

TOXICITY FORM

COBLT Recipient ID:

COBLT Name Code:

Center Code:

MCC Use Only
Date Recd.:

Assessment Period:

Day 28 Post-CBT

Day 42 Post-CBT

1. Date of evaluation

M D Y

2. Record the highest grade of toxicity diagnosed by the day of evaluation. Use the grading scale on the back of page 2 to determine the grade.

	<u>Grade 0</u>	<u>Grade I</u>	<u>Grade II</u>	<u>Grade III</u>	<u>Grade IV</u>
Cardiac	0 <input type="checkbox"/> No EKG abnormality	1 <input type="checkbox"/> Mild EKG abnormality	2 <input type="checkbox"/> Moderate EKG abnormality	3 <input type="checkbox"/> Severe EKG abnormality	4 <input type="checkbox"/> Fatal toxicity
Bladder	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Macro. hem. 2d. from last chemo	2 <input type="checkbox"/> Macro. hem. 7d. after last chemo	3 <input type="checkbox"/> Hem. cystitis with frank blood	4 <input type="checkbox"/> Fatal toxicity
Renal	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Creat. increase up to 2 x baseline	2 <input type="checkbox"/> Creat. above 2 x baseline	3 <input type="checkbox"/> Dialysis required	4 <input type="checkbox"/> Fatal toxicity
Pulmonary	0 <input type="checkbox"/> None	1 <input type="checkbox"/> See scale	2 <input type="checkbox"/> See scale	3 <input type="checkbox"/> See scale	4 <input type="checkbox"/> Fatal toxicity
Hepatic	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Mild hep. dysfunction	2 <input type="checkbox"/> Mod. hep. dysfunction	3 <input type="checkbox"/> Severe hep. dysfunction	4 <input type="checkbox"/> Fatal toxicity
CNS	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Somnolence + arousable	2 <input type="checkbox"/> Somnolence + confusion	3 <input type="checkbox"/> Seizures or coma	4 <input type="checkbox"/> Fatal toxicity
Stomatitis	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Pain and/or ulceration, no IV narc. drug	2 <input type="checkbox"/> Pain and/or ulceration with IV narc. drug	3 <input type="checkbox"/> Severe ulcer. and/or mucositis - see scale	4 <input type="checkbox"/> Fatal toxicity
GI Toxicity	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Watery stools >500 mL but ≤2,000 mL every d.	2 <input type="checkbox"/> Watery stools >2,000 mL every d.	3 <input type="checkbox"/> Ileus require nasogastric suction	4 <input type="checkbox"/> Fatal toxicity

3. Did the patient have an allergic reaction?

0 None

1 Bronchospasm,

no parenteral therapy needed

2 Anaphylaxis

4. Did the patient have persistent nausea and vomiting?

0 None

1 Nausea

3 Vomiting requiring therapy

2 Transient vomiting

4 Intractable vomiting

If assessment period #1 (Day 28), continue with question 5; otherwise, sign and submit form.

TOXICITY GRADING SCALE

	<u>GRADE I</u>	<u>GRADE II</u>	<u>GRADE III</u>
Cardiac toxicity	Mild EKG abnormality, not requiring medical intervention; or noted heart enlargement on CXR with no clinical symptoms	Moderate EKG abnormalities requiring and responding to medical intervention; or requiring continuous monitoring without treatment; or congestive heart failure responsive to digitals or diuretics	Severe EKG abnormalities with no or only partial response to medical intervention; or heart failure with no or only minor response to medical intervention; or decrease in voltage by more than 50%
Bladder toxicity	Macroscopic hematuria after 2 d from last chemotherapy dose with no subjective symptoms of cystitis and not caused by infection	Macroscopic hematuria after 7 d from last chemotherapy dose not caused by infection; or hematuria after 2 d with subjective symptoms of cystitis not caused by infection	Hemorrhagic cystitis with frank blood, necessitating invasive local intervention with installation of sclerosing agents, nephrostomy or other surgical procedure
Renal toxicity	Increase in creatinine up to twice the baseline value (usually the last recorded before start of conditioning)	Increase in creatinine above twice baseline but not requiring dialysis	Requirement of dialysis
Pulmonary toxicity	Dyspnea without CXR changes not caused by infection or congestive heart failure; or CXR showing isolated infiltrate or mild interstitial changes without symptoms not caused by infection or congestive heart failure	CXR with extensive localized infiltrate or moderate interstitial changes combined with dyspnea and not caused by infection or CHF, or decrease of PO ₂ (> 10% from baseline) but not requiring mechanical ventilation or > 50% O ₂ on mask and not caused by infection or CHF	Interstitial changes requiring mechanical ventilatory support or > 50% oxygen on mask and not caused by infection or CHF
Hepatic toxicity	Mild hepatic dysfunction with 2.0 mg% ≤ bilirubin ≤ 6.0 mg%; or weight gain > 2.5% and < 5% from baseline, of noncardiac origin; or SGOT increase more than 2-fold but less than 5-fold from lowest pre-conditioning	Moderate hepatic dysfunction bilirubin > 6 mg% < 20 mg%, or SGOT increase > 5-fold from pre-conditioning; or clinical escites or image documented escites > 100mL; or weight gain > 5% from baseline of noncardiac origin	Severe hepatic dysfunction with bilirubin > 20mg%; or hepatic encephalopathy; or ascites compromising respiratory function
CNS toxicity	Somnolence but the patient is easily arousable and oriented after arousal	Somnolence with confusion after arousal; or other new objectives CNS symptoms with no loss of consciousness not more easily explained by other medication, bleeding, or CNS infection	Seizures or coma not explained (documented) by other medication, CNS infection, or bleeding
Stomatitis	Pain and/or ulceration not requiring a continuous IV narcotic drug	Pain and/or ulceration requiring a continuous IV narcotic drug (morphine drip)	Severe ulceration and/or mucositis requiring preventive intubation; or resulting in documented aspiration pneumonia with or without intubation
GI toxicity	Watery stools > 500 ml but < 2,000 mL every d not related to infection	Watery stools > 2,000 ml every d not related to infection, or macroscopic hemorrhagic stools with no affect on cardiovascular status not caused by infection; or subileus not related to infection	Ileus requiring nasogastric suction and/or surgery and not related to infection; or hemorrhagic enterocolitis affecting cardiovascular status and requiring transfusion

Note: Grade IV regimen-related toxicity is defined as fatal toxicity.

Abbreviations: CXR, chest x-ray, IV, intravenous

Reference: Bearman SI, Appelbaum FR, Bucker CD, Peterson FB, Fisher LD, Clift RA, Thomas ED. (1988). Regimen-related toxicity in patients undergoing bone marrow transplantation. *Journal of Clinical Oncology* **6(10)**:1562-1568.