Form 2116 R4.0: Plasma Cell Disorders (PCD) Post-Infusion Data

Center: CRID:

Key Fields

Sequence Number: _____

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: __ __ __ __ - __ __- __ __

Visit

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

Specify: _____

Disease Specificity

Questions: 1 - 2

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

Questions: 3 - 53

Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

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 6 if there is a diagnosis of concurrent or history of Amyloidosis**
- ○ no

5 Date assessed: __ __ __ __ - __ __- __ __ **- 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 ○ no

8 Date assessed: __ __ __ __ - __ __- __ __

Laboratory studies at the time of best response

9 Serum creatinine

- ○ Known ○ Unknown

10 _____ ○ mg/dL ○ mmol/L ○ µmol/L

11 Upper limit of normal for serum creatinine: _____

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

- ○ Known ○ Unknown ○ Not applicable

13 _____ ○ mg/dL ○ g/dL ○ g/L

14 Serum immunofixation

- ○ Known ○ Unknown ○ Not applicable

Specify bands present:

15 Original monoclonal bands

- ○ yes ○ no

16 New monoclonal (or oligoclonal) bands

- ○ yes ○ no

17 Serum free light chains - κ (kappa)

- ○ Known ○ Unknown ○ Not applicable

18 _____ ○ mg/dL ○ mg/L

CIBMTR Form 2116 revision 4.0 last updated Friday, January 24, 2020
Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

19 Upper limit of normal for K (kappa) free light chain _____

20 Serum free light chains - λ (lambda)

○ Known ○ Unknown ○ Not applicable

21 _____ ○ mg/dL ○ mg/L

22 Upper limit of normal for λ (lambda) free light chain _____

23 Urinary monoclonal protein (M-spike) / 24 hours

○ Known ○ Unknown ○ Not applicable

24 _____ ○ mg/24 hours ○ g/24 hours

25 Urinary immunofixation

○ Known ○ Unknown ○ Not applicable

Specify bands present:

26 Original monoclonal bands

○ yes ○ no

27 New monoclonal (or oligoclonal) bands

○ yes ○ no

28 Total urine protein in 24 hours

○ Known ○ Unknown ○ Not applicable

29 _____ ○ mg/24 hours ○ g/24 hours

30 Urine albumin / creatinine ratio

○ Known ○ Unknown

31 _____ ○ mg/g ○ mg/mmol

32 Urine protein / creatinine ratio

○ Known ○ Unknown

33 _____ ○ mg/g ○ mg/mmol

34 Was minimal residual disease (MRD) assessed post-HCT / CT or post-infusion evaluation? (report only bone marrow or blood results)

○ Yes ○ No ○ Unknown

35 Next generation sequencing (NGS)

○ Positive ○ Negative ○ Not done

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: _____

39 Next generation flow (NGF)

○ Positive ○ Negative ○ Not done

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: _____

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

CIBMTR Form 2116 revision 4.0 last updated Friday, January 24, 2020
Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

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: __ __ __ __ - __ __- __ __

Organ Parameters of Amyloidosis at the Time of Best Response

Questions: 54 - 109

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

55 Date assessed

○ Known ○ Unknown ○ Previously reported

56 Date assessed: __ __ __ __ - __ __- __ __

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 _____ m m

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: __ __ __ __ - __ __- __ __

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 ○ no

71 _____ pg/mL

72 Upper limit of normal for NT-proBNP: _____

73 Troponin I

○ yes ○ no

74 _____ µg/L

75 Upper limit of normal for troponin I: _____

76 Troponin T

○ yes ○ no

77 _____ µg/L

78 Upper limit of normal for troponin T: _____

Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

79 High sensitivity troponin T

○ yes ○ no

80 _____ ng/L

81 Upper limit of normal for high sensitivity troponin T: _____

82 Was a 6 minute walk test performed?

○ Yes ○ No

83 Distance walked: _____ ○ meters ○ feet

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 ○ Unknown

86 _____ / _____ mm/Hg

87 Indicate body position during blood pressure measurement

○ Sitting ○ Standing ○ Supine ○ 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**

○ No response / stable disease **- Does not meet criteria for renal response or renal progression**

○ 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**

○ Not assessed

○ Not applicable

89 Date assessed

○ Known ○ Unknown ○ Previously reported

90 Date assessed: __ __ __ __ - __ __ - __ __

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**

○ No response / stable disease **- Does not meet criteria for hepatic response or hepatic progression**

○ Hepatic progression **- ≥ 50% increase of alkaline phosphatase above the lowest value**

○ Not assessed

○ Not applicable

92 Date assessed

○ Known ○ Unknown ○ Previously reported

93 Date assessed: __ __ __ __ - __ __ - __ __

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 ○ Unknown ○ Previously reported

100 Date assessed: __ __ __ __ - __ __ - __ __

CIBMTR Form 2116 revision 4.0 last updated Friday, January 24, 2020
Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

