ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Visit:
☐ 100 day
☐ 6 month
☐ year

Today's Date: Month Day 20 Year

Infusion Date: Month Day 20 Year

CIBMTR Center Number:

Initials:

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Waldenström's Macroglobulinemia Post-HSCT Data

Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number:

CIBMTR Recipient ID:

Today's Date: Month Day 20 Year

Date of HSCT for which this form is being completed: 🕮 Month Day Year

HSCT type: ☐ autologous ☐ allogeneic, unrelated ☐ allogeneic, related ☐ syngeneic (identical twin)

Product type: ☐ marrow ☐ PBSC ☐ cord blood ☐ other product, specify: _____

Visit: ☐ 100 day ☐ 6 month ☐ 1 year ☐ 2 years ☐ > 2 years, specify:

To be completed in conjunction with a Form 2100 – 100 Days Post-HSCT Data, Form 2200 – Six Months to Two Years Post-HSCT Data, or Form 2300 – Yearly Follow-Up for Greater Than Two Years Post-HSCT Data. Information reported here should reflect the date of last contact as reported in the post-HSCT data collection form, or immediately prior to death.

Questions followed by the symbol 🕮 indicate additional information necessary to complete the question is referenced in the forms instruction manual.

Disease Assessment at the Time of Best Response to HSCT

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." 🕮

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 post-HSCT treatment planned as of Day 0.)
   - 1 ☐ complete response (CR) — disappearance of monoclonal protein by immunofixation; no histologic evidence of bone marrow involvement, resolution of any adenopathy / organomegaly (confirmed by CT scan), or signs or symptoms attributable to WM. Reconfirmation of the CR status is required at least 6 weeks apart with a second immunofixation.
   - 2 ☐ partial response (PR) — at least 50% reduction of serum monoclonal IgM concentration on protein electrophoresis and at least 50% decrease in adenopathy / organomegaly on physical examination or on CT scan. No new symptoms or signs of active disease.
   - 3 ☐ minor response / stable disease (MR / SD) — at least 25% but less than 50% reduction of serum monoclonal IgM by protein electrophoresis. No new symptoms or signs of active disease.
     Or a less-than-25% reduction and less-than-25% increase of serum monoclonal IgM by electrophoresis without progression of adenopathy / organomegaly, cytopenias, or clinically significant symptoms due to disease and/or signs of WM.
   - 4 ☐ progressive disease (PD) — at least 25% increase in serum monoclonal IgM by protein electrophoresis confirmed by a second measurement or progression of clinically significant findings due to disease (ie, anemia, thrombocytopenia, leukopenia, bulky adenopathy / organomegaly) or symptoms (unexplained recurrent fever of at least 38.4° C, drenching night sweats, at least 10% body weight loss, or hyperviscosity, neuropathy, symptomatic cryoglobulinemia, or amyloidosis) attributable to WM.
   - 5 ☐ not assessed

2. Date the best response first began: Month Day Year ☐ date of the best response was previously reported

Mail this form to your designated campus (Milwaukee or Minneapolis). Retain the original at the transplant center.

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

ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Visit:
☐ 100 day
☐ 6 month
☐ ____ year

Today's Date: Month ____ Day ____ Year 20____

Infusion Date: Month ____ Day ____ Year 20____

CIBMTR Center Number:

Initials:

CIBMTR Center Number:

CIBMTR Recipient ID:

