

**Navigational Note: -**

### Fallopian tube anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic	Symptomatic; medical	Severe symptoms; invasive	Life-threatening	Death
finding; intervention not	intervention indicated	intervention indicated	consequences; urgent	
indicated			operative intervention	
			indicated	

**Definition:** A finding of leakage due to breakdown of a fallopian tube anastomosis (surgical connection of two separate anatomic structures).

# Fallopian tube perforation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Invasive intervention not	Invasive intervention	Life-threatening	Death
	indicated	indicated	consequences; urgent	
			operative intervention	
			indicated (e.g., organ	
			resection)	

**Definition:** A disorder characterized by a rupture of the fallopian tube wall.

Navigational Note: -

#### Fracture

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic but non-	Severe symptoms; displaced	Life-threatening	Death
diagnostic observations only;	displaced; immobilization	or open wound with bone	consequences; urgent	
intervention not indicated	indicated	exposure; operative	intervention indicated	
		intervention indicated;		
		limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A state in which the continuity of the bone is broken.

**Navigational Note: -**

### Gastric anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic	Symptomatic; medical	Severe symptoms; invasive	Life-threatening	Death
finding; intervention not	intervention indicated	intervention indicated	consequences; urgent	
indicated			operative intervention	
			indicated	

**Definition:** A finding of leakage due to breakdown of a gastric anastomosis (surgical connection of two separate anatomic structures). **Navigational Note:** -

#### Gastrointestinal anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic	Symptomatic; medical	Severe symptoms; invasive	Life-threatening	Death
finding; intervention not	intervention indicated	intervention indicated	consequences; urgent	
indicated			operative intervention	
			indicated	

**Definition:** A finding of leakage due to breakdown of a gastrointestinal anastomosis (surgical connection of two separate anatomic structures).

**Navigational Note: -**

#### Gastrointestinal stoma necrosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Superficial necrosis;	Severe symptoms;	Life-threatening	Death
	intervention not indicated	hospitalization indicated;	consequences; urgent	
		elective operative	intervention indicated	
		intervention indicated		

**Definition:** A disorder characterized by a necrotic process occurring in the gastrointestinal tract stoma.

Navigational Note: -

#### Infusion related reaction

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild transient reaction;	Therapy or infusion	Prolonged (e.g., not rapidly	Life-threatening	Death
infusion interruption not	interruption indicated but	responsive to symptomatic	consequences; urgent	
indicated; intervention not	responds promptly to	medication and/or brief	intervention indicated	
indicated	symptomatic treatment (e.g.,	interruption of infusion);		
	antihistamines, NSAIDS,	recurrence of symptoms		
	narcotics, IV fluids);	following initial		
	prophylactic medications	improvement; hospitalization		
	indicated for <=24 hrs	indicated for clinical sequelae		

**Definition:** A disorder characterized by adverse reaction to the infusion of pharmacological or biological substances.

**Navigational Note:** If the reaction is an allergic reaction related to an agent, consider reporting as Immune system disorders: Allergic reaction. Do not report both.

# Injury to carotid artery

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Repair or revision not	Severe symptoms (e.g.,	Life-threatening	Death
	indicated	transient cerebral ischemia);	consequences; urgent	
		repair or revision indicated;	intervention indicated	
		limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A finding of damage to the carotid artery.

Navigational Note: -

# Injury to inferior vena cava

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic	Symptomatic; repair or	Severe symptoms; repair or	Life-threatening	Death
finding; intervention not	revision not indicated	revision indicated; limiting	consequences; urgent	
indicated		self-care ADL or severe	intervention indicated	
		impact on age-appropriate		
		normal daily activity		
		(pediatric)		

**Definition:** A finding of damage to the inferior vena cava.

**Navigational Note: -**

# Injury to jugular vein

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Repair or revision not	Symptomatic; repair or	Life-threatening	Death
	indicated	revision indicated; limiting	consequences; urgent	
		self-care ADL or severe	intervention indicated	
		impact on age-appropriate		
		normal daily activity		
		(pediatric)		

**Definition:** A finding of damage to the jugular vein.

# Injury to superior vena cava

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic	Symptomatic; repair or	Severe symptoms; repair or	Life-threatening	Death
finding; intervention not	revision not indicated	revision indicated; limiting	consequences; urgent	
indicated		self-care ADL or severe	intervention indicated	
		impact on age-appropriate		
		normal daily activity		
		(pediatric)		

**Definition:** A finding of damage to the superior vena cava.

**Navigational Note: -**

# Injury, poisoning and procedural complications - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

Definition: -

#### Intestinal stoma leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic finding; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; invasive intervention indicated	Life-threatening consequences; urgent operative intervention	Death
marcacea			indicated	

**Definition:** A finding of leakage of contents from an intestinal stoma (surgically created opening on the surface of the body). **Navigational Note:** -

#### Intestinal stoma obstruction

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Self-limited; intervention not	Severe symptoms; IV fluids,	Life-threatening	Death
	indicated	tube feeding, or TPN	consequences; urgent	
		indicated >=24 hrs; elective	operative intervention	
		operative intervention	indicated	
		indicated		

**Definition:** A disorder characterized by blockage of the normal flow of the contents of the intestinal stoma.

Navigational Note: -

### Intestinal stoma site bleeding

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Minimal bleeding identified	Moderate bleeding; medical	Invasive intervention	Life-threatening	Death
on clinical exam; intervention	intervention indicated	indicated; hospitalization	consequences; urgent	
not indicated			intervention indicated	

**Definition:** A disorder characterized by bleeding from the intestinal stoma.

### Intraoperative arterial injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A finding of damage to an artery during a surgical procedure.

Navigational Note: -

### Intraoperative breast injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A finding of damage to the breast parenchyma during a surgical procedure.

Navigational Note: -

### Intraoperative cardiac injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Primary repair of injured	Life-threatening	Death
		organ/structure indicated	consequences; urgent	
			intervention indicated	

**Definition:** A finding of damage to the heart during a surgical procedure.

# Intraoperative ear injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured	Life-threatening consequences; urgent	Death
		organ/structure indicated; limiting self-care ADL (e.g., impaired hearing; impaired	intervention indicated	
		balance) or severe impact on age-appropriate normal daily		
		activity (pediatric)		

**Definition:** A finding of damage to the ear during a surgical procedure.

**Navigational Note: -**

### Intraoperative endocrine injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A finding of damage to the endocrine gland during a surgical procedure.

### Intraoperative gastrointestinal injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A finding of damage to the gastrointestinal system during a surgical procedure.

**Navigational Note: -**

# Intraoperative head and neck injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A finding of damage to the head and neck during a surgical procedure.

**Navigational Note: -**

### Intraoperative hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Postoperative invasive	Life-threatening	Death
		intervention indicated;	consequences; urgent	
		hospitalization	intervention indicated	

**Definition:** A finding of uncontrolled bleeding during a surgical procedure.

# Intraoperative hepatobiliary injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A finding of damage to the hepatic parenchyma and/or biliary tract during a surgical procedure.

Navigational Note: -

# Intraoperative musculoskeletal injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A finding of damage to the musculoskeletal system during a surgical procedure.

# Intraoperative neurological injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A finding of damage to the nervous system during a surgical procedure.

Navigational Note: -

# Intraoperative ocular injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A finding of damage to the eye during a surgical procedure.

# Intraoperative renal injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A finding of damage to the kidney during a surgical procedure.

Navigational Note: -

# Intraoperative reproductive tract injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A finding of damage to the reproductive organs during a surgical procedure.

# Intraoperative respiratory injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A finding of damage to the respiratory system during a surgical procedure.

Navigational Note: -

# Intraoperative splenic injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Primary repair of injured	Resection or reconstruction	Life-threatening	Death
	organ/structure indicated	of injured organ/structure	consequences; urgent	
		indicated; limiting self-care	intervention indicated	
		ADL or severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A finding of damage to the spleen during a surgical procedure.

# Intraoperative urinary injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A finding of damage to the urinary system during a surgical procedure.

**Navigational Note: -**

# Intraoperative venous injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Primary repair of injured organ/structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A finding of damage to a vein during a surgical procedure.

**Navigational Note: -**

## Kidney anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic finding; intervention not	Symptomatic; medical intervention indicated	Severe symptoms; invasive intervention indicated	Life-threatening consequences; urgent	Death
indicated			operative intervention indicated	

**Definition:** A finding of leakage of urine due to breakdown of a kidney anastomosis (surgical connection of two separate anatomic structures).

# Large intestinal anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic finding; intervention not	Symptomatic; medical intervention indicated	Severe symptoms; invasive intervention indicated	Life-threatening consequences; urgent	Death
indicated			operative intervention indicated	

**Definition:** A finding of leakage due to breakdown of an anastomosis (surgical connection of two separate anatomic structures) in the large intestine.

**Navigational Note: -**

## **Nerve injury**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Limiting instrumental ADL or	Invasive intervention	Life-threatening	Death
	mild/moderate impact on	indicated; hospitalization;	consequences; urgent	
	age-appropriate normal daily	limiting self-care ADL or	intervention indicated	
	activity (pediatric)	severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A finding of damage to a nerve.

**Navigational Note: -**

### Pancreatic anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic finding; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; invasive intervention indicated	Life-threatening consequences; urgent operative intervention	Death
			indicated	

**Definition:** A finding of leakage due to breakdown of a pancreatic anastomosis (surgical connection of two separate anatomic structures). **Navigational Note:** -

# Pharyngeal anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic finding; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; invasive intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death

**Definition:** A finding of leakage due to breakdown of a pharyngeal anastomosis (surgical connection of two separate anatomic structures). **Navigational Note:** -

# Post biopsy bleeding

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Requiring additional	Transfusion indicated;	Life-threatening	Death
	observation	invasive intervention	consequences; urgent	
		indicated; hospitalization	intervention indicated	

**Definition:** A disorder characterized by bleeding as a result of a biopsy procedure.

**Navigational Note: -**

## Postoperative hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate bleeding requiring	Transfusion indicated of >=2	Life-threatening	Death
not indicated	transfusion <2 units (10 cc/kg	units (10 cc/kg for pediatrics)	consequences; urgent	
	for pediatrics) of pRBCs	pRBCs; invasive intervention	intervention indicated	
		indicated; hospitalization		

**Definition:** A disorder characterized by bleeding occurring after a surgical procedure.

Navigational Note: Consider Injury, poisoning and procedural complications: Post biopsy bleeding.

# Postoperative thoracic procedure complication

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Extubated within 24 - 72 hrs	Extubated >72 hrs	Life-threatening airway	Death
	postoperatively	postoperatively, but before	compromise; urgent	
		tracheostomy indicated	intervention indicated (e.g.,	
			tracheotomy or intubation)	

**Definition:** A finding of a previously undocumented problem that occurs after a thoracic procedure.

**Navigational Note: -**

## Prolapse of intestinal stoma

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; reducible	Recurrent after manual reduction; local irritation or stool leakage; difficulty to fit appliance; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily	Severe symptoms; elective operative intervention indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent operative intervention indicated	Death
	activity (pediatric)			

**Definition:** A finding of protrusion of the intestinal stoma (surgically created opening on the surface of the body) above the abdominal surface.

**Navigational Note: -**

## **Prolapse of urostomy**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Local care or maintenance;	Dysfunctional stoma; elective	Life-threatening	Death
diagnostic observations only;	minor revision indicated	operative intervention or	consequences; urgent	
intervention not indicated		major stomal revision	intervention indicated	
		indicated		

**Definition:** A finding of displacement of the urostomy.

# Radiation recall reaction (dermatologic)

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Faint erythema or dry	Moderate to brisk erythema;	Moist desquamation in areas	Life-threatening	Death
desquamation	patchy moist desquamation,	other than skin folds and	consequences; skin necrosis	
	mostly confined to skin folds	creases; bleeding induced by	or ulceration of full thickness	
	and creases; moderate	minor trauma or abrasion	dermis; spontaneous	
	edema		bleeding from involved site;	
			skin graft indicated	

**Definition:** A finding of acute skin inflammatory reaction caused by drugs, especially chemotherapeutic agents, for weeks or months following radiotherapy. The inflammatory reaction is confined to the previously irradiated skin and the symptoms disappear after the removal of the pharmaceutical agent.

Navigational Note: -

#### Rectal anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic	Symptomatic; medical	Severe symptoms; invasive	Life-threatening	Death
finding; intervention not	intervention indicated	intervention indicated	consequences; urgent	
indicated			operative intervention	
			indicated	

**Definition:** A finding of leakage due to breakdown of a rectal anastomosis (surgical connection of two separate anatomic structures). **Navigational Note:** -

#### Seroma

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; simple	Symptomatic, elective		-
diagnostic observations only;	aspiration indicated	invasive intervention		
intervention not indicated		indicated		

**Definition:** A finding of tumor-like collection of serum in the tissues.

#### Small intestinal anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic finding; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; invasive intervention indicated	Life-threatening consequences; urgent operative intervention	Death
marcacea			indicated	

**Definition:** A finding of leakage due to breakdown of an anastomosis (surgical connection of two separate anatomic structures) in the small bowel.

**Navigational Note: -**

## Spermatic cord anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic	Symptomatic; medical	Severe symptoms; invasive	Life-threatening	Death
finding; intervention not	intervention indicated	intervention indicated	consequences; urgent	
indicated			operative intervention	
			indicated	

**Definition:** A finding of leakage due to breakdown of a spermatic cord anastomosis (surgical connection of two separate anatomic structures).

Navigational Note: -

## Stenosis of gastrointestinal stoma

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Symptomatic; IV fluids	Severely altered GI function;	Life-threatening	Death
	indicated <24 hrs; manual	tube feeding, TPN or	consequences; urgent	
	dilation at bedside	hospitalization indicated;	operative intervention	
		elective operative	indicated	
		intervention indicated		

**Definition:** A finding of narrowing of the gastrointestinal stoma (surgically created opening on the surface of the body). **Navigational Note:** -

#### Stomal ulcer

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; medical	Severe symptoms; elective	-	-
diagnostic observations only;	intervention indicated	operative intervention		
intervention not indicated		indicated		

**Definition:** A disorder characterized by a circumscribed, erosive lesion on the jejunal mucosal surface close to the anastomosis site following a gastroenterostomy procedure.

**Navigational Note: -**

# Systemic post-immunization reaction

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain; erythema 2.5 - 5	Moderate pain; erythema >5	Severe pain; erythema >10	Life-threatening	-
cm; induration/swelling 2.5 -	- 10 cm; Induration/swelling	cm; Induration/swelling >10	consequences; urgent	
5 cm; does not interfere with	>5 - 10 cm; lipodystrophy;	cm; necrosis; limiting self-	intervention indicated	
activity	limiting instrumental ADL or	care ADL or severe impact on		
	mild/moderate impact on	age-appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a systemic manifestation that occurs after the injection of a substance with antigenic properties, administered to activate the immune system.

Navigational Note: -

# **Tissue injury**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Limiting instrumental ADL or	Invasive intervention	Life-threatening	Death
	mild/moderate impact on	indicated; hospitalization;	consequences; urgent	
	age-appropriate normal daily	limiting self-care ADL or	intervention indicated	
	activity (pediatric)	severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A finding of damage to an organ or tissue as a result of a procedure.

# Tracheal hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the trachea.

**Navigational Note: -**

### **Tracheal obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Partial asymptomatic obstruction on examination	Symptomatic (e.g., noisy airway breathing), no	Stridor or respiratory distress; invasive intervention	Life-threatening airway compromise; urgent	Death
(e.g., visual, radiologic or endoscopic)	respiratory distress; medical intervention indicated (e.g.,	indicated (e.g., stent, laser); limiting self-care ADL or	intervention indicated (e.g., tracheotomy or intubation)	
. ,	steroids); limiting instrumental ADL or	severe impact on age- appropriate normal daily		
	mild/moderate impact on age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by blockage of the lumen of the trachea.

Navigational Note: -

# Tracheostomy site bleeding

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Minimal bleeding identified	Moderate bleeding; medical	Invasive intervention	Life-threatening	Death
on clinical exam; intervention	intervention indicated	indicated; hospitalization	consequences; urgent	
not indicated			intervention indicated	

**Definition:** A disorder characterized by bleeding from the tracheostomy site.

#### Ureteric anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic finding; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; invasive intervention indicated	Life-threatening consequences; urgent operative intervention	Death
marcacea			indicated	

**Definition:** A finding of leakage due to breakdown of a ureteral anastomosis (surgical connection of two separate anatomic structures). **Navigational Note:** -

### **Urethral anastomotic leak**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic	Symptomatic; medical	Severe symptoms; invasive	Life-threatening	Death
finding; intervention not	intervention indicated	intervention indicated	consequences; urgent	
indicated			operative intervention	
			indicated	

**Definition:** A finding of leakage due to breakdown of a urethral anastomosis (surgical connection of two separate anatomic structures). **Navigational Note:** -

# **Urostomy leak**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic finding; intervention not indicated	Symptomatic; medical intervention indicated	Severe symptoms; invasive intervention indicated	Life-threatening consequences; urgent operative intervention	Death
marcated			indicated	

**Definition:** A finding of leakage of contents from a urostomy.

# **Urostomy obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; dilation or	Altered organ function (e.g.,	Life-threatening	Death
diagnostic observations only;	endoscopic repair or stent	sepsis or hydronephrosis, or	consequences; organ failure;	
intervention not indicated	placement indicated	renal dysfunction); elective	urgent operative intervention	
		operative intervention	indicated	
		indicated		

**Definition:** A disorder characterized by blockage of the urostomy.

**Navigational Note: -**

# **Urostomy site bleeding**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Minimal bleeding identified	Moderate bleeding; medical	Invasive intervention	Life-threatening	Death
on clinical exam; intervention	intervention indicated	indicated; hospitalization	consequences; urgent	
not indicated			intervention indicated	

**Definition:** A disorder characterized by bleeding from the urostomy site.

Navigational Note: -

# **Urostomy stenosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Symptomatic but no	Symptomatic (e.g.,	Life-threatening	Death
	hydronephrosis, sepsis, or	hydronephrosis, or renal	consequences; urgent	
	renal dysfunction; dilation or	dysfunction); elective	operative intervention	
	endoscopic repair or stent	operative intervention	indicated	
	placement indicated	indicated		

**Definition:** A finding of narrowing of the opening of a urostomy.

### Uterine anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic finding; intervention not	Symptomatic; medical intervention indicated	Severe symptoms; invasive intervention indicated	Life-threatening consequences; urgent	Death
indicated			operative intervention indicated	

**Definition:** A finding of leakage due to breakdown of a uterine anastomosis (surgical connection of two separate anatomic structures). **Navigational Note:** -

# **Uterine perforation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Invasive intervention not	Invasive intervention	Life-threatening	Death
	indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by a rupture in the uterine wall.

**Navigational Note: -**

# Vaginal anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic finding; intervention not	Symptomatic; medical intervention indicated	Severe symptoms; invasive intervention indicated	Life-threatening consequences; urgent	Death
indicated			operative intervention indicated	

**Definition:** A finding of leakage due to breakdown of a vaginal anastomosis (surgical connection of two separate anatomic structures). **Navigational Note:** -

### Vas deferens anastomotic leak

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic	Symptomatic; medical	Severe symptoms; invasive	Life-threatening	Death
finding; intervention not	intervention indicated	intervention indicated	consequences; urgent	
indicated			operative intervention	
			indicated	

**Definition:** A finding of leakage due to breakdown of a vas deferens anastomosis (surgical connection of two separate anatomic structures).

Navigational Note: -

# Vascular access complication

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
TPA administration into line	Device dislodgement,	Pulmonary embolism, deep	Life-threatening	Death
with no intent for systemic	blockage, leak, or	vein or cardiac thrombosis;	consequences with	
therapy indicated	malposition; device	intervention indicated	hemodynamic or neurologic	
	replacement indicated		instability	

**Definition:** A finding of a previously undocumented problem related to the vascular access site.

**Navigational Note: -**

# **Venous injury**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic diagnostic	Symptomatic (e.g.,	Severe symptoms; repair or	Life-threatening	Death
finding; intervention not	claudication); repair or	revision indicated; limiting	consequences; evidence of	
indicated	revision not indicated	self-care ADL or severe	end organ damage; urgent	
		impact on age-appropriate	operative intervention	
		normal daily activity	indicated	
		(pediatric)		

**Definition:** A finding of damage to a vein.

# **Wound complication**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Observation only; topical	Bedside local care indicated	Operative intervention	Life-threatening	Death
intervention indicated		indicated	consequences	

**Definition:** A finding of development of a new problem at the site of an existing wound.

**Navigational Note:** Prior to using this term consider Injury, poisoning and procedural complications: Wound dehiscence or Infections and infestations: Wound infection.

