Form 2116 R3.0: Plasma Cell Disorders (PCD) Post-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: _____

Visit

100 day 6 months 1 year 2 years > 2 years,

Specify:

_____

Disease Specificity

Questions: 1 - 2

1 Was the recipient transplanted for or do they have a history of amyloidosis?

yes no

2 Did the recipient have features of multiple myeloma?

yes no

Disease Assessment at the Time of Best Response to HCT

Questions: 3 - 34

3 Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report?

(Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease.)

- Stringent complete remission (sCR) —CR as defined, plus: normal free light chain ratio, and absence of clonal cells in the bone marrow by immunohistochemistry or immunofluorescence (confirmation with repeat bone marrow biopsy not needed). (Presence and/or absence of clonal cells is based upon the K/λ ratio. An abnormal K/λ ratio by immunohistochemistry and/or immunofluorescence requires a minimum of 100 plasma cells for analysis. An abnormal ratio reflecting the presence of an abnormal clone is K/λ of > 4:1 or < 1:2.) sCR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy sCR requirements.
- Complete remission (CR) — negative immunofixation on serum and urine samples, and disappearance of any soft tissue plasmacytomas, and ≤ 5% plasma cells in the bone marrow (confirmation with repeat bone marrow biopsy not needed). CR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy CR requirements.
- Near complete remission (nCR) — serum & urine M-protein detectable by immunoelectrophoresis (IFE), but not on electrophoresis (negative SPEP & UPEP); ≤ 5% plasma cells in bone marrow. nCR requires two consecutive assessments made at any time before the initiation of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy nCR requirements.
- Very good partial remission (VGPR) — serum and urine M-protein detectable by immunofixation but not on electrophoresis, or ≥ 90% reduction in serum M-protein and urine M-protein level < 100 mg/24 hours. VGPR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy VGPR requirements.
- Partial remission (PR) — ≥ 50% reduction in serum M-protein, and reduction in 24-hour urinary M-protein by ≥ 90% or to < 200 mg/24 hours. If the serum and urine M-protein are unmeasurable (i.e., do not meet any of the following criteria: • serum M-protein ≥ 1 g/dL. Urine M-protein ≥ 200 mg/24 hours • serum free light chain assay shows involved level ≥ 10 mg/dL, provided serum free light chain ratio is abnormal), a ≥ 50% decrease in the difference between involved and uninvolved free light chain levels is required in place of the M-protein criteria. If serum and urine M-protein are unmeasurable, and serum free light assay is also unmeasurable, a ≥ 50% reduction in plasma cells is required in place of M-protein, provided the baseline bone marrow plasma cell percentage was ≥ 30%. In addition to the above listed criteria, a ≥ 50% reduction in the size of soft tissue plasmacytomas is also required, if present at baseline. PR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy PR requirements.
- Stable disease (SD) — not meeting the criteria for CR, VGPR, PR or PD. SD requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy SD requirements.
- Progressive disease (PD) — requires any one or more of the following: Increase of ≥ 25% from the lowest value achieved in: serum M-component with an absolute increase ≥ 0.5 g/dL (for progressive disease, serum M-component increases of ≥ 1 g/dL are sufficient to define relapse if the starting M-component is ≥ 5 g/dL); and/or urine M-component with an absolute increase ≥ 200 mg.24 hours; and/or for recipients without measurable serum and urine M-protein levels: the difference between involved and uninvolved free light chain levels with an absolute increase > 10 mg/dL; and/or bone marrow plasma cell percentage with absolute percentage ≥ 10% (relapse from CR has a 5% cutoff vs. 10% for other categories of relapse); and/or definite development of new bone lesions or soft tissue plasmacytomas, or definite increase in the size of any existing bone lesions or soft tissue plasmacytomas. Development of hypercalcemia (corrected serum calcium > 11.5 mg/dL or 2.65 mmol) that can be attributed solely to the plasma cell proliferative disorder PD requires two consecutive assessments made at any time before classification as disease progression, and/or the institution of any new therapy.
- Relapse from CR (Rel) (untreated) — requires one or more of the following: reappearance of serum or urine M-protein by immunofixation or electrophoresis, development of ≥ 5% plasma cells in the bone marrow (relapse from CR has a 5% cutoff vs. 10% for other categories of relapse) appearance of any other sign of progression (e.g., new plasmacytoma, lytic bone lesion, hypercalcemia) Rel requires two consecutive assessments made at any time before classification as relapse, and/or the institution of any new therapy.

