CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Plasma Cell Disorders (PCD) Pre-Infusion Data

Registry Use Only
Sequence Number:

Date Received:

CIBMTR Center Number: ___ ___ ___ ___ ___

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

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

Subsequent Transplant or Cellular Therapy

If this is a report of a second or subsequent transplant or cellular therapy for the same disease subtype and this baseline disease insert has not been completed for the previous transplant (e.g. patient was on TED track for the prior HCT or cellular therapy, prior HCT or cellular therapy was autologous with no consent, prior cellular therapy was not reported to the CIBMTR), mark "No" and begin the form at question one.

If this is a report of a second or subsequent transplant or cellular therapy for a different disease, mark "No" and begin the form at question one.

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

☐ Yes ***- Go to question 157***

☐ No ***- Go to question 1***

Disease Assessment at Diagnosis

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)

Diagnostic Studies (Measured Prior to Any Disease Treatment)

Report values prior to first treatment for plasma cell disorder.

3. Hemoglobin
   - ☐ Known → 4. ___ ___ ___ ___ • ___ ___ ☐ g/dL ☐ g/L ☐ mmol/L
   - ☐ Unknown

5. Serum calcium
   - ☐ Known → 6. ___ ___ • ___ ___ ☐ mg/dL ☐ mmol/L ☐ mEq/L
   - ☐ Unknown

7. Serum creatinine
   - ☐ Known → 8. ___ ___ ___ • ___ ___ ☐ mg/dL ☐ mmol/L ☐ µmol/L
     9. Upper limit of normal for serum creatinine: ___ ___ ___ • ___ ___
   - ☐ Unknown

10. Serum monoclonal protein (M-spike) (only from electrophoresis)
    - ☐ Known → 11. ___ ___ ___ ___ • ___ ☐ mg/dL ☐ g/dL ☐ g/L
    - ☐ Unknown
    - ☐ Not applicable

12. Serum immunofixation
    - ☐ Known →
      13. 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
    - ☐ Unknown
    - ☐ Not applicable

14. Serum free light chains — κ (kappa)
    - ☐ Known → 15. ___ ___ ___ • ___ ___ ☐ mg/dL ☐ mg/L
      16. Upper limit of normal for κ (kappa) free light chain: ___ ___ ___ • ___ ___
    - ☐ Unknown
    - ☐ Not applicable