### **Wound dehiscence**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Incisional separation,	Incisional separation, local	Fascial disruption or	Life-threatening	Death
intervention not indicated	care (e.g., suturing) or	dehiscence without	consequences; symptomatic	
	medical intervention	evisceration; revision by	hernia with evidence of	
	indicated (e.g., analgesic)	operative intervention	strangulation; fascial	
		indicated	disruption with evisceration;	
			major reconstruction flap,	
			grafting, resection, or	
			amputation indicated	

**Definition:** A finding of separation of the approximated margins of a surgical wound.

**Navigational Note:** Consider Infections and infestations: Wound infection.

## Activated partial thromboplastin time prolonged

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN - 1.5 x ULN	>1.5 - 2.5 x ULN	>2.5 x ULN; bleeding	-	-

**Definition:** A finding based on laboratory test results in which the partial thromboplastin time is found to be greater than the control value. As a possible indicator of coagulopathy, a prolonged partial thromboplastin time (PTT) may occur in a variety of diseases and disorders, both primary and related to treatment.

**Navigational Note: -**

#### Algnine aminotransferase increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN - 3.0 x ULN if baseline	>3.0 - 5.0 x ULN if baseline	>5.0 - 20.0 x ULN if baseline	>20.0 x ULN if baseline was	-
was normal or less than	was normal or less than	was normal or less than	normal or less than normal;	
normal; 1.0 - 1.5 x baseline if	normal; >1.5 - 2.0 x baseline	normal; >2.0 - 4.0 x baseline	>4.0 x baseline if baseline	
baseline was >ULN	if baseline was >ULN	if baseline was >ULN up to 5	was >ULN	
		x ULN		

**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:** Consider Hepatobiliary disorders: Hepatic failure. Report Autoimmune hepatitis under Hepatobiliary disorders: Other, specify.

# Alkaline phosphatase increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>Baseline and ULN	-	-	1	-

**Definition:** A finding based on laboratory test results that indicate an increase in the level of alkaline phosphatase (ALP) in a blood specimen.

### Aspartate aminotransferase increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN - 3.0 x ULN if baseline	>3.0 - 5.0 x ULN if baseline	>5.0 - 20.0 x ULN if baseline	>20.0 x ULN if baseline was	-
was normal or less than	was normal or less than	was normal or less than	normal or less than normal;	
normal; 1.0 - 1.5 x baseline if	normal; >1.5 - 2.0 x baseline	normal; >2.0 - 4.0 x baseline	>4.0 x baseline if baseline	
baseline was >ULN	if baseline was >ULN	if baseline was >ULN up to 5	was >ULN	
		x ULN		

**Definition:** A finding based on laboratory test results that indicate an increase in the level of aspartate aminotransferase (AST or SGOT) in a blood specimen.

**Navigational Note:** Consider Hepatobiliary disorders: Hepatic failure. Report Autoimmune hepatitis under Hepatobiliary disorders: Other, specify.

#### Blood antidiuretic hormone abnormal

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; medical	Hospitalization indicated	-	-
diagnostic observations only;	intervention indicated			
intervention not indicated				

**Definition:** A finding based on laboratory test results that indicate abnormal levels of antidiuretic hormone (ADH) in the blood specimen. **Navigational Note:** -

### **Blood bicarbonate decreased**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<lln and="" intervention<="" no="" td=""><td>-</td><td>-</td><td>-</td><td>-</td></lln>	-	-	-	-
initiated				

**Definition:** A finding based on laboratory test results that indicate a decrease in levels of bicarbonate in a venous blood specimen. **Navigational Note:** Consider Metabolism and nutrition disorders: Acidosis, Alkalosis.

#### **Blood bilirubin increased**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN - 1.5 x ULN if baseline	>1.5 - 3.0 x ULN if baseline	>3.0 - 10.0 x ULN if baseline	>10.0 x ULN if baseline was	-
was normal or less than	was normal or less than	was normal or less than	normal or less than normal;	
normal; 1.0 - 1.5 x baseline if	normal; >1.5 - 2.5 x baseline	normal; >2.5 - 10.0 x baseline	>10.0 x baseline if baseline	
baseline was >ULN	if baseline was >ULN	if baseline was >ULN	was >ULN	

**Definition:** A finding based on laboratory test results that indicate an abnormally high level of total bilirubin in the blood. Excess bilirubin is associated with jaundice.

**Navigational Note:** Consider Hepatobiliary disorders: Hepatic failure. Report Autoimmune hepatitis under Hepatobiliary disorders: Other, specify.

### **Blood corticotrophin decreased**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; medical	Hospitalization indicated	-	-
diagnostic observations only;	intervention indicated			
intervention not indicated				

**Definition:** A finding based on laboratory test results that indicate a decrease in the expected levels of corticotrophin (ACTH) in a blood specimen.

Navigational Note: -

### **Blood gonadotrophin abnormal**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; medical	-	-	-
diagnostic observations only;	intervention indicated			
intervention not indicated				

**Definition:** A finding based on laboratory test results that indicate abnormal levels of gonadotrophin hormone in a blood specimen. **Navigational Note:** -

# Blood lactate dehydrogenase increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN	-	-	-	-

**Definition:** A finding based on laboratory test results that indicate increased levels of lactate dehydrogenase (LDH) in the blood specimen. **Navigational Note:** -

### **Blood prolactin abnormal**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Moderate symptoms; limiting	-	-	-
diagnostic observations only;	instrumental ADL or			
intervention not indicated	mild/moderate impact on			
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A finding based on laboratory test results that indicate abnormal levels of prolactin hormone in a blood specimen.

Navigational Note: -

## Carbon monoxide diffusing capacity decreased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
3 - 5 units below LLN if no	6 - 8 units below LLN if no	Asymptomatic decrease of >8	-	-
baseline available; for follow-	baseline available; for follow-	units drop; >5 units drop		
up, a decrease of 3 - 5 units	up, an asymptomatic	along with the presence of		
(ml/min/mmHg) below the	decrease of >5 - 8 units	pulmonary symptoms (e.g.,		
baseline value; asymptomatic	(ml/min/mmHg) below the	>Grade 2 hypoxia or >Grade		
and intervention not	baseline value; symptomatic	2 dyspnea); intervention		
indicated	and intervention not	indicated		
	indicated			

**Definition:** A finding based on lung function test results that indicate a decrease in the lung capacity to absorb carbon monoxide (DLCO or TLCO).

Navigational Note: Consider Respiratory, thoracic and mediastinal disorders: Dyspnea, Respiratory failure.

### CD4 lymphocytes decreased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<lln -="" 0.5="" 500="" <lln="" mm3;="" td="" x<=""><td>&lt;500 - 200/mm3; &lt;0.5 - 0.2 x</td><td>&lt;200 - 50/mm3; &lt;0.2 - 0.05 x</td><td>&lt;50/mm3; &lt;0.05 x 10^9/L</td><td>-</td></lln>	<500 - 200/mm3; <0.5 - 0.2 x	<200 - 50/mm3; <0.2 - 0.05 x	<50/mm3; <0.05 x 10^9/L	-
10^9/L	10^9/L	10^9/L		

**Definition:** A finding based on laboratory test results that indicate a decrease in levels of CD4 lymphocytes in a blood specimen. **Navigational Note:** -

### **Cholesterol high**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN - 300 mg/dL; >ULN -	>300 - 400 mg/dL; >7.75 -	>400 - 500 mg/dL; >10.34 -	>500 mg/dL; >12.92 mmol/L	-
7.75 mmol/L	10.34 mmol/L	12.92 mmol/L		

**Definition:** A finding based on laboratory test results that indicate higher than normal levels of cholesterol in a blood specimen.

**Navigational Note: -**

#### Creatinine clearance decreased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	26 - 49 ml/min	10 - 25 ml/min	-	-

**Definition:** A finding based on laboratory test results that indicate a decrease in creatinine clearance (CrCl) in a 24-hour urine collection. **Navigational Note:** Report Grade 4 and 5 as Renal and urinary disorders: Acute kidney injury or Chronic kidney disease.

#### **Creatinine increased**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN - 1.5 x ULN	>1.5 - 3.0 x if baseline is	>3.0 x if baseline is below	>6.0 x ULN	-
	below LLN; >1.5 - 3.0 x ULN	LLN; >3.0 - 6.0 x ULN		

**Definition:** A finding based on laboratory test results that indicate increased levels of creatinine in a biological specimen.

Navigational Note: Consider Renal and urinary disorders: Acute kidney injury, Glomerulonephritis, Tubulointerstitial nephritis.

### Electrocardiogram QT corrected interval prolonged

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Average QTc 450 - 480 ms	Average QTc 481 - 500 ms	Average QTc >500 ms; >60 ms change from baseline	Life-threatening consequences; Torsade de pointes; polymorphic	-
			ventricular tachycardia	

**Definition:** A finding of a cardiac dysrhythmia characterized by an abnormally long corrected QT interval.

Navigational Note: Consider Cardiac disorders: Ventricular arrhythmia, Ventricular fibrillation, Ventricular tachycardia.

### Fibrinogen decreased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<1.0 - 0.75 x LLN; if abnormal,	<0.75 - 0.5 x LLN; if abnormal,	<0.5 - 0.25 x LLN; if abnormal,	<0.25 x LLN; if abnormal, 75%	-
<25% decrease from baseline	25 - <50% decrease from	50 - <75% decrease from	decrease from baseline;	
	baseline	baseline	absolute value <50 mg/dL	

**Definition:** A finding based on laboratory test results that indicate an decrease in levels of fibrinogen in a blood specimen.

Navigational Note: -

## Forced expiratory volume decreased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
FEV1% (percentages of	FEV1% 60 - 69%; GLI Z-score	FEV1% 50 - 59%; GLI Z-score	-	-
observed FEV1 and FVC	<-2.5 to -4	<-4		
related to their respective				
predicted values) 99 - 70%				
predicted; Global Lung				
Function Initiative (GLI) Z-				
score -1.65 to -2.5				

**Definition:** A finding based on test results that indicate a relative decrease in the fraction of the forced vital capacity that is exhaled in a specific number of seconds.

Navigational Note: Consider Respiratory, thoracic and mediastinal disorders: Dyspnea, Respiratory failure.

#### **GGT** increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN - 2.5 x ULN if baseline	>2.5 - 5.0 x ULN if baseline	>5.0 - 20.0 x ULN if baseline	>20.0 x ULN if baseline was	-
was normal or less than	was normal or less than	was normal or less than	normal or less than normal;	
normal; 1.0 - 1.5 x baseline if	normal; >1.5 - 3.0 x baseline	normal; >3.0 - 10.0 x baseline	>10.0 x baseline if baseline	
baseline was >ULN	if baseline was >ULN	if baseline was >ULN	was >ULN	

**Definition:** A finding based on laboratory test results that indicate higher than normal levels of the enzyme gamma-glutamyltransferase in the blood specimen. GGT (gamma-glutamyltransferase) catalyzes the transfer of a gamma glutamyl group from a gamma glutamyl peptide to another peptide, amino acids or water.

#### **Growth hormone abnormal**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; medical	-	-	-
diagnostic observations only;	intervention indicated;			
intervention not indicated	limiting instrumental ADL or			
	mild/moderate impact on			
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A finding based on laboratory test results that indicate abnormal levels of growth hormone (GH) in a biological specimen. **Navigational Note:** -

## Haptoglobin decreased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<lln< td=""><td>-</td><td>-</td><td>-</td><td>-</td></lln<>	-	-	-	-

**Definition:** A finding based on laboratory test results that indicate an decrease in levels of haptoglobin (HP) in a blood specimen. **Navigational Note:** -

#### **HDL** decreased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<lln< td=""><td>-</td><td>-</td><td>-</td><td>-</td></lln<>	-	-	-	-

**Definition:** A finding based on laboratory test results that indicate a decrease in HDL in a blood specimen.

Navigational Note: -

## Hemoglobin increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Increase in >0 - 2 g/dL above	Increase in >2 - 4 g/dL above	Increase in >4 g/dL above	-	-
ULN	ULN	ULN		

**Definition:** A finding based on laboratory test results that indicate increased levels of hemoglobin (Hgb) above normal.

#### **INR** increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>1.2 - 1.5; >1 - 1.5 x baseline	>1.5 - 2.5; >1.5 - 2.5 x	>2.5; >2.5 x baseline if on	-	-
if on anticoagulation;	baseline if on	anticoagulation; bleeding		
monitoring only indicated	anticoagulation; dose			
	adjustment indicated			

**Definition:** A finding based on laboratory test results that indicate an increase in the ratio of the patient's prothrombin time (PT) to a control sample in the blood.

**Navigational Note: -**

# Investigations - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

Definition: -

**Navigational Note: -**

### LDL increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN	-	-	1	-

**Definition:** A finding based on laboratory test results that indicate an increase in LDL in a blood specimen.

### Lipase increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN - 1.5 x ULN	>1.5 - 3.0 x ULN; >3.0 - 5.0 x	>3.0 - 5.0 x ULN with signs or	>5.0 x ULN and with signs or	-
	ULN and asymptomatic	symptoms; >5.0 x ULN and	symptoms	
		asymptomatic		

**Definition:** A finding based on laboratory test results that indicate an increase in the level of lipase in a biological specimen.

Navigational Note: Consider Gastrointestinal disorders: Pancreatitis.

### Lymphocyte count increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	>4000/mm3 - 20,000/mm3	>20,000/mm3	-	-

**Definition:** A finding based on laboratory test results that indicate an abnormal increase in the number of lymphocytes in the blood, effusions or bone marrow.

**Navigational Note: -**

### **Neutrophil count decreased**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<1500 - 1000/mm3; <1.5 - 1.0	<1000 - 500/mm3; <1.0 - 0.5 x	<500 - 100/mm3; <0.5 - 0.1 x	<100/mm3; <0.1 x 10^9/L	-
x 10^9/L	10^9/L	10^9/L		

**Definition:** A finding based on laboratory test results that indicate a decrease in number of neutrophils (ANC) in a blood specimen.

**Navigational Note: -**

## **Neutrophil count increased**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	-	-	-	-

**Definition:** A finding based on laboratory test results that indicate an increase in number of neutrophils (ANC) in a blood specimen.

### Serum amylase increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN - 1.5 x ULN	>1.5 - 2.0 x ULN; >2.0 - 5.0 x	>2.0 - 5.0 x ULN with	>5.0 x ULN and with signs or	-
	ULN and asymptomatic or	moderate or severe signs or	symptoms	
	with mild signs or symptoms	symptoms; >5.0 x ULN and		
		asymptomatic		

**Definition:** A finding based on laboratory test results that indicate an increase in the levels of amylase in a serum specimen.

**Navigational Note:** Consider Gastrointestinal disorders: Pancreatitis.

### Thyroid stimulating hormone increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
TSH increased and no	-	-	-	-
intervention indicated				

**Definition:** A disorder characterized by an increase in thyroid stimulating hormone (TSH).

Navigational Note: If intervention initiated or symptomatic, report as Endocrine disorders: Hypothyroidism.

# Urinary protein increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<b>Adult:</b> 1+ proteinuria; urinary	Adult: 2+ and 3+ proteinuria;	Adult: Urinary protein >=3.5	-	-
protein ≥ULN - <1.0 g/24 hrs;	urinary protein 1.0 - <3.5	g/24 hrs; 4+ proteinuria; P/C		
P/C <1;	g/24 hrs; P/C 1 - 3.5;	>3.5;		
Pediatric: 1 + proteinuria	Pediatric: Urine P/C	Pediatric: Urine P/C		
	(Protein/Creatinine) ratio 0.5	(Protein/Creatinine) ratio		
	- 1.9; 2 - 3+ proteinuria	>1.9, 4+ proteinuria		

**Definition:** A finding based on laboratory test results that indicate the presence of excessive protein in the urine. It is predominantly albumin, but also globulin.

**Navigational Note:** 24-hour urine collection takes precedence over dipstick.

### **Urine output decreased**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Adult: Oliguria (<80 ml in 8	Adult: Anuria (<240 ml in 24	-
		hr);	hr);	
		Infants: <1 ml/kg/hour;	Pediatric: No urine output	
		Children: <0.5 ml/kg/hour	over 12 hours	

**Definition:** A finding based on test results that indicate urine production is less relative to previous output.

**Navigational Note: -**

### Vital capacity abnormal

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
90 - 75% of predicted value	<75 - 50% of predicted value;	<50% of predicted value;	-	-
	limiting instrumental ADL or	limiting self-care ADL or		
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A finding based on pulmonary function test results that indicate an abnormal vital capacity (VC) (amount of exhaled after a maximum inhalation) when compared to the predicted value.

**Navigational Note:** Consider Investigations: Forced expiratory volume decreased; Respiratory, thoracic and mediastinal disorders: Dyspnea, Respiratory failure.

#### Vitamin D decreased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Vitamin D decreased <lln< td=""><td>1</td><td>-</td><td>-</td><td>-</td></lln<>	1	-	-	-

**Definition:** A finding based on laboratory test results that indicate a low concentration of Vitamin D in the blood.

**Navigational Note: -**

## Weight gain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
5 - <10% from baseline	10 - <20% from baseline	>=20% from baseline	-	-

**Definition:** A finding characterized by an unexpected or abnormal increase in overall body weight; for pediatrics, percentages represent the absolute increase above that expected from the baseline growth curve (not change in growth percentiles).

# **Weight loss**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
5 - <10% from baseline;	10 - <20% from baseline;	>=20% from baseline; tube	-	-
intervention not indicated	nutritional support indicated	feeding or TPN indicated		

**Definition:** A finding characterized by a decrease in overall body weight; for pediatrics, less than the baseline growth curve. **Navigational Note:** -

### White blood cell decreased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<lln -="" 3.0<="" 3000="" <lln="" mm3;="" td=""><td>&lt;3000 - 2000/mm3; &lt;3.0 - 2.0</td><td>&lt;2000 - 1000/mm3; &lt;2.0 - 1.0</td><td>&lt;1000/mm3; &lt;1.0 x 10^9/L</td><td>-</td></lln>	<3000 - 2000/mm3; <3.0 - 2.0	<2000 - 1000/mm3; <2.0 - 1.0	<1000/mm3; <1.0 x 10^9/L	-
x 10^9/L	x 10^9/L	x 10^9/L		

**Definition:** A finding based on laboratory test results that indicate an decrease in number of white blood cells (WBC) in a blood specimen. **Navigational Note:** -

#### **Acidosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
pH <normal, but="">=7.3</normal,>	-	pH <7.3	Life-threatening	Death
			consequences	

**Definition:** A disorder characterized by abnormally high acidity (high hydrogen-ion concentration) of the blood and other body tissues. **Navigational Note:** -

#### **Alcohol intolerance**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Present	Severe symptoms; limiting	Life-threatening	Death
		self-care ADL or severe	consequences; urgent	
		impact on age-appropriate	intervention indicated	
		normal daily activity		
		(pediatric)		

**Definition:** A disorder characterized by an increase in sensitivity to the adverse effects of alcohol, which can include nasal congestion, skin flushes, heart dysrhythmias, nausea, vomiting, indigestion and headaches.

**Navigational Note: -**

### **Alkalosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
pH >normal, but <=7.5	-	pH >7.5	Life-threatening	Death
			consequences	

**Definition:** A disorder characterized by abnormally high alkalinity (low hydrogen-ion concentration) of the blood and other body tissues. **Navigational Note:** -

#### **Anorexia**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Loss of appetite without	Oral intake altered without	Associated with significant	Life-threatening	Death
alteration in eating habits	significant weight loss or	weight loss or malnutrition	consequences; urgent	
	malnutrition; oral nutritional	(e.g., inadequate oral caloric	intervention indicated	
	supplements indicated	and/or fluid intake); tube		
		feeding or TPN indicated		

**Definition:** A disorder characterized by a loss of appetite.

**Navigational Note: -**

# Dehydration

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Increased oral fluids	IV fluids indicated	Hospitalization indicated	Life-threatening	Death
indicated; dry mucous			consequences; urgent	
membranes; diminished skin			intervention indicated	
turgor				

**Definition:** A disorder characterized by excessive loss of water from the body. It is usually caused by severe diarrhea, vomiting or diaphoresis.

Navigational Note: -

## Diabetes mellitus

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Abnormal glucose above	Oral antiglycemic agent	Insulin therapy initiated or	Life-threatening	Death
baseline; diet changes only;	initiated; insulin sliding scale	increased; hospitalization	consequences; urgent	
no change in baseline	initiated	indicated	intervention indicated;	
diabetic management			diabetic ketoacidosis	

**Definition:** A disorder characterized by increased Hgb A1C that may result in organ damage.

Navigational Note: Consider Metabolism and nutrition disorders: Hyperglycemia.