4 Was the date of best response previously reported?

- yes
- no

5 Date assessed: __ __ __ __ - __ __- __ __

Laboratory studies at the time of best response to HCT

6 Plasma cells in bone marrow aspirate

- Known
- Unknown

7 _____ %

8 Plasma cells in bone marrow biopsy

- Known
- Unknown

9 _____ %

10 Serum monoclonal protein (M-spike) (only from electrophoresis)

- Known
- Unknown
- Not applicable

11 _____

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

12 Serum immunofixation

- Known
- Unknown
- Not applicable

13 Specify monoclonal immunoglobulin result

Present Absent

Specify bands currently present:

14 Original monoclonal bands

yes no

15 New monoclonal (or oligoclonal) bands

yes no

16 Total urinary protein excretion

Known Unknown

17 _____ g/24 hours

18 Urinary monoclonal protein (M-spike)

Known Unknown Not applicable

19 _____ mg/24 hours

20 Urinary immunofixation

Known Unknown Not applicable

21 Specify monoclonal immunoglobulin result

Present Absent

Specify bands currently present:

22 Original monoclonal bands

yes no

23 New monoclonal (or oligoclonal) bands

yes no

24 Serum free light chains - κ (kappa)

Known Unknown Not applicable

25 _____ mg/dL mg/L

26 Upper limit of normal for κ free light chain: _____ mg/dL mg/L

27 Serum free light chains — λ (lambda)

Known Unknown Not applicable

28 _____ mg/dL mg/L

29 Upper limit of normal for λ free light chain: _____ mg/dL mg/L

30 Was the disease status assessed by cytogenetic testing (conventional or FISH)?

yes no

31 Was the disease status assessed via FISH?

yes no

32 Date assessed: __ __ __ __ - __ __- __ __

33 Was the disease status assessed via conventional cytogenetics?

yes no

34 Date assessed: __ __ __ __ - __ __- __ __

Hematologic and Organ Parameters at the Time of Best Response (for Amyloid Patients Only)

Questions: 35 - 60

Complete questions 35-60 for Amyloid patients only. If diagnosis was other than amyloidosis or there is no history of it, continue with question 61.

Specify the recipient's best response to the HCT for each of the following hematologic and organ systems:

Hematologic (Immunochemical)

35 Specify the recipient's best hematologic response to the HCT

- Complete response (CR) — requires all of the following: • serum and urine negative for monoclonal proteins by immunofixation • normal free light chain ratio • plasma cells in marrow < 5%
- Partial response (PR) — requires any of the following: • ≥ 50% reduction in current serum monoclonal protein levels > 0.5 g/dL • ≥ 50% reduction in current urine light chain levels > 100 mg/day with a visible peak • ≥ 50% reduction in current free light chain levels > 10 mg/dL
- No response (NR) / stable disease (SD) — does not meet criteria for CR, PR nor progressive disease
- Progressive disease — requires any of the following: • if progressing from CR, any detectable monoclonal protein or abnormal free light chain ratio (light chain must double) • if progressing from PR or SD, ≥ 50% increase in serum M-protein to > 0.5 g/dL, or ≥ 50% increase in urine M-protein to > 200 mg/day with visible peak present • free light chain increase of ≥ 50% to > 10 mg/dL (100 mg/L)
- Not assessed
- Not applicable

