# 2119: Waldenström's Macroglobulinemia Post-HSCT Data

## Key Fields

<table>
<thead>
<tr>
<th>Sequence Number:</th>
<th>CIBMTR Recipient ID:</th>
<th>Initials:</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Date Received:

2020-01-01

CIBMTR Center Number

CIBMTR Recipient ID:

Today's Date:

Date of HSCT for which this form is being completed:

Date of HSCT for which this form is being completed:

Autologous HSCT type (check all that apply):

- Autologous
- Allogeneic, unrelated
- Allogeneic, related
- Syngeneic (identical twin)
CIBMTR Center Number: ____________ CIBMTR Recipient ID: ____________________________

☐ Syngeneic (identical twin)
ELSE GOTO Marrow

Product type (check all that apply):
☐ Marrow
ELSE GOTO PBSC

☐ PBSC
ELSE GOTO Cord blood

☐ Cord blood
ELSE GOTO Other product

☐ Other product
IF Other product:= checked
THEN GOTO Specify:
ELSE GOTO Visit:

Specify: _____________________________
ELSE GOTO Visit:

Visit:
☐ 100 day
☐ 6 months
☐ 1 year
☐ 2 years
☐ > 2 years,
IF Visit::= > 2 years,
THEN GOTO Specify:
ELSE GOTO (1) Best response

Specify: ___________ ___________ ___________ ___________
ELSE GOTO (1) Best response

### Disease Assessment at the Time of Best Response to HSCT

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. 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.”
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.)

- **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.

- **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.

- **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 without progression of adenopathy / organomegaly, cytopenias, or clinically significant symptoms due to disease and/or signs of WM.

- **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.

If (1) Best response := not assessed
THEN GOTO (3) Absolute lymphocyte count:
ELSE GOTO (2) Date the best response first began:

Date the best response first began: ___ ___ ___ ___ ___ ___ ___

YYYY MM DD

Date of the best response was previously reported:

☐ date of the best response was previously reported := checked

THEN GOTO (13) Has the disease relapsed / progressed since the date of the last report?
ELSE GOTO (3) Absolute lymphocyte count:

Laboratory Studies at the Time of Best Response to HSCT

3 Absolute lymphocyte count:

- known
- not known

IF (3) Absolute lymphocyte count := not known
THEN GOTO (5) Lymphoplasmacytic infiltrate in bone marrow:
ELSE GOTO (4) Absolute lymphocyte count value

ABSOLUTE GOTO absolute lymphocyte count unit of measure

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

ELSE GOTO (5) Lymphoplasmacytic infiltrate in bone marrow:

5 Lymphoplasmacytic infiltrate in bone marrow:

- known
- not known

IF (5) Lymphoplasmacytic infiltrate in bone marrow := not known
<table>
<thead>
<tr>
<th>Line</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Serum IgM level: %</td>
</tr>
<tr>
<td>7</td>
<td>Serum IgM level: known/unknown</td>
</tr>
<tr>
<td>8</td>
<td>Serum monoclonal spike value mg/dL/g/L</td>
</tr>
<tr>
<td>9</td>
<td>Serum monoclonal spike: known/unknown (only from electrophoresis)</td>
</tr>
<tr>
<td>10</td>
<td>Urinary monoclonal light chains value mg/dL/g/L</td>
</tr>
<tr>
<td>11</td>
<td>Urinary monoclonal light chains: known/unknown (only from electrophoresis)</td>
</tr>
<tr>
<td>12</td>
<td>Has the disease relapsed/progressed since the date of the last report? g/24 hours</td>
</tr>
<tr>
<td>13</td>
<td>Has the disease relapsed/progressed since the date of the last report? yes/no/unknown</td>
</tr>
</tbody>
</table>

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THEN GOTO (14) Date of progression / relapse:
ELSE GOTO (15) Was any treatment given since the date of the last report?