17. Serum free light chains — λ (lambda)
- ☐ Known →
- ☐ Unknown
- ☐ Not applicable

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

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

Specify the following serum quantitative immunoglobulins

20. IgG
- ☐ Known →
- ☐ Unknown

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

22. Upper limit of normal for IgG: ___ ___ ___ ___ ___ • ___ ___

23. IgA
- ☐ Known →
- ☐ Unknown

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

25. Upper limit of normal for IgA: ___ ___ ___ ___ ___ • ___ ___

26. IgM
- ☐ Known →
- ☐ Unknown

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

28. Upper limit of normal for IgM: ___ ___ ___ ___ ___ • ___ ___

29. IgD
- ☐ Known →
- ☐ Unknown

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

31. Upper limit of normal for IgD: ___ ___ ___ ___ ___ • ___ ___

32. IgE
- ☐ Known →
- ☐ Unknown

33. ___ ___ ___ ___ ___ • ___ ___ IU/mL

34. Upper limit of normal for IgE: ___ ___ ___ ___ ___ • ___ ___

35. Urinary monoclonal protein (M-spike)/ 24 hours
- ☐ Known →
- ☐ Unknown
- ☐ Not applicable

36. ___ ___ ___ ___ ___ • ___ ☐ mg/24 hours ☐ g/24 hours

37. Urine light chain ☐ kappa ☐ lambda ☐ Not applicable

38. Total urine protein in 24 hours
- ☐ Known →
- ☐ Unknown
- ☐ Not applicable

39. ___ ___ ___ ___ ___ • ___ ☐ mg/24 hours ☐ g/24 hours

40. Urine albumin / creatinine ratio
- ☐ Known →
- ☐ Unknown

41. ___ ___ ___ • ___ ___ ☐ mg/g ☐ mg/mmol

42. Urine protein / creatinine ratio
- ☐ Known →
- ☐ Unknown

43. ___ ___ ___ • ___ ___ ☐ mg/g ☐ mg/mmol

44. Plasma cells in bone marrow aspirate by flow cytometry
- ☐ Known →
- ☐ Unknown

45. ___ ___ ___ • ___ ___ %

46. Plasma cells in bone marrow aspirate by morphologic assessment
- ☐ Known →
- ☐ Unknown

47. ___ ___ ___ %

48. Plasma cells in bone marrow biopsy
- ☐ Known →
- ☐ Unknown

49. ___ ___ ___ %

50. Were immunohistochemical stains obtained? (bone marrow biopsy)
- ☐ Yes →
- ☐ No
- ☐ Unknown

51. CD138: ☐ Positive ☐ Negative ☐ Unknown

52. CD38: ☐ Positive ☐ Negative ☐ Unknown

53. Was a gene expression profile performed?
- ☐ Yes →
- ☐ No

54. Were results considered high-risk myeloma? ☐ Yes ☐ No

55. Was documentation submitted to the CIBMTR (e.g. gene expression profile report)?
☐ Yes ☐ No

56. Was a PET/CT scan performed?
- ☐ Yes →
- ☐ No

57. Was the PET/CT scan positive for myeloma involvement at any disease site?
- ☐ Yes →
- ☐ No

58. Areas of involvement (check all that apply)
- ☐ Bone marrow
- ☐ Extramedullary plasmacytomas
- ☐ Lytic bone lesions
- ☐ Sclerotic bone lesions

59. Date of PET/CT scan
- ☐ Known →
- ☐ Unknown

60. Date of PET/CT scan: __ __ __ __ / __ __ / __ __
YYYY MM DD

Amyloidosis Organ Involvement at Diagnosis

Complete questions 61 - 124 for amyloid patients only. If diagnosis was other than amyloidosis, or there is no evidence or history of it, skip to question 125.

61. Sites of tissue with pathologic diagnosis of amyloidosis (check all that apply)

- ☐ Bone marrow
- ☐ Fat
- ☐ GI tract
- ☐ Heart
- ☐ Kidney
- ☐ Liver
- ☐ Lung
- ☐ Muscle
- ☐ Nerve
- ☐ Salivary gland
- ☐ Skin
- ☐ Tongue
- ☐ Other →

62. Specify other site: _____

63. Was amyloid subtyping performed?

- ☐ Yes →
- ☐ No

64. Indicate amyloid subtype

- ☐ AL kappa
- ☐ AL lambda
- ☐ AHL G kappa
- ☐ AHL A kappa
- ☐ AHL M kappa
- ☐ AHL D kappa
- ☐ AHL E kappa
- ☐ AHL G lambda
- ☐ AHL A lambda
- ☐ AHL M lambda
- ☐ AHL D lambda
- ☐ AHL E lambda
- ☐ AH G
- ☐ AH A
- ☐ AH M
- ☐ AH D
- ☐ AH E

65. Indicate method utilized for subtyping

- ☐ Immunohistochemistry
- ☐ Mass spectrometry
- ☐ Immunofluorescence
- ☐ Other →

66. Specify other method utilized for subtyping: _____

Cardiac Involvement

67. Was a cardiac imaging procedure performed?
- ☐ Yes →
- ☐ No

68. Was a cardiac MRI done?
- ☐ Yes →
- ☐ No

69. Specify cardiac MRI results
- ☐ Normal ☐ Abnormal ☐ Unknown

70. Was documentation submitted to the CIBMTR (e.g. MRI report)?
- ☐ Yes ☐ No

71. Was the left ventricular ejection fraction measured?
- ☐ Yes →
- ☐ No

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

73. Specify the method used to determine the left ventricular ejection fraction
- ☐ Echocardiogram
- ☐ Multiple gated acquisition (MUGA) scan
- ☐ Cardiac MRI
- ☐ Unknown

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

75. Specify the interventricular septal wall thickness measured by echocardiogram
- ☐ Known →
- ☐ Unknown

76. ___ ___ mm

77. Specify left ventricular (LV) strain percentage
- ☐ Known →
- ☐ Unknown

78. ___ ___ %

79. Were any serum cardiac biomarkers assessed?
- ☐ Yes →
- ☐ No
- ☐ Unknown

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

Specify the cardiac biomarkers assessed:

81. Brain natriuretic peptide (BNP)
- ☐ Yes →
- ☐ No

82. ___ ___ ___ ___ ___ • ___ pg/mL

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

84. N-terminal prohormone brain natriuretic peptide (NT-proBNP)
- ☐ Yes →
- ☐ No

85. ___ ___ ___ ___ ___ • ___ pg/mL

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

87. Troponin I
- ☐ Yes →
  - 88. ___ ___ ___ ___ • ___ ___ ___ µg/L
  - 89. Upper limit of normal for troponin I: ___ ___ ___ ___ • ___ ___ ___
- ☐ No