36 Date assessed

Known Unknown Previously reported

37 __ __ __ __ - __ __- __ __

Cardiac

38 Specify the recipient's best cardiac response to the HCT

- Cardiac response — requires any of the following: • ≥ 2 mm decrease in mean interventricular septal wall thickness by echocardiogram • ≥ 20% increase in left ventricular ejection fraction • ≥ 2 grade decrease in New York Heart Association functional class without an increase in diuretic use and no increase in wall thickness • reduction (≥30% and ≥300 ng/L) of NT-proBNP in patients in whom the eGFR is ≥45 mL/minute/1.73 m^2
- No response / stable disease — does not meet criteria for cardiac response nor progressive disease
- Progressive disease — requires any of the following: • ≥ 2 mm increase from baseline in interventricular septal wall thickness by echocardiogram • ≥ 10% decrease in left ventricular ejection fraction • ≥ 1 grade increase in New York Heart Association functional class
- Not assessed
- Not applicable

39 Date assessed

Known Unknown Previously reported

40 __ __ __ __ - __ __- __ __

41 Was there clinical improvement in GI involvement in response to the HCT?
(decrease in diarrhea)

yes no Unknown

42 Date assessed

Known Unknown Previously reported

43 __ __ __ __ - __ __- __ __

Hepatic

44 Specify the recipient's best hepatic response to the HCT

- Hepatic response — requires all of the following: • ≥ 2 cm decrease in liver span if hepatomegaly present (liver span > 15 cm) • ≥ 50% decrease and/or normalization of serum alkaline phosphatase level
- No response / stable disease — does not meet criteria for hepatic response nor progressive disease
- Progressive disease — requires the following: • ≥ 50% increase in serum alkaline phosphatase level
- Not assessed
- Not applicable

45 Date assessed

Known Unknown Previously reported

46 __ __ __ __ - __ __- __ __

Autonomic Nervous

47 Specify the best response of autonomic neuropathy to the HCT

- Autonomic neuropathy response — resolution of symptomatic orthostatic hypotension
- No response / stable disease — does not meet criteria for autonomic neuropathy response nor progressive disease
- Progressive disease — worsening of symptomatic orthostatic hypotension not attributable to medications or blood volume depletion
- Not assessed
- Not applicable

48 Date assessed

Known Unknown Previously reported

49 __ __ __ __ - __ __- __ __

50 Specify the best response of peripheral neuropathy to the HCT

- Peripheral neuropathy response — requires any of the following: • resolution of abnormal physical findings • resolution or improvement of abnormal EMG and/or NCV findings
- No response / stable disease — does not meet criteria for peripheral neuropathy response nor progressive disease
- Progressive disease — requires any of the following: • worsening of physical findings • worsening of EMG and/or NCV findings
- Not assessed
- Not applicable

51 Date assessed

Known Unknown Previously reported

52 __ __ __ __ - __ __- __ __

Renal

53 Specify the recipient's best renal response to the HCT

- Renal response — ≥ 50% decrease of at least 0.5 g/day in 24 hour urine protein of > 0.5 g/day pre-treatment – creatinine and creatinine clearance must not have worsened by ≥ 25% over baseline
- No response / stable disease — does not meet criteria for renal response nor progressive disease
- Progressive disease — requires any of the following: • ≥ 50% increase of at least 1 g/day for urine protein to > 1 g/day • 25% worsening of serum creatinine or creatinine clearance
- Not assessed
- Not applicable

54 Date assessed

Known Unknown Previously reported

55 __ __ __ __ - __ __- __ __

Other system

56 Did any other system respond to the HCT?

yes no

57 Specify other system: _____

58 Specify best response to HCT for this system

- Response
- No response / stable disease
- Progressive disease
- Not applicable

59 Date assessed

Known Unknown Previously reported

60 __ __ __ __ - __ __- __ __

Post-HCT Therapy

Questions: 61 - 101

61 Was therapy given since the date of the last report for reasons other than relapse or progressive disease?
(Include any maintenance and consolidation therapy.)

yes no Unknown

Line of Therapy (1)

