ERROR CORRECTION FORM

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CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Waldenström's Macroglobulinemia Pre-HSCT Data

Registry Use Only

Sequence Number: | |

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Date of HSCT for which this form is being completed: 🕮 Month | | Day | | | 2 0 | | | Year

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

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

This form must be accompanied by Form 2000 – Recipient Baseline Data. All information in the box above, including the date, should be identical with the corresponding Form 2000. Information should come from an actual examination by the Transplant Center physician, or the physician who is following the recipient pre-HSCT, or abstraction of the recipient's medical records.

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

If this is a report of a second or subsequent transplant, check here ☐ and continue with question 167.

Disease Assessment at Diagnosis

1. What was the date of diagnosis of Waldenström's macroglobulinemia? Month | | Day | | Year | | | |

Specify the immunoglobulin M (IgM) protein chains present at diagnosis:

	Source: Serum	Source: Urine
2. IgM heavy chain 1	1 ☐	2 ☐
3. IgM heavy chain 2	1 ☐	2 ☐

	Chain type: κ (kappa)	λ (lambda)	Biclonal	Source: Serum	Urine
4. IgM light chain 1	1 ☐	2 ☐	3 ☐	5. 1 ☐	2 ☐
6. IgM light chain 2	1 ☐	2 ☐	3 ☐	7. 1 ☐	2 ☐

Clinical Features Present at Diagnosis

8. Was peripheral neuropathy present at diagnosis?
   - 1 ☐ yes →
   - 2 ☐ no
   - 3 ☐ unknown

Specify the method(s) used to determine peripheral neuropathy:

9. 1 ☐ yes 2 ☐ no 3 ☐ unknown Clinical evidence
10. 1 ☐ yes 2 ☐ no 3 ☐ unknown Electromyography (EMG)
11. 1 ☐ yes 2 ☐ no 3 ☐ unknown Myelin-associated glycoprotein antibodies (anti-MAG) detected

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

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12. Did the recipient have known organ involvement with Waldenström's macroglobulinemia at diagnosis?
- 1 ☐ yes → Specify the site(s) of involvement:
- 2 ☐ no
- 3 ☐ unknown

