Form 2016 R3.0: Plasma Cell Disorders Pre-HCT Data

Center: CRID:

Key Fields

Sequence Number: _____

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

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

Date of HCT for which this form is being completed: __ __ __ __ - __ __- __ __

HCT type: (check all that apply)

- Autologous
- Allogeneic, unrelated
- Allogeneic, related

Product type: (check all that apply)

- Bone marrow
- PBSC
- Single cord blood unit
- Multiple cord blood units
- Other product

Specify: _____

Subsequent Transplant

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

yes no

Is the second or subsequent transplant for relapse or progression of the same disease?

yes no

Disease Assessment at Diagnosis

Questions: 1 - 8

1 What is the diagnosis?

- Multiple myeloma (symptomatic)
- Plasma cell leukemia (PCL)
- Solitary plasmacytoma (in absence of bone marrow findings diagnostic for multiple myeloma or PCL)
- Amyloidosis
- Osteosclerotic myeloma / POEMS syndrome
- Light chain deposition disease
- Other plasma cell disorder (PCD)

2 Specify other plasma cell disorder: _____

3 Solitary plasmacytoma was

Extramedullary Bone derived

4 What was the date of diagnosis? __ __ __ __ - __ __- __ __

5 Did the recipient have a preceding or concurrent plasma cell disorder?

yes no Unknown

Preceding/Concurrent Disorder (1)

Questions: 6 - 8

6 Specify preceding / concurrent disorder

- Multiple myeloma (symptomatic)
- Smoldering myeloma (asymptomatic)
- Plasma cell leukemia
- Solitary plasmacytoma
- Amyloidosis
- Osteosclerotic myeloma / POEMS syndrome
- Light chain deposition disease
- Monoclonal gammopathy of unknown significance (MGUS)
- Other plasma cell disorder (PCD)

7 Specify other preceding/concurrent disorder:

_____

8 Date of diagnosis of preceding/concurrent disorder: __ __ __ __ - __ __- __ __

Laboratory Studies at Diagnosis

Questions: 9 - 118

Report values prior to first treatment for plasma cell disorder.

9 WBC

Known Unknown

10 _____

- x 10^9/L (x 10^3/mm^3)
- x 10^6/L

11 Hemoglobin

Known Unknown

12 _____

g/dL g/L mmol/L

13 Platelets

Known Unknown

14 _____

- x 10^9/L (x 10^3/mm^3)
- x 10^6/L

15 Absolute number of plasma cells in blood
(For PCL only)

Known Unknown

16 _____

- x 10^9/L (x 10^3/mm^3)
- x 10^6/L

17 Plasma cells in blood
(For PCL only)

Known Unknown

18 _____ %

19 Serum albumin

Known Unknown

20 _____ g/dL g/L

21 Serum calcium

Known Unknown

22 _____ mg/dL mmol/L mEq/L

23 Serum creatinine

Known Unknown

24 _____ mg/dL mmol/L µmol/L

25 Upper limit of normal for serum creatinine: _____ mg/dL mmol/L µmol/L

26 LDH

Known Unknown

27 _____ U/L µkat/L

28 Upper limit of normal for LDH: _____ U/L µkat/L

29 Serum β2 microglobulin

Known Unknown

30 _____ µg/dL mg/L nmol/L

31 What was the Durie-Salmon staging?

Stage I (All of the following: Hgb > 10g/dL; serum calcium normal or <10.5 mg/dL; bone x-ray normal bone structure (scale 0), or solitary bone plasmacytoma only; low M-component production rates IgG < 5g/dL, IgA < 3g/dL; urine light chain M-component on electrophoresis <4g/24h)

Stage II (Fitting neither Stage I or Stage III)

Stage III (One or more of the following: Hgb < 8.5 g/dL; serum calcium > 12 mg/dL; advanced lytic bone lesions (scale 3); high M-component production rates IgG >7g/dL, IgA > 5g/dL; Bence Jones protein >12g/24h)

Unknown

32 What was the Durie-Salmon sub classification?

A - relatively normal renal function (serum creatinine < 2.0 mg/dL)

B - abnormal renal function (serum creatinine ≥ 2.0 mg/dL)