90. Troponin T
- ☐ Yes →
  - 91. ___ ___ ___ ___ • ___ ___ ___ µg/L
  - 92. Upper limit of normal for troponin T: ___ ___ ___ ___ • ___ ___ ___
- ☐ No

93. High sensitivity troponin T
- ☐ Yes →
  - 94. ___ ___ ___ ___ • ___ ___ ___ ng/L
  - 95. Upper limit of normal for high sensitivity troponin T: ___ ___ ___ ___ • ___ ___ ___
- ☐ No

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

98. 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

99. Recipient blood pressure (at diagnosis)
- ☐ Known →
  - 100. ___ ___ ___ / ___ ___ ___ mm/Hg
  - 101. Indicate body position during blood pressure measurement
    ☐ Sitting ☐ Standing ☐ Supine ☐ Unknown
- ☐ Unknown

102. Did the recipient develop pericardial effusion? ☐ Yes ☐ No

Hepatic Involvement

103. 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

104. Specify the level of serum alkaline phosphatase

☐ Known →
☐ Unknown

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

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

Gastrointestinal Involvement

107. Was there clinical suspicion of gastrointestinal (GI) involvement?

☐ Yes →
☐ No
☐ Unknown

108. Specify the site(s) of GI involvement (check all that apply)

☐ Tongue (macroglossia)
☐ Esophagus
☐ Stomach
☐ Small Intestine
☐ Colon
☐ Rectum

Peripheral Nervous System Involvement

109. Was a sensory / motor exam performed?

☐ Yes →
☐ No
☐ Unknown

110. Specify the exam results ☐ Normal ☐ Abnormal

111. Did the recipient display any other evidence of peripheral nerve involvement for amyloidosis?

☐ Yes →
☐ No

112. Specify other evidence: _____

Autonomic Neuropathy Involvement

113. Did the recipient display symptomatic orthostatic hypotension (not attributable to medications or volume depletion)? ☐ Yes ☐ No

114. Did the recipient display any other evidence of autonomic neuropathy involvement (e.g. pseudo-obstruction or intractable diarrhea)?

☐ Yes →
☐ No

115. Specify other evidence: _____

Other Organ Involvement

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

☐ Yes →
☐ No

117. Specify the evidence of other organ involvement (check all that apply)

☐ Arthropathy
☐ Lung
☐ Soft tissue
☐ Other organ involvement →

118. Specify other organ: _____

119. Was Factor X measured?

☐ Yes →

☐ No

120. ___ ___ ___ %

121. Indicate the type of Factor X measurement ☐ Activity ☐ Antigen

122. Was the recipient on Warfarin (Coumadin)? ☐ Yes ☐ No

123. Uric acid at diagnosis

☐ Known →

☐ Unknown

124. ___ ___ mg/dL

POEMS Syndrome Assessment at Diagnosis

Questions 125 - 156 for POEMS syndrome patients only. If diagnosis was other than POEMS or there is no evidence or history of it, skip to question 157.

125. 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 →

126. Specify other POEMS clinical feature:_____

127. Thyroid stimulating hormone (TSH)

- ☐ Known →
- ☐ Unknown

128. ___ ___ • ___ mU/L (µU/mL)