#### Failure to thrive

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Limiting instrumental ADL or	Limiting self-care ADL or	-	-
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A condition characterized by global decline with weight loss, decreased appetite, poor intake, and/or inactivity. **Navigational Note:** -

### Hypercalcemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Corrected serum calcium of	Corrected serum calcium of	Corrected serum calcium of	Corrected serum calcium of	Death
>ULN - 11.5 mg/dL; >ULN -	>11.5 - 12.5 mg/dL; >2.9 - 3.1	>12.5 - 13.5 mg/dL; >3.1 - 3.4	>13.5 mg/dL; >3.4 mmol/L;	
2.9 mmol/L; Ionized calcium	mmol/L; lonized calcium >1.5	mmol/L; lonized calcium >1.6	Ionized calcium >1.8 mmol/L;	
>ULN - 1.5 mmol/L	- 1.6 mmol/L; symptomatic	- 1.8 mmol/L; hospitalization	life-threatening	
		indicated	consequences	

**Definition:** A disorder characterized by laboratory test results that indicate an elevation in the concentration of calcium (corrected for albumin) in blood.

Navigational Note: -

### Hyperglycemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Fasting glucose value >ULN -	Fasting glucose value >160 -	>250 - 500 mg/dL; >13.9 -	>500 mg/dL; >27.8 mmol/L;	-
160 mg/dL; Fasting glucose	250 mg/dL; Fasting glucose	27.8 mmol/L; hospitalization	life-threatening	
value >ULN - 8.9 mmol/L	value >8.9 - 13.9 mmol/L	indicated	consequences	

**Definition:** A condition characterized by laboratory test results that indicate a confirmed, short lasting and unexpected elevation in the concentration of blood sugar (glycemia).

Navigational Note: Consider Metabolism and nutrition disorders: Diabetes mellitus.

# Hyperkalemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN - 5.5 mmol/L	>5.5 - 6.0 mmol/L;	>6.0 - 7.0 mmol/L;	>7.0 mmol/L; life-threatening	Death
	intervention initiated	hospitalization indicated	consequences	

**Definition:** A disorder characterized by laboratory test results that indicate an elevation in the concentration of potassium in the blood; associated with kidney failure or sometimes with the use of diuretic drugs.

**Navigational Note: -**

# Hyperlipidemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Requiring diet changes	Requiring pharmaceutical	Hospitalization	Life-threatening	-
	intervention		consequences	

**Definition:** A disorder characterized by laboratory test results that indicate an elevation in the concentration of lipids in blood.

Navigational Note: Consider Gastrointestinal disorders: Pancreatitis.

### Hypermagnesemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN - 3.0 mg/dL; >ULN -	-	>3.0 - 8.0 mg/dL; >1.23 - 3.30	>8.0 mg/dL; >3.30 mmol/L;	Death
1.23 mmol/L		mmol/L	life-threatening	
			consequences	

**Definition:** A disorder characterized by laboratory test results that indicate an elevation in the concentration of magnesium in the blood. **Navigational Note:** -

## Hypernatremia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN - 150 mmol/L	>150 - 155 mmol/L;	>155 - 160 mmol/L;	>160 mmol/L; life-	Death
	intervention initiated	hospitalization indicated	threatening consequences	

**Definition:** A disorder characterized by laboratory test results that indicate an elevation in the concentration of sodium in the blood. **Navigational Note:** -

### Hyperphosphatemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Laboratory finding only and	Noninvasive intervention	Severe or medically	Life-threatening	Death
intervention not indicated	indicated	significant but not	consequences; urgent	
		immediately life-threatening;	intervention indicated (e.g.,	
		hospitalization or	dialysis)	
		prolongation of existing		
		hospitalization indicated		

**Definition:** A disorder characterized by laboratory test results that indicate an elevation in the concentration of phosphate in a blood. **Navigational Note:** -

# Hypertriglyceridemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
150 mg/dL - 300 mg/dL; 1.71	>300 mg/dL - 500 mg/dL;	>500 mg/dL - 1000 mg/dL;	>1000 mg/dL; >11.4 mmol/L;	Death
mmol/L - 3.42 mmol/L	>3.42 mmol/L - 5.7 mmol/L	>5.7 mmol/L - 11.4 mmol/L	life-threatening	
			consequences	

**Definition:** A disorder characterized by laboratory test results that indicate an elevation in the concentration of triglyceride concentration in the blood.

Navigational Note: -

## Hyperuricemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
>ULN without physiologic	-	>ULN with physiologic	Life-threatening	Death
consequences		consequences	consequences	

**Definition:** A disorder characterized by laboratory test results that indicate an elevation in the concentration of uric acid.

## Hypoalbuminemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<lln -="" 3="" 30="" <lln="" dl;="" g="" l<="" td=""><td>&lt;3 - 2 g/dL; &lt;30 - 20 g/L</td><td>&lt;2 g/dL; &lt;20 g/L</td><td>Life-threatening</td><td>Death</td></lln>	<3 - 2 g/dL; <30 - 20 g/L	<2 g/dL; <20 g/L	Life-threatening	Death
			consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by laboratory test results that indicate a low concentration of albumin in the blood.

**Navigational Note: -**

# Hypocalcemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Corrected serum calcium of	Corrected serum calcium of	Corrected serum calcium of	Corrected serum calcium of	Death
<lln -="" 2.0<="" 8.0="" <lln="" dl;="" mg="" td=""><td>&lt;8.0 - 7.0 mg/dL; &lt;2.0 - 1.75</td><td>&lt;7.0 - 6.0 mg/dL; &lt;1.75 - 1.5</td><td>&lt;6.0 mg/dL; &lt;1.5 mmol/L;</td><td></td></lln>	<8.0 - 7.0 mg/dL; <2.0 - 1.75	<7.0 - 6.0 mg/dL; <1.75 - 1.5	<6.0 mg/dL; <1.5 mmol/L;	
mmol/L; lonized calcium	mmol/L; lonized calcium <1.0	mmol/L; lonized calcium <0.9	Ionized calcium <0.8 mmol/L;	
<lln -="" 1.0="" l<="" mmol="" td=""><td>- 0.9 mmol/L; symptomatic</td><td>- 0.8 mmol/L; hospitalization</td><td>life-threatening</td><td></td></lln>	- 0.9 mmol/L; symptomatic	- 0.8 mmol/L; hospitalization	life-threatening	
		indicated	consequences	

**Definition:** A disorder characterized by laboratory test results that indicate a low concentration of calcium (corrected for albumin) in the blood.

**Navigational Note: -**

# Hypoglycemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<lln -="" 3.0<="" 55="" <lln="" dl;="" mg="" td=""><td>&lt;55 - 40 mg/dL; &lt;3.0 - 2.2</td><td>&lt;40 - 30 mg/dL; &lt;2.2 - 1.7</td><td>&lt;30 mg/dL; &lt;1.7 mmol/L; life-</td><td>Death</td></lln>	<55 - 40 mg/dL; <3.0 - 2.2	<40 - 30 mg/dL; <2.2 - 1.7	<30 mg/dL; <1.7 mmol/L; life-	Death
mmol/L	mmol/L	mmol/L	threatening consequences;	
			seizures	

**Definition:** A condition characterized by laboratory test results that indicate a low concentration of glucose in the blood.

# Hypokalemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<lln -="" 3.0="" l<="" mmol="" td=""><td>Symptomatic with <lln -="" 3.0<="" td=""><td>&lt;3.0 - 2.5 mmol/L;</td><td>&lt;2.5 mmol/L; life-threatening</td><td>Death</td></lln></td></lln>	Symptomatic with <lln -="" 3.0<="" td=""><td>&lt;3.0 - 2.5 mmol/L;</td><td>&lt;2.5 mmol/L; life-threatening</td><td>Death</td></lln>	<3.0 - 2.5 mmol/L;	<2.5 mmol/L; life-threatening	Death
	mmol/L; intervention	hospitalization indicated	consequences	
	indicated			

**Definition:** A disorder characterized by laboratory test results that indicate a low concentration of potassium in the blood.

**Navigational Note: -**

# Hypomagnesemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<lln -="" 0.5<="" 1.2="" <lln="" dl;="" mg="" td=""><td>&lt;1.2 - 0.9 mg/dL; &lt;0.5 - 0.4</td><td>&lt;0.9 - 0.7 mg/dL; &lt;0.4 - 0.3</td><td>&lt;0.7 mg/dL; &lt;0.3 mmol/L;</td><td>Death</td></lln>	<1.2 - 0.9 mg/dL; <0.5 - 0.4	<0.9 - 0.7 mg/dL; <0.4 - 0.3	<0.7 mg/dL; <0.3 mmol/L;	Death
mmol/L	mmol/L	mmol/L	life-threatening	
			consequences	

**Definition:** A disorder characterized by laboratory test results that indicate a low concentration of magnesium in the blood.

Navigational Note: -

# Hyponatremia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<lln -="" 130="" l<="" mmol="" td=""><td>125 - &lt;130 mmol/L and</td><td>125 - &lt;130 mmol/L</td><td>&lt;120 mmol/L; life-</td><td>Death</td></lln>	125 - <130 mmol/L and	125 - <130 mmol/L	<120 mmol/L; life-	Death
	asymptomatic	symptomatic; 120 - <125	threatening consequences	
		mmol/L regardless of		
		symptoms		

**Definition:** A disorder characterized by laboratory test results that indicate a low concentration of sodium in the blood.

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## Hypophosphatemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Laboratory finding only and	Oral replacement therapy	Severe or medically	Life-threatening	Death
intervention not indicated	indicated	significant but not	consequences	
		immediately life-threatening;		
		hospitalization or		
		prolongation of existing		
		hospitalization indicated		

**Definition:** A disorder characterized by laboratory test results that indicate a low concentration of phosphates in the blood.

**Navigational Note: -**

#### Iron overload

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms;	Severe symptoms;	Life-threatening	Death
	intervention not indicated	intervention indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by accumulation of iron in the tissues.

**Navigational Note: -**

# Metabolism and nutrition disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** -

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#### **Tumor lysis syndrome**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Laboratory tumor lysis	LTLS AND creatinine >1.5 –	LTLS AND creatinine >3.0 –	LTLS AND creatinine >6.0 x	Death
syndrome (LTLS) AND	3.0 × ULN; cardiac	6.0 × ULN; cardiac	ULN; life-threatening cardiac	
creatinine >ULN - 1.5 × ULN	arrhythmia managed	arrhythmia controlled with	arrhythmia or seizure	
	medically; one brief	device (e.g. defibrillator);		
	generalized seizure;	seizure in which		
	seizure(s) well controlled by	consciousness is altered;		
	anticonvulsants; infrequent	poorly controlled seizure		
	focal motor seizures not	disorder; breakthrough		
	limiting age-appropriate	generalized seizures despite		
	instrumental ADL or	medical intervention		
	mild/moderate impact on			
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by metabolic abnormalities that result from a spontaneous or therapy-related cytolysis of tumor cells. Clinical tumor lysis syndrome (CTLS) requires one or more clinical manifestations along with criteria for laboratory tumor lysis syndrome (LTLS). LTLS is defined by two or more of the following laboratory abnormalities within 3 days before or 7 days after the initiation of chemotherapy: Uric acid  $\geq$  476 mcmol/L or 25% increase from baseline, Potassium  $\geq$  6.0 mmol/L or 25% increase from baseline, Phosphorous  $\geq$  2.1 mmol/L (children),  $\geq$ 1.45 mmol/L (adults) or 25% increase from baseline, Calcium  $\leq$  1.75 mmol/L or 25% decrease from baseline.

# Musculoskeletal and connective tissue disorders

#### Abdominal soft tissue necrosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Local wound care; medical intervention indicated (e.g., dressings or topical medications)	Operative debridement or other invasive intervention indicated (e.g., tissue reconstruction, flap, or	Life-threatening consequences; urgent intervention indicated	Death
		grafting)		

**Definition:** A disorder characterized by a necrotic process occurring in the soft tissues of the abdominal wall.

**Navigational Note: -**

# **Arthralgia**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in a joint.

**Navigational Note:** Report Inflammatory arthritis as Musculoskeletal and connective tissue disorder - Other, specify (Inflammatory arthritis).

#### **Arthritis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain with inflammation,	Moderate pain associated	Severe pain associated with	-	-
erythema, or joint swelling	with signs of inflammation,	signs of inflammation,		
	erythema, or joint swelling;	erythema, or joint swelling;		
	limiting instrumental ADL or	irreversible joint damage;		
	mild/moderate impact on	limiting self-care ADL or		
	age-appropriate normal daily	severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by inflammation involving a joint.

**Navigational Note:** Report Inflammatory arthritis as Musculoskeletal and connective tissue disorder - Other, specify (Inflammatory arthritis).

# Back pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the back region.

**Navigational Note:** Consider Injury, poisoning and procedural complications: Infusion related reaction; Record final diagnosis/cause once determined.

### Bone pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the bones.

Navigational Note: Record final diagnosis/cause once determined.

## **Buttock pain**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the buttocks.

Navigational Note: Record final diagnosis/cause once determined.

### Chest wall necrosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Local wound care; medical	Operative debridement or	Life-threatening	Death
	intervention indicated (e.g.,	other invasive intervention	consequences; urgent	
	dressings or topical	indicated (e.g., tissue	intervention indicated	
	medications)	reconstruction, flap, or		
		grafting)		

**Definition:** A disorder characterized by a necrotic process occurring in the soft tissues of the chest wall including breast.

## Chest wall pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the chest wall.

**Navigational Note:** Report Inflammatory costochondritis as Musculoskeletal and connective tissue disorder - Other, specify (Inflammatory costochondritis). Record final diagnosis/cause once determined.

#### **Exostosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; limiting	Severe symptoms; elective	-	-
diagnostic observations only;	instrumental ADL or	operative intervention		
intervention not indicated	mild/moderate impact on	indicated; limiting self-care		
	age-appropriate normal daily	ADL or severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by non-neoplastic overgrowth of bone.

## Fibrosis deep connective tissue

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up)	Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Severe induration; unable to slide or pinch skin; limiting joint or orifice movement (e.g., mouth, anus); limiting self-care ADL or severe impact on age-appropriate normal daily activity (pediatric)	Generalized; associated with signs or symptoms of impaired breathing or feeding	Death

**Definition:** A disorder characterized by fibrotic degeneration of the deep connective tissues.

**Navigational Note: -**

# Flank pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort on the lateral side of the body in the region below the ribs and above the hip.

Navigational Note: Record final diagnosis/cause once determined.

#### Generalized muscle weakness

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Symptomatic; perceived by	Symptomatic; evident on	Limiting self-care ADL or	-	-
patient but not evident on	physical exam; limiting	severe impact on age-		
physical exam	instrumental ADL or	appropriate normal daily		
	mild/moderate impact on	activity (pediatric)		
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by a reduction in the strength of muscles in multiple anatomic sites.

**Navigational Note:** Record final diagnosis/cause once determined.

#### **Growth accelerated**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	>=+2 SD (standard deviation)	-	-	-
	above mid parental height or			
	target height			

**Definition:** A disorder characterized by greater growth than expected for age.

**Navigational Note: -**

## **Growth suppression**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Reduction in growth velocity	Reduction in growth velocity	Reduction in growth velocity	-	-
by 10 - 29% ideally measured	by 30 - 49% ideally measured	of >=50% ideally measured		
over the period of a year	over the period of a year or 0	over the period of a year		
	- 49% reduction in growth			
	from the baseline growth			
	curve			

**Definition:** A disorder characterized by stature that is smaller than normal as expected for age.

#### Head soft tissue necrosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Local wound care; medical	Operative debridement or	Life-threatening	Death
	intervention indicated (e.g.,	other invasive intervention	consequences; urgent	
	dressings or topical	indicated (e.g., tissue	intervention indicated	
	medications)	reconstruction, flap, or		
		grafting)		

**Definition:** A disorder characterized by a necrotic process occurring in the soft tissues of the head.

Navigational Note: Consider Respiratory, thoracic and mediastinal disorders: Sinus disorder, Grade 4.

#### Joint effusion

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; limiting	Severe symptoms; invasive	-	-
diagnostic observations only;	instrumental ADL or	intervention indicated;		
intervention not indicated	mild/moderate impact on	limiting self-care ADL or		
	age-appropriate normal daily	severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by excessive fluid in a joint, usually as a result of joint inflammation.

Navigational Note: -

# Joint range of motion decreased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<=25% loss of ROM (range of	>25 - 50% decrease in ROM;	>50% decrease in ROM;	-	-
motion); decreased ROM	limiting instrumental ADL or	limiting self-care ADL or		
limiting athletic activity	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by a decrease in joint flexibility of any joint.

**Navigational Note:** Report Inflammatory arthritis as Musculoskeletal and connective tissue disorder - Other, specify (Inflammatory arthritis).

## Joint range of motion decreased cervical spine

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild restriction of rotation or	Rotation <60 degrees to right	Ankylosed/fused over	-	-
flexion between 60 - 70	or left; <60 degrees of flexion	multiple segments with no C-		
degrees		spine rotation		

**Definition:** A disorder characterized by a decrease in flexibility of a cervical spine joint.

**Navigational Note:** Report Inflammatory arthritis as Musculoskeletal and connective tissue disorder - Other, specify (Inflammatory arthritis).

## Joint range of motion decreased lumbar spine

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Stiffness; difficulty bending to	Pain with range of motion	<50% lumbar spine flexion;	-	-
the floor to pick up a very	(ROM) in lumbar spine;	associated with symptoms of		
light object but able to do	requires a reaching aid to	ankylosis or fused over		
athletic activity	pick up a very light object	multiple segments with no L-		
	from the floor	spine flexion (e.g., unable to		
		reach to floor to pick up a		
		very light object)		

**Definition:** A disorder characterized by a decrease in flexibility of a lumbar spine joint.

**Navigational Note:** Report Inflammatory arthritis as Musculoskeletal and connective tissue disorder - Other, specify (Inflammatory arthritis).

# **Kyphosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Moderate accentuation;	Severe accentuation;	-	-
diagnostic observations only;	limiting instrumental ADL or	operative intervention		
intervention not indicated	mild/moderate impact on	indicated; limiting self-care		
	age-appropriate normal daily	ADL or severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by an abnormal increase in the curvature of the thoracic portion of the spine.

#### Lordosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Moderate accentuation;	Severe accentuation;	-	-
diagnostic observations only;	limiting instrumental ADL or	operative intervention		
intervention not indicated	mild/moderate impact on	indicated; limiting self-care		
	age-appropriate normal daily	ADL or severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by an abnormal increase in the curvature of the lumbar portion of the spine.

Navigational Note: -

# Muscle cramp

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by marked cramping sensation originating from a muscle or group of muscles.

Navigational Note: Synonym: Muscle spasm

#### Muscle weakness lower limb

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Symptomatic; perceived by	Symptomatic; evident on	Limiting self-care ADL or	-	-
patient but not evident on	physical exam; limiting	severe impact on age-		
physical exam	instrumental ADL or	appropriate normal daily		
	mild/moderate impact on	activity (pediatric)		
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by a reduction in the strength of the lower limb muscles.

**Navigational Note:** Consider Musculoskeletal and connective tissue disorders: Myositis; Immune system disorders: Immune system disorders - Other, specify; Injury, poisoning and procedural complications: Fall.

#### Muscle weakness trunk

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Symptomatic; perceived by	Symptomatic; evident on	Limiting self-care ADL or	-	-
patient but not evident on	physical exam; limiting	severe impact on age-		
physical exam	instrumental ADL or	appropriate normal daily		
	mild/moderate impact on	activity (pediatric)		
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by a reduction in the strength of the trunk muscles.

**Navigational Note:** Consider Musculoskeletal and connective tissue disorders: Myositis; Immune system disorders: Immune system disorders - Other, specify; Injury, poisoning and procedural complications: Fall.

## Muscle weakness upper limb

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Symptomatic; perceived by	Symptomatic; evident on	Limiting self-care ADL or	-	-
patient but not evident on	physical exam; limiting	severe impact on age-		
physical exam	instrumental ADL or	appropriate normal daily		
	mild/moderate impact on	activity (pediatric)		
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by a reduction in the strength of the upper limb muscles.

**Navigational Note:** Consider Musculoskeletal and connective tissue disorders: Myositis; Immune system disorders: Immune system disorders - Other, specify; Injury, poisoning and procedural complications: Fall.

# Musculoskeletal and connective tissue disorder - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; limiting self-care ADL or severe impact on ageappropriate normal daily	Life-threatening consequences; urgent intervention indicated	Death
		activity (pediatric)		

**Definition:** -

Navigational Note: -

# Musculoskeletal deformity

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Cosmetically and functionally	Deformity, hypoplasia, or	Significant deformity,	-	-
insignificant hypoplasia	asymmetry able to be	hypoplasia, or asymmetry,		
	remediated by prosthesis	unable to be remediated by		
	(e.g., shoe insert) or covered	prosthesis or covered by		
	by clothing	clothing; limiting self-care		
		ADL or severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by an abnormality of the musculoskeletal system.

## Myalgia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by marked discomfort sensation originating from a muscle or group of muscles.

Navigational Note: Record final diagnosis/cause once determined.

## **Myositis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain associated	Pain associated with severe	Life-threatening	-
	with weakness; pain limiting	weakness; limiting self-care	consequences; urgent	
	instrumental ADL or	ADL or severe impact on age-	intervention indicated	
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by inflammation involving the skeletal muscles.

Navigational Note: Record final diagnosis/cause once determined.

# Neck pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the neck area.

Navigational Note: Record final diagnosis/cause once determined.

