

ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Initials:

Today's Date:

Month Day Year

Infusion Date:

Month Day Year

CIBMTR Center Number:

Form 2016 R4.0: Plasma Cell Disorders (PCD) Pre-Infusion Data

Center: _____ CRID: _____

Key Fields

Sequence Number: _____

Date Received: ____-____-____

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: ____-____-____

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 No

Disease Assessment at Diagnosis

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)

Diagnostic Studies (Measured Prior to Any Disease Treatment)

Questions: 3 - 60

Report values prior to first treatment for plasma cell disorder.

3 Hemoglobin

Known Unknown

4 _____ g/dL g/L mmol/L

5 Serum calcium

Known Unknown

6 _____ mg/dL mmol/L mEq/L

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Center:

CRID:

7 Serum creatinine

Known Unknown

8 _____ mg/dL mmol/L μ mol/L

9 Upper limit of normal for serum creatinine: _____

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

Known Unknown Not applicable

11 _____ mg/dL g/dL g/L

12 Serum immunofixation

Known Unknown Not applicable

13 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

14 Serum free light chains - κ (kappa)

Known Unknown Not applicable

15 _____ mg/dL mg/L

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

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

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Form 2016 R4.0: Plasma Cell Disorders (PCD) Pre-Infusion Data

Center:

CRID:

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

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Center: _____ CRID: _____

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: ____ - ____ - ____

Amyloidosis Organ Involvement at Diagnosis

Questions: 61 - 124

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 _____

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: _____ %

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CRID:

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: _____ - _____ - _____

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 no

88 _____ µg/L

89 Upper limit of normal for troponin I: _____

90 Troponin T

- yes no

91 _____ µg/L

92 Upper limit of normal for troponin T: _____

93 High sensitivity troponin T

- yes no

94 _____ ng/L

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

96 Was a 6 minute walk test performed?

- Yes No

97 Distance walked: _____ meters feet

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 Unknown

100 _____ / _____ mm/Hg

101 Indicate body position during blood pressure measurement

- Sitting Standing Supine Unknown

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Center: _____ CRID: _____

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

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Center: _____ CRID: _____

149 Total lung capacity

Known Unknown

150 _____ mL

151 Vascular endothelial growth factor (VEGF) serum value

Known Unknown

152 _____ pg/mL

153 Upper limit of normal for serum VEGF: _____ pg/mL

154 Vascular endothelial growth factor (VEGF) plasma value

Known Unknown

155 _____ pg/mL

156 Upper limit of normal for plasma VEGF: _____ pg/mL

Pre-Infusion Therapy

Questions: 157 - 187

157 Was therapy given?

yes no

Line of Therapy (1)

Questions: 158 - 187

158 Systemic therapy

yes no

159 Date therapy started

Known Unknown

160 Date started: _____ - _____ - _____

161 Date therapy stopped

Known
 Unknown
 Not applicable (still receiving therapy)

162 Date stopped: _____ - _____ - _____

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

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Center: _____ CRID: _____

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: _____ - _____ - _____

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CRID:

177 Date therapy stopped

- Known
 Unknown
 Not applicable (still receiving therapy)

178 Date stopped: ____-____-____

179 Dose of radiation therapy

- Known Unknown

180 Total dose: _____ Gy cGy

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

- yes - Also complete Pre-CTED Form 4000
 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)
 Unknown

183 Date assessed: ____-____-____

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)
 Unknown

185 Date assessed: ____-____-____

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

- yes no

187 Date of relapse/progression: ____-____-____

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

Questions: 188 - 255

188 Serum β_2 - microglobulin

- Known Unknown

189 _____ $\mu\text{g/dL}$ mg/L nmol/L

190 Plasma cells in blood by flow cytometry

- Known Unknown

191 _____ %

192 _____ $\times 10^9/\text{L}$ ($\times 10^3/\text{mm}^3$)

$\times 10^6/\text{L}$

193 Plasma cells in blood by morphologic assessment

- Known Unknown

194 _____ %

195 _____ $\times 10^9/\text{L}$ ($\times 10^3/\text{mm}^3$)

$\times 10^6/\text{L}$

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Center: _____ CRID: _____

196 Serum albumin

Known Unknown

197 _____ g/dL g/L

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

Known Unknown Not applicable

199 _____ mg/dL g/dL g/L

200 Serum immunofixation

Known Unknown Not applicable

Specify bands present:

201 Original monoclonal bands

yes no

202 New monoclonal (or oligoclonal) bands

yes no

203 Serum free light chains - κ (kappa)

Known Unknown Not applicable

204 _____ mg/dL mg/L

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

206 Serum free light chains - λ (lambda)

Known Unknown Not applicable

207 _____ mg/dL mg/L

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

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

Known Unknown Not applicable

210 _____ mg/24 hours g/24 hours

211 Urinary immunofixation

Known Unknown Not applicable

Specify bands present:

212 Original monoclonal bands

yes no

213 New monoclonal (or oligoclonal) bands

yes no

214 Total urine protein in 24 hours

Known Unknown Not applicable

215 _____ mg/24 hours g/24 hours

216 Urine albumin / creatinine ratio

Known Unknown

217 _____ mg/g mg/mmol

218 Urine protein / creatinine ratio

Known Unknown

219 _____ mg/g mg/mmol

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

Yes No Unknown

221 Next generation sequencing (NGS)

Positive Negative Not done

222 Sample source

Blood Bone marrow

223 Indicate the sensitivity of the NGS testing

10⁻⁴ 10⁻⁵ 10⁻⁶ Unknown Other

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Center:

CRID:

224 Specify other sensitivity: _____

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)

- +3
 +5
 +7
 +9
 +11
 +15
 +19
 t(4;14)
 t(6;14)
 t(11;14)
 t(14;16)
 t(14;20)
 del(13q) / 13q-
 del(17p) / 17p-
 -13
 -17
 Hyperdiploid (> 50)
 Hypodiploid (< 46)
 Any abnormality at 1q
 Any abnormality at 1p
 MYC rearrangement
 Other abnormality

240 Specify other abnormality: _____

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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)

- +3
- +5
- +7
- +9
- +11
- +15
- +19
- t(4;14)
- t(6;14)
- t(11;14)
- t(14;16)
- t(14;20)
- del(13q) / 13q-
- del(17p) / 17p-
- 13
- 17
- 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: ____-____-____

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

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

281 Was a 6 minute walk test performed?
 Yes No

282 Distance walked: _____ meters feet

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 Unknown

285 _____ / _____ mm/Hg

286 Indicate body position during blood pressure measurement
 Sitting Standing Supine 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 Unknown

289 _____ IU/L μ kat/L

290 Upper limit of normal for serum alkaline phosphatase : _____

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

Questions: 291 - 296

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: _____ pg/mL

294 Vascular endothelial growth factor (VEGF) plasma value
 Known Unknown

295 _____ pg/mL

296 Upper limit of normal for plasma VEGF: _____

First Name: _____

Last Name: _____

E-mail address: _____

Date: ____ - ____ - ____

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