Questions: 62 - 99

Line of Therapy

62 Systemic therapy

yes no

63 Date therapy started

Known Unknown

64 Date started: __ __ __ __ - __ __- __ __

65 Date therapy stopped

Known Unknown

66 Date stopped: __ __ __ __ - __ __- __ __

67 Number of cycles

Known Unknown

68 Number of cycles: _____

69 Bortezomib (Velcade)

yes no

70 Carfilzomib

yes no

71 Carmustine (BCNU, Gliadel)

yes no

72 Cisplatin (Platinol, CDDP)

yes no

73 Clarithromycin (Biaxin)

yes no

74 Corticosteroids

yes no

75 Cyclophosphamide (Cytoxan)

yes no

76 Cytarabine (Ara-C)

yes no

77 Doxorubicin (Adriamycin)

yes no

78 Doxorubicin liposomal (Doxil)

yes no

79 Etoposide (VP-16, VePesid)

yes no

80 Idarubicin (Idamycin)

yes no

81 Interferon-α (Intron, Roferon) (includes PEG)

yes no

82 Lenalidomide (Revlimid)

yes no

83 Melphalan (L-PAM, Alkeran)

yes no

84 MLN 9708

yes no

85 Mitoxantrone (Novantrone)

yes no

86 Rituximab (Rituxan, MabThera)

yes no

87 Thalidomide (Thalomid)

yes no

88 Vincristine (VCR, Oncovin)

yes no

89 Other systemic therapy

yes no

90 Specify other systemic therapy: _____

91 Radiation therapy

yes no

92 Date therapy started

Known Unknown

93 Date started:

__ __ __ __ - __ __- __ __

94 Date therapy stopped

Known Unknown

95 Date stopped: __ __ __ __ - __ __- __ __

96 Best response to line of therapy

- Stringent complete remission (sCR) —CR as defined, plus: normal free light chain ratio, and absence of clonal cells in the bone marrow by immunohistochemistry or immunofluorescence (confirmation with repeat bone marrow biopsy not needed). (Presence and/or absence of clonal cells is based upon the K/λ ratio. An abnormal K/λ ratio by immunohistochemistry and/or immunofluorescence requires a minimum of 100 plasma cells for analysis. An abnormal ratio reflecting the presence of an abnormal clone is K/λ of > 4:1 or < 1:2.) sCR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy sCR requirements.
- Complete remission (CR) — negative immunofixation on serum and urine samples, and disappearance of any soft tissue plasmacytomas, and ≤ 5% plasma cells in the bone marrow (confirmation with repeat bone marrow biopsy not needed). CR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy CR requirements.
- Near complete remission (nCR) — serum & urine M-protein detectable by immunoelectrophoresis (IFE), but not on electrophoresis (negative SPEP & UPEP); ≤ 5% plasma cells in bone marrow. nCR requires two consecutive assessments made at any time before the initiation of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy nCR requirements.
- Very good partial remission (VGPR) — serum and urine M-protein detectable by immunofixation but not on electrophoresis, or ≥ 90% reduction in serum M-protein and urine M-protein level < 100 mg/24 hours. VGPR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy VGPR requirements.
- Partial remission (PR) — ≥ 50% reduction in serum M-protein, and reduction in 24-hour urinary M-protein by ≥ 90% or to < 200 mg/24 hours. If the serum and urine M-protein are unmeasurable (i.e., do not meet any of the following criteria: • serum M-protein ≥ 1 g/dL. Urine M-protein ≥ 200 mg/24 hours • serum free light chain assay shows involved level ≥ 10 mg/dL, provided serum free light chain ratio is abnormal), a ≥ 50% decrease in the difference between involved and uninvolved free light chain levels is required in place of the M-protein criteria. If serum and urine M-protein are unmeasurable, and serum free light assay is also unmeasurable, a ≥ 50% reduction in plasma cells is required in place of M-protein, provided the baseline bone marrow plasma cell percentage was ≥ 30%. In addition to the above listed criteria, a ≥ 50% reduction in the size of soft tissue plasmacytomas is also required, if present at baseline. PR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy PR requirements.
- Stable disease (SD) — not meeting the criteria for CR, VGPR, PR or PD. SD requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy SD requirements.
- Progressive disease (PD) — requires any one or more of the following: Increase of ≥ 25% from the lowest value achieved in: serum M-component with an absolute increase ≥ 0.5 g/dL (for progressive disease, serum M-component increases of ≥ 1 g/dL are sufficient to define relapse if the starting M-component is ≥ 5 g/dL); and/or urine M-component with an absolute increase ≥ 200 mg.24 hours; and/or for recipients without measurable serum and urine M-protein levels: the difference between involved and uninvolved free light chain levels with an absolute increase > 10 mg/dL; and/or bone marrow plasma cell percentage with absolute percentage ≥ 10% (relapse from CR has a 5% cutoff vs. 10% for other categories of relapse); and/or definite development of new bone lesions or soft tissue plasmacytomas, or definite increase in the size of any existing bone lesions or soft tissue plasmacytomas. Development of hypercalcemia (corrected serum calcium > 11.5 mg/dL or 2.65 mmol) that can be attributed solely to the plasma cell proliferative disorder PD requires two consecutive assessments made at any time before classification as disease progression, and/or the institution of any new therapy.
- Unknown
- Not applicable (Amyloidosis with no evidence of myeloma)