13. Bone
- 1 ☐ yes → 14. Was a bone biopsy performed?
- 2 ☐ no
- 3 ☐ unknown

14. Was a bone biopsy performed?
- 1 ☐ yes → 15. Specify bone biopsy results:
- 2 ☐ no
- 3 ☐ unknown

15. Specify bone biopsy results:
- 1 ☐ positive
- 2 ☐ negative

16. Brain
- 1 ☐ yes → 17. Was a brain biopsy performed?
- 2 ☐ no
- 3 ☐ unknown

17. Was a brain biopsy performed?
- 1 ☐ yes → 18. Specify brain biopsy results:
- 2 ☐ no
- 3 ☐ unknown

18. Specify brain biopsy results:
- 1 ☐ positive
- 2 ☐ negative

19. Gastrointestinal
- 1 ☐ yes → 20. Was a GI biopsy performed?
- 2 ☐ no
- 3 ☐ unknown

20. Was a GI biopsy performed?
- 1 ☐ yes → 21. Specify GI biopsy results:
- 2 ☐ no
- 3 ☐ unknown

21. Specify GI biopsy results:
- 1 ☐ positive
- 2 ☐ negative

22. Kidney
- 1 ☐ yes → 23. Was a renal biopsy performed?
- 2 ☐ no
- 3 ☐ unknown

23. Was a renal biopsy performed?
- 1 ☐ yes → 24. Specify renal biopsy results:
- 2 ☐ no
- 3 ☐ unknown

24. Specify renal biopsy results:
- 1 ☐ positive
- 2 ☐ negative

25. Liver
- 1 ☐ yes → 26. Was a hepatic biopsy performed?
- 2 ☐ no
- 3 ☐ unknown

26. Was a hepatic biopsy performed?
- 1 ☐ yes → 27. Specify hepatic biopsy results:
- 2 ☐ no
- 3 ☐ unknown

27. Specify hepatic biopsy results:
- 1 ☐ positive
- 2 ☐ negative

28. Was the liver enlarged?
- 1 ☐ yes
- 2 ☐ no
- 3 ☐ unknown

29. Lung
- 1 ☐ yes → 30. Was a pulmonary biopsy performed?
- 2 ☐ no
- 3 ☐ unknown

30. Was a pulmonary biopsy performed?
- 1 ☐ yes → 31. Specify pulmonary biopsy results:
- 2 ☐ no
- 3 ☐ unknown

31. Specify pulmonary biopsy results:
- 1 ☐ positive
- 2 ☐ negative

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32. Lymph nodes
- 1 ☐ yes → 33. Specify the total number of nodal regions involved:
  - 1 ☐ one nodal region
  - 2 ☐ two or more nodal regions
  - 3 ☐ unknown
- 34. Specify the size of the two greatest dimensions of the largest nodal mass: | | x | | | cm
- 35. Was a lymph node biopsy performed?
  - 1 ☐ yes → 36. Specify lymph node biopsy results:
    - 1 ☐ positive
    - 2 ☐ negative
  - 2 ☐ no
  - 3 ☐ unknown
- 2 ☐ no
- 3 ☐ unknown

37. Pleura
- 1 ☐ yes → 38. Was a pleural biopsy performed?
  - 1 ☐ yes → 39. Specify pleural biopsy results:
    - 1 ☐ positive
    - 2 ☐ negative
  - 2 ☐ no
  - 3 ☐ unknown
- 2 ☐ no
- 3 ☐ unknown

40. Skin
- 1 ☐ yes → 41. Was a skin biopsy performed?
  - 1 ☐ yes → 42. Specify skin biopsy results:
    - 1 ☐ positive
    - 2 ☐ negative
  - 2 ☐ no
  - 3 ☐ unknown
- 2 ☐ no
- 3 ☐ unknown

43. Splenectomy
- 1 ☐ yes → 44. Speficy splenectomy results:
  - 1 ☐ positive for Waldenström's macroglobulinemia
  - 2 ☐ negative
  - 3 ☐ unknown
- 2 ☐ no
- 3 ☐ unknown

45. Other site
- 1 ☐ yes → 46. Specify site: _____
  - 47. Was a biopsy performed?
    - 1 ☐ yes → 48. Specify biopsy results:
      - 1 ☐ positive
      - 2 ☐ negative
    - 2 ☐ no
    - 3 ☐ unknown
- 2 ☐ no
- 3 ☐ unknown

49. Specify the size of the largest lesion at diagnosis: | | . | | x | | | . | | cm

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50. Were systemic symptoms (B symptoms) present at diagnosis (unexplained weight loss > 10% body weight in six months before diagnosis; unexplained fever > 38°C; or night sweats)?
1 ☐ yes
2 ☐ no
3 ☐ unknown

51. Was clinical hyperviscosity syndrome present at diagnosis?
1 ☐ yes →
2 ☐ no
3 ☐ unknown

Specify clinical symptoms present at diagnosis:
52. 1 ☐ yes 2 ☐ no 3 ☐ unknown Bleeding / bruising
53. 1 ☐ yes 2 ☐ no 3 ☐ unknown Dizziness
54. 1 ☐ yes 2 ☐ no 3 ☐ unknown Fatigue
55. 1 ☐ yes 2 ☐ no 3 ☐ unknown Visual disturbance
56. 1 ☐ yes 2 ☐ no 3 ☐ unknown Other → 57. Specify other symptom: _____

58. Relative serum viscosity:
1 ☐ known → | | . | |
2 ☐ not known

→ 59. Upper limit of normal for relative serum viscosity: | | . | |

60. Was plasmapheresis or plasma exchange required at diagnosis?
1 ☐ yes
2 ☐ no
3 ☐ unknown

Laboratory Studies at Diagnosis

Report findings prior to any first treatment for Waldenström's macroglobulinemia.

