CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Plasma Cell Disorders (PCD) Post-Infusion Data

Registry Use Only
Sequence Number:

Date Received:

CIBMTR Center Number: ___ ___ ___ ___ ___

CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Event date: __ __ __ __ / __ __ / __ __
YYYY MM DD

Visit ☐ 100 day ☐ 6 months ☐ 1 year ☐ 2 years ☐ > 2 years, Specify: ___ ___

Disease Specificity

1. Specify the multiple myeloma / plasma cell disorder (PCD) classification
   - ☐ Multiple myeloma (178)
   - ☐ Multiple myeloma-light chain only (186)
   - ☐ Multiple myeloma-non-secretory (187)
   - ☐ Plasma cell leukemia (172)
   - ☐ Solitary plasmacytoma (no evidence of myeloma) (175)
   - ☐ Smoldering myeloma (180)
   - ☐ Amyloidosis (174)
   - ☐ Osteosclerotic myeloma / POEMS syndrome (176)
   - ☐ Monoclonal gammopathy of renal significance (MGRS) (1611)
   - ☐ Other plasma cell disorder (179)
2. Specify preceding / concurrent disorder (check all that apply)
   - ☐ Multiple myeloma
   - ☐ Multiple myeloma - light chain only
   - ☐ Multiple myeloma - non-secretory
   - ☐ Plasma cell leukemia
   - ☐ Solitary plasmacytoma (no evidence of myeloma)
   - ☐ Smoldering myeloma
   - ☐ Amyloidosis
   - ☐ Osteosclerotic myeloma / POEMS syndrome
   - ☐ Monoclonal gammopathy of unknown significance (MGUS)
   - ☐ Monoclonal gammopathy of renal significance (MGRS)
   - ☐ Other plasma cell disorder (PCD)

Disease Assessment at the Time of Best Response to HCT or Cellular Therapy

Best response is based on response to the HCT or cellular therapy, and does NOT include response to any therapy given for disease relapse or progression post-HCT or post-cellular therapy.

- **If the HCT or cellular therapy was planned as part of initial therapy for a recipient with no disease progression or relapse at any time prior to HCT or cellular therapy, determine the best response by comparing to the disease assessment at the time of initial diagnosis.**
- **If the HCT or cellular therapy was performed later in the disease course for a patient who has not received any chemotherapy within 6 months of HCT or cellular therapy or has untreated relapse or progression, determine best response to HCT or cellular therapy by comparing to the disease status immediately prior to the start of the preparative regimen.**
- **If the patient had a disease progression or relapse of disease at any time prior to HCT or cellular therapy, and was treated to reduce the myeloma burden prior to the start of the preparative regimen, determine best response to HCT or cellular therapy by comparing to the disease evaluation at the time of relapse or progression. In other words, the baseline is reset to the time of relapse or progression.**
- **This comparison is meant to capture the best disease status in response to HCT or cellular therapy 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 indicate that the date was previously reported (question 4).**

3. For all recipients with primary disease multiple myeloma / plasma cell disorder (PCD) classifications excluding Amyloidosis, compared to the disease status prior to the preparative regimen, what was the best hematologic response to HCT or cellular therapy since the date of the last report? (Include response to any therapy given for post-HCT or post-cellular therapy maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease.)

- ☐ Continued complete response (CCR)
- ☐ Stringent complete response (sCR).
- ☐ Complete response (CR)
- ☐ Very good partial response (VGPR)
- ☐ Partial response (PR)
- ☐ No response (NR) / stable disease (SD)
- ☐ Progressive disease (PD)

4. Was the date of best response previously reported?

- ☐ Yes ***- Go to question 142,*** **else go to question 6 if there is a diagnosis of concurrent or history of Amyloidosis.**
- ☐ No →

5. Date assessed:__ __ __ __ / __ __ / __ __
YYYY MM DD

- Go to question 9, **else go to question 6 if there is a diagnosis of concurrent or history of Amyloidosis.**

6. For recipients with primary disease or concurrent / history of Amyloidosis, compared to the disease status prior to the preparative regimen, what was the best hematologic response to HCT or cellular therapy since the date of the last report? (Include response to any therapy given for post-HCT or post-cellular therapy maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease.)

- ☐ Continued complete response (CCR)
- ☐ Complete response (CR)
- ☐ Very good partial response (VGPR)
- ☐ Partial response (PR)
- ☐ No response (NR) / stable disease (SD)
- ☐ Progressive disease (PD)

7. Was the date of best response previously reported?

- ☐ Yes ***- Go to question 54***
- ☐ No →

8. Date assessed:__ __ __ __ / __ __ / __ __
YYYY MM DD

Laboratory studies at the time of best response

9. Serum creatinine
   - ☐ Known →
     - 10. ___ ___ ___ • ___ ___ ☐ mg/dL ☐ mmol/L ☐ µmol/L
     - 11. Upper limit of normal for serum creatinine: ___ ___ ___ • ___ ___
   - ☐ Unknown

12. Serum monoclonal protein (M-spike) (only from electrophoresis)
   - ☐ Known →
     - 13. ___ ___ ___ ___ • ___ ☐ mg/dL ☐ g/dL ☐ g/L
   - ☐ Unknown
   - ☐ Not applicable

14. Serum immunofixation
   - ☐ Known →
     - **Specify bands present:**
     - 15. Original monoclonal bands: ☐ Yes ☐ No
     - 16. New monoclonal (or oligoclonal) bands: ☐ Yes ☐ No
   - ☐ Unknown
   - ☐ Not applicable

17. Serum free light chains — κ (kappa)
   - ☐ Known →
     - 18. ___ ___ ___ • ___ ___ ☐ mg/dL ☐ mg/L
     - 19. Upper limit of normal for κ (kappa) free light chain: ___ ___ ___ • ___ ___
   - ☐ Unknown
   - ☐ Not applicable

20. Serum free light chains — λ (lambda)
   - ☐ Known →
     - 21. ___ ___ ___ • ___ ___ ☐ mg/dL ☐ mg/L
     - 22. Upper limit of normal for λ (lambda) free light chain: ___ ___ ___ • ___ ___
   - ☐ Unknown
   - ☐ Not applicable

23. Urinary monoclonal protein (M-spike) / 24 hours
   - ☐ Known →
     - 24. ___ ___ ___ ___ ___ • ___ ☐ mg/24 hours ☐ g/24 hours
   - ☐ Unknown
   - ☐ Not applicable