#### **Neck soft tissue necrosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Local wound care; medical	Operative debridement or	Life-threatening	Death
	intervention indicated (e.g.,	other invasive intervention	consequences; urgent	
	dressings or topical	indicated (e.g., tissue	intervention indicated	
	medications)	reconstruction, flap, or		
		grafting)		

**Definition:** A disorder characterized by a necrotic process occurring in the soft tissues of the neck.

**Navigational Note: -**

#### Osteonecrosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; medical	Severe symptoms; elective	Life-threatening	Death
diagnostic observations only;	intervention indicated (e.g.,	operative intervention	consequences; urgent	
intervention not indicated	analgesics or	indicated; limiting self-care	intervention indicated	
	bisphosphonates); limiting	ADL or severe impact on age-		
	instrumental ADL or	appropriate normal daily		
	mild/moderate impact on	activity (pediatric)		
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by necrotic changes in the bone tissue due to interruption of blood supply. Most often affecting the epiphysis of the long bones, the necrotic changes result in the collapse and the destruction of the bone structure.

### Osteonecrosis of jaw

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated (e.g., topical agents); limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Severe symptoms; elective operative intervention indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A disorder characterized by a necrotic process occurring in the bone of the mandible.

**Navigational Note: -**

# Osteoporosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Adult: Radiologic evidence of	Adult: BMD t-score <-2.5;	Adult: Loss of height >=2 cm;	-	-
osteoporosis or Bone Mineral	loss of height <2 cm; therapy	hospitalization indicated;		
Density (BMD) t-score -1 to -	to improve BMD indicated;	limiting self-care ADL;		
2.5 (osteopenia);	limiting instrumental ADL;	<b>Pediatric:</b> Severe impact on		
<b>Pediatric:</b> BMD z score of <=-	<b>Pediatric:</b> BMD z-score <=-	age-appropriate normal daily		
2.0 and no history of	2.0 and significant fracture	activity		
significant fractures	history (defined as a long			
	bone fracture of the lower			
	extremity, vertebral			
	compression, 2 or more long			
	bone fractures of the upper			
	extremities); mild/moderate			
	impact on age-appropriate			
	normal daily activity			

**Definition:** A disorder characterized by reduced bone mass, with a decrease in cortical thickness and in the number and size of the trabeculae of cancellous bone (but normal chemical composition), resulting in increased fracture incidence.

### Pain in extremity

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the upper or lower extremities.

Navigational Note: Record final diagnosis/cause once determined.

#### Pelvic soft tissue necrosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Local wound care; medical	Operative debridement or	Life-threatening	Death
	intervention indicated (e.g.,	other invasive intervention	consequences; urgent	
	dressings or topical	indicated (e.g., tissue	intervention indicated	
	medications)	reconstruction, flap, or		
		grafting)		

**Definition:** A disorder characterized by a necrotic process occurring in the soft tissues of the pelvis.

Navigational Note: -

## Rhabdomyolysis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention	Non-urgent intervention	Symptomatic, urgent	Life-threatening	Death
not indicated; laboratory	indicated	intervention indicated	consequences; dialysis	
findings only				

**Definition:** A disorder characterized by the breakdown of muscle tissue resulting in the release of muscle fiber contents into the bloodstream.

**Navigational Note:** Record final diagnosis/cause once determined.

# **Rotator cuff injury**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	-	-
symptoms; clinical or	noninvasive intervention	significant but not		
diagnostic observations only;	indicated; limiting	immediately life-threatening;		
intervention not indicated	instrumental AD or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by an injury of the rotator cuff.

Navigational Note: -

## **Scoliosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<20 degrees; clinically	>20 - 45 degrees; visible by	>45 degrees; scapular	-	-
undetectable	forward flexion; limiting	prominence in forward		
	instrumental ADL or	flexion; operative		
	mild/moderate impact on	intervention indicated;		
	age-appropriate normal daily	limiting self-care ADL or		
	activity (pediatric)	severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by a lateral curvature of the spine.

#### Soft tissue necrosis lower limb

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Local wound care; medical	Operative debridement or	Life-threatening	Death
	intervention indicated (e.g.,	other invasive intervention	consequences; urgent	
	dressings or topical	indicated (e.g., tissue	intervention indicated	
	medications)	reconstruction, flap, or		
		grafting)		

**Definition:** A disorder characterized by a necrotic process occurring in the soft tissues of the lower extremity.

**Navigational Note: -**

## Soft tissue necrosis upper limb

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Local wound care; medical	Operative debridement or	Life-threatening	Death
	intervention indicated (e.g.,	other invasive intervention	consequences; urgent	
	dressings or topical	indicated (e.g., tissue	intervention indicated	
	medications)	reconstruction, flap, or		
		grafting)		

**Definition:** A disorder characterized by a necrotic process occurring in the soft tissues of the upper extremity.

Navigational Note: -

## Superficial soft tissue fibrosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild induration, able to move	Moderate induration, able to	Severe induration; unable to	Generalized; associated with	Death
skin parallel to plane (sliding)	slide skin, unable to pinch	slide or pinch skin; limiting	signs or symptoms of	
and perpendicular to skin	skin; limiting instrumental	joint or orifice movement	impaired breathing or	
(pinching up)	ADL or mild/moderate	(e.g., mouth, anus); limiting	feeding	
	impact on age-appropriate	self-care ADL or severe		
	normal daily activity	impact on age-appropriate		
	(pediatric)	normal daily activity		
		(pediatric)		

**Definition:** A disorder characterized by fibrotic degeneration of the superficial soft tissues.

#### **Trismus**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Decreased ROM (range of	Decreased ROM requiring	Decreased ROM with inability	-	-
motion) without impaired	small bites, soft foods or	to adequately aliment or		
eating	purees	hydrate orally		

**Definition:** A disorder characterized by lack of ability to open the mouth fully due to a decrease in the range of motion of the muscles of mastication.

Navigational Note: -

# **Unequal limb length**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild length discrepancy <2	Moderate length discrepancy	Severe length discrepancy >5	-	-
cm	2 - 5 cm; shoe lift indicated;	cm; operative intervention		
	limiting instrumental ADL or	indicated; limiting self-care		
	mild/moderate impact on	ADL or severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by a discrepancy between the lengths of the lower or upper extremities.

# Neoplasms benign, malignant and unspecified (incl cysts and polyps)

# Differentiation syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local, or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting age	immediately life-threatening;	intervention indicated	
intervention not indicated	appropriate instrumental	limiting self-care ADL or		
	ADL	severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A potentially fatal complication of treatment in certain molecular subgroups of leukemia characterized by fever, rash, dyspnea and/or hypoxia, pulmonary infiltrates, peripheral edema with rapid weight gain, pleuropericardial effusion, acute renal failure, disseminated intravascular coagulation (DIC), bone pain and/or hypotension.

**Navigational Note: -**

#### Keratoacanthoma

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Present	-	-	-

**Definition:** A disorder characterized by a cutaneous tumor that most commonly presents a dome-shaped nodule with a central keratin-filled crater.

**Navigational Note: -**

### Leukemia secondary to oncology chemotherapy

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	Present	Death

**Definition:** A disorder characterized by leukemia arising as a result of the mutagenic effect of chemotherapy agents.

# Myelodysplastic syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	Life-threatening	Death
			consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by insufficiently healthy hematapoietic cell production by the bone marrow.

Navigational Note: -

# Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

Definition: -

**Navigational Note: -**

# Retinoic acid syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Fluid retention; <3 kg of	Moderate signs or	Severe symptoms;	Life-threatening	Death
weight gain; intervention with	symptoms; steroids indicated	hospitalization indicated	consequences; ventilatory	
fluid restriction and/or			support indicated	
diuretics indicated				

**Definition:** A disorder characterized by weight gain, dyspnea, pleural and pericardial effusions, leukocytosis and/or renal failure originally described in patients treated with all-trans retinoic acid.

# Skin papilloma

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; intervention	Intervention initiated	-		-
not indicated				

**Definition:** A disorder characterized by the presence of one or more warts.

**Navigational Note: -**

## Treatment related secondary malignancy

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Non life-threatening	Acute life-threatening	Death
		secondary malignancy	secondary malignancy; blast	
			crisis in leukemia	

**Definition:** A disorder characterized by development of a malignancy most probably as a result of treatment for a previously existing malignancy.

**Navigational Note: -**

# Tumor hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding in a tumor.

# Tumor pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort from a neoplasm that may be pressing on a nerve, blocking blood vessels, inflamed or fractured from metastasis.

**Navigational Note:** Record final diagnosis/cause once determined.

#### Abducens nerve disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
diagnostic observations only;	instrumental ADL or	self-care ADL or severe		
intervention not indicated	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by dysfunction of the abducens nerve (sixth cranial nerve).

**Navigational Note:** Consider Nervous system disorders: Peripheral motor neuropathy, Peripheral sensory neuropathy.

#### **Accessory nerve disorder**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
diagnostic observations only;	instrumental ADL or	self-care ADL or severe		
intervention not indicated	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by dysfunction of the accessory nerve (eleventh cranial nerve).

**Navigational Note:** Consider Nervous system disorders: Peripheral motor neuropathy, Peripheral sensory neuropathy.

#### **Acoustic nerve disorder NOS**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
diagnostic observations only;	instrumental ADL or	self-care ADL or severe		
intervention not indicated	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by dysfunction of the acoustic nerve (eighth cranial nerve).

**Navigational Note:** Consider Nervous system disorders: Peripheral motor neuropathy, Peripheral sensory neuropathy.

#### **Akathisia**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild restlessness or	Moderate restlessness or	Severe restlessness or	-	-
increased motor activity	increased motor activity;	increased motor activity;		
	limiting instrumental ADL or	limiting self-care ADL or		
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by an uncomfortable feeling of inner restlessness and inability to stay still; this is a side effect of some psychotropic drugs.

**Navigational Note: -**

#### **Amnesia**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild; transient memory loss	Moderate; short term	Severe; long term memory	-	-
	memory loss; limiting	loss; limiting self-care ADL or		
	instrumental ADL or	severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by systematic and extensive loss of memory.

**Navigational Note: -**

## **Anosmia**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	-	-	-	-

**Definition:** A disorder characterized by a change in the sense of smell.

Navigational Note: Consider Nervous system disorders: Olfactory nerve disorder.

#### **Arachnoiditis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms	Moderate symptoms; limiting	Severe symptoms; limiting	Life-threatening	Death
	instrumental ADL or	self-care ADL or severe	consequences; urgent	
	mild/moderate impact on	impact on age-appropriate	intervention indicated	
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by inflammation of the arachnoid membrane and adjacent subarachnoid space.

**Navigational Note: -**

#### **Ataxia**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms; limiting	Severe symptoms;	-	-
diagnostic observations only;	instrumental ADL or	mechanical assistance		
intervention not indicated	mild/moderate impact on	indicated; limiting self-care		
	age-appropriate normal daily	ADL or severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by lack of coordination of muscle movements resulting in the impairment or inability to perform voluntary activities.

Navigational Note: Record final diagnosis/cause once determined.

# **Autonomic neuropathy**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms	Moderate symptoms; limiting	Severe symptoms; limiting	Life-threatening	Death
	instrumental ADL or	self-care ADL or severe	consequences; urgent	
	mild/moderate impact on	impact on age-appropriate	intervention indicated	
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by damage to nerves that control your internal organs.

# **Brachial plexopathy**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
diagnostic observations only;	instrumental ADL or	self-care ADL or severe		
intervention not indicated	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by regional paresthesia of the brachial plexus, marked discomfort and muscle weakness, and limited movement in the arm or hand.

**Navigational Note: -**

# **Brain fog**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	Limiting instrumental ADL or	-	-	-
	mild/moderate impact on			
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by thinking and memory problems that a patient with cancer may have during or after cancer treatment.

**Navigational Note: -**

## Central nervous system necrosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
]	Moderate symptoms; corticosteroids indicated	Severe symptoms; medical intervention indicated	Life-threatening consequences; urgent	Death
intervention not indicated			intervention indicated	

**Definition:** A disorder characterized by a necrotic process occurring in the brain and/or spinal cord.

#### Cerebral venous sinus thrombosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Intervention not indicated	Medical intervention	Life-threatening	Death
		indicated (e.g.,	consequences; urgent	
		anticoagulants)	intervention indicated	

**Definition:** A disorder characterized by a thrombus (blood clot) in the brain's venous sinuses leading to swelling and bleeding.

**Navigational Note: -**

# Cerebrospinal fluid leakage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Post-craniotomy:	Post-craniotomy: moderate	Severe symptoms; medical	Life-threatening	Death
asymptomatic; post-lumbar	symptoms; medical	intervention indicated	consequences; urgent	
puncture: transient	intervention indicated; post-		intervention indicated	
headache; postural care	lumbar puncture: persistent			
indicated	moderate symptoms; blood			
	patch indicated			

**Definition:** A disorder characterized by loss of cerebrospinal fluid into the surrounding tissues.

Navigational Note: -

## Cognitive disturbance

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild cognitive disability; not	Moderate cognitive disability;	Severe cognitive disability;	-	-
interfering with	interfering with	significant impairment of		
work/school/life	work/school/life	work/school/life		
performance; specialized	performance but capable of	performance		
educational services/devices	independent living;			
not indicated	specialized resources on part			
	time basis indicated			

**Definition:** A disorder characterized by a conspicuous change in cognitive function.

**Navigational Note:** Record final diagnosis/cause once determined.

# **Concentration impairment**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild inattention or decreased	Moderate impairment in	Severe impairment in	-	-
level of concentration	attention or decreased level	attention or decreased level		
	of concentration; limiting	of concentration; limiting		
	instrumental ADL or	self-care ADL or severe		
	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by a deterioration in the ability to concentrate.

**Navigational Note: -**

## **Depressed level of consciousness**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Decreased level of alertness	Sedation; slow response to	Difficult to arouse	Life-threatening	Death
	stimuli; limiting instrumental		consequences; coma; urgent	
	ADL or mild/moderate		intervention indicated	
	impact on age-appropriate			
	normal daily activity			
	(pediatric)			

**Definition:** A disorder characterized by a decrease in ability to perceive and respond.

Navigational Note: Record final diagnosis/cause once determined.

## **Dizziness**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild unsteadiness or	Moderate unsteadiness or	Severe unsteadiness or	-	-
sensation of movement	sensation of movement;	sensation of movement;		
	limiting instrumental ADL or	limiting self-care ADL or		
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by a disturbing sensation of lightheadedness, unsteadiness, giddiness, spinning or rocking.

**Navigational Note:** Record final diagnosis/cause once determined.

#### Dysarthria

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild slurred speech	Moderate impairment of	Severe impairment of		-
	articulation or slurred speech	articulation or slurred speech		

**Definition:** A disorder characterized by slow and slurred speech resulting from an inability to coordinate the muscles used in speech. **Navigational Note:** Record final diagnosis/cause once determined.

## Dysesthesia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild sensory alteration	Moderate sensory alteration;	Severe sensory alteration;	-	-
	limiting instrumental ADL or	limiting self-care ADL or		
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by distortion of sensory perception, resulting in an abnormal and unpleasant sensation.

**Navigational Note:** Record final diagnosis/cause once determined.

# Dysgeusia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Altered taste but no change	Altered taste with change in	-	-	-
in diet	diet (e.g., oral supplements);			
	noxious or unpleasant taste;			
	loss of taste			

**Definition:** A disorder characterized by abnormal sensual experience with the taste of foodstuffs; it can be related to a decrease in the sense of smell.

# Dysphasia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Awareness of receptive or	Moderate receptive or	Severe receptive or	Total loss of the ability to	-
expressive characteristics;	expressive characteristics;	expressive characteristics;	read, write, or communicate	
not impairing ability to	impairing ability to	impairing ability to read,	intelligibly	
communicate	communicate spontaneously	write or communicate		
		intelligibly		

**Definition:** A disorder characterized by impairment of verbal communication skills, often resulting from brain damage.

Navigational Note: Record final diagnosis/cause once determined.

#### Edema cerebral

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Radiographic finding only	1	New onset; worsening from	Life-threatening	Death
and no medical management		baseline; initiation of steroid	consequences; urgent	
initiated		therapy	intervention indicated	

**Definition:** A disorder characterized by swelling due to an excessive accumulation of fluid in the brain.

Navigational Note: Record final diagnosis/cause once determined.

# **Encephalopathy**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms	Moderate symptoms; limiting	Severe symptoms; limiting	Life-threatening	Death
	instrumental ADL or	self-care ADL or severe	consequences; urgent	
	mild/moderate impact on	impact on age-appropriate	intervention indicated	
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by a pathologic process involving the brain.

## Extrapyramidal disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild involuntary movements	Moderate involuntary	Severe involuntary	Life-threatening	Death
	movements; limiting	movements or torticollis;	consequences; urgent	
	instrumental ADL or	limiting self-care ADL or	intervention indicated	
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by abnormal, repetitive, involuntary muscle movements, frenzied speech and extreme restlessness. **Navigational Note:** -

#### Facial muscle weakness

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
diagnostic observations only;	instrumental ADL or	self-care ADL or severe		
intervention not indicated	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by a reduction in the strength of the facial muscles.

Navigational Note: Record final diagnosis/cause once determined.

#### Facial nerve disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
diagnostic observations only;	instrumental ADL or	self-care ADL or severe		
intervention not indicated	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by dysfunction of the facial nerve (seventh cranial nerve).

## Glossopharyngeal nerve disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms; limiting	Severe symptoms; limiting	Life-threatening	Death
diagnostic observations only;	instrumental ADL or	self-care ADL or severe	consequences; urgent	
intervention not indicated	mild/moderate impact on	impact on age-appropriate	intervention indicated	
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by dysfunction of the glossopharyngeal nerve (ninth cranial nerve).

**Navigational Note: -**

## Guillain-Barre syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms	Moderate symptoms; limiting	Severe symptoms; limiting	Life-threatening	Death
	instrumental ADL or	self-care ADL or severe	consequences; urgent	
	mild/moderate impact on	impact on age-appropriate	intervention indicated;	
	age-appropriate normal daily	normal daily activity	intubation	
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by the body's immune system attacking the peripheral nervous system causing ascending paralysis. **Navigational Note:** -

#### Headache

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in various parts of the head, not confined to the area of distribution of any nerve.

## Hemiparesis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Symptomatic; perceived by	Symptomatic; evident on	Limiting self-care ADL or	-	-
patient but not evident on	physical exam; limiting	severe impact on age-		
physical exam	instrumental ADL or	appropriate normal daily		
	mild/moderate impact on	activity (pediatric)		
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by a reduction in the strength of the muscles on one side of the body.

**Navigational Note: -**

# **Hydrocephalus**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Moderate symptoms;	Severe symptoms or	Life-threatening	Death
diagnostic observations only;	intervention not indicated	neurological deficit;	consequences; urgent	
intervention not indicated		intervention indicated	intervention indicated	

**Definition:** A disorder characterized by an abnormal increase of cerebrospinal fluid in the ventricles of the brain.

**Navigational Note: -**

## Hypersomnia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild increased need for sleep	Moderate increased need for	Severe increased need for	-	-
	sleep	sleep		

**Definition:** A disorder characterized by excessive sleepiness during the daytime.

# Hypoglossal nerve disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
diagnostic observations only;	instrumental ADL or	self-care ADL or severe		
intervention not indicated	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by dysfunction of the hypoglossal nerve (twelfth cranial nerve).

Navigational Note: -

## Immune effector cell-associated neurotoxicity syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; Immune	Moderate symptoms; ICE	Severe symptoms; ICE score	Life-threatening	Death
Effector Cell-Associated	score 3 - 6; CAPD score 1 - 8	0 - 2; CAPD score >=9 AND	consequences; urgent	
Encephalopathy (ICE) score 7	AND awakens to voice;	awakens only to tactile	intervention indicated	
- 9; Cornell Assessment of	limiting instrumental ADL or	stimulus; limiting self-care		
Pediatric Delirium (CAPD)	mild/moderate impact on	ADL or severe impact on age-		
score 1 - 8 AND awakens	age-appropriate normal daily	appropriate normal daily		
spontaneously	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by a pathologic process involving the central nervous system following any immune therapy that results in the activation or engagement of endogenous or infused T cells and/or other immune effector cells. Symptoms or signs can be progressive and may include aphasia, altered level of consciousness, impairment of cognitive skills, motor weakness, seizures, and cerebral edema.

# Intracranial hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms;	Ventriculostomy, ICP	Life-threatening	Death
diagnostic observations only;	intervention indicated	monitoring, intraventricular	consequences; urgent	
intervention not indicated		thrombolysis, or invasive	intervention indicated	
		intervention indicated;		
		hospitalization		

**Definition:** A disorder characterized by bleeding from within the cranium.

**Navigational Note: -**

# Lethargy

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; reduced	Moderate symptoms; limiting	-	-	-
alertness and awareness	instrumental ADL or			
	mild/moderate impact on			
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by a decrease in consciousness characterized by mental and physical inertness.

