



BMT CTN 1702
Monthly Update Form 2534

Registry Use Only

Sequence Number: _____

Date Received: _____

Center Identification

CIBMTR Center Number: _____

Recipient Identification

CIBMTR Research ID: _____

Event date: __ __ / __ __ / __ __
 YYYY MM DD

Visit ID:

- Initial Form
- Month 1
- Month 2
- Month 3
- Month 4
- Month 5
- Month 6
- > 6 months. Specify: __ __

Clinical Status

1. What scale was used to determine the recipient's functional status?

Karnofsky (recipient age \geq 16 years)



Report performance status assessed within 30 days of the date the subject was determined evaluable:

2. Karnofsky Scale (recipient age \geq 16 years):

- 100 Normal; no complaints; no evidence of disease
- 90 Able to carry on normal activity
- 80 Normal activity with effort
- 70 Cares for self; unable to carry on normal activity or to do active work
- 60 Requires occasional assistance but is able to care for most needs
- 50 Requires considerable assistance and frequent medical care
- 40 Disabled; requires special care and assistance
- 30 Severely disabled; hospitalization indicated, although death not imminent
- 20 Very sick; hospitalization necessary
- 10 Moribund; fatal process progressing rapidly.

Lansky (recipient age \geq 1 year and $<$ 16 years)



3. Lansky Scale (recipient age $<$ 16 years):

- 100 Fully active
- 90 Minor restriction in physically strenuous play
- 80 Restricted in strenuous play, tires more easily, otherwise active
- 70 Both greater restrictions of, and less time spent in, active play
- 60 Ambulatory up to 50% of time, limited active play with assistance/supervision
- 50 Considerable assistance required for any active play; fully able to engage in quiet play
- 40 Able to initiate quiet activities
- 30 Needs considerable assistance for quiet activity
- 20 Limited to very passive activity initiated by others (e.g., TV)
- 10 Completely disabled, not even passive play

4. Target time to start of conditioning

- Less than 6 weeks Over 6 weeks up to 12 weeks Over 12 weeks up to 6 months

Recipient Socioeconomic Factors	
<p>5. Zip or postal code for place of recipient's residence: _____ - _____</p> <p>6. Is the recipient covered by health insurance?</p> <p><input type="checkbox"/> Yes →</p> <p><input type="checkbox"/> No</p>	<p style="color: #0070c0; margin: 0;">Specify type of health insurance:</p> <p>7. Specify type of health insurance: (check all that apply)</p> <p><input type="checkbox"/> Private health insurance</p> <p><input type="checkbox"/> National Health Insurance (Government-sponsored, non-U.S.)</p> <p><input type="checkbox"/> Medicare (Government-sponsored, U.S., includes Medicare Advantage plans)</p> <p><input type="checkbox"/> Medigap (Must have Medicare coverage)</p> <p><input type="checkbox"/> Medicaid (Government-sponsored, U.S.)</p> <p><input type="checkbox"/> Children's Health Insurance Program (CHIP)</p> <p><input type="checkbox"/> Military related health care (TRICARE (CHAMPUS) / VA health care / CHAMP-VA)</p> <p><input type="checkbox"/> Indian Health Service</p> <p><input type="checkbox"/> State-sponsored health plan</p> <p><input type="checkbox"/> Other government program →</p> <p><input type="checkbox"/> Other health insurance coverage →</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>8. Specify other government program: _____</p> </div> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>9. Specify other health insurance: _____</p> </div>
<p>10. Specify the recipient's marital status:</p> <p><input type="checkbox"/> Single, never married <input type="checkbox"/> Married or living with a partner <input type="checkbox"/> Separated <input type="checkbox"/> Divorced <input type="checkbox"/> Widowed <input type="checkbox"/> Unknown</p> <p>11. What is the highest educational grade the recipient completed?</p> <p><input type="checkbox"/> No primary education / under school age: no schooling (U.S. equivalent: less than 1st grade education)</p> <p><input type="checkbox"/> Less than primary or elementary education: some formal schooling, but less than a complete primary or elementary education (U.S. equivalent: more than 1st grade education, but less than 6th grade education)</p> <p><input type="checkbox"/> Primary or elementary education: beginning at age 5-7 and continuing for about 4-6 years (U.S. equivalent: starts with 1st grade and ends with 6th grade)</p> <p><input type="checkbox"/> Lower secondary education: beginning at about age 11-12 and continuing for about 2-3 years (U.S. equivalent: starts with 7th grade and typically ends with 9th grade)</p> <p><input type="checkbox"/> Upper secondary education: beginning at about age 15-16 and continuing for about 3 years (U.S. equivalent: starts with 10th grade and ends with 12th grade)</p> <p><input type="checkbox"/> Post-secondary, non-tertiary education: programs lasting 6 months-2 years (U.S. equivalent: vocational programs of study)</p> <p><input type="checkbox"/> Tertiary education, Type A: programs that provide education that is largely theoretical, lasting 3-4 years (U.S. equivalent: includes university programs that last 4 years and lead to the award of a bachelor's degree, and university programs that lead to a master's degree) Tertiary education, Type B: programs that focus on practical, technical or occupational skills with a minimum duration of 2 years of full-time enrollment (U.S. equivalent: programs typically offered at community colleges that lead to an associate's degree)</p> <p><input type="checkbox"/> Advanced research qualification: programs that lead to the award of an advanced post-graduate degree, such as a Ph.D. (U.S. equivalent: programs devoted to advanced study and original research)</p> <p><input type="checkbox"/> Unknown</p> <p>12. What is the recipient's most recent work status (within the last year)?</p> <p><input type="checkbox"/> Full time</p> <p><input type="checkbox"/> Part time, by choice and not due to illness</p> <p><input type="checkbox"/> Part time, due to illness</p> <p><input type="checkbox"/> Unemployed, by choice and not due to illness</p> <p><input type="checkbox"/> Unemployed, due to illness</p> <p><input type="checkbox"/> Medical disability</p> <p><input type="checkbox"/> Retired</p> <p><input type="checkbox"/> Unknown</p>	