25. Urinary immunofixation
   - ☐ Known →
     - **Specify bands present:**
     - 26. Original monoclonal bands ☐ Yes ☐ No
     - 27. New monoclonal (or oligoclonal) bands ☐ Yes ☐ No
   - ☐ Unknown
   - ☐ Not applicable

28. Total urine protein in 24 hours
- ☐ Known → 29. ___ ___ ___ ___ ___ • ___ ☐ mg/24 hours ☐ g/24 hours
- ☐ Unknown
- ☐ Not applicable

30. Urine albumin / creatinine ratio
- ☐ Known → 31. ___ ___ ___ • ___ ___ ☐ mg/g ☐ mg/mmol
- ☐ Unknown

32. Urine protein / creatinine ratio
- ☐ Known → 33. ___ ___ ___ • ___ ___ ☐ mg/g ☐ mg/mmol
- ☐ Unknown

34. Was minimal residual disease (MRD) assessed post-HCT / CT or post-infusion evaluation? (report only bone marrow or blood results)
- ☐ Yes →
  35. Next generation sequencing (NGS)
  - ☐ Positive →
    36. Sample source ☐ Blood ☐ Bone marrow
    37. Indicate the sensitivity of the NGS testing
    - ☐ 10^{-4}
    - ☐ 10^{-5}
    - ☐ 10^{-6}
    - ☐ Unknown
    - ☐ Other → 38. Specify other sensitivity: _____
  - ☐ Negative
  - ☐ Not done

  39. Next generation flow (NGF)
  - ☐ Positive →
    40. Sample source ☐ Blood ☐ Bone marrow
    41. Indicate the sensitivity of the NGF testing
    - ☐ 10^{-4}
    - ☐ 10^{-5}
    - ☐ 10^{-6}
    - ☐ Unknown
    - ☐ Other → 42. Specify other sensitivity: _____
  - ☐ Negative →
  - ☐ Not done
- ☐ No
- ☐ Unknown

43. Plasma cells in bone marrow aspirate by flow cytometry

☐ Known →
☐ Unknown

44. ___ ___ ___ • ___ ___ %

45. Plasma cells in bone marrow aspirate by morphologic assessment

☐ Known →
☐ Unknown

46. ___ ___ ___ %

47. Plasma cells in bone marrow biopsy

☐ Known →
☐ Unknown

48. ___ ___ ___ %

49. Was a PET/CT scan performed?

☐ Yes →
☐ No

50. Was the PET/CT scan positive for myeloma involvement at any disease site?

☐ Yes →
☐ No

51. Areas of involvement (check all that apply)

☐ Bone marrow
☐ Extramedullary plasmacytomas
☐ Lytic bone lesions
☐ Sclerotic bone lesions

52. Date of PET/CT scan

☐ Known →
☐ Unknown

53. Date of PET/CT scan:

__ __ __ __ / __ __ / __ __
YYYY MM DD

Organ Parameters of Amyloidosis at the Time of Best Response

Complete questions 54 – 109 for Amyloid patients only. If diagnosis was other than Amyloidosis or there is no history of it, continue with question 110.

Cardiac Involvement

54. Specify the recipient's best cardiac response

- ☐ Cardiac response **– NT-proBNP response (>30% and >300 ng/l decrease in patients with baseline NT-proBNP ≥ 650 ng/l) or New York Heart Association (NYHA) class response (≥ 2 class decrease in subjects with baseline NYHA class 3 or 4)** ***- Go to question 55***
- ☐ No response / stable disease **– Does not meet criteria for cardiac response or cardiac progression** ***- Go to question 55***
- ☐ Cardiac progression **– NT-proBNP progression (>30% and >300 ng/l increase) or cTn progression (≥ 33% increase) or ejection fraction progression (≥ 10% decrease)** ***- Go to question 55***
- ☐ Not assessed ***- Go to question 88***
- ☐ Not applicable ***- Go to question 88***

55. Date assessed

- ☐ Known ***- Go to question 56***
- ☐ Unknown ***- Go to question 57***
- ☐ Previously reported ***- Go to question 88***

56. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

57. Was the left ventricular ejection fraction measured?

- ☐ Yes →
- ☐ No

58. ___ ___ %

59. Specify the method used to determine the left ventricular ejection fraction

☐ Echocardiogram ☐ Multiple gated acquisition (MUGA) scan ☐ Cardiac MRI ☐ Unknown

60. Was diastolic dysfunction present? ☐ Yes ☐ No ☐ Unknown

61. Specify the interventricular septal wall thickness measured by echocardiogram

- ☐ Known →
- ☐ Unknown

62. ___ ___ mm

63. Specify left ventricular (LV) strain percentage

- ☐ Known →
- ☐ Unknown

64. ___ ___ %

65. Were any serum cardiac biomarkers assessed?

- ☐ Yes →
- ☐ No
- ☐ Unknown

66. Date cardiac biomarkers were assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

Specify the cardiac biomarkers assessed:

67. Brain natriuretic peptide (BNP)

- ☐ Yes →
- ☐ No

68. ___ ___ ___ ___ ___ • ___ pg/mL

69. Upper limit of normal for BNP: ___ ___ ___ ___ ___ • ___

70. N-terminal prohormone brain natriuretic peptide (NT-proBNP)
- ☐ Yes →
  - 71. ___ ___ ___ ___ ___ • ___ pg/mL
  - 72. Upper limit of normal for NT-proBNP: ___ ___ ___ ___ ___ • ___ pg/mL
- ☐ No

73. Troponin I
- ☐ Yes →
  - 74. ___ ___ ___ ___ • ___ ___ ___ µg/L
  - 75. Upper limit of normal for troponin I: ___ ___ ___ ___ • ___ ___ ___
- ☐ No

76. Troponin T
- ☐ Yes →
  - 77. ___ ___ ___ ___ • ___ ___ ___ µg/L
  - 78. Upper limit of normal for troponin T: ___ ___ ___ ___ • ___ ___ ___ µg/L
- ☐ No

79. High sensitivity troponin T
- ☐ Yes →
  - 80. ___ ___ ___ ___ • ___ ___ ___ ng/L
  - 81. Upper limit of normal for high sensitivity troponin T: ___ ___ ___ ___ • ___ ___ ___
- ☐ No