97 Date response established: __ __ __ __ - __ __- __ __

98 Did disease relapse/progress following this line of therapy?

yes no

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

100 Has the disease relapsed or progressed since the date of last report?

yes no

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

Disease Status at the Time of Evaluation for This Reporting Period

Questions: 102 - 136

102 Plasma cells in bone marrow aspirate

Known Unknown

103 _____ %

104 Plasma cells in bone marrow biopsy

Known Unknown

105 _____ %

106 Serum monoclonal protein (M-spike) (only from electrophoresis)

Known Unknown Not applicable

107 _____ mg/dL g/dL g/L

108 Serum immunofixation

Known Unknown Not applicable

109 Specify monoclonal immunoglobulin result

Present Absent

Specify bands currently present:

110 Original monoclonal bands

yes no

111 New monoclonal (or oligoclonal) bands

yes no

112 Total urinary protein excretion

Known Unknown Not applicable

113 _____ g/24 hours

114 Urinary monoclonal protein (M-spike)

Known Unknown Not applicable

115 _____ mg/24 hours

116 Urinary immunofixation

Known Unknown Not applicable

117 Specify monoclonal immunoglobulin result

Present Absent

Specify bands currently present:

118 Original monoclonal bands

yes no

119 New monoclonal (or oligoclonal) bands

yes no

120 Serum free light chains - κ(kappa)

Known Unknown Not applicable

121 _____ mg/dL mg/L

122 Upper limit of normal for κ free light chain: _____ mg/dL mg/L

123 Serum free light chains — λ(lambda)

Known Unknown Not applicable

124 _____ mg/dL mg/L

125 Upper limit of normal for λ free light chain: _____ mg/dL mg/L

126 Was the disease status assessed by cytogenetic testing (conventional or FISH)?

yes no

127 Was the disease status assessed via FISH?

yes no

128 Date assessed: __ __ __ __ - __ __- __ __

129 Was disease detected?

yes no

130 Was the status considered a disease relapse or progression?

yes no

131 Was the disease status assessed via conventional cytogenetics?

yes no

132 Date assessed: __ __ __ __ - __ __- __ __

133 Was disease detected?

yes no

134 Was the status considered a disease relapse or progression?

yes no

135 What was the disease status?

- Stringent complete remission (sCR) —CR as defined, plus: normal free light chain ratio, and absence of clonal cells in the bone marrow by immunohistochemistry or immunofluorescence (confirmation with repeat bone marrow biopsy not needed). (Presence and/or absence of clonal cells is based upon the K/λ ratio. An abnormal K/λ ratio by immunohistochemistry and/or immunofluorescence requires a minimum of 100 plasma cells for analysis. An abnormal ratio reflecting the presence of an abnormal clone is K/λ of > 4:1 or < 1:2.) sCR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy sCR requirements.
- Complete remission (CR) — negative immunofixation on serum and urine samples, and disappearance of any soft tissue plasmacytomas, and ≤ 5% plasma cells in the bone marrow (confirmation with repeat bone marrow biopsy not needed). CR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy CR requirements.
- Near complete remission (nCR) — serum & urine M-protein detectable by immunoelectrophoresis (IFE), but not on electrophoresis (negative SPEP & UPEP); ≤ 5% plasma cells in bone marrow. nCR requires two consecutive assessments made at any time before the initiation of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy nCR requirements.
- Very good partial remission (VGPR) — serum and urine M-protein detectable by immunofixation but not on electrophoresis, or ≥ 90% reduction in serum M-protein and urine M-protein level < 100 mg/24 hours. VGPR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy VGPR requirements.