14 Date of progression / relapse: ____________ MM ____________ DD

IF (14) Date of progression / relapse:= EXISTS
THEN GOTO (15) Was any treatment given since the date of the last report?
ELSE GOTO Date unknown

post-HSCT treatment for Waldenström's macroglobulinemia

questions: 15-49

15 Was any treatment given since the date of the last report?
O yes
O no
O unknown

IF (15) Was any treatment given since the date of the last report?= yes
THEN GOTO (16) Was therapy planned?
ELSE GOTO (50) Absolute lymphocyte count:

Line of Therapy

16 Was therapy planned?
O yes
O no
ELSE GOTO (17) Systemic Therapy:

17 Systemic Therapy:
O yes
O no

IF (17) Systemic Therapy:= no
THEN GOTO (41) Radiation Therapy:
ELSE GOTO (18) Date therapy started:

18 Date therapy started: ____________ MM ____________ DD
ELSE GOTO (19) Number of cycles

19 Number of cycles ____________

IF (19) Number of cycles:= EXITS
ELSE GOTO (20) aldesleukin (interleukin-2)
THEN GOTO (20) aldesleukin (interleukin-2)
ELSE GOTO Unknown/not applicable

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</table>

**Today's Date:**  
Month [ ] [ ]  Day [20] Year [ ] [ ] [ ]

**Infusion Date:**  
Month [ ] [ ]  Day [20] Year [ ] [ ] [ ]

**CIBMTR Center Number:**

<p>| | | | | | | | | |</p>
<table>
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<tbody>
<tr>
<td>20</td>
<td>aldesleukin (interleukin-2)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>O yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>O no</td>
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<tr>
<td></td>
<td>ELSE GOTO (21) Alemtuzumab (Campath)</td>
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<td></td>
</tr>
</tbody>
</table>

| 21 | Alemtuzumab (Campath) |   |   |   |   |   |   |   |
|    | O yes |   |   |   |   |   |   |   |
|    | O no  |   |   |   |   |   |   |   |
|    | ELSE GOTO (22) Chlorambucil (Leukeran) |   |   |   |   |   |   |   |

| 22 | Chlorambucil (Leukeran) |   |   |   |   |   |   |   |
|    | O yes |   |   |   |   |   |   |   |
|    | O no  |   |   |   |   |   |   |   |
|    | ELSE GOTO (23) Cladribine (2-CdA, Leustatin) |   |   |   |   |   |   |   |

| 23 | Cladribine (2-CdA, Leustatin) |   |   |   |   |   |   |   |
|    | O yes |   |   |   |   |   |   |   |
|    | O no  |   |   |   |   |   |   |   |
|    | ELSE GOTO (24) Corticosteroids |   |   |   |   |   |   |   |

| 24 | Corticosteroids |   |   |   |   |   |   |   |
|    | O yes |   |   |   |   |   |   |   |
|    | O no  |   |   |   |   |   |   |   |
|    | ELSE GOTO (25) Cyclophosphamide (Cytoxan) |   |   |   |   |   |   |   |

| 25 | Cyclophosphamide (Cytoxan) |   |   |   |   |   |   |   |
|    | O yes |   |   |   |   |   |   |   |
|    | O no  |   |   |   |   |   |   |   |
|    | ELSE GOTO (26) Doxorubicin (Adriamycin) |   |   |   |   |   |   |   |

| 26 | Doxorubicin (Adriamycin) |   |   |   |   |   |   |   |
|    | O yes |   |   |   |   |   |   |   |
|    | O no  |   |   |   |   |   |   |   |
|    | ELSE GOTO (27) Etoposide (VP-16, VePesid) |   |   |   |   |   |   |   |

| 27 | Etoposide (VP-16, VePesid) |   |   |   |   |   |   |   |
|    | O yes |   |   |   |   |   |   |   |
|    | O no  |   |   |   |   |   |   |   |
|    | ELSE GOTO (28) Fludarabine (Fludara) |   |   |   |   |   |   |   |

| 28 | Fludarabine (Fludara) |   |   |   |   |   |   |   |
|    | O yes |   |   |   |   |   |   |   |
|    | O no  |   |   |   |   |   |   |   |
|    | ELSE GOTO (29) Idarubicin (Idamycin) |   |   |   |   |   |   |   |

| 29 | Idarubicin (Idamycin) |   |   |   |   |   |   |   |

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</table>

O yes
O no

ELSE GOTO (30) Ifosfamide (Ifex)

30 Ifosfamide (Ifex)
O yes
O no

ELSE GOTO (31) interferon-α (Roferon-α)

31 interferon-α (Roferon-α)
O yes
O no

ELSE GOTO (32) Lenalidomide (Revlimid)

32 Lenalidomide (Revlimid)
O yes
O no

ELSE GOTO (33) Melphalan (L-PAM)

33 Melphalan (L-PAM)
O yes
O no

ELSE GOTO (34) Mitoxantrone (Novantrone)

34 Mitoxantrone (Novantrone)
O yes
O no

ELSE GOTO (35) Pentostatin (Nipent)

35 Pentostatin (Nipent)
O yes
O no

ELSE GOTO (36) Rituximab (anti-CD20, Rituxan)