82. Was a 6 minute walk test performed?
- ☐ Yes →
  - 83. Distance walked: __ __ __ ☐ meters ☐ feet
- ☐ No

84. Specify the recipient's New York Heart Association functional classification of heart failure (Symptoms may include dyspnea, chest pain, fatigue, and palpitations; activity level should be assessed with consideration for patient's age-group)
- ☐ Class I – Able to perform ordinary activities without symptoms; no limitation of physical activity
- ☐ Class II – Ordinary physical activity produces symptoms; slight limitation of physical activity
- ☐ Class III – Less-than-ordinary physical activity produces symptoms; moderate limitation of physical activity
- ☐ Class IV – Symptoms present even at rest; severe limitation of physical activity
- ☐ Unknown

85. Recipient blood pressure (at time of best response)
- ☐ Known →
  - 86. ___ ___ ___ / ___ ___ ___ mm/Hg
  - 87. Indicate body position during blood pressure measurement
    - ☐ Sitting ☐ Standing ☐ Supine ☐ Unknown
- ☐ Unknown

Renal Involvement

88. Specify the recipient's best renal response

- ☐ Renal response **– ≥ 50% decrease (at least 0.5 g/day) of 24 - hour urine protein (urine protein must be >0.5 g/day pre-treatment). Creatinine and creatinine clearance must not worsen by ≥ 25% over baseline** - ***Go to question 89***
- ☐ No response / stable disease **– Does not meet criteria for renal response or renal progression** - ***Go to question 89***
- ☐ Renal progression **– ≥ 50% increase (at least 1 g/day) of 24-hour urine protein to >1 g/day or 25% worsening of serum creatinine or creatinine clearance** - ***Go to question 89***
- ☐ Not assessed - ***Go to question 91***
- ☐ Not applicable - ***Go to question 91***

89. Date assessed
- ☐ Known → 90. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ Unknown
- ☐ Previously reported

Hepatic Involvement

91. Specify the recipient's best hepatic response

- ☐ Hepatic response **– ≥ 50% decrease in abnormal alkaline phosphatase value and/or normalization of serum alkaline phosphatase level and decrease in liver size radiographically ≥ 2 cm** - ***Go to question 92***
- ☐ No response / stable disease **– Does not meet criteria for hepatic response or hepatic progression** - ***Go to question 92***
- ☐ Hepatic progression **– ≥ 50% increase of alkaline phosphatase above the lowest value** - ***Go to question 92***
- ☐ Not assessed - ***Go to question 98***
- ☐ Not applicable - ***Go to question 98***

92. Date assessed
- ☐ Known → 93. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ Unknown - ***Go to question 94***
- ☐ Previously reported - ***Go to question 98***

94. Was hepatomegaly present on radiographic imaging (liver span > 15 cm) or on examination (liver edge palpable >3 cm below right costal margin)?

☐ Yes ☐ No ☐ Unknown

95. Specify the level of serum alkaline phosphatase
- ☐ Known →
- ☐ Unknown

96. ___ ___ ___ ___ • ___ ☐ IU/L ☐ µkat/L

97. Upper limit of normal for serum alkaline phosphatase: ___ ___ ___ ___ • ___

Gastrointestinal Involvement

98. Was there clinical improvement in GI involvement since the date of the last report?
- ☐ Yes →
- ☐ No →
- ☐ Unknown
- ☐ Not applicable

99. Date assessed
- ☐ Known → 100. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ Unknown
- ☐ Previously reported

Peripheral Nervous System Involvement

101. Specify the recipient's best peripheral nervous system response

- ☐ Peripheral nervous system response **– Improvement in electromyogram nerve conduction velocity** ***- Go to question 102***
- ☐ No response / stable disease **– Does not meet criteria for peripheral nervous system response or peripheral nervous system progression** ***- Go to question 102***
- ☐ Peripheral nervous system progression **– Progressive neuropathy by electromyography or nerve conduction velocity** ***- Go to question 102***
- ☐ Not assessed ***- Go to question 104***
- ☐ Not applicable ***- Go to question 104***

102. Date assessed

- ☐ Known → 103. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ Unknown
- ☐ Previously reported

Other Organ Involvement

104. Did the recipient display any other clinical organ involvement?

- ☐ Yes →
- ☐ No

105. Specify the evidence of other organ involvement

- ☐ Arthropathy
- ☐ Lung
- ☐ Soft tissue
- ☐ Other organ involvement → 106. Specify other organ involvement: _____

107. Specify best response to HCT or cellular therapy for this system

☐ Improved response ☐ Progression ☐ No response / stable disease

108. Date assessed

- ☐ Known → 109. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ Unknown
- ☐ Previously reported

Copy and paste questions 104 - 109 for each additional system involved with Amyloid.

POEMS Syndrome Assessment at the Time of Best Response

Complete questions 110 - 141 for POEMS syndrome patients only. If diagnosis was other than POEMS or there is no evidence or history of it, skip to question 142.

110. Specify POEMS clinical features at the time of best response (check all that apply)

- ☐ Castleman's disease
- ☐ Hepatomegaly
- ☐ Extravascular volume overload (ascites, peripheral edema, pleural effusion)
- ☐ Lymphadenopathy
- ☐ Papilledema
- ☐ Polyneuropathy
- ☐ Skin changes (hyperpigmentation, hypertrichosis, glomeruloid hemangiomata, plethora, acrocyanosis, flushing, white nails)
- ☐ Sclerotic bone lesions
- ☐ Splenomegaly
- ☐ Thrombocytosis / polycythemia
- ☐ Other →

111. Specify other POEMS clinical feature: _____

112. Thyroid stimulating hormone (TSH)

- ☐ Known →
- ☐ Unknown

113. ___ ___ • ___ mU/L (µU/mL)