Laboratory Studies at the Time of Best Response to HSCT

3. Absolute lymphocyte count:
   1 ☐ known → ____
   2 ☐ not known

   Specify units:
   1 ☐ x 10^9/L (x 10^3/mm^3)
   2 ☐ x 10^6/L

4. Lymphoplasmacytic infiltrate in bone marrow:
   1 ☐ known → ____ %
   2 ☐ not known

5. Serum IgM level:
   1 ☐ known → ____.____
   2 ☐ not known

   1 ☐ mg/dL
   2 ☐ g/dL
   3 ☐ g/L

6. Serum monoclonal spike: *(only from electrophoresis)*
   1 ☐ known → ____.____
   2 ☐ not known

   1 ☐ mg/dL
   2 ☐ g/dL
   3 ☐ g/L

7. Urinary monoclonal light chains:
   1 ☐ known → ____.____ g / 24 hours
   2 ☐ not known

8. Has the disease relapsed / progressed since the date of the last report?
   1 ☐ yes →
   2 ☐ no
   3 ☐ unknown

   9. Date of progression / relapse: Month ____ Day ____ Year 20____ ☐ date unknown

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

ERROR CORRECTION FORM

Sequence Number: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐

CIBMTR Recipient ID: ☐☐☐☐☐☐☐☐☐

Visit:
☐ 100 day
☐ 6 month
☐ ☐☐ year

Today's Date: ☐☐ Month ☐☐ Day 20☐☐ Year

Infusion Date: ☐☐ Month ☐☐ Day 20☐☐ Year

CIBMTR Center Number: ☐☐☐☐☐

Initials: ☐☐☐

CIBMTR Center Number: ☐☐☐☐☐

CIBMTR Recipient ID: ☐☐☐☐☐☐☐☐☐

Post-HSCT Treatment for Waldenström's Macroglobulinemia

10. Was any treatment given since the date of the last report?

1 ☐ yes → 2 ☐ no 3 ☐ unknown

Line of Therapy:	1st Line of Therapy	2nd Line of Therapy
Was therapy planned?	11. 1 ☐ yes 2 ☐ no	45. 1 ☐ yes 2 ☐ no
Systemic Therapy:	12. 1 ☐ yes 2 ☐ no → cont. with q. 36	46. 1 ☐ yes 2 ☐ no → cont. with q. 70
Date therapy started:	13. ☐☐ Month ☐☐ Day ☐☐☐☐ Year	47. ☐☐ Month ☐☐ Day ☐☐☐☐ Year
Number of cycles:	14. ☐☐ ☐ unknown/not applicable	48. ☐☐ ☐ unknown/not applicable
aldesleukin (interleukin-2)	15. 1 ☐ yes 2 ☐ no	49. 1 ☐ yes 2 ☐ no
alemtuzumab (Campath)	16. 1 ☐ yes 2 ☐ no	50. 1 ☐ yes 2 ☐ no
chlorambucil (Leukeran)	17. 1 ☐ yes 2 ☐ no	51. 1 ☐ yes 2 ☐ no
cladribine (2-CdA, Leustatin)	18. 1 ☐ yes 2 ☐ no	52. 1 ☐ yes 2 ☐ no
corticosteroids 🕮	19. 1 ☐ yes 2 ☐ no	53. 1 ☐ yes 2 ☐ no
cyclophosphamide (Cytoxan)	20. 1 ☐ yes 2 ☐ no	54. 1 ☐ yes 2 ☐ no
doxorubicin (Adriamycin)	21. 1 ☐ yes 2 ☐ no	55. 1 ☐ yes 2 ☐ no
etoposide (VP-16, VePesid)	22. 1 ☐ yes 2 ☐ no	56. 1 ☐ yes 2 ☐ no
fludarabine (Fludara)	23. 1 ☐ yes 2 ☐ no	57. 1 ☐ yes 2 ☐ no
idarubicin (Idamycin)	24. 1 ☐ yes 2 ☐ no	58. 1 ☐ yes 2 ☐ no
ifosfamide (Ifex)	25. 1 ☐ yes 2 ☐ no	59. 1 ☐ yes 2 ☐ no
interferon-α (Roferon-α)	26. 1 ☐ yes 2 ☐ no	60. 1 ☐ yes 2 ☐ no
lenalidomide (Revlimid)	27. 1 ☐ yes 2 ☐ no	61. 1 ☐ yes 2 ☐ no
melphalan (L-PAM)	28. 1 ☐ yes 2 ☐ no	62. 1 ☐ yes 2 ☐ no
mitoxantrone (Novantrone)	29. 1 ☐ yes 2 ☐ no	63. 1 ☐ yes 2 ☐ no
pentostatin (Nipent)	30. 1 ☐ yes 2 ☐ no	64. 1 ☐ yes 2 ☐ no
rituximab (anti-CD20, Rituxan)	31. 1 ☐ yes 2 ☐ no	65. 1 ☐ yes 2 ☐ no
thalidomide (Thalomid)	32. 1 ☐ yes 2 ☐ no	66. 1 ☐ yes 2 ☐ no
vincristine (VCR, Oncovin)	33. 1 ☐ yes 2 ☐ no	67. 1 ☐ yes 2 ☐ no
other systemic therapy	34. 1 ☐ yes 2 ☐ no	68. 1 ☐ yes 2 ☐ no
specify other therapy	35. _____	69. _____
Radiation Therapy:	36. 1 ☐ yes 2 ☐ no → cont. with q. 41	70. 1 ☐ yes 2 ☐ no → cont. with q. 75
Date therapy started:	37. ☐☐ Month ☐☐ Day ☐☐☐☐ Year	71. ☐☐ Month ☐☐ Day ☐☐☐☐ Year
Specify radiation site(s):	38. _____	72. _____
	39. _____	73. _____
	40. _____	74. _____
Best Response to Line of Therapy: *(see definitions at question 1)*	41. 1 ☐ CR 2 ☐ PR 3 ☐ MR / SD 4 ☐ PD 5 ☐ not assessed	75. 1 ☐ CR 2 ☐ PR 3 ☐ MR / SD 4 ☐ PD 5 ☐ not assessed
Date response evaluated:	42. ☐☐ Month ☐☐ Day ☐☐☐☐ Year	76. ☐☐ Month ☐☐ Day ☐☐☐☐ Year
Did patient relapse/progress following this line of therapy?	43. 1 ☐ yes 2 ☐ no	77. 1 ☐ yes 2 ☐ no
Date of relapse/progression:	44. ☐☐ Month ☐☐ Day ☐☐☐☐ Year	78. ☐☐ Month ☐☐ Day ☐☐☐☐ Year

