

# Blood and Marrow Transplant Clinical Trials Network

## Toxicity Form (T29)

Web Version: 1.0; 2.00; 06-07-17

Segment (*PROTSEG*): A

Visit Number (*VISNO*):

1. Record date of evaluation: (*TXYE VLDT*)  (mm/dd/yyyy)

Record the highest grade of toxicity diagnosed since the previous evaluation. If this is the first evaluation, record the highest toxicity diagnosed since Day 0. The toxicity grades are based on the NCI CTCAE Version 4.02.

### GI Disorders

2. Mucositis: (*MUCOSITI*)

0 - Grades 0-2  
3 - Severe pain; interfering with oral intake; limiting self care ADL  
4 - Life-threatening consequences; urgent intervention indicated  
5 - Death

### Renal Disorders

3. Cystitis noninfective: (*CYSTNINF*)

0 - Grades 0-2  
3 - Gross hematuria; transfusion, IV meds or hosp indicated;  
4 - Life-threatening consequences; urgent radiologic or operative intervention indicated  
5 - Death

4. Acute kidney injury: (*ACKIDINJ*)

0 - Grades 0-2  
3 - Creatinine >3x baseline; >4.0 mg/dL; hospitalization indicated  
4 - Life-threatening consequences; dialysis indicated  
5 - Death

5. Chronic kidney disease: (*CHKIDDIS*)

0 - Grades 0-2  
3 - eGFR or CrCl 29-15 ml/min/1.73 m<sup>2</sup>  
4 - eGFR <15 ml/min/1.73 m<sup>2</sup>; dialysis or renal transplant indicated  
5 - Death

6. Did the patient receive dialysis? (*RCVDIALY*)

1 - Yes  2 - No

7. If yes, were laboratory values corrected? (*LBVALCOR*)

1 - Yes  2 - No

### Hemorrhagic Disorders

8. Hemorrhage: (*HEMORRHG*)

0 - Grades 0-2  
3 - Transfusion, radiologic, endoscopic, or elective operative intervention indicated  
4 - Life-threatening consequences; urgent intervention indicated  
5 - Death

9. Which organ system was the hemorrhage associated with? (*ORGSYHEM*)

1 - CNS  
2 - Gastrointestinal  
3 - Genitourinary  
4 - Pulmonary, Upper Respiratory  
5 - Other

Specify other organ system: (*ORGSYHSP*)

### Cardiac Disorders

10. Cardiac arrhythmia: (*CRDARRHY*)

0 - Grades 0-2  
3 - Severe, medically significant; medical intervention indicated  
4 - Life-threatening consequences; hemodynamic compromise; urgent intervention indicated  
5 - Death

11. Specify arrhythmia: (*CRDARRSP*)

12. Left ventricular systolic dysfunction:(LFTVSYDF)

0 - Grades 0-2  
3 - Symptomatic due to drop in ejection fraction responsive to intervention  
4 - Refractory or poorly controlled HF; ventricular device, iv vaso, or heart transplant indicated  
5 - Death

**Nervous System Disorders**

13. Somnolence:(SOMNOLN)

0 - Grades 0-2  
3 - Obtundation or Stupor  
4 - Life-threatening consequences; urgent intervention indicated  
5 - Death

14. Reversible posterior leukoencephalopathy syndrome (PRES):(TXXPRES)

0 - Grades 0-2  
3 - Severe symptoms; very abnormal imaging studies; limiting self care ADL  
4 - Life-threatening consequences; urgent intervention indicated  
5 - Death

**Blood and Lymphatic Disorders**

15. Thrombotic thrombocytopenic purpura:(THRMBPUR)

0 - Grades 0-2  
3 - Laboratory findings with clinical consequences [e.g., renal insufficiency, petechiae]  
4 - Life-threatening consequences [e.g., CNS hemorrhage or thrombosis/embolism or renal failure]  
5 - Death

**Vascular Disorders**

16. Capillary leak syndrome:(CAPLKSYN)

0 - Grades 0-2  
3 - Severe symptoms; intervention indicated  
4 - Life-threatening consequences; urgent intervention indicated  
5 - Death

17. Hypertension:(HYPERTSN)

0 - Grades 0-2  
3 - Stage 2 [SBP 160+ mmHg or DBP 100+ mmHg]; medical intervention indicated  
4 - Life-threatening consequences; urgent intervention indicated  
5 - Death

**Pulmonary Toxicity**

18. Dyspnea:(TXDYSPNA)

0 - Grades 0-2  
3 - Shortness of breath at rest; limiting self care ADL  
4 - Life-threatening consequences; urgent intervention indicated  
5 - Death