114. Upper limit of normal for thyroid stimulating hormone (TSH): ___ ___ • ___

115. Testosterone level

- ☐ Known →
- ☐ Unknown

116. ___ ___ ___ ___ • ___ ☐ ng/dL ☐ nmol/L

117. Upper limit of normal for testosterone level: ___ ___ ___ ___ • ___

118. Estradiol level

- ☐ Known →
- ☐ Unknown

119. ___ ___ ___ • ___ ___ pg/mL

120. Upper limit of normal for estradiol level: ___ ___ ___ • ___ ___

121. Prolactin level

- ☐ Known →
- ☐ Unknown

122. ___ ___ ___ ng/mL

123. Upper limit of normal for prolactin level: ___ ___ ___

124. Cortisol level

- ☐ Known →
- ☐ Unknown

125. ___ ___ ___ • ___ ☐ µg/dL ☐ nmol/L

126. Upper limit of normal for cortisol level: ___ ___ ___ • ___

127. Interleukin-6

☐ Known → 128. ___ ___ ___ • ___ pg/mL

129. Upper limit of normal for interleukin-6: ___ ___ ___ • ___

☐ Unknown

130. Was pulmonary artery hypertension present?

☐ Yes → 131. Specify the estimated systolic artery pressure: ___ ___ ___ mm Hg

☐ No

132. Forced vital capacity (FVC)

☐ Known → 133. ___ ___ ___ %

☐ Unknown

134. Total lung capacity

☐ Known → 135. ___ ___ ___ ___ mL

☐ Unknown

136. Vascular endothelial growth factor (VEGF) serum value

☐ Known → 137. ___ ___ ___ • ___ pg/mL

138. Upper limit of normal for serum VEGF: ___ ___ ___ • ___

☐ Unknown

139. Vascular endothelial growth factor (VEGF) plasma value

☐ Known → 140. ___ ___ ___ • ___ pg/mL

141. Upper limit of normal for plasma VEGF: ___ ___ ___ ___ • ___

☐ Unknown

Post-Infusion Therapy

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

☐ Yes →
☐ No
☐ Unknown

Line of Therapy

143. Systemic therapy

☐ Yes →
☐ No

144. Date therapy started

☐ Known →
☐ Unknown

145. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

146. Date therapy stopped

☐ Known - ***Go to question 147***
☐ Unknown - ***Go to question 148***
☐ Not applicable **(still receiving therapy)** - ***Go to question 150***

147. Date stopped: __ __ __ __ / __ __ / __ __
YYYY MM DD

148. Reason therapy stopped

☐ No response / progression
☐ Toxicity
☐ Completed prescribed course / end of treatment protocol
☐ Unknown
☐ Other →

149. Specify other reason therapy stopped:_____

150. Was a standard drug regimen given? (as part of this line of therapy) (with or without additional therapy)

☐ Yes →
☐ No

151. Specify regimen (given as part of this line of therapy)

☐ VCD/CVD/CyBorD (Bortezomib (Velcade), Cyclophosphamide (Cytoxan), dexamethasone)
☐ RVD/VRD (Bortezomib (Velcade), Lenalidomide (Revlimid), dexamethasone)
☐ DVD (Daratumumab (Darzalex), Bortezomib (Velcade), dexamethasone)
☐ RD (Lenalidomide (Revlimid), dexamethasone)
☐ KRD (Carfilzomib (Kyprolis), Lenalidomide (Revlimid), dexamethasone)

152. Were systemic drugs given? (as part of this line of therapy) (Report drugs given that were not already reported as one of the standard regimens, OR drugs given in addition to one of the standard regimens reported above as part of the same line of therapy)

☐ Yes →
☐ No

153. Systemic drugs (check all drugs given as part of this line of therapy)

☐ Bendamustine
☐ Bortezomib (Velcade)
☐ Carfilzomib
☐ Carmustine (BCNU, Gliadel)
☐ Cisplatin (Platinol, CDDP)
☐ Clarithromycin (Biaxin)
☐ Corticosteroids
☐ Cyclophosphamide (Cytoxan)
☐ Cytarabine (Ara-C)
☐ Daratumumab (Darzalex)
☐ Doxorubicin (Adriamycin)
☐ Doxorubicin liposomal (Doxil)
☐ Elotuzumab
☐ Etoposide (VP-16, VePesid)
☐ Idarubicin (Idamycin)
☐ Interferon-α (Intron, Roferon) (includes PEG)
☐ Isatuximab
☐ Ixazomib
☐ Lenalidomide (Revlimid)
☐ Marizomib
☐ Melphalan (L-PAM, Alkeran)
☐ Oprozomib
☐ Panobinostat
☐ Pomalidomide
☐ Rituximab
☐ Selinexor
☐ Thalidomide (Thalomid)
☐ Venetoclax
☐ Vorinostat
☐ Other systemic therapy →

154. Specify other systemic therapy:

_____

155. Radiation therapy

☐ Yes →

☐ No

156. Date therapy started

☐ Known →

☐ Unknown

157. Date started:

__ __ __ __ / __ __ / __ __
YYYY MM DD

158. Date therapy stopped

☐ Known - ***Go to question 159***

☐ Unknown - ***Go to question 160***

☐ Not applicable **(still receiving therapy)** - ***Go to question 162***

159. Date stopped:

__ __ __ __ / __ __ / __ __
YYY MM DD

160. Dose of radiation therapy

☐ Known →

☐ Unknown

161. Total dose: ___ ___ ___ ___

☐ Gy ☐ cGy

162. Cellular therapy (e.g. CAR-T cells)

☐ Yes – Also complete Pre-CTED Form 4000 ☐ No

163. Best hematologic response to line of therapy

☐ Stringent complete response (sCR)

☐ Complete response (CR)

☐ Very good partial response (VGPR)

☐ Partial response (PR)

☐ No response (NR) / stable disease (SD)

☐ Progressive disease (PD)

☐ Relapse from CR (Rel) (untreated)

☐ Unknown →

164. Date assessed: __ __ __ __ / __ __ / __ __
YYYY MM DD

165. Best hematologic response to line of therapy (for Amyloid patients only)

- ☐ Complete response (CR)
- ☐ Very good partial response (VGPR)
- ☐ Partial response (PR)
- ☐ No response (NR) / stable disease (SD)
- ☐ Progressive disease (PD)
- ☐ Relapse from CR (Rel) (untreated)
- ☐ Unknown →

166. Date assessed:

__ __ __ __ / __ __ / __ __
YYYY MM DD

Copy questions 143 - 166 to report more than one line of therapy.