Copy this page to report more than 2 lines of therapy; check here ☐ if additional pages are attached.

CIBMTR Form 2119 (MAC) v1.0 (3–5) July 2007

For internal use only: Document F00511 version 1.0 Replaces: n/a

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

ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Visit:
☐ 100 day
☐ 6 month
☐ ____ year

Today's Date: Month ____ Day ____ 20__ Year

Infusion Date: Month ____ Day ____ 20__ Year

CIBMTR Center Number:

Initials:

CIBMTR Center Number:

CIBMTR Recipient ID:

Laboratory Studies at the Time of Evaluation for This Reporting Period

This section refers to laboratory values obtained for recipients who have not undergone any further therapy for Waldenström's Macroglobulinemia. If this recipient has received any disease treatments or therapies (other than planned treatment per protocol), continue with the signature lines at question 99.

79. Absolute lymphocyte count:
1 ☐ known → ____
2 ☐ not known

Specify units:
1 ☐ x 10^9/L (x 10^3/mm^3)
2 ☐ x 10^6/L

80. Lymphoplasmacytic infiltrate in bone marrow:
1 ☐ known → ____ %
2 ☐ not known

81. Serum monoclonal spike: *(only from electrophoresis)*
1 ☐ known → ____ . ____
2 ☐ not known

1 ☐ mg/dL
2 ☐ g/dL
3 ☐ g/L

82. Urinary monoclonal light chains:
1 ☐ known → ____ . ____ g / 24 hours
2 ☐ not known

83. LDH:
1 ☐ known → ____ . ____
2 ☐ not known

1 ☐ U/L
2 ☐ µkat/L → 84. Upper limit of normal for LDH: ____ . ____

85. Bone marrow aspirate examined to assess response to HSCT:
1 ☐ known → ____ %
2 ☐ not known

86. Bone marrow biopsy examined to assess response to HSCT:
1 ☐ known → ____ %
2 ☐ not known

87. Bone marrow, sample source unknown, examined to assess response to HSCT:
1 ☐ known → ____ %
2 ☐ not known

88. Specify the type of histological involvement in marrow:
1 ☐ lymphoplasmacytoid
2 ☐ lymphoplasmacytic
3 ☐ polymorphous
4 ☐ unknown

89. IgM:
1 ☐ known → ____ . ____
2 ☐ not known

1 ☐ mg/dL
2 ☐ g/dL
3 ☐ g/L

→ 90. Upper limit of normal for IgM: ____ . ____

91. Lower limit of normal for IgM: ____ . ____

92. Was there any clinical or radiological evidence of organ involvement at the time of evaluation for this reporting period?
1 ☐ yes →
2 ☐ no

Specify site(s) of organ involvement:
93. 1 ☐ yes 2 ☐ no Lymph nodes
94. 1 ☐ yes 2 ☐ no Spleen
95. 1 ☐ yes 2 ☐ no Other site → 96. Specify site: _____

CIBMTR Form 2119 (MAC) v1.0 (4–5) July 2007

For internal use only: Document F00511 version 1.0 Replaces: n/a

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

ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Visit:
☐ 100 day
☐ 6 month
☐ ____ year

Today's Date: Month Day 20__ Year

Infusion Date: Month Day 20__ Year

CIBMTR Center Number:

Initials:

CIBMTR Center Number:

CIBMTR Recipient ID:

Disease Status at the Time of Asessment for This Reporting Period

97. What is the current disease status?
1 ☐ complete remission
2 ☐ not in complete remission

98. Date the current disease status was established in this reporting period: Month Day 20__ Year

99. Signed: _____
Person completing form

Please print name: _____

Phone: (_____) _____

Fax: (_____) _____

E-mail address: _____

CIBMTR Form 2119 (MAC) v1.0 (5–5) July 2007

For internal use only: Document F00511 version 1.0 Replaces: n/a

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