**Navigational Note:** Record final diagnosis/cause once determined.

# Leukoencephalopathy

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; small focal	Moderate symptoms; focal	Severe symptoms; extensive	Life-threatening	Death
T2/FLAIR hyperintensities;	T2/FLAIR hyperintensities,	T2/FLAIR hyperintensities,	consequences; extensive	
involving periventricular	involving periventricular	involving periventricular	T2/FLAIR hyperintensities,	
white matter or <1/3 of	white matter extending into	white matter involving 2/3 or	involving periventricular	
susceptible areas of	centrum semiovale or	more of susceptible areas of	white matter involving most	
cerebrum +/- mild increase in	involving 1/3 to 2/3 of	cerebrum +/- moderate to	of susceptible areas of	
subarachnoid space (SAS)	susceptible areas of	severe increase in SAS and/or	cerebrum +/- moderate to	
and/or mild ventriculomegaly	cerebrum +/- moderate	moderate to severe	severe increase in SAS and/or	
	increase in SAS and/or	ventriculomegaly	moderate to severe	
	moderate ventriculomegaly		ventriculomegaly	

**Definition:** A disorder characterized by diffuse reactive astrocytosis with multiple areas of necrotic foci without inflammation. **Navigational Note:** -

# **Memory impairment**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild memory impairment	Moderate memory	Severe memory impairment;	-	-
	impairment; limiting	limiting self-care ADL or		
	instrumental ADL or	severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a deterioration in memory function.

# Meningismus

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms	Moderate symptoms; limiting	Severe symptoms; limiting	Life-threatening	Death
	instrumental ADL or	self-care ADL or severe	consequences; urgent	
	mild/moderate impact on	impact on age-appropriate	intervention indicated	
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by neck stiffness, headache, and photophobia resulting from irritation of the cerebral meninges. **Navigational Note:** -

# **Movements involuntary**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
	instrumental ADL or	self-care ADL or severe		
	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by uncontrolled and purposeless movements.

# Myasthenia gravis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; limiting self-care ADL or severe impact on ageappropriate normal daily	Life-threatening consequences; urgent intervention indicated	Death
		activity (pediatric)		

**Definition:** A disorder characterized by weakness and rapid fatigue of any of the skeletal muscles.

Navigational Note: -

# Nervous system disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

Definition: -

# Neuralgia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by intense painful sensation along a nerve or group of nerves.

**Navigational Note: -**

### **Nystagmus**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
	instrumental ADL or	self-care ADL or severe		
	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by involuntary movements of the eyeballs.

Navigational Note: -

### Oculomotor nerve disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
diagnostic observations only;	instrumental ADL or	self-care ADL or severe		
intervention not indicated	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by dysfunction of the oculomotor nerve (third cranial nerve).

# Olfactory nerve disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
	instrumental ADL or	self-care ADL or severe		
	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by dysfunction of the olfactory nerve (first cranial nerve).

**Navigational Note: -**

# **Optic neuritis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Treatment indicated; best	Severe or medically	Sight-threatening	-
symptoms; only	corrected visual acuity 20/40	significant but not	consequences; urgent	
enhancement on MRI scan	and better or 3 lines or less	immediately sight-	intervention indicated; best	
with no change in vision	decreased vision from known	threatening; decrease in	corrected visual acuity of	
	baseline in the affected eye;	visual acuity (best corrected	20/200 or worse in the	
	limiting instrumental ADL or	visual acuity worse than	affected eye: significant	
	mild/moderate impact on	20/40 or more than 3 lines of	visual field loss; marked optic	
	age-appropriate normal daily	decreased vision from known	disc edema or enhancement	
	activity (pediatric)	baseline, up to 20/200) in the	on MRI scan; intravenous	
		affected eye; oral steroids	steroids indicated; blindness	
		indicated; limiting self-care		
		ADL or severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by inflammation and demyelination of the optic nerve that causes acute, usually monocular, visual loss.

#### **Paresthesia**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
	instrumental ADL or	self-care ADL or severe		
	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by functional disturbances of sensory neurons resulting in abnormal cutaneous sensations of tingling, numbness, pressure, cold, and/or warmth.

Navigational Note: Consider Nervous system disorders: Peripheral motor neuropathy, Peripheral sensory neuropathy.

### Peripheral motor neuropathy

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms; limiting	Severe symptoms; limiting	Life-threatening	Death
diagnostic observations only	instrumental ADL or	self-care ADL or severe	consequences; urgent	
	mild/moderate impact on	impact on age-appropriate	intervention indicated	
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by damage or dysfunction of the peripheral motor nerves.

Navigational Note: Consider Nervous system disorders: Peripheral sensory neuropathy.

### Peripheral sensory neuropathy

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms	Moderate symptoms; limiting	Severe symptoms; limiting	Life-threatening	-
	instrumental ADL or	self-care ADL or severe	consequences; urgent	
	mild/moderate impact on	impact on age-appropriate	intervention indicated	
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by damage or dysfunction of the peripheral sensory nerves.

#### Phantom pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort related to a limb or an organ that is removed from or is not physically part of the body.

**Navigational Note:** Record final diagnosis/cause once determined.

### Presyncope

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Present (e.g., near fainting)	-	-	-

**Definition:** A disorder characterized by an episode of lightheadedness and dizziness which may precede an episode of syncope. **Navigational Note:** Record final diagnosis/cause once determined.

### Pyramidal tract syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms; limiting	Severe symptoms; limiting	Life-threatening	Death
diagnostic observations only;	instrumental ADL or	self-care ADL or severe	consequences; urgent	
intervention not indicated	mild/moderate impact on	impact on age-appropriate	intervention indicated	
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by dysfunction of the corticospinal (pyramidal) tracts of the spinal cord. Symptoms include an increase in the muscle tone in the lower extremities, hyperreflexia, positive Babinski and a decrease in fine motor coordination. **Navigational Note:** -

#### **Radiculitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms	Moderate symptoms; medical intervention indicated; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Severe symptoms; limiting self-care ADL or severe impact on age-appropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A disorder characterized by inflammation involving a nerve root. Patients experience marked discomfort radiating along a nerve path because of spinal pressure on the connecting nerve root.

**Navigational Note: -**

## Recurrent laryngeal nerve palsy

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms	Severe symptoms; medical	Life-threatening	Death
diagnostic observations only;		intervention indicated (e.g.,	consequences; urgent	
intervention not indicated		thyroplasty, vocal cord	intervention indicated	
		injection)		

**Definition:** A disorder characterized by paralysis of the recurrent laryngeal nerve.

#### Reversible posterior leukoencephalopathy syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate symptoms; limiting	Severe symptoms;	Life-threatening	Death
	instrumental ADL or	hospitalization; limiting self-	consequences	
	mild/moderate impact on	care ADL or severe impact on		
	age-appropriate normal daily	age-appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by headaches, mental status changes, visual disturbances, and/or seizures associated with imaging findings of posterior leukoencephalopathy. It has been observed in association with hypertensive encephalopathy, eclampsia, and immunosuppressive and cytotoxic drug treatment. It is an acute or subacute reversible condition. Also known as posterior reversible encephalopathy syndrome (PRES).

Navigational Note: -

#### Seizure

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Brief partial/focal seizure and	Brief generalized seizure;	New onset seizures	Life-threatening	Death
no loss of consciousness	seizure(s) well controlled by	(partial/focal or generalized);	consequences; prolonged	
	anticonvulsants; infrequent	multiple seizures despite	repetitive generalized	
	partial/focal motor seizures	medical intervention	seizures	

**Definition:** A disorder characterized by a sudden, involuntary skeletal muscular contractions of cerebral or brain stem origin. **Navigational Note:** -

#### Somnolence

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild but more than usual	Moderate sedation; limiting	Obtundation or stupor	Life-threatening	Death
drowsiness or sleepiness	instrumental ADL or		consequences; urgent	
	mild/moderate impact on		intervention indicated	
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by characterized by excessive sleepiness and drowsiness.

### **Spasticity**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild or slight increase in	Moderate increase in muscle	Severe increase in muscle	Life-threatening	Death
muscle tone	tone and increase in	tone and increase in	consequences; unable to	
	resistance through range of	resistance through range of	move active or passive range	
	motion	motion	of motion	

**Definition:** A disorder characterized by increased involuntary muscle tone that affects the regions interfering with voluntary movement. It results in gait, movement, and speech disturbances.

**Navigational Note: -**

### Spinal cord compression

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Radiologic findings only	Mild or moderate symptoms;	Severe symptoms; limiting	Life-threatening	Death
	limiting instrumental ADL or	self-care ADL or severe	consequences; urgent	
	mild/moderate impact on	impact on age-appropriate	intervention indicated	
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by pressure on the spinal cord.

**Navigational Note: -**

#### **Stroke**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Incidental radiographic findings only	Mild to moderate neurologic deficit; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity	Severe neurologic deficit; hospitalization; limiting self- care ADL or severe impact on age-appropriate normal daily activity (pediatric)	Life-threatening consequences; urgent	Death
	(pediatric)			

**Definition:** A disorder characterized by an interruption of blood supply to parts of the brain resulting in neurological damage.

#### **Syncope**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Fainting; orthostatic collapse	-	-

**Definition:** A disorder characterized by spontaneous loss of consciousness caused by insufficient blood supply to the brain.

Navigational Note: Record final diagnosis/cause once determined.

#### **Tendon reflex decreased**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Ankle reflex reduced	Ankle reflex absent; other	Absence of all reflexes	1	-
	reflexes reduced			

**Definition:** A disorder characterized by less than normal deep tendon reflexes.

Navigational Note: Consider Nervous system disorders: Peripheral motor neuropathy, Peripheral sensory neuropathy.

#### Transient ischemic attacks

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild neurologic deficit with	Moderate neurologic deficit	-	-	-
or without imaging	with or without imaging			
confirmation	confirmation			

**Definition:** A disorder characterized by a brief attack (less than 24 hours) of cerebral dysfunction of vascular origin, with no persistent neurological deficit.

Navigational Note: If >24 hours, Consider Nervous system disorders: Stroke.

#### **Tremor**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
	instrumental ADL or	self-care ADL or severe		
	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by the uncontrolled shaking movement of the whole body or individual parts.

## Trigeminal nerve disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
diagnostic observations only;	instrumental ADL or	self-care ADL or severe		
intervention not indicated	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by dysfunction of the trigeminal nerve (fifth cranial nerve).

Navigational Note: -

### Trochlear nerve disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
diagnostic observations only;	instrumental ADL or	self-care ADL or severe		
intervention not indicated	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by dysfunction of the trochlear nerve (fourth cranial nerve).

# Tumor inflammation-associated neurotoxicity

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Grade 1  Headaches associated with fevers; mild worsening of existing neurological clinical signs and symptoms from baseline, resulting in minor functional deficits for which only observation or symptomatic management is needed	Moderate changes in the neurological exam from baseline that substantially affect function	Grade 3  Severe neurological clinical signs and symptoms that may affect critical cardiorespiratory functions; clinical signs and symptoms of increased intracranial pressure (>20 mmHg) that are responsive to intervention	Life-threatening, clinically significant elevated ICP (>20 mmHg) refractory to CSF drainage with no improvement in clinical symptoms in response to CSF drainage, possibly warranting urgent escalation of neurosurgical intervention; clinical signs and symptoms of impending/early herniation; severe medullary	Grade 5 Death
			dysfunction; severe meduliary dysfunction requiring endotracheal intubation for airway protection and/or	
			mechanical ventilation	

**Definition:** A disorder characterized by localized neurotoxicity related to cellular therapies or other immunotherapies for CNS tumors (TIAN).

Navigational Note: -

## Vagus nerve disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms; limiting	Severe symptoms; limiting	Life-threatening	Death
diagnostic observations only;	instrumental ADL or	self-care ADL or severe	consequences; urgent	
intervention not indicated	mild/moderate impact on	impact on age-appropriate	intervention indicated	
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by dysfunction of the vagus nerve (tenth cranial nerve).

**Navigational Note:** Record final diagnosis/cause once determined.

## Vasovagal reaction

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	No management indicated	Requires active management	Life-threatening	Death
			consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by a sudden drop of the blood pressure, bradycardia, and peripheral vasodilation that may lead to loss of consciousness. It results from an increase in the stimulation of the vagus nerve.

# Pregnancy, puerperium and perinatal conditions

# Fetal growth retardation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	5 - <10% percentile of weight	1 - <5% percentile of weight	<1% percentile of weight for	-
	for gestational age	for gestational age	gestational age	

**Definition:** A disorder characterized by inhibition of fetal growth resulting in the inability of the fetus to achieve its potential weight. **Navigational Note:** -

### **Pregnancy loss**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	Fetal loss at any gestational	-
			age	

**Definition:** Death in utero. **Navigational Note:** -

## Pregnancy, puerperium and perinatal conditions - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** -

# **Premature delivery**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Delivery of a liveborn infant	-			
at >34 to 37 weeks gestation	at >28 to 34 weeks gestation	at 24 to 28 weeks gestation	at 24 weeks of gestation or	
			less	

**Definition:** A disorder characterized by delivery of a viable infant before the normal end of gestation. Typically, viability is achievable between the twentieth and thirty-seventh week of gestation.

# **Agitation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild mood alteration	Moderate mood alteration	Severe agitation;	Life-threatening	-
		hospitalization not indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by a state of restlessness associated with unpleasant feelings of irritability and tension.

**Navigational Note: -**

# **Anorgasmia**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Inability to achieve orgasm	Inability to achieve orgasm			-
not adversely affecting	adversely affecting			
relationship	relationship			

**Definition:** A disorder characterized by an inability to achieve orgasm.

Navigational Note: -

# **Anxiety**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms; limiting	Severe symptoms;	Life-threatening	-
not indicated	instrumental ADL or	hospitalization indicated;	consequences; urgent	
	mild/moderate impact on	limiting self-care ADL or	intervention indicated	
	age-appropriate normal daily	severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by apprehension of danger and dread accompanied by restlessness, tension, tachycardia, and dyspnea unattached to a clearly identifiable stimulus.

#### Confusion

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild disorientation	Moderate disorientation;	Severe disorientation;	Life-threatening	-
	limiting instrumental ADL or	limiting self-care ADL or	consequences; urgent	
	mild/moderate impact on	severe impact on age-	intervention indicated	
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by a lack of clear and orderly thought and behavior.

**Navigational Note: -**

### Delayed orgasm

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Delay in achieving orgasm	Delay in achieving orgasm	-	-	-
not adversely affecting	adversely affecting			
relationship	relationship			

**Definition:** A disorder characterized by sexual dysfunction characterized by a delay in climax.

**Navigational Note: -**

# Delirium

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild acute confusional state	Moderate and acute confusional state; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily	Severe and acute confusional state; hospitalization indicated; urgent intervention indicated; new onset; limiting self-care ADL	Life-threatening consequences, threats of harm to self or others; urgent intervention indicated	Death
	activity (pediatric)	or severe impact on age- appropriate normal daily activity (pediatric)		

**Definition:** A disorder characterized by the acute and sudden development of confusion, illusions, movement changes, inattentiveness, agitation, and hallucinations. Usually, it is a reversible condition.

#### **Delusions**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Moderate delusional	Severe delusional symptoms;	Life-threatening	Death
	symptoms	outpatient management;	consequences, threats of	
		new onset	harm to self or others;	
			hospitalization indicated	

**Definition:** A disorder characterized by false personal beliefs held contrary to reality, despite contradictory evidence and common sense. **Navigational Note:** -

### Depression

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild depressive symptoms	Moderate depressive	Severe depressive	Life-threatening	Death
	symptoms; limiting	symptoms; hospitalization	consequences, threats of	
	instrumental ADL or	not indicated; limiting self-	harm to self or others;	
	mild/moderate impact on	care ADL or severe impact on	hospitalization indicated	
	age-appropriate normal daily	age-appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by melancholic feelings of grief or unhappiness.

**Navigational Note: -**

## **Euphoria**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild mood elevation	Moderate mood elevation	Severe mood elevation (e.g.,	-	-
		hypomania)		

**Definition:** A disorder characterized by an exaggerated feeling of well-being which is disproportionate to events and stimuli.

#### **Hallucinations**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild hallucinations (e.g., perceptual distortions)	Moderate hallucinations	Severe hallucinations; hospitalization not indicated	Life-threatening consequences, threats of harm to self or others; hospitalization indicated	Death

**Definition:** A disorder characterized by a false sensory perception in the absence of an external stimulus.

Navigational Note: -

#### Insomnia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild difficulty falling asleep,	Moderate difficulty falling	Severe difficulty in falling	-	-
staying asleep or waking up	asleep, staying asleep or	asleep, staying asleep or		
early	waking up early	waking up early		

**Definition:** A disorder characterized by difficulty in falling asleep and/or remaining asleep.

**Navigational Note: -**

# Irritability

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild; easily consolable	Moderate; increased	Severe abnormal or	-	-
	attention indicated; limiting	excessive response;		
	instrumental ADL or	inconsolable; medical or		
	mild/moderate impact on	psychiatric intervention		
	age-appropriate normal daily	indicated; limiting self-care		
	activity (pediatric)	ADL or severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by an abnormal responsiveness to stimuli or physiological arousal; may be in response to pain, fright, a drug, an emotional situation or a medical condition.

#### Libido decreased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Decrease in sexual interest	Decrease in sexual interest	-	-	-
not adversely affecting	adversely affecting			
relationship	relationship			

**Definition:** A disorder characterized by a decrease in sexual desire.

Navigational Note: -

#### Libido increased

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	-	-	-	-

**Definition:** A disorder characterized by an increase in sexual desire.

**Navigational Note: -**

#### Mania

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild manic symptoms (e.g.,	Moderate manic symptoms	Severe manic symptoms	Life-threatening	Death
elevated mood, rapid	(e.g., relationship and work	(e.g., hypomania; major	consequences, threats of	
thoughts, rapid speech,	difficulties; poor hygiene)	sexual or financial	harm to self or others;	
decreased need for sleep)		indiscretions); hospitalization	hospitalization indicated	
		not indicated; new onset		

**Definition:** A disorder characterized by excitement of psychotic proportions manifested by mental and physical hyperactivity, disorganization of behavior and elevation of mood.

Navigational Note: -

# Personality change

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild personality change	Moderate personality change	Severe personality change;	Life-threatening	-
		hospitalization not indicated	consequences, threats of	
			harm to self or others;	
			hospitalization indicated	

**Definition:** A disorder characterized by a conspicuous change in a person's behavior and thinking.

### Psychiatric disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences;	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	hospitalization or urgent	
intervention not indicated	instrumental ADL or	limiting self-care ADL or	intervention indicated	
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** -

Navigational Note: -

## **Psychosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild psychotic symptoms	Moderate psychotic	Severe psychotic symptoms	Life-threatening	Death
	symptoms (e.g., disorganized	(e.g., paranoid, extreme	consequences, threats of	
	speech; impaired reality	disorganization);	harm to self or others;	
	testing)	hospitalization not indicated;	hospitalization indicated	
		new onset		

**Definition:** A disorder characterized by personality change, impaired functioning, and loss of touch with reality. It may be a manifestation of schizophrenia, bipolar disorder or brain tumor.

**Navigational Note: -**

### **Restlessness**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
not indicated	instrumental ADL or	self-care ADL or severe		
	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by an inability to rest, relax or be still.

## Suicidal ideation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Increased thoughts of death	Suicidal ideation with no	Specific plan to commit	Specific plan to commit	-
but no wish to kill oneself	specific plan or intent	suicide without serious intent	suicide with serious intent to	
		to die which may not require	die which requires	
		hospitalization	hospitalization	

**Definition:** A disorder characterized by thoughts of taking one's own life.

Navigational Note: -

# Suicide attempt

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Suicide attempt or gesture	Suicide attempt with intent to	Death
		without intent to die	die which requires	
			hospitalization	

**Definition:** A disorder characterized by self-inflicted harm in an attempt to end one's own life.

# Acute kidney injury

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Hospitalization indicated	Life-threatening consequences; dialysis	Death
			indicated	

**Definition:** A disorder characterized by the acute loss of renal function (within 2 weeks).

Navigational Note: Consider Investigations: Creatinine increased; Renal and urinary disorders: Tubulointerstitial nephritis.