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

130. Testosterone level:

- ☐ Known →
- ☐ Unknown

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

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

133. Estradiol level

- ☐ Known →
- ☐ Unknown

134. ___ ___ ___ • ___ ___ pg/mL

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

136. Prolactin level

- ☐ Known →
- ☐ Unknown

137. ___ ___ ___ ng/mL

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

139. Cortisol level

- ☐ Known →
- ☐ Unknown

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

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

142. Interleukin-6

☐ Known → 143. ___ ___ ___ • ___ pg/mL

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

☐ Unknown

145. Was pulmonary artery hypertension present?

☐ Yes → 146. Specify the estimated systolic artery pressure: ___ ___ ___ mm Hg

☐ No

147. Forced vital capacity (FVC)

☐ Known → 148. ___ ___ ___ %

☐ Unknown

149. Total lung capacity

☐ Known → 150. ___ ___ ___ ___ mL

☐ Unknown

151. Vascular endothelial growth factor (VEGF) serum value

☐ Known → 152. ___ ___ ___ • ___ pg/mL

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

☐ Unknown

154. Vascular endothelial growth factor (VEGF) plasma value

☐ Known → 155. ___ ___ ___ ___ • ___ pg/mL

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

☐ Unknown

Pre-Infusion Therapy

157. Was therapy given?

- ☐ Yes →
- ☐ No

Line of Therapy

158. Systemic therapy

- ☐ Yes →
- ☐ No

159. Date therapy started

- ☐ Known →
- ☐ Unknown

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

161. Date therapy stopped

- ☐ Known ***- Go to question 162***
- ☐ Unknown ***- Go to question 163***
- ☐ Not applicable **(still receiving therapy)** ***- Go to question 165***

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

163. Reason stopped

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

164. Specify other reason therapy stopped: _____

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

- ☐ Yes →
- ☐ No

166. 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)

167. 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

168. 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 →

169. Specify other systemic therapy:

_____

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

☐ Yes ☐ No

171. Did the recipient receive any amyloid fibril-directed therapies?

☐ Yes →
☐ No

172. Specify amyloid fibril-directed therapies (check all that apply)

☐ Doxycycline
☐ EGCG / green tea
☐ CAEL- 101
☐ NEOD- 001
☐ Other →

173. Specify other: _____

174. Radiation therapy

☐ Yes →
☐ No

175. Date therapy started

☐ Known →
☐ Unknown

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

177. Date therapy stopped

☐ Known ***- Go to question 178***
☐ Unknown ***- Go to question 179***
☐ Not applicable **(still receiving therapy)** ***- Go to question 181***

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

179. Dose of radiation therapy

☐ Known →
☐ Unknown

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

181. Cellular therapy (e.g. CAR-T cells) ☐ Yes ☐ No

182. 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)

183. Date assessed __ __ __ __ / __ __ / __ __
YYYY MM DD

- ☐ Unknown ***- Go to question 184***

184. 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)

185. Date assessed __ __ __ __ / __ __ / __ __
YYYY MM DD

- ☐ Unknown ***- Go to question 186***

186. Did disease relapse/progress following this line of therapy?

- ☐ Yes → 187. Date of relapse/progression: __ __ __ __ / __ __ / __ __
YYYY MM DD
- ☐ No

Copy questions 158 - 187 to report more than one line of therapy.

Laboratory Studies at Last Evaluation Prior to the Start of the Preparative Regimen / Infusion

188. Serum β2 – microglobulin

☐ Known → 189. ___ ___ ___ • ___ ___ ___ ☐ µg/dL ☐ mg/L ☐ nmol/L

☐ Unknown

190. Plasma cells in blood by flow cytometry

☐ Known → 191. ___ ___ • ___ ___%

192. ___ ___ ___ ___ ___ • ___ ___ ☐ x 10^9/L (x 10^3/mm^3) ☐ x 10^6/L

☐ Unknown

193. Plasma cells in blood by morphologic assessment

☐ Known → 194. ___ ___%

195. ___ ___ ___ ___ ___ • ___ ___ ☐ x 10^9/L (x 10^3/mm^3) ☐ x 10^6/L

☐ Unknown

196. Serum albumin

☐ Known → 197. ___ ___ • ___ ☐ g/dL ☐ g/L

☐ Unknown

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

☐ Known → 199. ___ ___ ___ ___ • ___ ☐ mg/dL ☐ g/dL ☐ g/L

☐ Unknown

☐ Not applicable

200. Serum immunofixation

☐ Known →

Specify bands present:

201. Original monoclonal bands: ☐ Yes ☐ No

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

☐ Unknown

☐ Not applicable

203. Serum free light chains — κ (kappa)

☐ Known → 204. ___ ___ ___ • ___ ___ ☐ mg/dL ☐ mg/L

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

☐ Unknown

☐ Not applicable

206. Serum free light chains — λ (lambda)

☐ Known → 207. ___ ___ ___ • ___ ___ ☐ mg/dL ☐ mg/L

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

☐ Unknown

☐ Not applicable

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

- ☐ Known → 210. ___ ___ ___ ___ ___ • ___ ☐ mg/24 hours ☐ g/24 hours
- ☐ Unknown
- ☐ Not applicable

211. Urinary immunofixation

- ☐ Known → **Specify bands present:**
  - 212. Original monoclonal bands ☐ Yes ☐ No
  - 213. New monoclonal (or oligoclonal) bands ☐ Yes ☐ No
- ☐ Unknown
- ☐ Not applicable