19. Did the patient experience idiopathic pneumonia syndrome (IPS)?(TXXIPS)

1 - Yes  2 - No

20. Did the patient have radiographic evidence of bilateral, multi-lobar infiltrates by chest x-ray or CT scan without evidence of an infection?(TXXRADDEV)

1 - Yes  2 - No

21. Date of IPS:(TXXIPSDT)

(mm/dd/yyyy)

22. Did the patient have evidence for abnormal respiratory physiology based upon a room air oxygen saturation <93%, or the need for supplemental oxygen to maintain an oxygen saturation  $\geq$ 93%?(ABNRESP)

1 - Yes  2 - No

**Hepatic Disorders**

23. ALT:(TXALT)

0 - Grades 0-2  
3 - > 5.0 - 20.0 x ULN  
4 - > 20.0 x ULN

24. AST:(TXAST)

0 - Grade 0-2  
3 - > 5.0 - 20.0 x ULN  
4 - > 20.0 x ULN

25. Bilirubin:(TXBILIRB)

0 - Grades 0-2  
3 - >3.0-10.0 x ULN  
4 - >10.0 x ULN

26. Alkaline Phosphatase: (TXALKPH)

0 - Grades 0-2  
 3 - >5.0-20.0 x ULN  
 4 - >20.0 ULN

**Indicate all clinical signs/symptoms of abnormal liver functioning present during this assessment period:**

27. Jaundice: (TXJAUND)  1 - Yes  2 - No  
 28. Hepatomegaly: (HEPTMGLY)  1 - Yes  2 - No  
 29. Right upper quadrant pain: (RTQUADPN)  1 - Yes  2 - No  
 30. Weight gain (>5%) from baseline: (TXWGHTGN)  1 - Yes  2 - No

**Indicate the etiology of the abnormal liver function:**

	Etiology	Biopsy Results	Doppler Ultrasound Results
31. VOD:	(VODETIOL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(VODBIOP) <input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative <input type="checkbox"/> 3 - Equivocal <input type="checkbox"/> 4 - Not Done	(VODDOPP) <input type="checkbox"/> 1 - Confirmed <input type="checkbox"/> 2 - Not Confirmed <input type="checkbox"/> 3 - Not Done
32. GVHD:	(GVHETIOL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GVHBIOP) <input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative <input type="checkbox"/> 3 - Equivocal <input type="checkbox"/> 4 - Not Done	(GVHDOPP) <input type="checkbox"/> 1 - Confirmed <input type="checkbox"/> 2 - Not Confirmed <input type="checkbox"/> 3 - Not Done
33. Infection:	(INFETIOL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(INFBIOPI) <input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative <input type="checkbox"/> 3 - Equivocal <input type="checkbox"/> 4 - Not Done	(INFDOPI) <input type="checkbox"/> 1 - Confirmed <input type="checkbox"/> 2 - Not Confirmed <input type="checkbox"/> 3 - Not Done
34. Other:	(OTHETIOL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(OTHBIOP) <input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative <input type="checkbox"/> 3 - Equivocal <input type="checkbox"/> 4 - Not Done	(OTHDOPI) <input type="checkbox"/> 1 - Confirmed <input type="checkbox"/> 2 - Not Confirmed <input type="checkbox"/> 3 - Not Done
35. Unknown:	(UNKETIOL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	N/A	N/A

Specify other etiology: (OTHETSP)

**Transfusion Reaction**

36. Did the patient receive a transfusion during this reporting period? (TRANSREC)  1 - Yes  2 - No  
 37. Infusion related reaction: (INFRLRXN)

0 - Grades 0-2  
 3 - Prolonged; recurrence of symptoms following initial improvement; hospitalization indicated  
 4 - Life-threatening consequences; urgent intervention indicated  
 5 - Death

38. Fever: (TXFEVER)

0 - Grades 0-2  
 3 - >40.0 degrees C (>104.0 degrees F) for <= 24 hours  
 4 - >40 degrees C (>104.0 degrees F) for >24 hours  
 5 - Death

39. Maculo-papular rash: (MAPARASH)

0 - Grades 0-2  
 3 - Macules/papules covering >30% BSA with or without associated symptoms; limiting self-care ADL

40. Urticaria: (URTICARI)

0 - Grades 0-2  
 3 - Urticarial lesions covering >30% BSA; IV intervention indicated

41. Allergic reaction: (ALRGCRXN)

0 - Grades 0-2  
 3 - Prolonged; recurrence of symptoms following initial improvement; hospitalization indicated  
 4 - Life-threatening consequences; urgent intervention indicated  
 5 - Death