Peripheral Nervous System Involvement

101 Specify the recipient's best peripheral nervous system response

- ○ Peripheral nervous system response **— Improvement in electromyogram nerve conduction velocity**
- ○ No response / stable disease **— Does not meet the criteria for peripheral nervous system response or peripheral nervous system progression**
- ○ Peripheral nervous system progression **— Progressive neuropathy by electromyography or nerve conduction velocity**
- ○ Not assessed
- ○ Not applicable

102 Date assessed

○ Known ○ Unknown ○ Previously reported

103 Date assessed: __ __ __ __ - __ __- __ __

Other Organ Involvement (1) — Questions: 104 - 109

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 ○ Unknown ○ Previously reported

109 Date assessed: __ __ __ __ - __ __- __ __

POEMS Syndrome Assessment at the Time of Best Response — Questions: 110 - 141

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

CIBMTR Form 2116 revision 4.0 last updated Friday, January 24, 2020
Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

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 ○ Unknown

128 _____ pg/mL

129 Upper limit of normal for interleukin-6: _____

130 Was pulmonary artery hypertension present?

○ Yes ○ No

131 Specify the estimated systolic artery pressure: _____ mm Hg

132 Forced vital capacity (FVC)

○ Known ○ Unknown

133 _____ %

134 Total lung capacity

○ Known ○ Unknown

135 _____ mL

136 Vascular endothelial growth factor (VEGF) serum value

○ Known ○ Unknown

137 _____ pg/mL

138 Upper limit of normal for serum VEGF: _____

139 Vascular endothelial growth factor (VEGF) plasma value

○ Known ○ Unknown

140 _____ pg/mL

141 Upper limit of normal for plasma VEGF: _____

Post-Infusion Therapy

Questions: 142 - 210

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 (1)

Questions: 143 - 166

Line of Therapy

143 Systemic therapy

○ yes ○ no

144 Date therapy started

○ Known ○ Unknown

145 Date started: __ __ __ __ - __ __ - __ __

146 Date therapy stopped

○ Known

○ Unknown

○ Not applicable **(still receiving therapy)**

147 Date stopped: __ __ __ __ - __ __ - __ __

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)

Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

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: __ __ __ __ - __ __- __ __

158 Date therapy stopped

○ Known

○ Unknown

○ Not applicable **(still receiving therapy)**

159 Date stopped: __ __ __ __ - __ __- __ __

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

CIBMTR Form 2116 revision 4.0 last updated Friday, January 24, 2020
Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

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: __ __ __ __ - __ __- __ __

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: __ __ __ __ - __ __- __ __

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

○ Yes ○ No ○ Unknown

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

169 Was treatment given for relapse or progression?

○ Yes ○ No

Line of Therapy (For Relapse or Progression) (1) — Questions: 170 - 189

Line of Therapy

170 Systemic therapy

○ yes ○ no

171 Date therapy started

○ Known ○ Unknown

172 Date started: __ __ __ __ - __ __- __ __

173 Date therapy stopped

- ○ Known
- ○ Unknown
- ○ Not applicable **(still receiving therapy)**

174 Date stopped: __ __ __ __ - __ __- __ __

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

CIBMTR Form 2116 revision 4.0 last updated Friday, January 24, 2020
Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

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: __ __ __ __ - __ __- __ __

185 Date therapy stopped

- ○ Known
- ○ Unknown
- ○ Not applicable **(still receiving therapy)**

186 Date stopped: __ __ __ __ - __ __- __ __

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

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

○ Yes ○ No ○ Unknown ○ Not Applicable

Line of Therapy (Maintenance) (1) **Questions: 191 - 210**

CIBMTR Form 2116 revision 4.0 last updated Friday, January 24, 2020
Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

Line of Therapy

191 Systemic therapy

○ yes ○ no

192 Date therapy started

○ Known ○ Unknown

193 Date started: __ __ __ __ - __ __- __ __

194 Date therapy stopped

○ Known

○ Unknown

○ Not applicable **(still receiving therapy)**

195 Date stopped: __ __ __ __ - __ __- __ __

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

Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

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: __ __ __ __ - __ __ - __ __

206 Date therapy stopped

○ Known

○ Unknown

○ Not applicable **(still receiving therapy)**

207 Date stopped: __ __ __ __ - __ __ - __ __

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

Disease Status at the Time of Evaluation for This Reporting Period

Questions: 211 - 252

211 Serum creatinine

○ Known ○ Unknown

212 _____ ○ mg/dL ○ mmol/L ○ µmol/L

213 Upper limit of normal for serum creatinine: _____

CIBMTR Form 2116 revision 4.0 last updated Friday, January 24, 2020
Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

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 K (kappa) free light chain _____