Preferred Donor Source

13. Has the donor been selected

Yes - **Go to question 30**

No →

14. Was the priority ranking revised since the date of last report?

Yes →

No - **Go to question 32**

15. Was the priority ranking revised more than once since the date of last report?

Yes →

No

16. What number revision was this in the month? ____

17. Rationale for change:

Inability to find suitable initially preferred donor

Suitable donor identified, but not available in preferred time frame

Patient clinical status warranted switch to different donor type or transplant timing

Insurance or financial consideration

Research protocol availability

Patient choice

Other →

18. Specify other: _____

For questions 19 - 28, please indicate the donor source priority list.

19. How many alternative donor sources would you consider for this patient among the following: mismatched unrelated, haploidentical, and cord blood (please include any donor sources that you would potentially use for this patient's transplant) _____

20. Which alternative donor source is the first preference

Mismatched unrelated donor

Haploidentical related

Cord Blood

More than one graft source infused at the same time →

21. Specify multiple graft sources: _____

22. Which alternative donor source is the second preference?

Mismatched unrelated donor

Haploidentical related

Cord Blood

More than one graft source infused at the same time →

23. Specify multiple graft sources: _____

24. Which alternative donor source is the third preference?

Mismatched unrelated donor

Haploidentical related

Cord Blood

More than one graft source infused at the same time →

25. Specify multiple graft sources: _____

26. Which alternative donor source is the fourth preference?

- Mismatched unrelated donor
- Haploidentical related
- Cord Blood
- More than one graft source infused at the same time →

27. Specify multiple graft sources: _____

28. Which alternative donor source is the fifth preference?

- Mismatched unrelated donor
- Haploidentical related
- Cord Blood
- More than one graft source infused at the same time →

29. Specify multiple graft sources: _____

Copy and complete questions 15 - 29 for each revision of the donor ranking.

Hematopoietic Cell Transplant Delay and/or Cancellation

30. Has the patient started a conditioning/preparative regimen? Yes No

31. Has the patient gone to transplant?
 Yes – **Also complete Indication for CRID Assignment Form 2814** No

32. Was the HCT delayed and/or cancelled?
 Yes →
 No - **Go to Signature Line** ↓

33. Was the HCT delayed?

- Yes →
- No

34. Date HCT delay decided: ___/___/___
YYYY MM DD

35. Primary reason for HCT delay

Due directly to disease or health

- Lack of disease response
- Disease progression
- Excellent disease response so transplant no longer recommended
- Due to general health
- Worsening of pre-existing co-morbidities (organ function, psychiatric illness)
- Newly diagnosed or developed co-morbidity (including infection)
- Worsening performance status, not related to a specific comorbidity

Donor issues

- Change in donor suitability or eligibility criteria
- Donor not available for requested product type
- Identified donor not available for the desired timeline

Financial or logistical challenges

- Lack of insurance or insurance denial
- Lack of a caregiver
- Transfer search or transplant to another center

Patient choice

- Patient preference to pursue non-transplant therapy
- Patient preference to stop treatment or enroll in hospice
- Patient lost to follow-up
- Other →

