Form 2019 R3.0: Waldenström's Macroglobulinemia/ Lymphoplasmacytic Lymphoma (MAC) Pre-HCT Data

Center: CRID:

Key Fields

Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

Date of HCT for which this form is being completed: __ __ __ __ - __ __- __ __

HCT Type (check all that apply):

- Autologous
- Allogeneic, unrelated
- Allogeneic, related

Product Type: (check all that apply)

- Bone marrow
- PBSC
- Single cord blood unit
- Multiple cord blood units
- Other product

Specify: _____

Subsequent Transplant

Is this the report of a second or subsequent transplant for the same disease?

yes no

Is the second or subsequent transplant for relapse or progression of the same disease?

yes no

Disease Assessment at Diagnosis

Questions: 1 - 2

1 What is the diagnosis?

- Lymphoplasmacytic lymphoma (LPL)
- Waldenström's macroglobulinemia (MAC)

2 What was the date of diagnosis? __ __ __ __ - __ __- __ __

Clinical Features at Diagnosis

Questions: 3 - 23

3 Was peripheral neuropathy present?

yes no Unknown

4 Did the recipient have known nodal involvement?

yes no

5 Specify the size of the largest nodal mass: _____ cm X _____ cm

6 Was there any known extranodal or splenic involvement?

yes no Unknown

Specify the site(s) of involvement:

7 Bone

yes no

8 Gastrointestinal (GI) tract

yes no

9 Kidney

yes no

10 Liver

yes no

11 Lung

yes no

12 Spleen

yes no

13 Other site

yes no

14 Specify other site: _____

15 Were systemic symptoms (B symptoms) present?
(unexplained fever > 38 C; night sweats; or unexplained weight loss > 10% body weight in six months before diagnosis)

yes no Unknown

16 Was clinical hyperviscosity syndrome present?

yes no Unknown

Specify clinical symptoms present at diagnosis:

17 Bleeding / bruising

yes no Unknown

18 Dizziness

yes no Unknown

19 Fatigue

yes no Unknown

20 Visual disturbance

yes no Unknown

21 Other

yes no Unknown

22 Specify other symptom: _____

23 Was plasmapheresis or plasma exchange required?

yes no Unknown

Laboratory Studies at Diagnosis **Questions: 24 - 75**

Report findings prior to any first treatment for LPL or MAC

24 Absolute lymphocyte count

Known Unknown

25 _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

26 Hemoglobin

Known Unknown

27 _____ g/dL g/L mmol/L

28 Platelets

Known Unknown

29 _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

30 Bone marrow aspirate (examined for histologic involvement)

Known Unknown Not applicable

31 _____ %

32 Bone marrow biopsy (examined for histiologic involvement)

Known Unknown Not applicable

33 _____ %

34 Specify the type of histological involvement in marrow

lymphoplasmacytoid lymphoplasmacytic polymorphous Unknown

35 Was flow cytometry (immunophenotyping) performed?

yes no Unknown

36 CD5

Positive Negative Not Done

37 CD19

Positive Negative Not Done

38 CD20

Positive Negative Not Done

39 CD22

Positive Negative Not Done

40 CD79

Positive Negative Not Done

41 Surface IgM

Positive Negative Not Done

42 Was documentation submitted to the CIBMTR?
(e.g. flow cytometry (immunophenotype) report)

yes no

43 Serum β2 microglobulin

Known Unknown

44 _____ µg/dL mg/L nmol/L

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

45 Serum heavy chain - IgM

yes no

46 Urine heavy chain - IgM

yes no

47 Serum light chain

kappa lambda

48 Urine light chain

kappa lambda

49 Relative serum viscosity

Known Unknown

50 _____

51 Upper limit of normal for relative serum viscosity: _____

52 Serum monoclonal protein (M-spike): (only from electrophoresis)

Known Unknown

53 _____ mg/dL g/dL g/L

54 Urinary monoclonal protein (M-spike)

Known Unknown

55 _____ mg / 24 hours

56 LDH

Known Unknown

57 _____ U/L µkat/L

58 Upper limit of normal for LDH: _____ U/L µkat/L

59 Cold agglutinins

Positive (for agglutination in titers at or below 1:16 or IgM antibodies that bind at < 37°C)

Negative

Unknown

60 Cryoglobulin

Present Absent Unknown

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

61 IgG

Known Unknown

62 _____ mg/dL g/dL g/L

63 Upper limit of normal for IgG: _____ mg/dL g/dL g/L

64 IgA

Known Unknown

65 _____ mg/dL g/dL g/L

66 Upper limit of normal for IgA: _____ mg/dL g/dL g/L

67 IgM

Known Unknown

68 _____ mg/dL g/dL g/L

69 Upper limit of normal for IgM: _____ mg/dL g/dL g/L

70 Were cytogenetics tested (conventional or FISH)?

yes no Unknown

71 Results of tests

Abnormalities identified

No evaluable metaphases

No abnormalities

72 del(6q) / 6q–

yes no

73 Other abnormality

yes no

74 Specify other abnormality: _____

75 Was documentation submitted to the CIBMTR?
(e.g. cytogenetic or FISH report)

yes no

Pre-HCT Therapy

Questions: 76 - 120

76 Was therapy given?
(including chemotherapy used to mobilize stem cells)

yes no

Line of Therapy (1)