61. WBC:
1 ☐ known → | | | | | | | . | |
2 ☐ not known
Specify units:
1 ☐ x 10^9/L (x 10^3/mm^3)
2 ☐ x 10^6/L

62. Absolute lymphocyte count:
1 ☐ known → | | | | | | |
2 ☐ not known
1 ☐ x 10^9/L (x 10^3/mm^3)
2 ☐ x 10^6/L

63. Hemoglobin:
1 ☐ known → | | | | | . | |
2 ☐ not known
1 ☐ g/dL
2 ☐ g/L
3 ☐ mmol/L
→ 64. Was RBC transfused in the prior 30 days?
1 ☐ yes
2 ☐ no

65. Platelets:
1 ☐ known → | | | | | | | |
2 ☐ not known
1 ☐ x 10^9/L (x 10^3/mm^3)
2 ☐ x 10^6/L
→ 66. Were platelets transfused in the prior 7 days?
1 ☐ yes
2 ☐ no

67. Involvement in bone marrow aspirate:
1 ☐ known → | | | | %
2 ☐ not known

68. Involvement in bone marrow biopsy:
1 ☐ known → | | | | %
2 ☐ not known

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69. Involvement in bone marrow, sample source unknown:
- 1 ☐ known → | | | | %
- 2 ☐ not known

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

71. Disease immunophenotype:
- 1 ☐ known →
- 2 ☐ not known

72. Specify immunophenotype:
- 1 ☐ CD5
- 2 ☐ CD19
- 3 ☐ CD20
- 4 ☐ CD22
- 5 ☐ CD79
- 6 ☐ surface IgM

73. Is a copy of the immunophenotype report (flow cytometry) attached?
- 1 ☐ yes
- 2 ☐ no

74. Serum albumin:
- 1 ☐ known → | | . |
- 2 ☐ not known

Specify units:
- 1 ☐ g/dL
- 2 ☐ g/L

75. Serum β_2 microglobulin:
- 1 ☐ known → | | | . | | |
- 2 ☐ not known

- 1 ☐ µg/dL
- 2 ☐ mg/L
- 3 ☐ nmol/L

76. Serum creatinine:
- 1 ☐ known → | | . | |
- 2 ☐ not known

- 1 ☐ mg/dL
- 2 ☐ mmol/L
- 3 ☐ µmol/L

→ 77. Upper limit of normal for serum creatinine: | | . |

78. Serum monoclonal spike: *(only from electrophoresis)*
- 1 ☐ known → | | | | . |
- 2 ☐ not known

- 1 ☐ mg/dL
- 2 ☐ g/dL
- 3 ☐ g/L

79. Urinary monoclonal protein / spike:
- 1 ☐ known → | | | . | g / 24 hours
- 2 ☐ not known

80. LDH:
- 1 ☐ known → | | | | | . | |
- 2 ☐ not known

- 1 ☐ U/L
- 2 ☐ µkat/L

→ 81. Upper limit of normal for LDH: | | | | | . |

82. Cold agglutinins:
- 1 ☐ known →
- 2 ☐ not known

83. Specify results:
- 1 ☐ positive for agglutination in titers at or below 1:16 or IgM antibodies that bind at < 37° C
- 2 ☐ negative

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84. Cryoglobulin:
- 1 ☐ known → 85. Specify:
  - 1 ☐ cryoglobulins present
  - 2 ☐ absent
- 2 ☐ not known

Specify the following serum quantitative immunoglobulins (measured prior to any disease treatment):

86. IgG:
- 1 ☐ known → | | | | | | . | | |
- 2 ☐ not known

1 ☐ mg/dL
2 ☐ g/dL
3 ☐ g/L

87. Upper limit of normal for IgG: | | | | | | . | | |

88. Lower limit of normal for IgG: | | | | | | . | | |

89. IgA:
- 1 ☐ known → | | | | | | . | | |
- 2 ☐ not known

1 ☐ mg/dL
2 ☐ g/dL
3 ☐ g/L

90. Upper limit of normal for IgA: | | | | | | . | | |

91. Lower limit of normal for IgA: | | | | | | . | | |

92. IgM:
- 1 ☐ known → | | | | | | . | | |
- 2 ☐ not known

1 ☐ mg/dL
2 ☐ g/dL
3 ☐ g/L

93. Upper limit of normal for IgM: | | | | | | . | | |

94. Lower limit of normal for IgM: | | | | | | . | | |

95. Was cytogenetic or FISH testing performed at any time between diagnosis and the start of the preparative regimen?
- 1 ☐ yes → 96. Was del (6q) / 6q– present?
  - 1 ☐ yes
  - 2 ☐ no