### **Bladder perforation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Invasive intervention not	Invasive intervention	Life-threatening	Death
	indicated	indicated	consequences; organ failure;	
			urgent operative intervention	
			indicated	

**Definition:** A disorder characterized by a rupture in the bladder wall.

**Navigational Note: -**

### Bladder spasm

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Intervention not indicated	Antispasmodics indicated	Hospitalization indicated	-	-

**Definition:** A disorder characterized by a sudden and involuntary contraction of the bladder wall.

# Chronic kidney disease

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
eGFR (estimated Glomerular	eGFR or CrCl <60 - 30	eGFR or CrCl <30 - 15	eGFR or CrCl <15 ml/min/1.73	Death
Filtration Rate) or CrCl	ml/min/1.73 m2	ml/min/1.73 m2	m2; dialysis or renal	
(creatinine clearance) <lln -<="" td=""><td></td><td></td><td>transplant indicated</td><td></td></lln>			transplant indicated	
60 ml/min/1.73 m2 or				
proteinuria 2+ present; urine				
protein/creatinine >0.5				

**Definition:** A disorder characterized by loss of kidney function greater than three months duration.

**Navigational Note: -**

# **Cystitis noninfective**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Microscopic hematuria;	Moderate hematuria;	Gross hematuria;	Life-threatening	Death
minimal increase in	moderate increase in	transfusion, IV medications,	consequences; urgent	
frequency, urgency, dysuria,	frequency, urgency, dysuria,	or hospitalization indicated;	invasive intervention	
or nocturia; new onset of	nocturia or incontinence;	elective invasive intervention	indicated	
incontinence	urinary catheter placement	indicated		
	or bladder irrigation			
	indicated; limiting			
	instrumental ADL or			
	mild/moderate impact on			
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by inflammation of the bladder which is not caused by an infection of the urinary tract.

### Dysuria

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	-	-	-	-

**Definition:** A disorder characterized by painful urination.

**Navigational Note:** If associated with an infection, report the infection. For grades higher than Grade 1, consider Renal and urinary disorders: Bladder spasm, Cystitis noninfective; Infections and infestations: Urinary tract infection.

### Glomerulonephritis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; laboratory	Declining glomerular	IV therapy indicated;	Life-threatening	Death
findings only	filtration rate (GFR); edema;	immunosuppressant	consequences; urgent	
	hypertension; oral	indicated; hospitalization or	intervention indicated; renal	
	management indicated	prolongation of existing	replacement therapy	
		hospitalization indicated;		
		limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by inflammation of the glomerulus, usually based on renal biopsy.

**Navigational Note: -**

#### Glucosuria

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	-	-	-	-

**Definition:** A disorder characterized by laboratory test results that indicate glucose in the urine.

#### Hematuria

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; urinary	Gross hematuria;	Life-threatening	Death
diagnostic observations only;	catheter or bladder irrigation	transfusion, IV medications,	consequences; urgent	
intervention not indicated	indicated; limiting	or hospitalization indicated;	invasive intervention	
	instrumental ADL or	elective invasive intervention	indicated	
	mild/moderate impact on	indicated; limiting self-care		
	age-appropriate normal daily	ADL or severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by laboratory test results that indicate blood in the urine.

Navigational Note: -

# Hemoglobinuria

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or		-	-	-
diagnostic observations only;				
intervention not indicated				

**Definition:** A disorder characterized by laboratory test results that indicate the presence of free hemoglobin in the urine.

**Navigational Note:** Report underlying AE if > Grade 1.

### Nephrotic syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	IV therapy indicated;	Life-threatening	Death
		hospitalization or	consequences; urgent	
		prolongation of existing	intervention indicated; renal	
		hospitalization indicated;	replacement therapy;	
		limiting self-care ADL or	anasarca	
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by symptoms that include severe edema, proteinuria, and hypoalbuminemia; it is indicative of renal dysfunction.

Navigational Note: -

### **Nocturia**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	-	-	-	-

**Definition:** A disorder characterized by the need to get up at night on a regular basis to urinate.

# Renal and urinary disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** -

**Navigational Note: -**

### Renal calculi

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Symptomatic; oral	Hospitalization indicated; IV	Life-threatening	Death
symptoms; occasional use of	antiemetics indicated;	intervention (e.g., analgesics,	consequences; urgent	
nonprescription analgesics	around the clock	antiemetics); elective invasive	invasive intervention	
indicated	nonprescription analgesics or	intervention indicated	indicated	
	any oral narcotic analgesics			
	indicated			

**Definition:** A disorder characterized by the formation of crystals/kidney stones in the pelvis of the kidney.

#### Renal colic

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain not interfering with	Moderate pain; prescription	Hospitalization indicated;	-	-
activity; nonprescription	medication indicated; limiting	limiting self-care ADL or		
medication indicated	instrumental ADL or	severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by paroxysmal and severe flank marked discomfort radiating to the inguinal area. Often, the cause is the passage of crystals/kidney stones.

Navigational Note: -

### Renal hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Analgesics and hematocrit	Hospitalization	Life-threatening	Death
not indicated	monitoring indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the kidney.

Navigational Note: -

## **Tubulointerstitial nephritis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Laboratory findings without	Increase in creatinine; oral	IV therapy indicated;	Life-threatening	Death
increase in creatinine	management indicated with	hospitalization or	consequences; urgent	
	steroid	prolongation of existing	intervention indicated	
		hospitalization indicated;		
		limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by inflammation of the renal tubule and surrounding tissues.

## **Urinary fistula**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			invasive intervention	
			indicated	

**Definition:** A disorder characterized by an abnormal communication between any part of the urinary system and another organ or anatomic site.

Navigational Note: -

# **Urinary frequency**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	Medical management	-	-	-
	indicated; limiting			
	instrumental ADL or			
	mild/moderate impact on			
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by urination at short intervals.

**Navigational Note: -**

### **Urinary incontinence**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Occasional (e.g., with	Spontaneous; pads indicated;	Intervention indicated (e.g.,	-	-
coughing, sneezing, etc.),	limiting instrumental ADL or	clamp, collagen injections);		
pads not indicated	mild/moderate impact on	operative intervention		
	age-appropriate normal daily	indicated; limiting self-care		
	activity (pediatric)	ADL or severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by inability to control the flow of urine from the bladder.

# **Urinary retention**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Urinary, suprapubic or	Placement of urinary,	Elective invasive intervention	Life-threatening	Death
intermittent catheter	suprapubic or intermittent	indicated; substantial loss of	consequences; organ failure;	
placement not indicated; able	catheter placement	affected kidney function or	urgent operative intervention	
to void with some residual	indicated; medication	mass	indicated	
	indicated			

**Definition:** A disorder characterized by accumulation of urine within the bladder because of the inability to urinate.

**Navigational Note: -**

### **Urinary tract obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic but no	Altered organ function (e.g.,	Life-threatening	Death
diagnostic observations only;	hydronephrosis, sepsis, or	hydronephrosis or renal	consequences; urgent	
intervention not indicated	renal dysfunction; urethral	dysfunction); invasive	intervention indicated	
	dilation, urinary or	intervention indicated		
	suprapubic catheter			
	indicated			

**Definition:** A disorder characterized by blockage of the normal flow of contents of the urinary tract.

**Navigational Note: -**

### **Urinary tract pain**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the urinary tract.

**Navigational Note:** Record final diagnosis/cause once determined.

# **Urinary urgency**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	Medical management	-	-	-
	indicated; limiting			
	instrumental ADL or			
	mild/moderate impact on			
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by a sudden compelling urge to urinate.

**Navigational Note: -**

### **Urine discoloration**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	-	-	1	-

**Definition:** A disorder characterized by a change in the color of the urine.

# Reproductive system and breast disorders

#### Amenorrhea

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Present	-	-	-

**Definition:** A disorder characterized by the abnormal absence of menses for at least three consecutive menstrual cycles.

**Navigational Note: -**

### Azoospermia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Absence of sperm in	-	-	-
	ejaculate			

**Definition:** A disorder characterized by laboratory test results that indicate complete absence of spermatozoa in the semen.

**Navigational Note: -**

### **Breast pain**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the breast region.

Navigational Note: Record final diagnosis/cause once determined.

## Dysmenorrhea

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
not indicated	instrumental ADL or	self-care ADL or severe		
	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by abnormally painful abdominal cramps during menses.

**Navigational Note: -**

### Dyspareunia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild discomfort or pain	Moderate discomfort or pain	Severe discomfort or pain	-	-
associated with vaginal	associated with vaginal	associated with vaginal		
penetration; discomfort	penetration; discomfort or	penetration; discomfort or		
relieved with use of vaginal	pain partially relieved with	pain unrelieved by vaginal		
lubricants or estrogen	use of vaginal lubricants or	lubricants or estrogen		
	estrogen			

**Definition:** A disorder characterized by painful or difficult coitus.

**Navigational Note: -**

### **Ejaculation disorder**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Diminished ejaculation	Anejaculation or retrograde	-		_
	ejaculation			

**Definition:** A disorder characterized by problems related to ejaculation. This category includes premature, delayed, retrograde and painful ejaculation.

### **Erectile dysfunction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Decrease in erectile function (frequency or rigidity of erections) but intervention not indicated (e.g., medication or use of mechanical device, penile pump)	Decrease in erectile function (frequency/rigidity of erections), erectile intervention indicated, (e.g., medication or mechanical devices such as penile pump)	Decrease in erectile function (frequency/rigidity of erections) but erectile intervention not helpful (e.g., medication or mechanical devices such as penile pump); placement of a permanent penile prosthesis indicated (not previously present)	-	-

**Definition:** A disorder characterized by the persistent or recurrent inability to achieve or to maintain an erection during sexual activity. **Navigational Note:** -

# Fallopian tube obstruction

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; elective	Severe symptoms; invasive	-	-
diagnostic observations only;	intervention indicated	intervention indicated		
intervention not indicated				

**Definition:** A disorder characterized by blockage of the normal flow of the contents in the fallopian tube.

**Navigational Note: -**

# Feminization acquired

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	-	-	-
not indicated	medical intervention			
	indicated			

**Definition:** A disorder characterized by the development of secondary female sex characteristics in males due to extrinsic factors.

## **Gynecomastia**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic (e.g., pain or	Severe symptoms; elective	-	-
	psychosocial impact)	operative intervention		
		indicated		

**Definition:** A disorder characterized by excessive development of the breasts in males.

**Navigational Note: -**

# Hematosalpinx

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Minimal bleeding identified	Moderate bleeding; medical	Invasive intervention	Life-threatening	Death
on imaging study or	intervention indicated	indicated; hospitalization	consequences; urgent	
laparoscopy; intervention not			operative intervention	
indicated			indicated	

**Definition:** A disorder characterized by the presence of blood in a fallopian tube.

**Navigational Note: -**

# Irregular menstruation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Intermittent/irregular	Intermittent/irregular	-	-	-
menses for <=3 consecutive	menses for >3 consecutive			
menstrual cycles	menstrual cycles			

**Definition:** A disorder characterized by a change in cycle or duration of menses from baseline.

Navigational Note: Consider Reproductive system and breast disorders: Amenorrhea.

### **Lactation disorder**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild changes in lactation, not	Changes in lactation,	-	-	-
significantly affecting	significantly affecting breast			
production or expression of	production or expression of			
breast milk	breast milk			

**Definition:** A disorder characterized by disturbances of milk secretion. It is not necessarily related to pregnancy that is observed in females and can be observed in males.

**Navigational Note: -**

### Menorrhagia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild; iron supplements	Moderate symptoms;	Hospitalization; operative	Life-threatening	Death
indicated	medical intervention	intervention indicated (e.g.,	consequences; urgent	
	indicated (e.g., hormones)	hysterectomy)	intervention indicated	

**Definition:** A disorder characterized by abnormally heavy vaginal bleeding during menses.

**Navigational Note: -**

# Nipple deformity

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; asymmetry	Symptomatic; asymmetry of	-	-	-
with slight retraction and/or	nipple areolar complex with			
thickening of the nipple	moderate retraction and/or			
areolar complex	thickening of the nipple			
	areolar complex			

**Definition:** A disorder characterized by an abnormality of the nipple.

# Oligospermia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Sperm concentration >0 to	-	-		-
<15 million/ml				

**Definition:** A disorder characterized by a decrease in the number of spermatozoa in the semen.

Navigational Note: -

### Ovarian function insufficiency

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Intermittent/irregular	Amenorrhea for 3	-	-	-
menses for 3 consecutive	consecutive months with			
months with basal FSH levels	basal FSH levels >40 IU/L or			
>25 IU/L but less than	in the postmenopausal range			
postmenopausal range				

**Definition:** A disorder characterized by the development of oligomenorrhea or amenorrhea for at least 3 consecutive months and serum follicle-stimulating hormone (FSH) levels in the menopausal range before age 40. Symptoms of estrogen deficiency may include hot flashes, night sweats, mood swings, and vaginal dryness. Laboratory findings include elevated serum FSH. Other supportive laboratory findings include decreased serum estradiol and anti-Mullerian hormone (AMH) levels.

Navigational Note: -

### Ovarian hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the ovary.

# Ovarian rupture

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic clinical or	Symptomatic and	Transfusion; invasive	Life-threatening	Death
diagnostic observations only;	intervention not indicated	intervention indicated	consequences; urgent	
intervention not indicated			intervention indicated	

**Definition:** A disorder characterized by tearing or disruption of the ovarian tissue.

**Navigational Note: -**

# **Ovulation pain**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Present	-	-	-

**Definition:** A disorder characterized by a sensation of marked discomfort in one side of the abdomen between menstrual cycles, around the time of the discharge of the ovum from the ovarian follicle.

**Navigational Note:** Record final diagnosis/cause once determined.

#### Pelvic floor muscle weakness

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic, not interfering	Severe symptoms; limiting	-	-
diagnostic observations only;	with bladder, bowel, or	self-care ADL or severe		
intervention not indicated	vaginal function; limiting	impact on age-appropriate		
	instrumental ADL or	normal daily activity		
	mild/moderate impact on	(pediatric)		
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by a reduction in the strength of the muscles of the pelvic floor.

### Pelvic pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the pelvis.

Navigational Note: Record final diagnosis/cause once determined.

### Penile pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the penis.

Navigational Note: Record final diagnosis/cause once determined.

# Perineal pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the area between the genital organs and the anus.

Navigational Note: Record final diagnosis/cause once determined.

#### Prostatic hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the prostate gland.

**Navigational Note: -**

#### **Prostatic obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; elective	Severe symptoms; invasive	-	-
diagnostic observations only;	intervention indicated	intervention indicated		
intervention not indicated				

**Definition:** A disorder characterized by compression of the urethra secondary to enlargement of the prostate gland. This results in voiding difficulties (straining to void, slow urine stream, and incomplete emptying of the bladder).

Navigational Note: -

### Prostatic pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the prostate gland.

Navigational Note: Record final diagnosis/cause once determined.

# Reproductive system and breast disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** -

**Navigational Note: -**

### Scrotal pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the scrotal area.

**Navigational Note:** Record final diagnosis/cause once determined.

# Spermatic cord hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the spermatic cord.

### Spermatic cord obstruction

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; elective	Severe symptoms; invasive	-	-
diagnostic observations only;	intervention indicated	intervention indicated		
intervention not indicated				

**Definition:** A disorder characterized by blockage of the normal flow of the contents of the spermatic cord.

**Navigational Note: -**

#### **Testicular disorder**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic but not	Severe symptoms; interfering	Life-threatening	-
diagnostic observations only;	interfering with sexual	with sexual function;	consequences; urgent	
intervention not indicated	function; intervention not	intervention indicated;	intervention indicated	
	indicated; limiting	limiting self-care ADL or		
	instrumental ADL or	severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by abnormal function or appearance of the testis.

Navigational Note: Consider other AE terms in the Renal and urinary disorders SOC or Reproductive system and breast disorders SOC.

# Testicular hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the testis.

### Testicular pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the testis.

Navigational Note: Record final diagnosis/cause once determined.

#### Uterine fistula

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the uterus and another organ or anatomic site.

**Navigational Note: -**

### Uterine hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the uterus.

**Navigational Note: -**

#### **Uterine obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; elective	Severe symptoms; invasive	-	-
diagnostic observations only;	intervention indicated	intervention indicated		
intervention not indicated				

**Definition:** A disorder characterized by blockage of the uterine outlet.

# **Uterine pain**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the uterus.

Navigational Note: Record final diagnosis/cause once determined.

### Vaginal discharge

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild vaginal discharge	Moderate to heavy vaginal	-	-	-
(greater than baseline for	discharge; use of perineal			
patient)	pad or tampon indicated			

**Definition:** A disorder characterized by vaginal secretions. Mucus produced by the cervical glands is discharged from the vagina naturally, especially during the childbearing years.

**Navigational Note: -**

# Vaginal dryness

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild vaginal dryness not	Moderate vaginal dryness	Severe vaginal dryness	-	-
interfering with sexual	interfering with sexual	resulting in dyspareunia or		
function	function or causing frequent	severe discomfort		
	discomfort			

**Definition:** A disorder characterized by an uncomfortable feeling of itching and burning in the vagina.

### Vaginal fistula

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the vagina and another organ or anatomic site.

**Navigational Note: -**

# Vaginal hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by bleeding from the vagina.

**Navigational Note: -**

# **Vaginal inflammation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild discomfort or pain,	Moderate discomfort or pain,	Severe discomfort or pain,	Life-threatening	-
edema, or redness	edema, or redness; limiting	edema, or redness; small	consequences; widespread	
	instrumental ADL or	areas of mucosal ulceration;	areas of mucosal ulceration;	
	mild/moderate impact on	limiting self-care ADL or	urgent intervention indicated	
	age-appropriate normal daily	severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by inflammation involving the vagina. Symptoms may include redness, edema, marked discomfort and an increase in vaginal discharge.

# **Vaginal obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; elective	Severe symptoms; invasive	-	-
diagnostic observations only;	intervention indicated	intervention indicated		
intervention not indicated				

**Definition:** A disorder characterized by blockage of vaginal canal.

Navigational Note: -

# Vaginal pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the vagina.

**Navigational Note:** Record final diagnosis/cause once determined.

# **Vaginal perforation**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Invasive intervention not	Invasive intervention	Life-threatening	Death
	indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by a rupture in the vaginal wall.

# Vaginal stricture

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; mild vaginal shortening or narrowing	Vaginal narrowing and/or shortening not interfering with physical examination	Vaginal narrowing and/or shortening interfering with the use of tampons, sexual	-	Death
		activity or physical examination		

**Definition:** A disorder characterized by a narrowing of the vaginal canal.

# Respiratory, thoracic and mediastinal disorders

### Adult respiratory distress syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Present with radiologic	Life-threatening respiratory	Death
		findings; intubation not	or hemodynamic	
		indicated	compromise; intubation or	
			urgent intervention indicated	

**Definition:** A disorder characterized by progressive and life-threatening pulmonary distress in the absence of an underlying pulmonary condition, usually following major trauma or surgery.

Navigational Note: Consider Respiratory, thoracic and mediastinal disorders: Pneumonitis.

### **Allergic rhinitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	-	-	-
not indicated	medical intervention			
	indicated			

**Definition:** A disorder characterized by an inflammation of the nasal mucous membranes caused by an IgE-mediated response to external allergens. The inflammation may also involve the mucous membranes of the sinuses, eyes, middle ear, and pharynx. Symptoms include sneezing, nasal congestion, rhinorrhea and itching.

**Navigational Note: -**

## **Aphonia**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Voicelessness; unable to	-	-
		speak		

**Definition:** A disorder characterized by the inability to speak. It may result from injuries to the vocal cords or may be functional (psychogenic).

## Apnea

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Present; medical intervention	Life-threatening respiratory	Death
		indicated	or hemodynamic	
			compromise; intubation or	
			urgent intervention indicated	

**Definition:** A disorder characterized by cessation of breathing.

Navigational Note: -

# **Aspiration**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Clinical or diagnostic observations only; intervention not indicated	Altered eating habits; coughing or choking episodes after eating or swallowing; medical intervention indicated (e.g., suction or oxygen)	Dyspnea and pneumonia symptoms (e.g., aspiration pneumonia); hospitalization indicated; unable to aliment orally	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death

**Definition:** A disorder characterized by inhalation of solids or liquids into the lungs.

**Navigational Note: -**

# **Atelectasis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic (e.g., dyspnea,	Supplemental oxygen	Life-threatening respiratory	Death
diagnostic observations only;	cough); medical intervention	indicated; hospitalization or	or hemodynamic	
intervention not indicated	indicated (e.g., chest	elective operative	compromise; intubation or	
	physiotherapy, suctioning);	intervention indicated (e.g.,	urgent intervention indicated	
	bronchoscopic suctioning	stent, laser)		

**Definition:** A disorder characterized by the collapse of part or the entire lung.

#### **Bronchial fistula**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the bronchus and another organ or anatomic site.

**Navigational Note: -**

#### **Bronchial obstruction**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic (e.g., mild	Shortness of breath with	Life-threatening respiratory	Death
diagnostic observations only;	wheezing); endoscopic	stridor; endoscopic	or hemodynamic	
intervention not indicated	evaluation indicated;	intervention indicated (e.g.,	compromise; intubation or	
	radiographic evidence of	laser, stent placement)	urgent intervention indicated	
	atelectasis/lobar collapse;			
	medical management			
	indicated (e.g., steroids,			
	bronchodilators)			

**Definition:** A disorder characterized by blockage of a bronchus passage, most often by bronchial secretions and exudates.