33 Immunochemical type

secretory non-secretory

Specify paraproteins present:

34 Serum heavy chain

- IgG
- IgA
- IgM
- IgD
- IgE
- Biclonal
- Not applicable (light chain only disease)

35 Specify biclonal heavy chains: _____

36 Serum light chain

kappa lambda

37 Urine heavy chain

- IgG
- IgA
- IgM
- IgD
- IgE
- Biclonal
- Not applicable (light chain only disease)

38 Specify biclonal heavy chains: _____

39 Urine light chain

kappa lambda

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

Known Unknown

41 _____ mg/dL g/dL g/L

42 Urinary monoclonal protein (M-spike)

Known Unknown

43 _____ mg/24 hours

44 Total urinary protein excretion

Known Unknown

45 _____ g/24 hours

46 24-hour creatinine clearance

Known Unknown

47 _____ ml/minute

48 Serum free light chains — κ (kappa)

Known Unknown

49 _____ mg/dL mg/L

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

51 Serum free light chains — λ (lambda)

Known Unknown

52 _____ mg/dL mg/L

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

Specify the following serum quantitative immunoglobulins (measured prior to any disease treatment):

54 IgG

Known Unknown

55 _____ mg/dL g/dL g/L

56 Upper limit of normal for IgG: _____ mg/dL g/dL g/L

57 IgA

Known Unknown

58 _____ mg/dL g/dL g/L

59 Upper limit of normal for IgA: _____ mg/dL g/dL g/L

60 IgM

Known Unknown

61 _____ mg/dL g/dL g/L

62 Upper limit of normal for IgM: _____ mg/dL g/dL g/L

63 IgD

Known Unknown

64 _____ mg/dL g/dL g/L

65 Upper limit of normal for IgD: _____ mg/dL g/dL g/L

66 IgE

Known Unknown

67 _____ IU/mL

68 Upper limit of normal for IgE: _____ IU/mL

69 Plasma cells in bone marrow aspirate

Known Unknown

70 _____ %

71 Plasma cells in bone marrow biopsy

Known Unknown

72 _____ %

73 Were conventional cytogenetics tested?

yes no Unknown

74 Results of tests

Abnormalities identified

No evaluable metaphases

No abnormalities

Specify cytogenetic abnormalities identified via conventional cytogenetics at diagnosis:

Trisomy

75 +3

yes no

76 +5

yes no

77 +7

yes no

78 +9

yes no

79 +11

yes no

80 +15

yes no

81 +19

yes no

Translocation

82 t(4;14)

yes no

83 t(6;14)

yes no

84 t(11;14)

yes no

85 t(14;16)

yes no

86 t(14;20)

yes no

Deletion

87 del(13q) / 13q-

yes no

88 del (17p) / 17p-

yes no

Other

89 Hyperdiploid (>50)

yes no

90 Hypodiploid (<46)

yes no

91 Any abnormality at 1q

yes no

92 Any abnormality at 1p

yes no

93 Other abnormality

yes no

94 Specify other abnormality:

_____

95 Was documentation submitted to the CIBMTR?
(e.g. cytogenetic report)

yes no

96 Were cytogenetics tested via FISH?

yes no Unknown

97 Results of tests

Abnormalities identified

No abnormalities

Specify cytogenetic abnormalities identified via FISH at diagnosis:

Trisomy

98 +3

yes no

99 +5

yes no

100 +7

yes no

101 +9

yes no

102 +11

yes no

103 +15

yes no

104 +19

yes no

Translocation

105 t(4;14)

yes no

106 t(6;14)

yes no

107 t(11;14)

yes no

108 t(14;16)

yes no

109 t(14;20)

yes no

Deletion

110 del(13q) / 13q-

yes no

111 del (17p) / 17p-

yes no

Other

112 Any abnormality at 1q

yes no

113 Any abnormality at 1p

yes no

114 Other abnormality

yes no

115 Specify other abnormality: _____

116 Was documentation submitted to the CIBMTR?
(e.g. FISH report)

yes no

117 Was a gene expression profile performed?

yes no

118 Were results considered high risk myeloma?

yes no

Amyloidosis Organ Involvement at Diagnosis

Questions: 119 - 187

Questions 119 – 187 are for amyloid patients only. If diagnosis was other than amyloidosis (question 1), or there is no evidence or history of it (question 6), skip to question 188.
Specify organ involvement prior to any treatment:

119 Was an abdominal fat aspirate performed?

yes no

120 Specify the aspirate results

Positive (for amyloid involvement)

Negative

Unknown

Renal Involvement

121 Was a renal biopsy performed?

yes no

122 Specify the renal biopsy results

- Positive (for amyloid involvement)
- Negative
- Unknown

Cardiac Involvement

123 Was a cardiographic imaging procedure performed?

- yes
- no

124 Was a cardiac MRI done?

- yes
- no

125 Specify cardiac MRI results

- Normal
- Abnormal
- Unknown

126 Was the left ventricular ejection fraction measured?

- yes
- no

127 Specify the left ventricular ejection fraction: _____ %

128 Specify the method used to determine the left ventricular ejection fraction

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

129 Was diastolic dysfunction present?

- yes
- no
- Unknown

130 Specify the interventricular septal wall thickness measured by echocardiogram

- Known
- Unknown

131 _____ mm

132 Was a cardiac biopsy performed?

- yes
- no

133 Specify the cardiac biopsy results

- Positive (for amyloid involvement)
- Negative
- Unknown

134 Were any serum cardiac biomarkers assessed?

- yes
- no
- Unknown

Specify the cardiac biomarkers assessed:

135 Brain natriuretic peptide (BNP)

- yes
- no

136 Specify the BNP level: _____ pg/mL

137 Upper limit of normal for BNP: _____ pg/mL

138 N-terminal prohormone brain natriuretic peptide (NT-proBNP)

yes no

139 Specify the NT-proBNP level: _____ pg/mL

140 Upper limit of normal for NT-proBNP: _____ pg/mL

141 Troponin I

yes no

142 Specify the troponin I level: _____ µg/L

143 Upper limit of normal for troponin I: _____ µg/L

144 Troponin T

yes no

145 Specify the troponin T level: _____ µg/L

146 Upper limit of normal for troponin T: _____ µg/L

147 High sensitivity troponin T

yes no

148 Specify the high sensitivity troponin T level: _____ µg/L

149 Upper limit of normal for high sensitivity troponin T: _____ µg/L

150 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

Gastrointestinal Involvement

151 Was there clinical suspicion of gastrointestinal (GI) involvement?

yes no Unknown

Specify the site(s) of GI involvement:

152 Upper GI tract

yes no

153 Lower GI tract

yes no

154 Was a gastrointestinal biopsy performed?

yes no

Specify site(s) of GI biopsy:

155 Rectal

yes no

156 Specify the rectal biopsy results

Positive (for amyloid involvement)

Negative

Unknown

157 Other site

yes no

158 Specify other GI biopsy site: _____

159 Specify the biopsy results

Positive (for amyloid involvement)

Negative

Unknown

Hepatic Involvement

160 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

161 Specify the level of serum alkaline phosphatase

Known Unknown

162 _____ IU/L μkat/L

163 Upper limit of normal for serum alkaline phosphatase : _____ IU/L μkat/L

164 Was a liver biopsy performed?

yes no

165 Specify the liver biopsy results

Positive (for amyloid involvement)

Negative

Unknown

Peripheral Neuropathy

166 Was a sensory / motor exam performed?

yes no Unknown

167 Specify the exam results

Normal Abnormal Unknown

168 Was a nerve biopsy performed?

yes no

Specify site(s) of nerve biopsy:

169 Sural

yes no

170 Specify the sural nerve biopsy results

Positive (for amyloid involvement)

Negative

Unknown

171 Other site

yes no

Other Nerve Biopsy Site (1) **Questions: 172 - 173**

172 Specify other nerve biopsy site: _____

173 Specify other nerve biopsy results

- Positive (for amyloid involvement)
- Negative
- Unknown

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

yes no

175 Specify other evidence: _____

Autonomic Neuropathy

176 Did the recipient display symptomatic orthostatic hypotension (not attributable to medications or volume depletion)?

yes no

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

yes no

178 Specify other evidence: _____

Other Site(s)