36. Specify other: _____

37. Contributing causes for HCT delay (check all that apply)

Due directly to disease or health

- Lack of disease response
- Disease progression
- Excellent disease response so transplant no longer recommended
- Due to general health
- Worsening of pre-existing co-morbidities (organ function, psychiatric illness)
- Newly diagnosed or developed co-morbidity (including infection)
- Worsening performance status, not related to a specific comorbidity

Donor issues

- Change in donor suitability or eligibility criteria
- Donor not available for requested product type
- Identified donor not available for the desired timeline

Financial or logistical challenges

- Lack of insurance or insurance denial
- Lack of a caregiver
- Transfer search or transplant to another center

Patient choice

- Patient preference to pursue non-transplant therapy
- Patient preference to stop treatment or enroll in hospice
- Patient lost to follow-up
- Other →

38. Specify other: _____

Copy and complete questions 33 - 38 for each delay that occurs since the date of last report.

39. Was the HCT cancelled?

- Yes
- No - *Go to Signature Line*

40. Date of HCT cancellation: ___ / ___ / ___
YYYY MM DD

41. Primary reason for transplant cancellation

Due directly to disease or health

- Lack of disease response
- Disease progression
- Excellent disease response so transplant no longer recommended
- Due to general health
- Patient death – **Also complete Recipient Death Data Form 2900**

42. Date of death: ___ / ___ / ___ - *Go to question 44*
YYYY MM DD

- Worsening of pre-existing co-morbidities (organ function, psychiatric illness)
- Newly diagnosed or developed co-morbidity (including infection)
- Worsening performance status, not related to a specific comorbidity

Donor Issues

- Change in donor suitability or eligibility criteria
- Donor not available for requested product type
- Identified donor not available for the desired timeline

Financial or logistical challenges

- Lack of insurance or insurance denial
- Lack of a caregiver
- Transfer search or transplant to another center

Patient choice

- Patient preference to pursue non-transplant therapy
- Patient preference to stop treatment or enroll in hospice
- Patient lost to follow-up
- Other →

43. Specify other: _____

44. Contributing cause for HCT cancellation (check all that apply)

Due directly to disease or health

- Lack of disease response
- Disease progression
- Excellent disease response so transplant no longer recommended
- Due to general health
- Patient death
- Worsening of pre-existing co-morbidities (organ function, psychiatric illness)
- Newly diagnosed or developed co-morbidity (including infection)
- Worsening performance status, not related to a specific comorbidity

Donor Issues

- Change in donor suitability or eligibility criteria
- Donor not available for requested product type
- Identified donor not available for the desired timeline

Financial or logistical challenges

- Lack of insurance or insurance denial
- Lack of a caregiver
- Transfer search or transplant to another center

Patient choice

- Patient preference to pursue non-transplant therapy
- Patient preference to stop treatment or enroll in hospice
- Patient lost to follow-up
- Other →

45. Specify other: _____

46. On how many unrelated donors was a sample requested but not received? ___

47. On how many related donors was a sample requested but not received? ___

Substudy Enrollment

48. Did the recipient proceed to transplant with a 8/8 HLA-matched unrelated donor or haploidentical family member donor?

- Yes - **Go to question 49**
- No - **Go to Signature Line**

49. At the time of transplant did the recipient have AML or ALL in first complete remission or early stage MDS?

- Yes - **Go to question 50**
- No - **Go to Signature Line**

50. Specify the recipient's conditioning regimen:

- Cyclophosphamide and total body irradiation +/- fludarabine - **Go to question 51**
- Cyclophosphamide and busulfan +/- total body irradiation - **Go to question 51**
- Fludarabine and melphalan +/- total body irradiation - **Go to question 51**
- Fludarabine and busulfan - **Go to question 51**
- Fludarabine and myeloablative dose total body irradiation - **Go to question 51**
- None of the above - **Go to Signature Line**

51. Specify the recipient's GVHD prophylaxis:

- Calcineurin-inhibitor and methotrexate or mycophenolate mofetil +/- antithymocyte globulin - **Go to question 52**
- Calcineurin-inhibitor and sirolimus - **Go to question 52**
- Post-transplant cyclophosphamide +/- others - **Go to question 52**
- None of the above - **Go to Signature Line**

52. Is the recipient at least 8 years old?

- Yes - **Go to question 53**
- No - **Go to Signature Line**

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

53. Is the recipient free of any psychosocial conditions that would prevent study compliance?

Yes - **Go to question 54**

No - **Go to Signature Line**

54. Is the recipient able to read English or Spanish?

Yes - **Also complete Recipient Contact Form 2820**

No

First Name: _____

Last Name: _____

E-mail address: _____

Date: ___ / ___ / ___
 YYYY MM DD