**Navigational Note: -**

### **Bronchial stricture**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic (e.g., rhonchi or	Shortness of breath with	Life-threatening respiratory	Death
diagnostic observations only;	wheezing) but without	stridor; endoscopic	or hemodynamic	
intervention not indicated	respiratory distress; medical	intervention indicated (e.g.,	compromise; intubation or	
	intervention indicated (e.g.,	laser, stent placement)	urgent intervention indicated	
	steroids, bronchodilators)			

**Definition:** A disorder characterized by a narrowing of the bronchial tube.

### **Bronchopleural fistula**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Hospitalization; invasive	Life-threatening	Death
	intervention not indicated	intervention indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between a bronchus and the pleural cavity.

**Navigational Note: -**

### Bronchopulmonary hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	invasive intervention not		consequences; intubation or	
	indicated		urgent intervention indicated	

**Definition:** A disorder characterized by bleeding from the bronchial wall and/or lung parenchyma.

**Navigational Note: -**

## **Bronchospasm**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Symptomatic; medical	Supplemental oxygen	Life-threatening respiratory	Death
not indicated	intervention indicated;	indicated; limiting self-care	or hemodynamic	
	limiting instrumental ADL or mild/moderate impact on	ADL or severe impact on age- appropriate normal daily	compromise; intubation or urgent intervention indicated	
	age-appropriate normal daily activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by a sudden contraction of the smooth muscles of the bronchial wall or narrowing of the airway. May be manifested as wheezing.

## Chylothorax

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; medical	Severe symptoms; elective	Life-threatening respiratory	Death
diagnostic observations only;	intervention indicated (e.g.,	operative intervention	or hemodynamic	
intervention not indicated	fat-restricted diet);	indicated	compromise; intubation or	
	thoracentesis or tube		urgent intervention indicated	
	drainage indicated			

**Definition:** A disorder characterized by milky pleural effusion (abnormal collection of fluid) resulting from accumulation of lymph fluid in the pleural cavity.

**Navigational Note: -**

# Cough

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms;	Moderate symptoms,	Severe symptoms; limiting	-	-
nonprescription intervention	medical intervention	self-care ADL or severe		
indicated	indicated; limiting	impact on age-appropriate		
	instrumental ADL or	normal daily activity		
	mild/moderate impact on	(pediatric)		
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by sudden, often repetitive, spasmodic contraction of the thoracic cavity, resulting in violent release of air from the lungs and usually accompanied by a distinctive sound.

Navigational Note: Record final diagnosis/cause once determined.

### Dyspnea

Grade 3	Grade 4	Grade 5
n; limiting limiting self-care ADL or severe impact on age-appropriate normal daily activity (pediatric)	; Life-threatening consequences; urgent intervention indicated	Death
	h; limiting limiting self-care ADL or severe impact on age-appropriate normal daily	n; limiting limiting self-care ADL or severe impact on age-appropriate normal daily normal daily activity (pediatric) consequences; urgent intervention indicated

**Definition:** A disorder characterized by an uncomfortable sensation of difficulty breathing.

Navigational Note: Consider Cardiac disorders: Heart failure; Record final diagnosis/cause once determined.

# **Epistaxis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Transfusion; invasive	Life-threatening	Death
not indicated	medical intervention	intervention indicated (e.g.,	consequences; urgent	
	indicated (e.g., nasal packing,	hemostasis of bleeding site)	intervention indicated	
	cauterization; topical			
	vasoconstrictors)			

**Definition:** A disorder characterized by bleeding from the nose.

**Navigational Note: -**

### **Hiccups**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Severe symptoms; interfering	-	-
not indicated	medical intervention	with sleep; limiting self-care		
	indicated; limiting	ADL or severe impact on age-		
	instrumental ADL or	appropriate normal daily		
	mild/moderate impact on	activity (pediatric)		
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by repeated gulp sounds that result from an involuntary opening and closing of the glottis. This is attributed to a spasm of the diaphragm.

#### Hoarseness

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild or intermittent voice	Moderate or persistent voice	Severe voice changes	-	-
change; fully understandable;	changes; may require	including predominantly		
self-resolves	occasional repetition but	whispered speech		
	understandable on			
	telephone; medical			
	evaluation indicated			

**Definition:** A disorder characterized by harsh and raspy voice arising from or spreading to the larynx.

**Navigational Note: -**

# Hypoxia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic decrease in	Decreased oxygen saturation	Decreased oxygen saturation	Life-threatening airway	Death
oxygen saturation <lln< td=""><td>with exercise (e.g., pulse</td><td>at rest (e.g., pulse oximeter</td><td>compromise; urgent</td><td></td></lln<>	with exercise (e.g., pulse	at rest (e.g., pulse oximeter	compromise; urgent	
	oximeter <88%); intermittent	<88% or PaO2 <=55 mmHg);	intervention indicated (e.g.,	
	supplemental oxygen	continuous supplemental	tracheotomy or intubation)	
		oxygen		

**Definition:** A disorder characterized by a decrease in the level of oxygen in the body.

**Navigational Note:** Consider Respiratory, thoracic and mediastinal disorders: Dyspnea, Pneumonitis; Record final diagnosis/cause once determined.

# Laryngeal edema

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; medical	Stridor; respiratory distress;	Life-threatening airway	Death
diagnostic observations only;	intervention indicated (e.g.,	hospitalization indicated	compromise; urgent	
intervention not indicated	dexamethasone,		intervention indicated (e.g.,	
	epinephrine, antihistamines)		tracheotomy or intubation)	

**Definition:** A disorder characterized by swelling due to an excessive accumulation of fluid in the larynx.

Navigational Note: Record final diagnosis/cause once determined.

### Laryngeal fistula

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the larynx and another organ or anatomic site.

**Navigational Note: -**

# Laryngeal hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild cough or trace	Moderate symptoms;	Hospitalization	Life-threatening	Death
hemoptysis; laryngoscopic	intervention indicated		consequences; urgent	
findings			intervention indicated (e.g.,	
			tracheotomy or intubation)	

**Definition:** A disorder characterized by bleeding from the larynx.

**Navigational Note: -**

# Laryngeal inflammation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild sore throat; raspy voice	Moderate sore throat;	Severe throat pain;	-	-
	analgesics indicated	endoscopic intervention		
		indicated		

**Definition:** A disorder characterized by an inflammation involving the larynx.

# Laryngeal mucositis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Endoscopic findings only;	Moderate pain, analgesics	Severe pain; severely altered	Life-threatening airway	Death
mild discomfort with normal	indicated; altered oral intake;	eating/swallowing; medical	compromise; urgent	
intake	limiting instrumental ADL or	intervention indicated	intervention indicated (e.g.,	
	mild/moderate impact on		tracheotomy or intubation)	
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by ulceration or inflammation involving the mucous membrane of the larynx. **Navigational Note:** -

# Laryngeal obstruction

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic (e.g., noisy airway breathing), no respiratory distress; medical intervention indicated (e.g., steroids); limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily	Stridor; endoscopic intervention indicated (e.g., stent, laser); limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death
	activity (pediatric)			

**Definition:** A disorder characterized by blockage of the laryngeal airway.

# Laryngeal stenosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic (e.g., noisy airway breathing), no respiratory distress; medical intervention indicated (e.g., steroids); limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Stridor; endoscopic intervention indicated (e.g., stent, laser); limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening consequences; urgent intervention indicated	Death

**Definition:** A disorder characterized by a narrowing of the laryngeal airway.

Navigational Note: -

# Laryngopharyngeal dysesthesia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; no anxiety;	Moderate symptoms; mild	Severe symptoms; dyspnea	Life-threatening	Death
intervention not indicated	anxiety, but no dyspnea;	and swallowing difficulty;	consequences	
	short duration of observation	limiting self-care ADL or		
	and/or anxiolytic indicated;	severe impact on age-		
	limiting instrumental ADL or	appropriate normal daily		
	mild/moderate impact on	activity (pediatric)		
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by an uncomfortable persistent sensation in the area of the laryngopharynx.

### Laryngospasm

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Transient episode;	Recurrent episodes;	Persistent or severe episodes	Death
	intervention not indicated	noninvasive intervention	associated with syncope;	
		indicated (e.g., breathing	urgent intervention indicated	
		technique, pressure point	(e.g., fiberoptic laryngoscopy,	
		massage)	intubation, botox injection)	

**Definition:** A disorder characterized by paroxysmal spasmodic muscular contraction of the vocal cords.

**Navigational Note: -**

# Mediastinal hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated; radiologic	intervention indicated		consequences; urgent	
evidence only			intervention indicated	

**Definition:** A disorder characterized by bleeding from the mediastinum.

**Navigational Note: -**

# Nasal congestion

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Associated with bloody nasal	-	-
not indicated	medical intervention	discharge or epistaxis		
	indicated			

**Definition:** A disorder characterized by obstruction of the nasal passage due to mucosal edema.

# Oropharyngeal pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; altered oral	Severe pain; severely altered	-	-
	intake; non-narcotics	eating/swallowing; narcotics		
	initiated; topical analgesics	initiated; requires parenteral		
	initiated	nutrition		

**Definition:** A disorder characterized by a sensation of marked discomfort in the oropharynx or pain on swallowing.

**Navigational Note:** Record final diagnosis/cause once determined.

### Pharyngeal fistula

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the pharynx and another organ or anatomic site. **Navigational Note:** -

### Pharyngeal hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	Hospitalization	Life-threatening	Death
not indicated	intervention indicated		consequences; intubation or	
			urgent intervention indicated	

**Definition:** A disorder characterized by bleeding from the pharynx.

# Pharyngeal mucositis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Endoscopic findings only;	Moderate pain, analgesics	Severe pain; unable to	Life-threatening	Death
minimal symptoms with	indicated; altered oral intake;	adequately aliment or	consequences; urgent	
normal oral intake; mild pain	limiting instrumental ADL or	hydrate orally; limiting self-	intervention indicated	
but analgesics not indicated	mild/moderate impact on	care ADL or severe impact on		
	age-appropriate normal daily	age-appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by ulceration or inflammation involving the mucous membrane of the pharynx. **Navigational Note:** -

# Pharyngeal necrosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Inability to aliment	Life-threatening	Death
		adequately by Gl tract;	consequences; urgent	
		invasive intervention	operative intervention	
		indicated; tube feeding or	indicated	
		TPN indicated		

**Definition:** A disorder characterized by a necrotic process occurring in the pharynx.

# Pharyngeal stenosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic (e.g., noisy airway breathing), no respiratory distress; medical intervention indicated (e.g., steroids); limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Stridor; endoscopic intervention indicated (e.g., stent, laser); limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening airway compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death

**Definition:** A disorder characterized by a narrowing of the pharyngeal airway.

**Navigational Note: -**

# Pharyngolaryngeal pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the pharyngolaryngeal region.

Navigational Note: Record final diagnosis/cause once determined.

#### Pleural effusion

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; intervention	Symptomatic with respiratory	Life-threatening respiratory	Death
diagnostic observations only;	indicated (e.g., diuretics or	distress and hypoxia;	or hemodynamic	
intervention not indicated	therapeutic thoracentesis)	operative intervention	compromise; intubation or	
		including chest tube or	urgent intervention indicated	
		pleurodesis indicated		

**Definition:** A disorder characterized by an increase in amounts of fluid within the pleural cavity. Symptoms include shortness of breath, cough and marked chest discomfort.

Navigational Note: Record final diagnosis/cause once determined.

# Pleural hemorrhage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; mild	Symptomatic or associated	>1000 ml of blood evacuated;	Life-threatening	Death
hemorrhage confirmed by	with pneumothorax; chest	persistent bleeding (150-200	consequences; intubation or	
thoracentesis	tube drainage indicated	ml/hr for 2 - 4 hr); persistent	urgent intervention indicated	
		transfusion indicated;		
		elective operative		
		intervention indicated;		
		hospitalization		

**Definition:** A disorder characterized by bleeding from the pleural cavity.

Navigational Note: -

# Pleuritic pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the pleura.

Navigational Note: Record final diagnosis/cause once determined.

#### **Pneumonitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; medical	Severe symptoms; oxygen	Life-threatening respiratory	Death
diagnostic observations only;	intervention indicated;	indicated; limiting self-care	compromise; urgent	
intervention not indicated	limiting instrumental ADL or	ADL or severe impact on age-	intervention indicated (e.g.,	
	mild/moderate impact on	appropriate normal daily	tracheotomy or intubation)	
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by inflammation focally or diffusely affecting the lung parenchyma.

Navigational Note: -

#### **Pneumothorax**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; intervention	Sclerosis and/or operative	Life-threatening	Death
diagnostic observations only;	indicated	intervention indicated;	consequences; urgent	
intervention not indicated		hospitalization indicated	intervention indicated	

**Definition:** A disorder characterized by abnormal presence of air in the pleural cavity resulting in the collapse of the lung. **Navigational Note:** -

# Postnasal drip

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	-	-	-
not indicated	medical intervention			
	indicated			

**Definition:** A disorder characterized by excessive mucous secretion in the back of the nasal cavity or throat, causing sore throat and/or coughing.

## **Productive cough**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Occasional/minimal	Moderate sputum	Persistent or copious	-	-
production of sputum with	production; limiting	production of sputum;		
cough	instrumental ADL or	limiting self-care ADL or		
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by expectorated secretions upon coughing.

**Navigational Note:** Record final diagnosis/cause once determined.

### Pulmonary edema

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Radiologic findings only; minimal dyspnea on exertion	Moderate dyspnea on exertion; medical intervention indicated; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Severe dyspnea or dyspnea at rest; oxygen indicated; limiting self-care ADL or severe impact on ageappropriate normal daily activity (pediatric)	Life-threatening respiratory compromise; urgent intervention or intubation with ventilatory support indicated	Death

**Definition:** A disorder characterized by accumulation of fluid in the lung tissues that causes a disturbance of the gas exchange that may lead to respiratory failure.

**Navigational Note:** Unless there is a clear non-cardiac cause, please record this event as Cardiac disorders: Heart failure. Record final diagnosis/cause once determined.

### **Pulmonary fibrosis**

Grade 2	Grade 3	Grade 4	Grade 5
Evidence of pulmonary hypertension; radiographic bulmonary fibrosis 25 - 50% associated with hypoxia	Severe hypoxia; evidence of right-sided heart failure; radiographic pulmonary fibrosis >50 - 75%	Life-threatening consequences (e.g., hemodynamic/pulmonary complications); intubation with ventilatory support indicated; radiographic pulmonary fibrosis >75%	Death
בו טו	vidence of pulmonary ypertension; radiographic ulmonary fibrosis 25 - 50%	vidence of pulmonary vpertension; radiographic lulmonary fibrosis 25 - 50%  Severe hypoxia; evidence of right-sided heart failure; radiographic pulmonary	Severe hypoxia; evidence of pulmonary right-sided heart failure; radiographic sociated with hypoxia  Severe hypoxia; evidence of right-sided heart failure; radiographic pulmonary fibrosis 25 - 50% fibrosis >50 - 75% complications); intubation with ventilatory support indicated; radiographic

**Definition:** A disorder characterized by the replacement of the lung tissue by connective tissue, leading to progressive dyspnea, respiratory failure or right heart failure.

**Navigational Note: -**

## Pulmonary fistula

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the lung and another organ or anatomic site. **Navigational Note:** -

### **Pulmonary hypertension**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; radiographic,	Symptomatic; requiring	Severe symptoms, associated	Life-threatening airway	Death
physical, or diagnostic	medical intervention	with hypoxia, right heart	consequences; urgent	
findings		failure; oxygen indicated	intervention indicated (e.g.,	
			tracheotomy or intubation)	

**Definition:** A disorder characterized by an increase in pressure within the pulmonary circulation due to lung or heart disorder. **Navigational Note:** -

### **Respiratory failure**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	Life-threatening	Death
			consequences; urgent	
			intervention, intubation, or	
			ventilatory support indicated	

**Definition:** A disorder characterized by impaired gas exchange by the respiratory system resulting in hypoxia and a decrease in oxygenation of the tissues that may be associated with an increase in arterial levels of carbon dioxide.

Navigational Note: Consider Respiratory, thoracic and mediastinal disorders: Pneumonitis.

### Respiratory, thoracic and mediastinal disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

Definition: -

**Navigational Note: -**

### Rhinorrhea

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	-	-	-	-

**Definition:** A disorder characterized by excessive mucous secretions draining from the nose.

### Sinus disorder

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic mucosal crusting; blood-tinged secretions	Symptomatic stenosis or edema/narrowing interfering with airflow; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Stenosis with significant nasal obstruction; limiting self-care ADL or severe impact on age-appropriate normal daily activity (pediatric)	Necrosis of soft tissue or bone; urgent operative intervention indicated	Death

**Definition:** A disorder characterized by involvement of the paranasal sinuses.

**Navigational Note: -**

# Sinus pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the face, between the eyes, or upper teeth originating from the sinuses.

**Navigational Note:** Record final diagnosis/cause once determined.

# Sleep apnea

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Snoring and nocturnal sleep	Moderate apnea and oxygen	Oxygen desaturation;	Cardiovascular or	Death
arousal without apneic	desaturation; excessive	associated with pulmonary	neuropsychiatric symptoms;	
periods	daytime sleepiness; medical	hypertension; medical	urgent operative intervention	
	evaluation indicated; limiting	intervention indicated;	indicated	
	instrumental ADL or	limiting self-care ADL or		
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by cessation of breathing for short periods during sleep.

**Navigational Note: -**

# **Sneezing**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms;	-	-	-
not indicated	medical intervention			
	indicated			

**Definition:** A disorder characterized by the involuntary expulsion of air from the nose.

Navigational Note: -

### Sore throat

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting ability to	-	-
	instrumental ADL or	swallow; limiting self-care		
	mild/moderate impact on	ADL or severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by marked discomfort in the throat.

#### **Stridor**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Respiratory distress; medical	Life-threatening airway	Death
		intervention indicated;	compromise; urgent	
		limiting self-care ADL or	intervention indicated (e.g.,	
		severe impact on age-	tracheotomy or intubation)	
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by a high pitched breathing sound due to laryngeal or upper airway obstruction. **Navigational Note:** -

#### Tracheal fistula

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic, invasive	Invasive intervention	Life-threatening	Death
	intervention not indicated	indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by an abnormal communication between the trachea and another organ or anatomic site. **Navigational Note:** -

# Tracheal mucositis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Endoscopic findings only;	Moderate symptoms;	Severe pain; hemorrhage or	Life-threatening	Death
minimal hemoptysis, pain, or	medical intervention	respiratory symptoms;	consequences; urgent	
respiratory symptoms	indicated; limiting	limiting self-care ADL or	intervention indicated	
	instrumental ADL or	severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by an inflammation or ulceration involving the mucous membrane of the trachea. **Navigational Note:** -

## **Tracheal stenosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic (e.g., noisy airway breathing), no respiratory distress; medical intervention indicated (e.g., steroids); limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Stridor or respiratory distress; invasive intervention indicated (e.g., stent, laser); limiting self-care ADL or severe impact on age- appropriate normal daily activity (pediatric)	Life-threatening airway compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death

**Definition:** A disorder characterized by a narrowing of the trachea.

Navigational Note: -

## **Voice alteration**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild or intermittent change	Moderate or persistent	Severe voice changes	-	-
from normal voice	change from normal voice;	including predominantly		
	still understandable	whispered speech; may		
		require frequent repetition		
		or face-to-face contact for		
		understandability; may		
		require assistive technology		

**Definition:** A disorder characterized by a change in the sound and/or speed of the voice.

## Skin and subcutaneous tissue disorders

## Alopecia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Hair loss of <50% of normal	Hair loss of >=50% normal	-	-	-
for that individual that is not	for that individual that is			
obvious from a distance but	readily apparent to others; a			
only on close inspection; a	wig or hair piece is necessary			
different hair style may be	if the patient desires to			
required to cover the hair	completely camouflage the			
loss but it does not require a	hair loss; associated with			
wig or hair piece to	psychosocial impact			
camouflage				

**Definition:** A disorder characterized by a decrease in density of hair compared to normal for a given individual at a given age and body location.

**Navigational Note: -**

## **Body odor**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild odor; physician	Pronounced odor;	-	-	-
intervention not indicated;	psychosocial impact; patient			
self care interventions	seeks medical intervention			

**Definition:** A disorder characterized by an abnormal body smell resulting from the growth of bacteria on the body.

**Navigational Note: -**

## Dermatitis psoriasiform

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present; topical intervention	oral intervention indicated	IV intervention indicated	-	-
indicated				

**Definition:** A disorder characterized by large, red, rounded plaques covered with thicker scales.

#### **Dermatosis bullous**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Painful blisters; limiting	Blisters covering >50% BSA;	Blisters covering >75% BSA;	Death
	instrumental ADL or	limiting self-care ADL or	associated with fluid or	
	mild/moderate impact on	severe impact on age-	electrolyte abnormalities; ICU	
	age-appropriate normal daily	appropriate normal daily	care or burn unit indicated	
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by inflammation of the skin characterized by the presence of bullae which are filled with fluid. **Navigational Note:** If infectious, consider Infections and infestations: Rash pustular or other site-specific Infections and infestations term.