- Partial remission (PR) — ≥ 50% reduction in serum M-protein, and reduction in 24-hour urinary M-protein by ≥ 90% or to < 200 mg/24 hours. If the serum and urine M-protein are unmeasurable (i.e., do not meet any of the following criteria: • serum M-protein ≥ 1 g/dL. Urine M-protein ≥ 200 mg/24 hours • serum free light chain assay shows involved level ≥ 10 mg/dL, provided serum free light chain ratio is abnormal), a ≥ 50% decrease in the difference between involved and uninvolved free light chain levels is required in place of the M-protein criteria. If serum and urine M-protein are unmeasurable, and serum free light assay is also unmeasurable, a ≥ 50% reduction in plasma cells is required in place of M-protein, provided the baseline bone marrow plasma cell percentage was ≥ 30%. In addition to the above listed criteria, a ≥ 50% reduction in the size of soft tissue plasmacytomas is also required, if present at baseline. PR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy PR requirements.
- Stable disease (SD) — not meeting the criteria for CR, VGPR, PR or PD. SD requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy SD requirements.
- Progressive disease (PD) — requires any one or more of the following: Increase of ≥ 25% from the lowest value achieved in: serum M-component with an absolute increase ≥ 0.5 g/dL (for progressive disease, serum M-component increases of ≥ 1 g/dL are sufficient to define relapse if the starting M-component is ≥ 5 g/dL); and/or urine M-component with an absolute increase ≥ 200 mg.24 hours; and/or for recipients without measurable serum and urine M-protein levels: the difference between involved and uninvolved free light chain levels with an absolute increase > 10 mg/dL; and/or bone marrow plasma cell percentage with absolute percentage ≥ 10% (relapse from CR has a 5% cutoff vs. 10% for other categories of relapse); and/or definite development of new bone lesions or soft tissue plasmacytomas, or definite increase in the size of any existing bone lesions or soft tissue plasmacytomas. Development of hypercalcemia (corrected serum calcium > 11.5 mg/dL or 2.65 mmol) that can be attributed solely to the plasma cell proliferative disorder PD requires two consecutive assessments made at any time before classification as disease progression, and/or the institution of any new therapy.
- Relapse from CR (Rel) (untreated) — requires one or more of the following: reappearance of serum or urine M-protein by immunofixation or electrophoresis, development of ≥ 5% plasma cells in the bone marrow (relapse from CR has a 5% cutoff vs. 10% for other categories of relapse) appearance of any other sign of progression (e.g., new plasmacytoma, lytic bone lesion, hypercalcemia) Rel requires two consecutive assessments made at any time before classification as relapse, and/or the institution of any new therapy.
- Unknown
- Not applicable (Amyloidosis with no evidence of myeloma)

136 Date assessed: __ __ __ __ - __ __- __ __

Current Status of Amyloidosis for This Reporting Period (for Amyloid Patients Only) Questions: 137 - 162

Complete questions 137-162 for Amyloid patients only. If diagnosis was other than amyloidosis or there is no history of it, continue with signature line.

Specify the recipient's current disease status for each of the following hematologic and organ systems:

Hematologic (Immunochemical)

137 Specify the recipient's current hematologic status

- Complete response (CR) — requires all of the following: • serum and urine negative for monoclonal proteins by immunofixation • normal free light chain ratio • plasma cells in marrow < 5%
- Partial response (PR) — requires any of the following: • ≥ 50% reduction in current serum monoclonal protein levels > 0.5 g/dL • ≥ 50% reduction in current urine light chain levels > 100 mg/day with a visible peak • ≥ 50% reduction in current free light chain levels > 10 mg/dL
- No response (NR) / stable disease (SD) — does not meet criteria for CR, PR nor progressive disease
- Progressive disease — requires any of the following: • if progressing from CR, any detectable monoclonal protein or abnormal free light chain ratio (light chain must double) • if progressing from PR or SD, ≥ 50% increase in serum M-protein to > 0.5 g/dL, or ≥ 50% increase in urine M-protein to > 200 mg/day with visible peak present • free light chain increase of ≥ 50% to > 10 mg/dL (100 mg/L)
- Not assessed
- Not applicable