214. Total urine protein in 24 hours

- ☐ Known → 215. ___ ___ ___ ___ ___ • ___ ☐ mg/24 hours ☐ g/24 hours
- ☐ Unknown
- ☐ Not applicable

216. Urine albumin / creatinine ratio

- ☐ Known → 217. ___ ___ ___ • ___ ___ ☐ mg/g ☐ mg/mmol
- ☐ Unknown

218. Urine protein / creatinine ratio

- ☐ Known → 219. ___ ___ ___ • ___ ___ ☐ mg/g ☐ mg/mmol
- ☐ Unknown

220. Was minimal residual disease (MRD) assessed during the pre-HCT or pre-infusion evaluation? (report only bone marrow or blood results)

- ☐ Yes →
  - 221. Next generation sequencing (NGS)
    - ☐ Positive →
      - 222. Sample source ☐ Blood ☐ Bone marrow
      - 223. Indicate the sensitivity of the NGS testing
        - ☐ 10^{-4}
        - ☐ 10^{-5}
        - ☐ 10^{-6}
        - ☐ Unknown
        - ☐ Other → 224. Specify other sensitivity: _____
    - ☐ Negative
    - ☐ Not done
- ☐ No
- ☐ Unknown

225. Next generation flow (NGF)

- ☐ Positive →
- ☐ Negative →
- ☐ Not done

226. Sample source ☐ Blood ☐ Bone marrow

227. Indicate the sensitivity of the NGF testing

- ☐ 10^{-4}
- ☐ 10^{-5}
- ☐ 10^{-6}
- ☐ Unknown
- ☐ Other →

228. Specify other sensitivity: _____

229. Plasma cells in bone marrow aspirate by flow cytometry

- ☐ Known →
- ☐ Unknown

230. ___ ___ ___ • ___ ___ %

231. Plasma cells in bone marrow aspirate by morphologic assessment

- ☐ Known →
- ☐ Unknown

232. ___ ___ ___ %

233. Plasma cells in bone marrow biopsy

- ☐ Known →
- ☐ Unknown

234. ___ ___ ___ %

235. Were cytogenetics tested (karyotyping or FISH)?

- ☐ Yes →
- ☐ No
- ☐ Unknown

236. Were cytogenetics tested via FISH?

- ☐ Yes →
- ☐ No

237. Results of tests

- ☐ Abnormalities identified →
- ☐ No abnormalities

Specify cytogenetic abnormalities identified via FISH at last evaluation prior to the start of the preparative regimen:

238. International System for Human Cytogenetic Nomenclature (ISCN) compatible string: _____

239. Specify abnormalities (check all that apply)

Trisomy

- ☐ + 3
- ☐ + 5
- ☐ + 7
- ☐ + 9
- ☐ + 11
- ☐ + 15
- ☐ + 19

Translocation

- ☐ t(4;14)
- ☐ t(6;14)
- ☐ t(11;14)
- ☐ t(14;16)
- ☐ t(14;20)

Deletion

- ☐ del (13q) /13q-
- ☐ del (17p) /17p-

Monosomy

- ☐ - 13
- ☐ - 17

Other

- ☐ Hyperdiploid (>50)
- ☐ Hypodiploid (<46)
- ☐ Any abnormality at 1q
- ☐ Any abnormality at 1p
- ☐ MYC rearrangement
- ☐ Other abnormality →

240. Specify other abnormality: _____

241. Was documentation submitted to the CIBMTR? (e.g. FISH report) ☐ Yes ☐ No

242. Were cytogenetics tested via karyotyping?

- ☐ Yes →
- ☐ No

243. Results of tests

- ☐ Abnormalities identified →
- ☐ No evaluable metaphases
- ☐ No abnormalities

Specify cytogenetic abnormalities identified via conventional cytogenetics at last evaluation prior to the start of the preparative regimen:

244. International System for Human Cytogenetic Nomenclature (ISCN) compatible string: _____

245. Specify abnormalities (check all that apply)

Trisomy

- ☐ + 3
- ☐ + 5
- ☐ + 7
- ☐ + 9
- ☐ + 11
- ☐ + 15
- ☐ + 19

Translocation

- ☐ t(4;14)
- ☐ t(6;14)
- ☐ t(11;14)
- ☐ t(14;16)
- ☐ t(14;20)