## Dry skin

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
No associated erythema or	Associated with erythema or	-	-	-
pruritus	pruritus; limiting			
	instrumental ADL or			
	mild/moderate impact on			
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by flaky and dull skin; the pores are generally fine, the texture is a papery thin texture. **Navigational Note:** -

#### **Eczematous dermatitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present; topical intervention	Oral intervention indicated	IV intervention indicated	1	-
indicated				

**Definition:** A disorder characterized by dry and itchy patches of skin involving the epidermis and superficial dermis and includes some scaling, crusting, or serous oozing.

#### Erythema multiforme

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Not associated with skin	Associated with skin	Associated with oral or	Associated with fluid or	Death
tenderness	tenderness	genital erosions	electrolyte abnormalities; ICU	
			care or burn unit indicated	

**Definition:** A disorder characterized by target lesions (a pink-red ring around a pale center).

**Navigational Note: -**

## Erythroderma

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Erythema covering >90% BSA	Erythema covering >90% BSA	Erythema covering >90% BSA	Death
	without associated	with associated symptoms	with associated fluid or	
	symptoms; limiting	(e.g., pruritus or tenderness);	electrolyte abnormalities; ICU	
	instrumental ADL or	limiting self-care ADL or	care or burn unit indicated	
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by generalized inflammatory erythema and exfoliation. The inflammatory process involves >90% of the body surface area.

Navigational Note: -

#### **Exfoliative dermatitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present; topical intervention	oral intervention indicated	IV intervention indicated	Life-threatening	Death
indicated			consequences	

**Definition:** A disorder characterized by diffuse erythema and scaling involving > 90% of the body surface area.

Navigational Note: -

#### Hair color changes

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	-	-	-	-

**Definition:** A disorder characterized by change in hair color or loss of normal pigmentation.

#### Hair texture abnormal

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	1	-	-	-

**Definition:** A disorder characterized by a change in the way the hair feels.

**Navigational Note: -**

#### **Hirsutism**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
In women, increase in length,	In women, increase in length,	-	-	-
thickness or density of hair in	thickness or density of hair in			
a male distribution that the	a male distribution that			
patient is able to camouflage	requires daily shaving or			
by periodic shaving,	consistent destructive means			
bleaching, or removal of hair	of hair removal to			
	camouflage; associated with			
	psychosocial impact			

**Definition:** A disorder characterized by the presence of excess hair growth in women in anatomic sites where growth is considered to be a secondary male characteristic and under androgen control (beard, moustache, chest, abdomen).

Navigational Note: -

## **Hyperhidrosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Limited to one site (palms,	Involving >1 site; patient	Associated with	-	-
soles, or axillae); self care	seeks medical intervention;	electrolyte/hemodynamic		
interventions	associated with psychosocial	imbalance		
	impact			

**Definition:** A disorder characterized by excessive sweating. **Navigational Note:** Synonym: Night sweats, diaphoresis.

## **Hyperkeratosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	-	Limiting self-care ADLs or	-	-
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by a thickening of the outer layer of the skin.

Navigational Note: -

## **Hypertrichosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Increase in length, thickness	Increase in length, thickness	-	-	-
or density of hair that the	or density of hair at least on			
patient is either able to	the usual exposed areas of			
camouflage by periodic	the body [face (not limited to			
shaving or removal of hairs	beard/moustache area)			
or is not concerned enough	plus/minus arms] that			
about the overgrowth to use	requires frequent shaving or			
any form of hair removal	use of destructive means of			
	hair removal to camouflage;			
	associated with psychosocial			
	impact			

**Definition:** A disorder characterized by hair density or length beyond the accepted limits of normal in a particular body region, for a particular age or race.

## **Hypohidrosis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Symptomatic; limiting	Increase in body	Life-threatening	Death
	instrumental ADL or	temperature; limiting self-	consequences; urgent	
	mild/moderate impact on	care ADL or severe impact on	intervention indicated	
	age-appropriate normal daily	age-appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by reduced sweating.

**Navigational Note: -**

#### Lichenoid dermatitis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present; topical intervention	oral intervention indicated	IV intervention indicated	-	-
indicated				

**Definition:** A disorder characterized by a symmetric eruption of flat-topped, red or purple papules on the trunk and extremities.

Navigational Note: -

## **Nail changes**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	-	-	-	-

**Definition:** A disorder characterized by a change in the nails.

**Navigational Note: -**

#### **Nail discoloration**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	1	-	-	-

**Definition:** A disorder characterized by a change in the color of the nail plate.

#### **Nail loss**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic separation of	Symptomatic separation of	-	-	-
the nail bed from the nail	the nail bed from the nail			
plate or nail loss	plate or nail loss; limiting			
·	instrumental ADL or			
	mild/moderate impact on			
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by loss of all or a portion of the nail.

**Navigational Note: -**

## Nail ridging

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	-	-	-	-

**Definition:** A disorder characterized by vertical or horizontal ridges on the nails.

**Navigational Note: -**

#### Pain of skin

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the skin.

**Navigational Note:** Record final diagnosis/cause once determined.

## Palmar-plantar erythrodysesthesia syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Minimal skin changes or	Skin changes (e.g., peeling,	Severe skin changes (e.g.,	-	-
dermatitis (e.g., erythema,	blisters, bleeding, fissures,	peeling, blisters, bleeding,		
edema, or hyperkeratosis)	edema, or hyperkeratosis)	fissures, edema, or		
without pain	with pain; limiting	hyperkeratosis) with pain;		
	instrumental ADL or	limiting self-care ADL or		
	mild/moderate impact on	severe impact on age-		
	age-appropriate normal daily	appropriate normal daily		
	activity (pediatric)	activity (pediatric)		

**Definition:** A disorder characterized by redness, marked discomfort, swelling, and tingling in the palms of the hands or the soles of the feet. Also known as Hand-Foot Syndrome.

**Navigational Note: -**

## Papulovesicular rash

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Associated with psychosocial	Covering >50% BSA;	Blisters covering >75% BSA;	Death
	impact; mild symptoms	moderate or severe	life-threatening	
		symptoms	consequences	

**Definition:** A disorder characterized by an eruption consisting of papules (a small, raised pimple) and vesicles (a small fluid filled blister). **Navigational Note:** -

## **Photosensitivity**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Painless erythema	Tender erythema	Erythema with blistering; oral	Life-threatening	Death
		corticosteroid therapy	consequences; urgent	
		indicated; pain control	intervention indicated	
		indicated (e.g., narcotics or		
		NSAIDs)		

**Definition:** A disorder characterized by an increase in sensitivity of the skin to light.

#### **Pruritus**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild or localized; topical intervention indicated	Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated;	Widespread and constant; systemic corticosteroid or immunosuppressive therapy indicated; limiting sleep or self-care ADL or severe impact on age-appropriate	-	-
	limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	normal daily activity (pediatric)		

**Definition:** A disorder characterized by an intense itching sensation.

**Navigational Note: -**

## **Purpura**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Combined area of lesions	Combined area of lesions	Combined area of lesions	-	-
covering <10% BSA	covering 10 - 30% BSA	covering >30% BSA		

**Definition:** A disorder characterized by hemorrhagic areas of the skin and mucous membrane. Newer lesions appear reddish in color. Older lesions are usually a darker purple color and eventually become a brownish-yellow color.

#### Pustular drug eruption

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Associated with psychosocial	Severe symptoms; IV	Life-threatening	Death
	impact; oral antibiotics or	antibiotic or steroid	consequences	
	steroid indicated; local	indicated; limiting self-care		
	intervention indicated (e.g.,	ADL or severe impact on age-		
	topical antibiotic, antifungal,	appropriate normal daily		
	or antiviral); limiting	activity (pediatric)		
	instrumental ADL or			
	mild/moderate impact on			
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by the development of nonfollicular, sterile pustules on an erythematous base. **Navigational Note:** -

## Rash maculo-papular

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Mild symptoms	Macules/papules covering	Life-threatening	Death
		>50% BSA; moderate or	consequences; urgent	
		severe symptoms	intervention indicated	

**Definition:** A disorder characterized by the presence of macules (flat) and papules (elevated). Also known as morbilliform rash, it is one of the most common cutaneous adverse events, frequently affecting the upper trunk, spreading centripetally and associated with pruritis. **Navigational Note:** Consider Skin and subcutaneous tissue disorders: Pustular drug eruption.

#### Scalp pain

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild pain	Moderate pain; limiting	Severe pain; limiting self-care	-	-
	instrumental ADL or	ADL or severe impact on age-		
	mild/moderate impact on	appropriate normal daily		
	age-appropriate normal daily	activity (pediatric)		
	activity (pediatric)			

**Definition:** A disorder characterized by a sensation of marked discomfort in the skin covering the top and the back of the head. **Navigational Note:** Record final diagnosis/cause once determined.

## Skin and subcutaneous tissue disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** -

**Navigational Note: -**

## Skin atrophy

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Associated with	Associated with striae or	Associated with ulceration	-	-
telangiectasias or changes in	adnexal structure loss			
skin color				

**Definition:** A disorder characterized by the degeneration and thinning of the epidermis and dermis.

Navigational Note: -

## Skin hyperpigmentation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	Associated with psychosocial	-	-	-
	impact			

**Definition:** A disorder characterized by darkening of the skin due to excessive melanin deposition.

## Skin hypopigmentation

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	Associated with psychosocial	-		-
	impact			

**Definition:** A disorder characterized by loss of skin pigment (e.g., vitiligo).

**Navigational Note: -**

#### **Skin induration**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild induration, able to move	Moderate induration, able to	Severe induration; unable to	Generalized; associated with	Death
skin parallel to plane (sliding)	slide skin, unable to pinch	slide or pinch skin; limiting	signs or symptoms of	
and perpendicular to skin	skin; limiting instrumental	joint or orifice movement	impaired breathing or	
(pinching up)	ADL or mild/moderate	(e.g., mouth, anus); limiting	feeding	
	impact on age-appropriate	self-care ADL or severe		
	normal daily activity	impact on age-appropriate		
	(pediatric)	normal daily activity		
		(pediatric)		

**Definition:** A disorder characterized by an area of hardness in the skin.

**Navigational Note: -**

## Skin ulceration

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Combined area of ulcers <1	Combined area of ulcers 1 - 2	Combined area of ulcers >2	Any size ulcer with extensive	Death
cm; nonblanchable erythema	cm; partial thickness skin loss	cm; full-thickness skin loss	destruction, tissue necrosis,	
of intact skin with associated	involving skin or	involving damage to or	or damage to muscle, bone,	
warmth or edema	subcutaneous fat	necrosis of subcutaneous	or supporting structures with	
		tissue that may extend down	or without full thickness skin	
		to fascia	loss	

**Definition:** A disorder characterized by a circumscribed, erosive lesion on the skin.

## Stevens-Johnson syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Skin sloughing covering <10%	Skin sloughing covering	Death
		BSA	>=10% BSA; life-threatening	
			consequences	

**Definition:** A disorder characterized by less than 10% total body skin area separation of dermis. The syndrome is thought to be a hypersensitivity complex affecting the skin and the mucous membranes.

**Navigational Note: -**

#### Subcutaneous emphysema

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	-	-
symptoms; clinical or	noninvasive intervention	significant but not		
diagnostic observations only;	indicated	immediately life-threatening;		
intervention not indicated		hospitalization or		
		prolongation of existing		
		hospitalization indicated;		
		limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by air in the subcutaneous tissue.

Navigational Note: -

## Telangiectasia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Present	Associated with psychosocial	-	-	-
	impact			

**Definition:** A disorder characterized by local dilatation of small vessels resulting in red discoloration of the skin or mucous membranes. **Navigational Note:** -

#### Toxic epidermal necrolysis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	-	Skin sloughing covering	Death
			>=30% BSA with associated	
			symptoms (e.g., erythema,	
			purpura, or epidermal	
			detachment); life-threatening	
			consequences	

**Definition:** A disorder characterized by greater than 30% total body skin area separation of dermis. The syndrome is thought to be a hypersensitivity complex affecting the skin and the mucous membranes.

**Navigational Note: -**

#### Urticaria

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Topical intervention indicated	Oral intervention indicated	IV intervention indicated	-	-

**Definition:** A disorder characterized by an itchy skin eruption characterized by wheals with pale interiors and well-defined red margins. **Navigational Note:** Consider Immune system disorders: Allergic reaction, Anaphylaxis.

# **Social circumstances**

# Social circumstances - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

Definition: -

# **Surgical and medical procedures**

# Surgical and medical procedures - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting instrumental ADL or mild/moderate impact on age-appropriate normal daily activity (pediatric)	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; limiting self-care ADL or severe impact on age-	Life-threatening consequences; urgent intervention indicated	Death
		appropriate normal daily activity (pediatric)		

Definition: -

#### **Vascular disorders**

#### Arterial thromboembolism

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	-	Urgent intervention indicated	Life-threatening	Death
			consequences;	
			hemodynamic or neurologic	
			instability; organ damage;	
			loss of extremity(ies)	

**Definition:** A disorder characterized by occlusion of an arterial vessel by a blood clot that develops in an artery.

**Navigational Note:** Consider Nervous system disorders: Stroke, Transient ischemic attacks for CNS-related events or Cardiac disorders: Myocardial infarction.

## Capillary leak syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic	Symptomatic; medical	Severe symptoms	Life-threatening	Death
	intervention indicated		consequences	

**Definition:** A disorder characterized by leakage of intravascular fluids into the extravascular space. This syndrome is observed in patients who demonstrate a state of generalized leaky capillaries following shock syndromes, low-flow states, ischemia-reperfusion injuries, toxemias, medications, or poisoning. It can lead to generalized edema and multiple organ failure.

Navigational Note: -

## Cyanosis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Present	-	-	-

**Definition:** A disorder characterized by a bluish discoloration of the skin and/or mucous membranes.

## **Flushing**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; clinical or	Moderate symptoms; limiting	Symptomatic, associated	-	-
diagnostic observations only	instrumental ADL or	with hypotension and/or		
	mild/moderate impact on	tachycardia; limiting self-care		
	age-appropriate normal daily	ADL or severe impact on age-		
	activity (pediatric)	appropriate normal daily		
		activity (pediatric)		

**Definition:** A disorder characterized by episodic reddening of the skin, especially face, neck, or chest.

**Navigational Note: -**

#### Hematoma

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Minimally invasive	Transfusion; invasive	Life-threatening	Death
not indicated	evacuation or aspiration	intervention indicated	consequences; urgent	
	indicated		intervention indicated	

**Definition:** A disorder characterized by a localized collection of blood, usually clotted, in an organ, space, or tissue, due to a break in the wall of a blood vessel.

Navigational Note: Report subdural and epidural hematoma under Nervous system disorders: Intracranial hemorrhage.

## **Hot flashes**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild symptoms; intervention	Moderate symptoms; limiting	Severe symptoms; limiting	-	-
not indicated	instrumental ADL or	self-care ADL or severe		
	mild/moderate impact on	impact on age-appropriate		
	age-appropriate normal daily	normal daily activity		
	activity (pediatric)	(pediatric)		

**Definition:** A disorder characterized by an uncomfortable and temporary sensation of intense body warmth, flushing, sometimes accompanied by sweating upon cooling.

## Hypertension

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Adult: Systolic BP 140 - 159	Adult: Systolic BP 160 - 179	Adult and Pediatric:	Death
	mmHg or diastolic BP 90 - 99	mmHg or diastolic BP 100 -	SBP≥180 or DBP ≥110 mmHg	
	mmHg; recurrent or	109 mmHg persisting over 1	persisting over 1 hour; BP	
	persistent;	hour; SBP >140 and plus	associated with acute	
	Pediatric and adolescent:	either increase in SBP >20	hypertension mediated	
	Recurrent or persistent (>=24	mmHg or increase MAP >15	organ damage; life-	
	hrs) BP >ULN; monotherapy	mmHg from baseline;	threatening consequences	
	indicated; systolic and /or	Pediatric and adolescent:	(e.g., malignant hypertension,	
	diastolic BP between the 95th	Systolic and/or diastolic >5	transient or permanent	
	percentile and 5 mmHg	mmHg above the 99 <sup>th</sup>	neurologic deficit,	
	above the 99th percentile;	percentile	hypertensive crisis); urgent	
	Adolescent: Systolic		intervention indicated	
	between 130 - 139 or			
	diastolic between 80 - 89			
	even if <95th percentile			

**Definition:** A disorder characterized by a pathological increase in blood pressure.

**Navigational Note: -**

## Hypotension

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention	Non-urgent medical	Medical intervention	Life-threatening	Death
not indicated	intervention indicated	indicated; hospitalization	consequences and urgent	
		indicated	intervention indicated	

**Definition:** A disorder characterized by a blood pressure that is below the normal expected for an individual in a given environment. **Navigational Note:** -

## Lymph leakage

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Symptomatic; medical	Severe symptoms; invasive	Life-threatening	Death
	intervention indicated	intervention indicated	consequences; urgent	
			intervention indicated	

**Definition:** A disorder characterized by the loss of lymph fluid into the surrounding tissue or body cavity.

**Navigational Note: -**

## Lymphedema

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Trace thickening or faint	Marked discoloration;	Severe symptoms; limiting	-	-
discoloration	leathery skin texture;	self-care ADL or severe		
	papillary formation; limiting	impact on age-appropriate		
	instrumental ADL or	normal daily activity		
	mild/moderate impact on	(pediatric)		
	age-appropriate normal daily			
	activity (pediatric)			

**Definition:** A disorder characterized by excessive fluid collection in tissues that causes swelling.

Navigational Note: Record final diagnosis/cause once determined.

## Lymphocele

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; clinical or	Symptomatic; medical	Severe symptoms; invasive	-	-
diagnostic observations only;	intervention indicated	intervention indicated		
intervention not indicated				

**Definition:** A disorder characterized by a cystic lesion containing lymph.

#### Peripheral ischemia

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Brief (<24 hrs) episode of	Prolonged (>=24 hrs) or	Life-threatening	Death
	ischemia managed medically	recurring symptoms and/or	consequences; major tissue	
	and without permanent	invasive intervention	loss; urgent operative	
	deficit; claudication	indicated; pain at rest	intervention indicated	

**Definition:** A disorder characterized by impaired circulation to an extremity.

Navigational Note: -

#### **Phlebitis**

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Present	-	1	-

**Definition:** A disorder characterized by inflammation of the wall of a peripheral vein associated with an intravenous line.

Navigational Note: -

#### Superficial thrombophlebitis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
-	Present	1	1	-

**Definition:** A disorder characterized by a blood clot and inflammation involving a superficial vein of the extremities.

Navigational Note: -

## Superior vena cava syndrome

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic; incidental	Symptomatic; medical	Severe symptoms; multi-	Life-threatening	Death
finding of SVC thrombosis	intervention indicated (e.g.,	modality intervention	consequences; urgent multi-	
	anticoagulation, radiation or	indicated (e.g.,	modality intervention	
	chemotherapy)	anticoagulation,	indicated (e.g., lysis,	
		chemotherapy, radiation,	thrombectomy, surgery)	
		stenting)		

**Definition:** A disorder characterized by obstruction of the blood flow in the superior vena cava. Signs and symptoms include swelling and cyanosis of the face, neck, and upper arms, cough, orthopnea and headache.

## Vascular disorders - Other, specify

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic or mild	Moderate; minimal, local or	Severe or medically	Life-threatening	Death
symptoms; clinical or	noninvasive intervention	significant but not	consequences; urgent	
diagnostic observations only;	indicated; limiting	immediately life-threatening;	intervention indicated	
intervention not indicated	instrumental ADL or	hospitalization or		
	mild/moderate impact on	prolongation of existing		
	age-appropriate normal daily	hospitalization indicated;		
	activity (pediatric)	limiting self-care ADL or		
		severe impact on age-		
		appropriate normal daily		
		activity (pediatric)		

Definition: -

Navigational Note: -

## Vasculitis

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Asymptomatic, intervention	Moderate symptoms,	Severe symptoms, medical	Life-threatening	Death
not indicated	medical intervention	intervention indicated (e.g.,	consequences; evidence of	
	indicated	steroids)	peripheral or visceral	
			ischemia; urgent intervention	
			indicated	

**Definition:** A disorder characterized by inflammation involving the wall of a vessel.

#### Venous thromboembolism

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Medical intervention not	Medical intervention	Urgent medical intervention	Life-threatening	Death
indicated (e.g., superficial	indicated	indicated	consequences with	
thrombosis)			hemodynamic or neurologic	
			instability	

**Definition:** A disorder characterized by occlusion of a vessel by a thrombus that has migrated from a distal site via the blood stream (for example, deep vein thrombosis (DVT), pulmonary embolism (PE), etc.).

**Navigational Note:** Consider Nervous system disorders: Stroke, Transient ischemic attacks for CNS-related events. Use Vascular disorders: Arterial thromboembolism for arterial thrombi. Use Injury, poisoning and procedural complications: Vascular access complication if related to a catheter.