138 Date assessed

Known Unknown

139 __ __ __ __ - __ __ - __ __

Cardiac

140 Specify the recipient's current cardiac status

Cardiac response — requires any of the following: • ≥ 2 mm decrease in mean interventricular septal wall thickness by echocardiogram • ≥ 20% increase in left ventricular ejection fraction • ≥ 2 grade decrease in New York Heart Association functional class without an increase in diuretic use and no increase in wall thickness • reduction (≥30% and ≥300 ng/L) of NT-proBNP in patients in whom the eGFR is ≥45 mL/minute/1.73 m^2

No response / stable disease — does not meet criteria for cardiac response nor progressive disease

Progressive disease — requires any of the following: • ≥ 2 mm increase from baseline in interventricular septal wall thickness by echocardiogram • ≥ 10% decrease in left ventricular ejection fraction • ≥ 1 grade increase in New York Heart Association functional class

Not assessed

Not applicable

141 Date assessed

Known Unknown

142 __ __ __ __ - __ __ - __ __

Gastrointestinal

143 Was there clinical improvement in GI involvement since the date of the last report?

yes no Unknown

144 Date assessed

Known Unknown

145 __ __ __ __ - __ __ - __ __

Hepatic

146 Specify the recipient's current hepatic status

Hepatic response — requires all of the following: • ≥ 2 cm decrease in liver span if hepatomegaly present (liver span > 15 cm) • ≥ 50% decrease and/or normalization of serum alkaline phosphatase level

No response / stable disease — does not meet criteria for hepatic response nor progressive disease

Progressive disease — requires any of the following: • ≥ 50% increase in serum alkaline phosphatase level

Not assessed

Not applicable

147 Date assessed

Known Unknown

148 __ __ __ __ - __ __ - __ __

Autonomic Nervous

149 Specify the current status of autonomic neuropathy

- Autonomic neuropathy response — resolution of symptomatic orthostatic hypotension
- No response / stable disease — does not meet criteria for autonomic neuropathy response nor progressive disease
- Progressive disease — worsening of symptomatic orthostatic hypotension not attributable to medications or blood volume depletion
- Not assessed
- Not applicable

150 Date assessed

- Known
- Unknown

151 __ __ __ __ - __ __ - __ __

152 Specify the current status of peripheral neuropathy

- Peripheral neuropathy response — requires any of the following: • resolution of abnormal physical findings • resolution or improvement of abnormal EMG and/or NCV findings
- No response / stable disease — does not meet criteria for peripheral neuropathy response nor progressive disease
- Progressive disease — requires any of the following: • worsening of physical findings • worsening of EMG and/or NCV findings
- Not assessed
- Not applicable

153 Date assessed

- Known
- Unknown

154 __ __ __ __ - __ __ - __ __

Renal

155 Specify the recipient's current renal status

- Renal response — ≥ 50% decrease of at least 0.5 g/day in 24 hour urine protein of > 0.5 g/day pre-treatment – creatinine and creatinine clearance must not have worsened by ≥ 25% over baseline
- No response / stable disease — does not meet criteria for renal response nor progressive disease
- Progressive disease — requires any of the following: • ≥ 50% increase of at least 1 g/day for urine protein to > 1 g/day • 25% worsening of serum creatinine or creatinine clearance
- Not assessed
- Not applicable

156 Date assessed

- Known
- Unknown

157 __ __ __ __ - __ __ - __ __

Other system

158 Was any other system assessed for current status?

- yes
- no

159 Specify other system: _____

160 Specify the current status of this system

- Response
- No response / stable disease
- Progressive disease
- Not applicable

161 Date assessed

Known Unknown

162 __ __ __ __ - __ __- __ __

First Name: _____

Last Name: _____

E-mail address: _____

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