Disease Assessment at the Time of Best Response to HSCT

1. Compared to the disease status prior to the preparative regimen, what was the best response to HSCT since the date of the last report? (Include response to any planned post-HSCT treatment.)
   1. complete response (CR) — no lymphadenopathy; no organomegaly; neutrophils > 1.5 x 10⁹/L; platelets > 100 x 10⁹/L; hemoglobin > 11.0 g/dL; lymphocytes < 4 x 10⁹/L; bone marrow < 30% lymphocytes; absence of constitutional symptoms
   2. nodular partial response (nPR) — CR with persistent lymphoid nodules in the bone marrow
   3. partial response (PR) — ≥ 50% decrease in peripheral blood lymphocyte count from pretreatment value; ≥ 50% reduction in lymphadenopathy if present pretreatment; ≥ 50% reduction in liver and spleen size if enlarged pretreatment; one or more of the following: neutrophils ≥ 1.5 x 10⁹/L or 50% improvement over baseline, platelets > 100 x 10⁹/L or 50% improvement over baseline, hemoglobin > 11.0 g/dL or 50% improvement over baseline
   4. stable disease — no change; not CR, PR or progressive
   5. progressive disease — one or more of the following: ≥ 50% increase in sum of products of 2 or more lymph nodes (1 or more nodes must be ≥ 2 cm) or new nodes; ≥ 50% increase in liver or spleen size or new hepatomegaly or splenomegaly; ≥ 50% increase in absolute lymphocyte count to ≥ 5 x 10⁹/L; transformation to a more aggressive histology
   6. not assessed

2. Date best response first began: 
   month day year
   date of best response was previously reported

Best response is based on response to the HSCT, but does NOT include response to any therapy given for disease relapse or progression post-HSCT. When determining the best response to HSCT, compare the post-HSCT disease status to the status immediately prior to the preparative regimen, regardless of time since HSCT. This comparison is meant to capture the BEST disease status in response to HSCT that occurred in the reporting interval, even if a subsequent disease relapse or progression occurred during the same reporting interval. If a recipient already achieved their best response in a previous reporting interval, confirm the best response and check the box to indicate “date previously reported.”

CIBMTR Form 2113 (CLL) v1.0 (1–4) July 2007
Copyright © 2007 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.
For internal use only: Document 00499 version 1.0. Replaces: n/a

Visit:
  □ 100 day  □ 6 month  □ year

Mail this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).
Laboratory Studies Supporting Best Response to HSCT

3. Was molecular testing / immunophenotyping performed at the time of the disease assessment for best response to HSCT reported at question 1?
   1 □ yes
   2 □ no

Specify the testing method(s) used:

4. Immunophenotyping (4 color flow cytometry)
   1 □ yes
   2 □ no

5. Specify the date immunophenotyping was performed:
   [Month Day Year]

6. Was disease detected?
   1 □ yes
   2 □ no

7. Heavy chain gene rearrangement (ASO-PCR)
   1 □ yes
   2 □ no

8. Specify the date the heavy chain gene rearrangement testing was performed:
   [Month Day Year]

9. Was disease detected?
   1 □ yes
   2 □ no

Post-HSCT Planned Treatment for CLL

10. Was planned treatment given per protocol since the date of the last report? (Include any maintenance therapy, but exclude any treatment for relapse / progressive disease.)
    1 □ yes
    2 □ no

Specify the treatment(s) given:

11. Chemotherapy
    1 □ yes
    2 □ no

12. Radiation
    1 □ yes
    2 □ no

13. Immune therapy / monoclonal antibody (mAb)
    1 □ yes
    2 □ no

Specify treatment(s) given:

14. 1 □ yes 2 □ no aldesleukin (interleukin-2, IL-2)
15. 1 □ yes 2 □ no alemtuzumab (Campath)
16. 1 □ yes 2 □ no rituximab (anti-CD20, Rituxan)
17. 1 □ yes 2 □ no other mAb 18. Specify other mAb:

19. 1 □ yes 2 □ no other immune therapy
20. Specify immune therapy:

21. Other treatment
    1 □ yes
    2 □ no

22. Specify treatment:
**Disease Relapse or Progression Post-HSCT**

23. Was a disease relapse or progression detected by any method since the date of the last report?

1. **Yes**
2. **No**

24. Date disease relapse or progression was detected: [ ] [ ] [ ]

25. Was molecular testing performed at the time of disease relapse or progression?

1. **Yes**
2. **No**

Specify the testing method(s) used:

- [ ] 26. Immunophenotyping (4 color flow cytometry)
- [ ] 29. Heavy chain gene rearrangement (ASO-PCR)

26. Specify the date immunophenotyping was performed: [ ] [ ] [ ]

27. Specify the date heavy chain gene rearrangement testing was performed: [ ] [ ] [ ]

28. Was disease detected?

1. **Yes**
2. **No**

29. Specify the date heavy chain gene rearrangement testing was performed: [ ] [ ] [ ]

30. Specify the date the heavy chain gene rearrangement testing was performed: [ ] [ ] [ ]

31. Was disease detected?

1. **Yes**
2. **No**

**Disease Status at the Time of Assessment for This Reporting Period**

32. Was molecular testing / immunophenotyping performed at the time of disease assessment reported at question 39?

1. **Yes**
2. **No**

Specify the testing method(s) used:

- [ ] 33. Immunophenotyping (4 color flow cytometry)
- [ ] 36. Heavy chain gene rearrangement (ASO-PCR)

33. Specify the date immunophenotyping was performed: [ ] [ ] [ ]

34. Specify the date the heavy chain gene rearrangement testing was performed: [ ] [ ] [ ]

35. Was disease detected?

1. **Yes**
2. **No**

36. Specify the date the heavy chain gene rearrangement testing was performed: [ ] [ ] [ ]

37. Specify the date the heavy chain gene rearrangement testing was performed: [ ] [ ] [ ]

38. Was disease detected?

1. **Yes**
2. **No**
39. What is the current disease status?
   1 □ complete remission
   2 □ not in complete remission

40. Date the current disease status was established in this reporting period:  
   [ ] [ ] [ ] Month  [ ] [ ] [ ] Day  [ ] [ ] [ ] Year

41. Signed: ____________________________________________________________
   Person completing form

   Please print name: ______________________________________________________
   Phone number: (__________) ____________________________________________
   Fax number: (__________) _____________________________________________
   E-mail address: ________________________________________________________