Questions: 77 - 120

Line of Therapy:

77 Systemic therapy

yes no

78 Date therapy started

Known Unknown

79 Date started: __ __ __ __ - __ __- __ __

80 Date therapy stopped

Known Unknown

81 Date stopped: __ __ __ __ - __ __- __ __

82 Number of cycles

Known Unknown

83 Number of cycles: _____

84 Alemtuzumab (Campath)

yes no

85 Bendamustine

yes no

86 Bortezomib (Velcade)

yes no

87 Carfilzomib

yes no

88 Chlorambucil (Leukeran)

yes no

89 Cladribine (2-CdA, Leustatin)

yes no

90 Corticosteroids

yes no

91 Cyclophosphamide (Cytoxan)

yes no

92 Doxorubicin (Adriamycin)

yes no

93 Etoposide (VP-16, VePesid)

yes no

94 Everolimus (RAD-001)

yes no

95 Fludarabine (Fludara)

yes no

96 Idarubicin (Idamycin)

yes no

97 Ifosfamide (Ifex)

yes no

98 Lenalidomide (Revlimid)

yes no

99 Melphalan (L-PAM, Alkeran)

yes no

100 Mitoxantrone

yes no

101 Pentostatin (Nipent)

yes no

102 Rituximab (Rituxan, MabThera)

yes no

103 Temsirolimus (Torisel)

yes no

104 Thalidomide (Thalomid)

yes no

105 Vincristine (VCR, Oncovin)

yes no

106 Other systemic therapy

yes no

107 Specify other systemic therapy: _____

108 Was this line of therapy given for stem cell mobilization (priming)?

yes no

109 Radiation therapy

yes no

110 Date therapy started

Known Unknown

111 Date started: __ __ __ __ - __ __- __ __

112 Date therapy stopped

Known Unknown

113 Date stopped: __ __ __ __ - __ __- __ __

Specify site(s) of radiation therapy:

114 _____

115 _____

116 _____

117 Best response to line of therapy:

- Complete remission (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 MAC/LPL. 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 HCT.
- Partial remission (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.
- Minor remission / 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 wihtout progression of adenopathy / organomegaly, cytopenias, or clinically significant symptoms due to disease and/or signs of MAC/LPL.
- 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 MAC/LPL.
- Not assessed

118 Date assessed: __ __ __ __ - __ __- __ __

119 Did patient relapse/progress following this line of therapy?

- yes
- no

120 Date of relapse/progression: __ __ __ __ - __ __- __ __

Laboratory Studies at Last Evaluation Prior to the Start of the Preparative Regimen (Conditioning) Questions: 121 - 150

121 Absolute lymphocyte count

- Known
- Unknown

122 _____

- x 10^9/L (x 10^3/mm^3)
- x 10^6/L

123 Bone marrow aspirate (examined for histologic involvement)

- Known
- Unknown
- Not applicable

124 _____ %

125 Bone marrow biopsy (examined for histiologic involvement)

- Known
- Unknown
- Not applicable

126 _____ %

127 Serum β2 microglobulin

- Known
- Unknown

128 _____

- µg/dL
- mg/L
- nmol/L

129 Relative serum viscosity

- Known
- Unknown

130 _____

131 Serum monoclonal protein (M-spike): (only from electrophoresis)

- Known
- Unknown

132 _____

- mg/dL
- g/dL
- g/L

133 Urinary monoclonal protein (M-spike)

Known Unknown

134 _____ mg / 24 hours

135 Cold agglutinins

Positive (for agglutination in titers at or below 1:16 or IgM antibodies that bind at < 37°C)

Negative

Unknown

136 Cryoglobulin

Present Absent Unknown

137 IgG

Known Unknown

138 _____ mg/dL g/dL g/L

139 Upper limit of normal for IgG: _____ mg/dL g/dL g/L

140 IgA

Known Unknown

141 _____ mg/dL g/dL g/L

142 Upper limit of normal for IgA: _____ mg/dL g/dL g/L

143 IgM

Known Unknown

144 _____ mg/dL g/dL g/L

145 Upper limit of normal for IgM: _____ mg/dL g/dL g/L

146 Were cytogenetics tested (conventional or FISH)?

yes no Unknown

147 Results of tests

Abnormalities identified

No evaluable metaphases

No abnormalities

148 del(6q) / 6q–

yes no

149 Other abnormality

yes no

150 Specify other abnormality: _____

Disease Status at Last Evaluation Prior to the Preparative Regimen (Conditioning)

Questions: 151 - 152

151 What was the disease status at the last evaluation prior to the preparative regimen?

- Complete remission (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 MAC/LPL. 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 HCT.
- Partial remission (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.
- Minor remission / 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 or MAC/LPL.
- 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, leukepenia, 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 MAC/LPL.
- Not assessed

152 Date assessed: __ __ __ __ - __ __- __ __

First Name: _____

Last Name: _____

E-mail address: _____

Date: __ __ __ __ - __ __- __ __