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

- ☐ Yes →
- ☐ No
- ☐ Unknown

168. Date of relapse / progression: __ __ __ __ / __ __ / __ __
YYYY MM DD

169. Was treatment given for relapse or progression?

- ☐ Yes →
- ☐ No

Line of Therapy

170. Systemic therapy

- ☐ Yes →
- ☐ No

171. Date therapy started

- ☐ Known →
- ☐ Unknown

172. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

173. Date therapy stopped

- ☐ Known - ***Go to question 174***
- ☐ Unknown - ***Go to question 175***
- ☐ Not applicable **(still receiving therapy)** - ***Go to question 177***

174. Date stopped: __ __ __ __ / __ __ / __ __
YYYY MM DD

175. Reason stopped

- ☐ No response / progression
- ☐ Toxicity
- ☐ Completed prescribed course / end of treatment protocol
- ☐ Unknown
- ☐ Other →

176. Specify other reason therapy stopped:_____

177. Was a standard drug regimen given? (as part of this line of therapy) (with or without additional therapy)

- ☐ Yes →
- ☐ No

178. Specify regimen (given as part of this line of therapy)

- ☐ VCD/CVD/CyBorD (Bortezomib (Velcade), Cyclophosphamide (Cytoxan), dexamethasone)
- ☐ RVD/VRD (Bortezomib (Velcade), Lenalidomide (Revlimid), dexamethasone)
- ☐ DVD (Daratumumab (Darzalex), Bortezomib (Velcade), dexamethasone)
- ☐ RD (Lenalidomide (Revlimid), dexamethasone)
- ☐ KRD (Carfilzomib (Kyprolis), Lenalidomide (Revlimid), dexamethasone)

179. Were systemic drugs given? (as part of this line of therapy) (Report drugs given that were not already reported as one of the standard regimens, OR drugs given in addition to one of the standard regimens reported above as part of the same line of therapy)

- ☐ Yes →
- ☐ No

180. Systemic drugs (check all drugs given as part of this line of therapy)

- ☐ Bendamustine
- ☐ Bortezomib (Velcade)
- ☐ Carfilzomib
- ☐ Carmustine (BCNU, Gliadel)
- ☐ Cisplatin (Platinol, CDDP)
- ☐ Clarithromycin (Biaxin)
- ☐ Corticosteroids
- ☐ Cyclophosphamide (Cytoxan)
- ☐ Cytarabine (Ara-C)
- ☐ Daratumumab (Darzalex)
- ☐ Doxorubicin (Adriamycin)
- ☐ Doxorubicin liposomal (Doxil)
- ☐ Elotuzumab
- ☐ Etoposide (VP-16, VePesid)
- ☐ Idarubicin (Idamycin)
- ☐ Interferon-α (Intron, Roferon) (includes PEG)
- ☐ Isatuximab
- ☐ Ixazomib
- ☐ Lenalidomide (Revlimid)

- ☐ Marizomib
- ☐ Melphalan (L-PAM, Alkeran)
- ☐ Oprozomib
- ☐ Panobinostat
- ☐ Pomalidomide
- ☐ Rituximab
- ☐ Selinexor
- ☐ Thalidomide (Thalomid)
- ☐ Venetoclax
- ☐ Vorinostat
- ☐ Other systemic therapy →

181. Specify other systemic therapy:
_____

182. Radiation therapy

- ☐ Yes →
- ☐ No

183. Date therapy started

- ☐ Known →
- ☐ Unknown

184. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

185. Date therapy stopped

- ☐ Known - ***Go to question 186***
- ☐ Unknown - ***Go to question 187***
- ☐ Not applicable **(still receiving therapy)** - ***Go to question 189***

186. Date stopped: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

187. Dose of radiation therapy

- ☐ Known →
- ☐ Unknown

188. Total dose: ___ ___ ___ ___ ☐ Gy ☐ cGy

189. Cellular therapy (e.g. CAR-T cells) ☐ Yes – Also complete Pre-CTED Form 4000 ☐ No

Copy questions 170 - 189 to report more than one line of therapy.

190. Was maintenance therapy given after treatment of relapse / progression since the date of last report?

- ☐ Yes
- ☐ No
- ☐ Unknown
- ☐ Not applicable

Line of Therapy

191. Systemic therapy

- ☐ Yes
- ☐ No

192. Date therapy started

- ☐ Known
- ☐ Unknown

193. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

194. Date therapy stopped

- ☐ Known - ***Go to question 195***
- ☐ Unknown - ***Go to question 196***
- ☐ Not applicable **(still receiving therapy)** - ***Go to question 198***

195. Date stopped: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

196. Reason stopped

- ☐ No response / progression
- ☐ Toxicity
- ☐ Completed prescribed course / end of treatment protocol
- ☐ Unknown
- ☐ Other

197. Specify other reason therapy stopped:_____

198. Was a standard drug regimen given? (as part of this line of therapy) (with or without additional therapy)

- ☐ Yes
- ☐ No

199. Specify regimen (given as part of this line of therapy)

- ☐ VCD/CVD/CyBorD (Bortezomib (Velcade), Cyclophosphamide (Cytoxan), dexamethasone)
- ☐ RVD/VRD (Bortezomib (Velcade), Lenalidomide (Revlimid), dexamethasone)
- ☐ DVD (Daratumumab (Darzalex), Bortezomib (Velcade), dexamethasone)
- ☐ RD (Lenalidomide (Revlimid), dexamethasone)
- ☐ KRD (Carfilzomib (Kyprolis), Lenalidomide (Revlimid), dexamethasone)

200. Were systemic drugs given (as part of this line of therapy) (Report drugs given that were not already reported as one of the standard regimens, OR drugs given in addition to one of the standard regimens reported above as part of the same line of therapy)

☐ Yes →
☐ No

201. Systemic drugs (check all drugs given as part of this line of therapy)

- ☐ Bendamustine
- ☐ Bortezomib (Velcade)
- ☐ Carfilzomib
- ☐ Carmustine (BCNU, Gliadel)
- ☐ Cisplatin (Platinol, CDDP)
- ☐ Clarithromycin (Biaxin)
- ☐ Corticosteroids
- ☐ Cyclophosphamide (Cytoxan)
- ☐ Cytarabine (Ara-C)
- ☐ Daratumumab (Darzalex)
- ☐ Doxorubicin (Adriamycin)
- ☐ Doxorubicin liposomal (Doxil)
- ☐ Elotuzumab
- ☐ Etoposide (VP-16, VePesid)
- ☐ Idarubicin (Idamycin)
- ☐ Interferon-α (Intron, Roferon) (includes PEG)
- ☐ Isatuximab
- ☐ Ixazomib
- ☐ Lenalidomide (Revlimid)
- ☐ Marizomib
- ☐ Melphalan (L-PAM, Alkeran)
- ☐ Oprozomib
- ☐ Panobinostat
- ☐ Pomalidomide
- ☐ Rituximab
- ☐ Selinexor
- ☐ Thalidomide (Thalomid)
- ☐ Venetoclax
- ☐ Vorinostat
- ☐ Other systemic therapy →