42. Bronchospasm:(BRCHSPAM)

0 - Grades 0-2  
3 - Limiting self-care ADL; oxygen saturation decreased  
4 - Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated  
5 - Death

43. Hypotension:(HYPOTEN)

0 - Grades 0-2  
3 - Medical intervention or hospitalization indicated  
4 - Life-threatening and urgent intervention indicated  
5 - Death

44. Hypoxia (for more than 24 hours):(TXHYPXIA)

0 - Grades 0-2  
3 - Decreased oxygen saturation at rest (e.g. pulse oximeter <88% or PaO2 <= 55 mm Hg)  
4 - Life-threatening airway compromise; urgent intervention indicated  
5 - Death

45. Anaphylaxis:(ANAPHYLX)

0 - No event  
3 - Symptomatic bronchospasm; parenteral intervention indicated; allergy-related edema/angioedema  
4 - Life-threatening consequences; urgent intervention indicated  
5 - Death

46. Hematuria:(HEMATURI)

0 - Grades 0-2  
3 - Gross hematuria; transfusion, IV med, hosp., endoscopic, radiologic/operative intervention indicated  
4 - Life-threatening; urgent radiologic or operative intervention indicated  
5 - Death

47. Hemolysis:(HEMOLYSI)

0 - Grades 0-2  
3 - Transfusion or medical intervention indicated (e.g. steroids)  
4 - Life-threatening; urgent radiologic or operative intervention indicated  
5 - Death

48. Infection:(INFECTIN)

0 - Grades 0-2  
3 - IV antibiotic, antifungal, or antiviral indicated; radiologic, operative intervention indicated  
4 - Life-threatening consequences; urgent intervention indicated  
5 - Death

49. Iron overload:(IRONOVER)

0 - Grades 0, 2  
3 - Severe symptoms; intervention indicated  
4 - Life-threatening; urgent radiologic or operative intervention indicated  
5 - Death

50. Did the patient develop allo-antibodies?  
(ALLOANTB)

1 - Yes  2 - No

**Hydroxyurea Reaction**

51. Did the patient receive Hydroxyurea during this reporting period? (HUREC)

1 - Yes  2 - No

52. Anemia:(ANEMIA)

0 - Grades 0-2  
3 - Hgb <8.0-6.5g/dL; <4.9-4.0mmol/L; <80-65g/L; transfusion indicated  
4 - Life-threatening consequences; urgent intervention indicated  
5 - Death

53. Neutropenia (Neutrophil count decreased):  
(NEUPENIA)

0 - Grades 0-2  
3 - <1000 - 500/mm<sup>3</sup>; <1.0 - 0.5 x 10<sup>9</sup> /L  
4 - <500/mm<sup>3</sup>; <0.5 x 10<sup>9</sup> /L

54. Thrombocytopenia (Platelet count decreased):  
(THROMBTP)

0 - Grades 0-2  
3 - <50,000 - 25,000/mm<sup>3</sup>; <50.0 - 25.0 x 10<sup>9</sup> /L  
4 - <25,000/mm<sup>3</sup>; <25.0 x 10<sup>9</sup> /L

55. Nausea:(TXNAUSEA)

0 - Grades 0-2  
3 - Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated

56. Diarrhea:(DIARRHEA)

0 - Grades 0-2  
3 - Increase of >=7 stools per day; incontinence; severe increase in ostomy; limiting self care ADL  
4 - Life-threatening consequences; urgent intervention indicated  
5 - Death

57. Constipation:(*CONSTIPA*)

0 - Grades 0-2  
3 - Obstipation with manual evacuation indicated; limiting self care ADL  
4 - Life-threatening consequences; urgent intervention indicated  
5 - Death

58. Does the patient have hyperpigmentation of the skin under the nails? (*HYPEPIGM*)

1 - Yes  2 - No

59. Does the patient have thinning hair? (*THINHAIR*)

1 - Yes  2 - No

60. Oligospermia (reduced sperm): (*OLGSPERM*)

0 - Grades 0-2  
3 - Sperm concentration <13 million/mL or motility <32%

**Serious Adverse Event Reporting**

61. Did any of the events reported above lead to an advanced care intervention or Intensive Care Unit admission/transfer as outlined in the AE reporting section of chapter 4 of the protocol? (*SAEDFMET*)

1 - Yes  2 - No  3 - Not Applicable

62. Specify event(s): (*SAEDFSP*)

Comments: (*T29COMM*)