  97. Is a copy of the cytogenetic report attached?
  - 1 ☐ yes
  - 2 ☐ no
- 2 ☐ yes, but no evaluable metaphases
- 3 ☐ no
- 4 ☐ unknown

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Pre-HSCT Treatment for Waldenström's Macroglobulinemia

98. Was any therapy given between diagnosis and the start of the preparative regimen (including chemotherapy used to mobilize stem cells)?
    1 ☐ yes →
    2 ☐ no

Line of Therapy:		1st Line of Therapy		2nd Line of Therapy
Systemic Therapy:	99.	1 ☐ yes 2 ☐ no → cont. with 122	133.	1 ☐ yes 2 ☐ no → cont. with 156
Date therapy started:	100.	Month / Day / Year	134.	Month / Day / Year
Date therapy stopped:	101.	Month / Day / Year	135.	Month / Day / Year
Number of cycles:	102.	☐ unknown/not applicable	136.	☐ unknown/not applicable
alemtuzumab (Campath)	103.	1 ☐ yes 2 ☐ no	137.	1 ☐ yes 2 ☐ no
chlorambucil (Leukeran)	104.	1 ☐ yes 2 ☐ no	138.	1 ☐ yes 2 ☐ no
cladribine (2-CdA, Leustatin)	105.	1 ☐ yes 2 ☐ no	139.	1 ☐ yes 2 ☐ no
corticosteroids 🕮	106.	1 ☐ yes 2 ☐ no	140.	1 ☐ yes 2 ☐ no
cyclophosphamide (Cytoxan)	107.	1 ☐ yes 2 ☐ no	141.	1 ☐ yes 2 ☐ no
doxorubicin (Adriamycin)	108.	1 ☐ yes 2 ☐ no	142.	1 ☐ yes 2 ☐ no
etoposide (VP-16, VePesid)	109.	1 ☐ yes 2 ☐ no	143.	1 ☐ yes 2 ☐ no
fludarabine (Fludara)	110.	1 ☐ yes 2 ☐ no	144.	1 ☐ yes 2 ☐ no
idarubicin (Idamycin)	111.	1 ☐ yes 2 ☐ no	145.	1 ☐ yes 2 ☐ no
ifosfamide (Ifex)	112.	1 ☐ yes 2 ☐ no	146.	1 ☐ yes 2 ☐ no
lenalidomide (Revlimid)	113.	1 ☐ yes 2 ☐ no	147.	1 ☐ yes 2 ☐ no
melphalan (L-PAM)	114.	1 ☐ yes 2 ☐ no	148.	1 ☐ yes 2 ☐ no
mitoxantrone (Novantrone)	115.	1 ☐ yes 2 ☐ no	149.	1 ☐ yes 2 ☐ no
pentostatin (Nipent)	116.	1 ☐ yes 2 ☐ no	150.	1 ☐ yes 2 ☐ no
rituximab (anti-CD20, Rituxan)	117.	1 ☐ yes 2 ☐ no	151.	1 ☐ yes 2 ☐ no
thalidomide (Thalomid)	118.	1 ☐ yes 2 ☐ no	152.	1 ☐ yes 2 ☐ no
vincristine (VCR, Oncovin)	119.	1 ☐ yes 2 ☐ no	153.	1 ☐ yes 2 ☐ no
other systemic therapy	120.	1 ☐ yes 2 ☐ no	154.	1 ☐ yes 2 ☐ no
specify other therapy	121.	_____	155.	_____
Radiation Therapy:	122.	1 ☐ yes 2 ☐ no → cont. with 128	156.	1 ☐ yes 2 ☐ no → cont. with 162
Date therapy started:	123.	Month / Day / Year	157.	Month / Day / Year
Date therapy stopped:	124.	Month / Day / Year	158.	Month / Day / Year
Specify radiation site(s):	125.	_____	159.	_____
	126.	_____	160.	_____
	127.	_____	161.	_____
Given for stem cell priming?	128.	1 ☐ yes 2 ☐ no	162.	1 ☐ yes 2 ☐ no
Best Response to Line of Therapy: *(see definitions at q. 186)*	129.	1 ☐ chemosensitive 2 ☐ chemoresistant 3 ☐ not assessed / unknown	163.	1 ☐ chemosensitive 2 ☐ chemoresistant 3 ☐ not assessed / unknown
Date response established:	130.	Month / Day / Year	164.	Month / Day / Year
Did disease relapse/progress following this line of therapy?	131.	1 ☐ yes 2 ☐ no	165.	1 ☐ yes 2 ☐ no
Date of relapse/progression:	132.	Month / Day / Year	166.	Month / Day / Year