223 Serum free light chains — λ (lambda)

○ Known ○ Unknown ○ Not applicable

224 _____ ○ mg/dL ○ mg/L

225 Upper limit of normal for λ (lambda) free light chain _____

226 Total urine protein in 24 hours

○ Known ○ Unknown ○ Not applicable

227 _____ ○ mg/24 hours ○ g/24 hours

228 Urine albumin / creatinine ratio

○ Known ○ Unknown

229 _____ ○ mg/g ○ mg/mmol

230 Urine protein / creatinine ratio

○ Known ○ Unknown

231 _____ ○ mg/g ○ mg/mmol

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

○ Known ○ Unknown ○ Not applicable

233 _____ ○ mg/24 hours ○ g/24 hours

234 Urinary immunofixation

○ Known ○ Unknown ○ Not applicable

Specify bands present:

235 Original monoclonal bands

○ yes ○ no

CIBMTR Form 2116 revision 4.0 last updated Friday, January 24, 2020
Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

236 New monoclonal (or oligoclonal) bands
○ yes ○ no

237 Plasma cells in bone marrow aspirate by flow cytometry
○ Known ○ Unknown

238 _____ %

239 Plasma cells in bone marrow aspirate by morphologic assessment
○ Known ○ Unknown

240 _____ %

241 Plasma cells in bone marrow biopsy
○ Known ○ Unknown

242 _____ %

243 Did the recipient receive dialysis?
○ Yes ○ No

244 Date of dialysis
○ Known ○ Unknown

245 Date of dialysis: __ __ __ __ - __ __- __ __

246 Was a PET/CT scan performed during this reporting period?
○ yes ○ no

247 Was the PET/CT scan positive for myeloma involvement at any disease site?
○ Yes ○ No

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

249 Date of PET scan
○ Known ○ Unknown

250 Date of PET/CT scan: __ __ __ __ - __ __- __ __

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: __ __ __ __ - __ __- __ __

Current Status of Amyloidosis for This Reporting Period

Questions: 253 - 311

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: __ __ __ __ - __ __- __ __

CIBMTR Form 2116 revision 4.0 last updated Friday, January 24, 2020
Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

Form 2116 R4.0: Plasma Cell Disorders (PCD) Post-Infusion Data

Center: CRID:

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

257 Date assessed

Known Unknown

258 Date assessed: __ __ __ __ - __ __- __ __

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 Unknown

264 _____ m m

265 Specify left ventricular (LV) strain percentage

Known Unknown

266 _____ %

267 Were any serum cardiac biomarkers assessed?

yes no Unknown

268 Date cardiac biomarkers were assessed: __ __ __ __ - __ __- __ __

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

CIBMTR Form 2116 revision 4.0 last updated Friday, January 24, 2020
Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

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**
- ○ No response / stable disease **- Does not meet criteria for renal response or renal progression**
- ○ 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**
- ○ Not assessed
- ○ Not applicable

291 Date assessed

○ Known ○ Unknown

292 Date assessed: __ __ __ __ - __ __- __ __

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**
- ○ No response / stable disease **- Does not meet criteria for hepatic response or hepatic progression**
- ○ Hepatic progression **- ≥ 50% increase of alkaline phosphatase above the lowest value**
- ○ Not assessed
- ○ Not applicable

294 Date assessed

○ Known ○ Unknown

295 Date assessed: __ __ __ __ - __ __- __ __

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: __ __ __ __ - __ __- __ __

Peripheral Nervous System Involvement

303 Specify the recipient's current peripheral nervous system response

- ○ Peripheral nervous system response **- Improvement in electromyogram nerve conduction velocity (rare)**
- ○ No response / stable disease **- Does not meet criteria for peripheral nervous system response or peripheral nervous system progression**
- ○ Peripheral nervous system progression **- Progressive neuropathy by electromyography or nerve conduction velocity**
- ○ Not assessed
- ○ Not applicable

304 Date assessed

○ Known ○ Unknown

305 Date assessed: __ __ __ __ - __ __- __ __

CIBMTR Form 2116 revision 4.0 last updated Friday, January 24, 2020
Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

Other Organ Involvement (1) — Questions: 306 - 311

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: __ __ __ __ - __ __ - __ __

Current Status of POEMS Syndrome for This Reporting Period — Questions: 312 - 343

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: _____

CIBMTR Form 2116 revision 4.0 last updated Friday, January 24, 2020
Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.

Center: CRID:

332 Was pulmonary artery hypertension present?

○ Yes ○ No

333 Specify the estimated systolic artery pressure: _____ mm Hg

334 Forced vital capacity (FVC)

○ Known ○ Unknown

335 _____ %

336 Total lung capacity

○ Known ○ Unknown

337 _____ mL

338 Vascular endothelial growth factor (VEGF) serum value

○ Known ○ Unknown

339 _____ pg/mL

340 Upper limit of normal for serum VEGF: _____

341 Vascular endothelial growth factor (VEGF) plasma value

○ Known ○ Unknown

342 _____ pg/mL

343 Upper limit of normal for plasma VEGF: _____

First Name: _____

Last Name: _____

E-mail address: _____

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

CIBMTR Form 2116 revision 4.0 last updated Friday, January 24, 2020
Copyright(c) 2012 National Marrow Donor Program and
The Medical College of Wisconsin, Inc. All rights reserved.