Deletion

- ☐ del (13q) /13q-
- ☐ del (17p) /17p-

Monosomy

- ☐ - 13
- ☐ - 17

Other

- ☐ Hyperdiploid (>50)
- ☐ Hypodiploid (<46)
- ☐ Any abnormality at 1q
- ☐ Any abnormality at 1p
- ☐ MYC rearrangement
- ☐ Other abnormality →

246. Specify other abnormality: _____

247. Was documentation submitted to the CIBMTR? (e.g. karyotyping report) ☐ Yes ☐ No

248. Did the recipient receive dialysis?

☐ Yes →
☐ No

249. Date of dialysis

☐ Known →
☐ Unknown

250. Date of dialysis: __ __ __ __ / __ __ / __ __
YYYY MM DD

251. Was a PET/CT scan performed?

☐ Yes →
☐ No

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

☐ Yes →
☐ No

253. Areas of involvement (check all that apply)

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

254. Date of PET/CT scan

☐ Known →
☐ Unknown

255. Date of PET/CT scan: __ __ __ __ / __ __ / __ __
YYYY MM DD

Amyloidosis Assessment at Last Evaluation Prior to the Start of the Preparative Regimen / Infusion

Complete questions 256 – 290 for amyloid patients only. If diagnosis was other than amyloidosis or there is no history of it, continue with 291.

Cardiac Involvement

256. Was the left ventricular ejection fraction measured?

☐ Yes →
- 257. ___ ___ %
- 258. Specify the method used to determine the left ventricular ejection fraction
  ☐ Echocardiogram ☐ Multiple gated acquisition (MUGA) scan ☐ Cardiac MRI ☐ Unknown

☐ No

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

260. Specify the interventricular septal wall thickness measured by echocardiogram

☐ Known →
- 261. ___ ___ mm

☐ Unknown

262. Specify left ventricular (LV) strain percentage

☐ Known →
- 263. ___ ___ %

☐ Unknown

264. Were any serum cardiac biomarkers assessed?

☐ Yes →
- 265. Date cardiac biomarkers were assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

Specify the cardiac biomarkers assessed:

266. Brain natriuretic peptide (BNP)

☐ Yes →
- 267. ___ ___ ___ ___ ___ • ___ pg/mL
- 268. Upper limit of normal for BNP: ___ ___ ___ ___ ___ • ___

☐ No

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

☐ Yes →
- 270. ___ ___ ___ ___ ___ • ___ pg/mL
- 271. Upper limit of normal for NT-proBNP: ___ ___ ___ ___ ___ • ___

☐ No

272. Troponin I

☐ Yes →
- 273. ___ ___ ___ ___ • ___ ___ ___ µg/L
- 274. Upper limit of normal for troponin I: ___ ___ ___ ___ • ___ ___ ___

☐ No

275. Troponin T

☐ Yes →
- 276. ___ ___ ___ ___ • ___ ___ ___ µg/L
- 277. Upper limit of normal for troponin T: ___ ___ ___ ___ • ___ ___ ___

☐ No

278. High sensitivity troponin T

☐ Yes →

279. ___ ___ ___ ___ • ___ ___ ___ ng/L

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

☐ No

281. Was a 6 minute walk test performed?

☐ Yes →

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

☐ No

283. 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

284. Recipient blood pressure (at last assessment prior to the start of preparative regimen)

☐ Known →

285. ___ ___ ___ / ___ ___ ___ mm/Hg

286. Indicate body position during blood pressure measurement:

☐ Sitting ☐ Standing ☐ Supine ☐ Unknown

☐ Unknown

Hepatic Involvement

287. 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

288. Specify the level of serum alkaline phosphatase

☐ Known →

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

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

☐ Unknown

POEMS Syndrome Assessment at Last Evaluation Prior to the Start of the Preparative Regimen / Infusion

Questions 291 - 296 for POEMS syndrome patients only. If diagnosis was other than POEMS or there is no evidence or history of it, skip to Signature Line.

291. Vascular endothelial growth factor (VEGF) serum value

☐ Known →

☐ Unknown

292. ___ ___ ___ • ___ pg/mL

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

294. Vascular endothelial growth factor (VEGF) plasma value

☐ Known →

☐ Unknown

295. ___ ___ ___ ___ • ___ pg/mL

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

First Name (person completing form): _____

Last Name:_____

E-mail address: _____

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

Response Codes

Stringent complete response (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 κ/λ ratio. 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/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 response (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.

No response (NR) / 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 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) (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.