202. Specify other systemic therapy:

_____

203. Radiation therapy

☐ Yes →

☐ No

204. Date therapy started

☐ Known →

☐ Unknown

205. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

206. Date therapy stopped

☐ Known - ***Go to question 207***

☐ Unknown - ***Go to question 208***

☐ Not applicable **(still receiving therapy)** - ***Go to question 210***

207. Date stopped: __ __ __ __ / __ __ / __ __
YYYY MM DD

208. Dose of radiation therapy

☐ Known →

☐ Unknown

209. Total dose: ___ ___ ___ ___ ☐ Gy ☐ cGy

210. Cellular therapy (e.g. CAR-T cells) ☐ Yes – Also complete Pre-CTED Form 4000 ☐ No

Copy questions 191 - 210 to report more than one line of therapy.

Disease Status at the Time of Evaluation for This Reporting Period

211. Serum creatinine

☐ Known →
☐ Unknown

212. ___ ___ ___ • ___ ___ ☐ mg/dL ☐ mmol/L ☐ µmol/L

213. Upper limit of normal for serum creatinine: ___ ___ ___ • ___ ___

214. Serum monoclonal protein (M-spike) (only from electrophoresis)

☐ Known →
☐ Unknown
☐ Not applicable

215. ___ ___ ___ ___ • ___ ☐ mg/dL ☐ g/dL ☐ g/L

216. Serum immunofixation

☐ Known →
☐ Unknown
☐ Not applicable

217. What was the M-spike type? (check all that apply)

☐ IgG kappa
☐ IgA kappa
☐ IgM kappa
☐ IgD kappa
☐ IgE kappa
☐ IgG lambda
☐ IgA lambda
☐ IgM lambda
☐ IgD lambda
☐ IgE lambda
☐ IgG (heavy chain only)
☐ IgA (heavy chain only)
☐ IgM (heavy chain only)
☐ IgD (heavy chain only)
☐ IgE (heavy chain only)
☐ Kappa (light chain only)
☐ Lambda (light chain only)
☐ No bands present

Specify bands present:

218. Original monoclonal bands ☐ Yes ☐ No

219. New monoclonal (or oligoclonal) bands ☐ Yes ☐ No

220. Serum free light chains — κ (kappa)

☐ Known →
☐ Unknown
☐ Not applicable

221. ___ ___ ___ • ___ ___ ☐ mg/dL ☐ mg/L

222. Upper limit of normal for κ (kappa) free light chain: ___ ___ ___ • ___ ___

223. Serum free light chains — λ (lambda)

☐ Known → 224. ___ ___ ___ • ___ ___ ☐ mg/dL ☐ mg/L

225. Upper limit of normal for λ (lambda) free light chain: ___ ___ ___ • ___ ___

☐ Unknown

☐ Not applicable

226. Total urine protein in 24 hours

☐ Known → 227. ___ ___ ___ ___ ___ • ___ ☐ mg/24 hours ☐ g/24 hours

☐ Unknown

☐ Not applicable

228. Urine albumin / creatinine ratio

☐ Known → 229. ___ ___ ___ • ___ ___ ☐ mg/g ☐ mg/mmol

☐ Unknown

230. Urine protein / creatinine ratio

☐ Known → 231. ___ ___ ___ • ___ ___ ☐ mg/g ☐ mg/mmol

☐ Unknown

232. Urinary monoclonal protein (M-spike) / 24 hours

☐ Known → 233. ___ ___ ___ ___ ___ • ___ ☐ mg/24 hours ☐ g/24 hours

☐ Unknown

☐ Not applicable

234. Urinary immunofixation

☐ Known →

Specify bands present:

235. Original monoclonal bands: ☐ Yes ☐ No

236. New monoclonal (or oligoclonal) bands: ☐ Yes ☐ No

☐ Unknown

☐ Not applicable

237. Plasma cells in bone marrow aspirate by flow cytometry

☐ Known → 238. ___ ___ ___ • ___ ___%

☐ Unknown

239. Plasma cells in bone marrow aspirate by morphologic assessment

☐ Known → 240. ___ ___ ___%

☐ Unknown

241. Plasma cells in bone marrow biopsy

☐ Known → 242. ___ ___ ___%

☐ Unknown

243. Did the recipient receive dialysis?

☐ Yes → 244. Date of dialysis

☐ No

☐ Known → 245. Date of dialysis: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

☐ Unknown

246. Was a PET / CT scan performed during this reporting period?

☐ Yes → 247. Was the PET / CT scan positive for myeloma involvement at any disease site?

☐ No

☐ Yes → 248. Areas of involvement (check all that apply)

☐ No

☐ Bone marrow

☐ Extramedullary plasmacytomas

☐ Lytic bone lesions

☐ Sclerotic bone lesions

249. Date of PET scan

☐ Known → 250. Date of PET / CT scan: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

☐ Unknown

251. What is the hematologic disease status at the time of the most current evaluation?

☐ Stringent complete response (sCR)

☐ Complete response (CR)

☐ Very good partial response (VGPR)

☐ Partial response (PR)

☐ No response (NR) / stable disease (SD)

☐ Progressive disease (PD)

☐ Relapse from CR (Rel) (untreated)

☐ Unknown

252. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

Current Status of Amyloidosis for This Reporting Period

Complete questions 253 - 311 for Amyloid patients only. If diagnosis was other than Amyloidosis or there is no history of it, continue with question 312.