36 Rituximab (anti-CD20, Rituxan)
O yes
O no

ELSE GOTO (37) Thalidomide (Thalomid)

37 Thalidomide (Thalomid)
O yes
O no

ELSE GOTO (38) Vincristine (VCR, Oncovin)

38 Vincristine (VCR, Oncovin)
O yes
O no
ELSE GOTO (39) Other systemic therapy

39 Other systemic therapy
  O yes
  O no
IF (39) Other systemic therapy := no
THEN GOTO (41) Radiation Therapy:
ELSE GOTO (40) Specify other therapy:

40 Specify other therapy: __________________________
ELSE GOTO (41)

41 Radiation Therapy:
  O yes
  O no
IF (41) Radiation Therapy := yes
THEN GOTO (42) Date therapy started:
ELSE GOTO (46) Best Response to Line of Therapy: (see definitions at question 1)

42 Date therapy started: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
ELSE GOTO (43) mac_post_tx_rad_site1_yn

Specify radiation site(s):

43 IF (43) mac_post_tx_rad_site1_yn := EXISTS
THEN GOTO (44) mac_post tx_rad site2_yn
ELSE GOTO (46) Best Response to Line of Therapy: (see definitions at question 1)

44 IF (44) mac_post_tx_rad_site2_yn := EXISTS
THEN GOTO (45) mac_post tx_rad site3_yn
ELSE GOTO (46) Best Response to Line of Therapy: (see definitions at question 1)

45 ELSE GOTO (46) Best Response to Line of Therapy: (see definitions at question 1)

46 Best Response to Line of Therapy: (see definitions at question 1)
  O 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.
  O 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.
  O minor response / - 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%
stable disease (MR / SD) 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.

- 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.

O not assessed

IF (46) Best Response to Line of Therapy: (see definitions at question 1) := not assessed
THEN GOTO (48) Did patient relapse/progress following this line of therapy?
ELSE GOTO (47) Date response evaluated:

47 Date response evaluated: __________ MM ______ DD ______ YYYY

ELSE GOTO (48) Did patient relapse/progress following this line of therapy?

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

O yes

O no

IF (48) Did patient relapse/progress following this line of therapy? := no
THEN GOTO (50) Absolute lymphocyte count:
ELSE GOTO (49) Date of relapse/progression:

49 Date of relapse/progression: __________ MM ______ DD ______ YYYY

ELSE GOTO (50) Absolute lymphocyte count:

Copy questions 16-49 if needed for Line of Therapy
52 Lymphoplasmacytic infiltrate in bone marrow:
   ○ known
   ○ not known
   IF (52) Lymphoplasmacytic infiltrate in bone marrow := not known
   THEN GOTO (54) Serum monoclonal spike: (only from electrophoresis)
   ELSE GOTO (53) lymphoplasmacytic infiltrate percentage

53 .  .  .  .  .  .  .  .  .  .  .  .  .  %

   ELSE GOTO (54) Serum monoclonal spike: (only from electrophoresis)

54 Serum monoclonal spike: (only from electrophoresis)
   ○ known
   ○ not known
   IF (54) Serum monoclonal spike: (only from electrophoresis) := not known
   THEN GOTO (56) Urinary monoclonal light chains:
   ELSE GOTO (55) serum monoclonal spike value

55 .  .  .  .  .  .  .  .  .  .  .  .  .  mg/dL

   ELSE GOTO serum monoclonal spike unit of measure

   ○ g/dL

   ○ g/L

   ELSE GOTO (56) Urinary monoclonal light chains:

56 Urinary monoclonal light chains:
   ○ known
   ○ not known
   IF (56) Urinary monoclonal light chains := not known
   THEN GOTO (58) LDH:
   ELSE GOTO (57) urinary monoclonal light chains value

57 .  .  .  .  .  .  .  .  .  .  .  .  .  g / 24 hours

   ELSE GOTO (58) LDH:

58 LDH:
   ○ known
   ○ not known
   IF (58) LDH := not known
   THEN GOTO (61) Bone marrow aspirate examined to assess response to HSCT:
   ELSE GOTO (59) LDH value

59  .  .  .  .  .  .  .  .  .  .  .  .  U/L

   ELSE GOTO LDH unit of measure

   ○ µkat/L

   ELSE GOTO (60) Upper limit of normal for LDH:

59  .  .  .  .  .  .  .  .  .  .  .  .  U/L

   ELSE GOTO LDH unit of measure

   ○ µkat/L

   ELSE GOTO (60) Upper limit of normal for LDH:

60 Upper limit of normal for LDH:  .  .  .  .  .  .  .  .  .  .  .  .  µkat/L

   ELSE GOTO (61) Bone marrow aspirate examined to assess response to HSCT:
### CIBMTR Form 2119

**Sequence Number:**

**CIBMTR Recipient ID:**

**Initials:**

**Today’s Date:**

**Infusion Date:**

**CIBMTR Center Number:**

---

### Bone marrow aspirate examined to assess response to HSCT:

<table>
<thead>
<tr>
<th>Known</th>
<th>Not known</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

**IF** (61) Bone marrow aspirate examined to assess response to HSCT::= not known

**THEN GOTO** (63) Bone marrow biopsy examined to assess response to HSCT:

**ELSE GOTO** (62) Bone marrow aspirate percentage

<table>
<thead>
<tr>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

**ELSE GOTO** (63) Bone marrow biopsy examined to assess response to HSCT:

---

### Bone marrow biopsy examined to assess response to HSCT:

<table>
<thead>
<tr>
<th>Known</th>
<th>Not known</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

**IF** (63) Bone marrow biopsy examined to assess response to HSCT::= not known

**THEN GOTO** (65) Bone marrow, sample source unknown, examined to assess response to HSCT:

**ELSE GOTO** (64) Bone marrow biopsy percentage

<table>
<thead>
<tr>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

**ELSE GOTO** (65) Bone marrow, sample source unknown, examined to assess response to HSCT:

---

### Bone marrow, sample source unknown, examined to assess response to HSCT:

<table>
<thead>
<tr>
<th>Known</th>
<th>Not known</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

**IF** (65) Bone marrow, sample source unknown, examined to assess response to HSCT::= not known

**THEN GOTO** (67) Specify the type of histological involvement in marrow:

**ELSE GOTO** (66) Bone marrow source unknown percent

<table>
<thead>
<tr>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**ELSE GOTO** (67) Specify the type of histological involvement in marrow:

---

### Specify the type of histological involvement in marrow:

<table>
<thead>
<tr>
<th>Lymphoplasmacytoid</th>
<th>Lymphoplasmacytic</th>
<th>Polymorphous</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

**ELSE GOTO** (68) IgM:

### IgM:

<table>
<thead>
<tr>
<th>Known</th>
<th>Not known</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

**IF** (68) IgM::= not known

**THEN GOTO** (72) Was there any clinical or radiological evidence of organ involvement at the time of evaluation for this reporting period?

**ELSE GOTO** (69) IgM value

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69 ELSE GOTO IgM unit of measure
   O mg/dL
   O g/dL
   O g/L
   ELSE GOTO (70) Upper limit of normal for IgM:

70 Upper limit of normal for IgM: ____________
   ELSE GOTO (71) Lower limit of normal for IgM:

71 Lower limit of normal for IgM: ____________
   ELSE GOTO (72) Was there any clinical or radiological evidence of organ involvement at the time of evaluation for this reporting period?

72 Was there any clinical or radiological evidence of organ involvement at the time of evaluation for this reporting period?
   O yes
   O no
   IF (72) Was there any clinical or radiological evidence of organ involvement at the time of evaluation for this reporting period?:= no
   THEN GOTO (77) What is the current disease status?
   ELSE GOTO (73) Lymph nodes

73 Lymph nodes
   O yes
   O no
   ELSE GOTO (74) Spleen

74 Spleen
   O yes
   O no
   ELSE GOTO (75) Other site:

75 Other site:
   O yes
   O no
   IF (75) Other site::= no
   THEN GOTO (77) What is the current disease status?
   ELSE GOTO (76) Specify site:

76 Specify site:
   ELSE GOTO (77) What is the current disease status?

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

77 What is the current disease status?

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Today’s Date: [ ] [ ] [ ] Infusion Date: [ ] [ ] [ ] CIBMTR Center Number: [ ] [ ] [ ]

Month Day Year Month Day Year

Date the current disease status was established in this reporting period:

O complete remission
O not in complete remission

ELSE GOTO (78) Date the current disease status was established in this reporting period:

78 Date the current disease status was established in this reporting period: [YYYY MM DD]

ELSE GOTO First name

First Name: ____________________________________________

ELSE GOTO Last name

Last Name: ____________________________________________

ELSE GOTO Phone number:

Phone number: _________________________________________

ELSE GOTO Fax number:

Fax number: ___________________________________________

ELSE GOTO E-mail address:

E-mail address: _________________________________________

ELSE GOTO End of Form