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

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Laboratory Studies Prior to the Start of the Preparative Regimen

167. 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

168. Involvement in bone marrow aspirate:
1 ☐ known → | | | |
2 ☐ not known
%

169. Involvement in bone marrow biopsy:
1 ☐ known → | | | |
2 ☐ not known
%

170. Involvement in bone marrow, sample source unknown:
1 ☐ known → | | | |
2 ☐ not known
%

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

172. Serum albumin:
1 ☐ known → | | . |
2 ☐ not known
1 ☐ g/dL
2 ☐ g/L

173. Serum β_2 microglobulin:
1 ☐ known → | | | . | | |
2 ☐ not known
1 ☐ µg/dL
2 ☐ mg/L
3 ☐ nmol/L

174. Relative serum viscosity:
1 ☐ known → | . |
2 ☐ not known
→ 175. Upper limit of normal for relative serum viscosity: | . |

176. Serum creatinine:
1 ☐ known → | | | . | |
2 ☐ not known
1 ☐ mg/dL
2 ☐ mmol/L
3 ☐ µmol/L
→ 177. Upper limit of normal for serum creatinine: | | | . |

178. Serum IgM level:
1 ☐ known → | | | | . |
2 ☐ not known
1 ☐ mg/dL
2 ☐ g/dL
3 ☐ g/L

179. Serum monoclonal spike: *(only from electrophoresis)*
1 ☐ known → | | | | . |
2 ☐ not known
1 ☐ mg/dL
2 ☐ g/dL
3 ☐ g/L

180. LDH:
1 ☐ known → | | | | | . | |
2 ☐ not known
1 ☐ U/L
2 ☐ µkat/L
→ 181. Upper limit of normal for LDH: | | | | | . |

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182. Cold agglutinins:
- 1 ☐ known → 183. Specify results:
  - 1 ☐ positive for agglutination in titers at or below 1:16 or IgM antibodies that bind at < 37° C
  - 2 ☐ negative
- 2 ☐ not known

184. Cryoglobulin:
- 1 ☐ known → 185. Specify:
  - 1 ☐ cryoglobulins present
  - 2 ☐ absent
- 2 ☐ not known

Disease Status at the Last Assessment Prior to the Preparative Regimen

186. What was the sensitivity of the disease to any systemic treatment(s) completed ≤ 6 months prior to the HSCT?
- 1 ☐ sensitive — ≥ 50% reduction in measurable tumor cell mass, bone marrow and serum paraprotein
- 2 ☐ resistant — < 50% reduction in measurable tumor cell mass, bone marrow and serum paraprotein
- 3 ☐ not applicable — no systemic therapy prior to the preparative regimen, or systemic therapy ended > 6 months prior to the preparative regimen
- 4 ☐ unknown

187. What was the disease status at the last evaluation prior to the preparative regimen?
- 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 unless disease assessment is less than 6 weeks from HSCT.
- 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

188. Date of the most recent assessment for disease status prior to the preparative regimen: Month | | Day | | | 2 | 0 | | | Year

189. Signed: _____
Person completing form

Please print name: _____

Phone: (_____) _____

Fax: (_____) _____

E-mail address: _____

CIBMTR Form 2019 (MAC) v1.0 (9–9) July 2007

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