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

253. Specify the recipient's current hematologic status

- ☐ Complete response (CR)
- ☐ Very good partial response (VGPR)
- ☐ Partial response (PR)
- ☐ No response (NR) / stable disease (SD)
- ☐ Progressive disease (PD)
- ☐ Relapse from CR (Rel) (untreated)
- ☐ Unknown

254. Date assessed

- ☐ Known →
- ☐ Unknown

255. Date assessed: __ __ __ __ / __ __ / __ __
YYYY MM DD

Cardiac Involvement

256. Specify the recipient's current cardiac response

- ☐ Cardiac response **– NT-proBNP response (>30% and >300 ng/l decrease in patients with baseline NT-proBNP ≥ 650 ng/l) or New York Heart Association (NYHA) class response (≥ 2 class decrease in subjects with baseline NYHA class 3 or 4)** ***- Go to question 257***
- ☐ No response / stable disease **– Does not meet criteria for cardiac response or cardiac progression** ***- Go to question 257***
- ☐ Cardiac progression **– NT-proBNP progression (>30% and >300 ng/l increase) or cTn progression (≥ 33% increase) or ejection fraction progression (≥ 10% decrease)** ***- Go to question 257***
- ☐ Not assessed ***- Go to question 290***
- ☐ Not applicable ***- Go to question 290***

257. Date assessed

- ☐ Known →
- ☐ Unknown

258. Date assessed: __ __ __ __ / __ __ / __ __
YYYY MM DD

259. Was the left ventricular ejection fraction measured?

- ☐ Yes →
- ☐ No

260. Specify the left ventricular ejection fraction: ___ ___ %

261. Specify the method used to determine the left ventricular ejection fraction

- ☐ Echocardiogram
- ☐ Multiple gated acquisition (MUGA) scan
- ☐ Cardiac MRI
- ☐ Unknown

262. Was diastolic dysfunction present? ☐ Yes ☐ No ☐ Unknown

263. Specify the interventricular septal wall thickness measured by echocardiogram

☐ Known → 264. ___ ___ mm

☐ Unknown

265. Specify left ventricular (LV) strain percentage

☐ Known → 266. ___ ___ %

☐ Unknown

267. Were any serum cardiac biomarkers assessed?

☐ Yes →

☐ No

☐ Unknown

268. Date cardiac biomarkers were assessed: __ __ __ __ / __ __ / __ __
YYYY MM DD

Specify the cardiac biomarkers assessed:

269. Brain natriuretic peptide (BNP)

☐ Yes →

☐ No

270. ___ ___ ___ ___ ___ • ___ pg/mL

271. Upper limit of normal for BNP: ___ ___ ___ ___ ___ • ___

272. N-terminal prohormone brain natriuretic peptide (NT-proBNP)

☐ Yes →

☐ No

273. ___ ___ ___ ___ ___ • ___ pg/mL

274. Upper limit of normal for NT-proBNP: ___ ___ ___ ___ ___ • ___

275. Troponin I

☐ Yes →

☐ No

276. ___ ___ ___ ___ • ___ ___ ___ µg/L

277. Upper limit of normal for troponin I: ___ ___ ___ ___ • ___ ___ ___

278. Troponin T

☐ Yes →

☐ No

279. ___ ___ ___ ___ • ___ ___ ___ µg/L

280. Upper limit of normal for troponin T: ___ ___ ___ ___ • ___ ___ ___

281. High sensitivity troponin T

☐ Yes →

☐ No

282. ___ ___ ___ ___ • ___ ___ ___ ng/L

283. Upper limit of normal for high sensitivity troponin T: ___ ___ ___ ___ • ___ ___ ___

284. Was a 6 minute walk test performed?

☐ Yes →

☐ No

285. Distance walked: __ __ __ ☐ meters ☐ feet

286. Specify the recipient's New York Heart Association functional classification of heart failure (Symptoms may include dyspnea, chest pain, fatigue, and palpitations; activity level should be assessed with consideration for patient's age group)

- ☐ Class I – Able to perform ordinary activities without symptoms; no limitation of physical activity
- ☐ Class II – Ordinary physical activity produces symptoms; slight limitation of physical activity
- ☐ Class III – Less-than-ordinary physical activity produces symptoms; moderate limitation of physical activity
- ☐ Class IV – Symptoms present even at rest; severe limitation of physical activity
- ☐ Unknown

287. Recipient blood pressure

- ☐ Known →
- ☐ Unknown

288. ___ ___ ___ / ___ ___ ___ mm/Hg

289. Indicate body position during blood pressure measurement

☐ Sitting ☐ Standing ☐ Supine ☐ Unknown

Renal Involvement

290. Specify the recipient's current renal response

- ☐ Renal response **– ≥ 50% decrease (at least 0.5 g/day) of 24 - hour urine protein (urine protein must be >0.5 g/day pre-treatment). Creatinine and creatinine clearance must not worsen by ≥ 25% over baseline** ***- Go to question 291***
- ☐ No response / stable disease **– Does not meet criteria for renal response or renal progression** ***- Go to question 291***
- ☐ Renal progression **– ≥ 50% increase (at least 1 g/day) of 24-hour urine protein to >1 g/day or 25% worsening of serum creatinine or creatinine clearance** ***- Go to question 291***
- ☐ Not assessed ***- Go to question 293***
- ☐ Not applicable ***- Go to question 293***

291. Date assessed

- ☐ Known →
- ☐ Unknown

292. Date assessed: __ __ __ __ / __ __ / __ __
YYYY MM DD

Hepatic Involvement

293. Specify the recipient's current hepatic response

- ☐ Hepatic response **– ≥ 50% decrease in abnormal alkaline phosphatase value and/or normalization of serum alkaline phosphatase level and decrease in liver size radiographically ≥ 2 cm** ***- Go to question 294***
- ☐ No response / stable disease **– Does not meet criteria for hepatic response nor hepatic progression** ***- Go to question 294***
- ☐ Hepatic progression **– ≥ 50% increase of alkaline phosphatase above the lowest value** ***- Go to question 294***
- ☐ Not assessed ***- Go to question 300***
- ☐ Not applicable ***- Go to question 300***

294. Date assessed

- ☐ Known →
- ☐ Unknown

295. Date assessed: __ __ __ __ / __ __ / __ __
YYYY MM DD

296. Was hepatomegaly present on radiographic imaging (liver span > 15 cm) or on examination (liver edge palpable >3 cm below right costal margin)?

☐ Yes ☐ No ☐ Unknown

297. Specify the level of serum alkaline phosphatase

☐ Known →

☐ Unknown

298. ___ ___ ___ ___ • ___ ☐ IU/L ☐ µkat/L

299. Upper limit of normal for serum alkaline phosphatase: ___ ___ ___ ___ • ___

Gastrointestinal Involvement

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

☐ Yes →

☐ No →

☐ Unknown

☐ Not applicable

301. Date assessed

☐ Known →

☐ Unknown

302. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

Peripheral Nervous System Involvement

303. Specify the recipient's current peripheral nervous system response

☐ Peripheral nervous system response **– Improvement in electromyogram nerve conduction velocity** ***- Go to question 304***

☐ No response / stable disease **– Does not meet criteria for peripheral nervous system response or peripheral nervous system progression** ***- Go to question 304***

☐ Peripheral nervous system progression **– Progressive neuropathy by electromyography or nerve conduction velocity** ***- Go to question 304***

☐ Not assessed ***- Go to question 306***

☐ Not applicable ***- Go to question 306***

304. Date assessed

☐ Known →

☐ Unknown

305. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

Other Organ Involvement

306. Did the recipient display any other clinical organ involvement?

☐ Yes →

☐ No

307. Specify the evidence of other organ involvement

☐ Arthropathy →

☐ Lung

☐ Soft tissue

☐ Other organ involvement

308. Specify other organ involvement: _____

309. Specify the current status of this system

☐ Improved response ☐ Progression ☐ No response / stable disease

310. Date assessed

☐ Known →

☐ Unknown

311. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

Copy and paste questions 306 - 311 for each additional system involved with Amyloid.

Current Status of POEMS Syndrome for This Reporting Period

Complete questions 312 - 343 for POEMS syndrome patients only. If diagnosis was other than POEMS or there is no evidence or history of it, skip to Signature Line.

312. Specify POEMS clinical features (check all that apply)

- ☐ Castleman's disease
- ☐ Hepatomegaly
- ☐ Extravascular volume overload (ascites, peripheral edema, pleural effusion)
- ☐ Lymphadenopathy
- ☐ Papilledema
- ☐ Polyneuropathy
- ☐ Skin changes (hyperpigmentation, hypertrichosis, glomeruloid hemangiomata, plethora, acrocyanosis, flushing, white nails)
- ☐ Sclerotic bone lesions
- ☐ Splenomegaly
- ☐ Thrombocytosis / polycythemia
- ☐ Other →

313. Specify other POEMS clinical feature: _____

314. Thyroid stimulating hormone (TSH)

- ☐ Known →
- ☐ Unknown

315. ___ ___ • ___ mU/L (µU/mL)

316. Upper limit of normal for thyroid stimulating hormone (TSH): ___ ___ • ___

317. Testosterone level

- ☐ Known →
- ☐ Unknown

318. ___ ___ ___ ___• ___ ___ ☐ ng/dL ☐ nmol/L

319. Upper limit of normal for testosterone level: ___ ___ ___ ___ • ___ ___

320. Estradiol level

- ☐ Known →
- ☐ Unknown

321. ___ ___ ___ • ___ ___ pg/mL

322. Upper limit of normal for estradiol level: ___ ___ ___ • ___ ___

323. Prolactin level

- ☐ Known →
- ☐ Unknown

324. ___ ___ ___ ng/mL

325. Upper limit of normal for prolactin level: ___ ___ ___

326. Cortisol level

- ☐ Known →
- ☐ Unknown

327. ___ ___ ___ • ___ ☐ µg/dL ☐ nmol/L

328. Upper limit of normal for cortisol level: ___ ___ ___ • ___

329. Interleukin-6

- ☐ Known →
- ☐ Unknown

330. ___ ___ ___ • ___ pg/mL

331. Upper limit of normal for interleukin-6: ___ ___ ___ • ___

332. Was pulmonary artery hypertension present?

☐ Yes → 333. Specify the estimated systolic artery pressure: ___ ___ ___ mm Hg

☐ No

334. Forced vital capacity (FVC)

☐ Known → 335. ___ ___ ___ %

☐ Unknown

336. Total lung capacity

☐ Known → 337. ___ ___ ___ ___ mL

☐ Unknown

338. Vascular endothelial growth factor (VEGF) serum value

☐ Known → 339. ___ ___ ___ • ___ pg/mL

340. Upper limit of normal for serum VEGF: ___ ___ ___ • ___

☐ Unknown

341. Vascular endothelial growth factor (VEGF) plasma value

☐ Known → 342. ___ ___ ___ ___ • ___ pg/mL

343. Upper limit of normal for plasma VEGF: ___ ___ ___ ___ • ___

☐ Unknown

First Name (person completing form): _____

Last Name:_____

E-mail address: _____

Date: __ __ __ __ / __ __ / __ __
YYYY MM DD

Response Codes

Continued complete remission — for recipients already in CR prior to the start of the preparative regimen (only applicable at the time of best response)

Stringent complete response (sCR) — CR as defined below, 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 κ/λratio. An abnormal κ/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 κ/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 response (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.

Very good partial response (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/24hours

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 response (PR) — ≥ 50% reduction in serum M-protein, and reduction in 24-hour urinary M-protein by ≥ 90% or to < 200 mg/24hours.

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.

No response (NR) / Stable disease (SD) — not meeting the criteria for CR, VGPR, PRor 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 baseline (from the lowest response 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 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 (absolute increase > 10 mg/dL). Bone marrow plasma cell percentage (absolute percentage ≥ 10%); and/or Definite development of new bone lesions or soft tissue plasmacytomas, and/or definite increase in the size of any existing bone lesions or soft tissue plasmacytomas; and/or 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) — 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.

Amyloidosis Response Codes

Continued complete remission — for recipients already in CR prior to the start of the preparative regimen (only applicable at the time of best response)

Complete response — Normalization of the free serum light chain level and ratio, negative serum and urine immunofixation

Very good partial response — Reduction in the dFLC (difference between involved serum free light and uninvolved serum free light chain) to < 40 mg/l

Partial response — A greater than 50% reduction in the dFLC (difference between serum involved free light and uninvolved serum free light chain)

No response / stable disease — Less than a PR

Progressive disease — From PR, 50% increase in serum M protein to > 0.5 g/dl or 50% increase in urine M protein to >200 mg/day (a visible peak must be present)
— Free light chain increase of 50% to > 100 mg/l

Relapse — From CR, any detectable monoclonal protein or abnormal free light chain ratio (light chain must double)