179 Did the recipient display any other clinical organ involvement?

yes no

Specify the evidence of other organ involvement:

180 Arthropathy

yes no

181 Lung

yes no

182 Soft tissue

yes no

183 Tongue (macroglossia)

yes no

184 Other organ involvement

yes no

185 Specify other organ: _____

186 Was a biopsy performed?

yes no

187 Specify the biopsy results

- Positive (for amyloid involvement)
- Negative
- Unknown

Pre-HCT Therapy

Questions: 188 - 232

188 Was therapy given?

yes no

189 Systemic therapy

yes no

190 Date therapy started

Known Unknown

191 Date started: __ __ __ __ - __ __- __ __

192 Date therapy stopped

Known Unknown

193 Date stopped: __ __ __ __ - __ __- __ __

194 Number of cycles

Known Unknown

195 Number of cycles: _____

196 VCD (Bortezomib (Velcade), cyclophosphamide, dexamethasone)

yes no

197 RVD/VRD (Bortezomib (Velcade), dexamethasone, Lenalidomide (Revlimid))

yes no

198 DVD/VDD (Bortezomib (Velcade), dexamethasone, liposomal doxorubicin (Doxil))

yes no

199 RD (Dexamethasone, Lenalidomide (Revlimid))

yes no

200 Bendamustine

yes no

201 Bortezomib (Velcade)

yes no

202 Carfilzomib

yes no

203 Carmustine (BCNU, Gliadel)

yes no

204 Cisplatin (Platinol, CDDP)

yes no

205 Clarithromycin (Biaxin)

yes no

206 Corticosteroids

yes no

207 Cyclophosphamide (Cytoxan)

yes no

208 Cytarabine (Ara-C)

yes no

209 Doxorubicin (Adriamycin)

yes no

210 Doxorubicin liposomal (Doxil)

yes no

211 Elotuzumab

yes no

212 Etoposide (VP-16, VePesid)

yes no

213 Idarubicin (Idamycin)

yes no

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

yes no

215 Lenalidomide (Revlimid)

yes no

216 Melphalan (L-PAM, Alkeran)

yes no

217 MLN 9708

yes no

218 Pomalidomide

yes no

219 Thalidomide (Thalomid)

yes no

220 Vorinostat

yes no

221 Other systemic therapy

yes no

222 Specify other systemic therapy: _____

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

yes no

224 Radiation therapy

yes no

225 Date therapy started

Known Unknown

226 Date started: __ __ __ __ - __ __- __ __

227 Date therapy stopped

Known Unknown

228 Date stopped: __ __ __ __ - __ __- __ __

229 Best response to line of therapy

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

230 Date assessed: __ __ __ __ - __ __- __ __

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

- yes
- no

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

Laboratory Studies at Last Evaluation Prior to Start of Preparative Regimen(Conditioning)

Questions: 233 - 325

233 Absolute number of plasma cells in blood
(For PCL only)

- Known
- Unknown

234 _____

- x 10^9/L (x 10^3/mm^3)
- x 10^6/L

235 Plasma cells in blood

(For PCL only)

Known Unknown

236 _____ %

237 Serum albumin

Known Unknown

238 _____ g/dL g/L

239 Serum calcium

Known Unknown

240 _____ mg/dL mmol/L mEq/L

241 Serum β2 microglobulin

Known Unknown

242 _____ µg/dL mg/L nmol/L

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

Known Unknown

244 _____ mg/dL g/dL g/L

245 Serum immunofixation

Known Unknown

246 Specify monoclonal immunoglobulin result

Present Absent

Specify bands present:

247 Original monoclonal bands

yes no

248 New monoclonal (or oligoclonal) bands

yes no

249 Urinary monoclonal protein (M-spike)

Known Unknown

250 _____ mg/24 hours

251 Urinary immunofixation

Known Unknown

252 Specify monoclonal immunoglobulin result

Present Absent

Specify bands present:

253 Original monoclonal bands

yes no

254 New monoclonal (or oligoclonal) bands

yes no

255 Total urinary protein excretion

Known Unknown

256 _____ g/24 hours

257 24-hour creatinine clearance

Known Unknown

258 _____ ml/minute

259 Serum free light chains — κ (kappa)

Known Unknown

260 _____ mg/dL mg/L

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

262 Serum free light chains — λ (lambda)

Known Unknown

263 _____ mg/dL mg/L

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

Specify the following serum quantitative immunoglobulins:

265 IgG

Known Unknown

266 _____ mg/dL g/dL g/L

267 Upper limit of normal for IgG: _____ mg/dL g/dL g/L

268 IgA

Known Unknown

269 _____ mg/dL g/dL g/L

270 Upper limit of normal for IgA: _____ mg/dL g/dL g/L

271 IgM

Known Unknown

272 _____ mg/dL g/dL g/L

273 Upper limit of normal for IgM: _____ mg/dL g/dL g/L

274 IgD

Known Unknown

275 _____ mg/dL g/dL g/L

276 Upper limit of normal for IgD: _____ mg/dL g/dL g/L

277 IgE

Known Unknown

278 _____ IU/mL

279 Upper limit of normal for IgE: _____ IU/mL

280 Plasma cells in bone marrow aspirate

Known Unknown

281 _____ %

282 Plasma cells in bone marrow biopsy

Known Unknown

283 _____ %

284 Were conventional cytogenetics tested?

yes no Unknown

285 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:

Trisomy

286 +3

yes no

287 +5

yes no

288 +7

yes no

289 +9

yes no

290 +11

yes no

291 +15

yes no

292 +19

yes no

Translocation

293 t(4;14)

yes no

294 t(6;14)

yes no

295 t(11;14)

yes no

296 t(14;16)

yes no

297 t(14;20)

yes no

Deletion

298 del(13q) / 13q-

yes no

299 del (17p) / 17p-

yes no

Other

300 Hyperdiploid (>50)

yes no

301 Hypodiploid (<46)

yes no

302 Any abnormality at 1q

yes no

303 Any abnormality at 1p

yes no

304 Other abnormality

yes no

305 Specify other abnormality: _____

306 Were cytogenetics tested via FISH?

yes no Unknown

307 Results of tests

Abnormalities identified

No abnormalities

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

Trisomy

308 +3

yes no

309 +5

yes no

310 +7

yes no

311 +9

yes no

312 +11

yes no

313 +15

yes no

314 +19

yes no

Translocation

315 t(4;14)

yes no

316 t(6;14)

yes no

317 t(11;14)

yes no

318 t(14;16)

yes no

319 t(14;20)

yes no

Deletion

320 del(13q) / 13q-

yes no

321 del (17p) / 17p-

yes no

Other

322 Any abnormality at 1q

yes no

323 Any abnormality at 1p

yes no

324 Other abnormality

yes no

325 Specify other abnormality: _____

Amyloidosis Organ Involvement at Last Evaluation Prior to Start of Preparative Regimen(Conditioning) Questions: 326 - 362

Complete questions 326 – 362 are for amyloid patients only. If diagnosis was other than amyloidosis (question 1), or there is no evidence or history of it (question 6), skip to question 363.
Specify organ involvement prior to any treatment:

Cardiac Involvement

326 Was a cardiographic imaging procedure performed?

yes no Unknown

327 Was a cardiac MRI done?

yes no

328 Specify cardiac MRI results

Normal Abnormal Unknown

329 Was the left ventricular ejection fraction measured?

yes no

330 Specify the left ventricular ejection fraction: _____ %

331 Specify the method used to determine the left ventricular ejection fraction

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

332 Was diastolic dysfunction present?

yes no Unknown

333 Specify the interventricular septal wall thickness measured by echocardiogram

Known Unknown

334 _____ mm

335 Were any serum cardiac biomarkers assessed?

yes no Unknown

Specify the cardiac biomarkers assessed:

336 Brain natriuretic peptide (BNP)

yes no

337 Specify the BNP level: _____ pg/mL

338 Upper limit of normal for BNP: _____ pg/mL

339 N-terminal prohormone brain natriuretic peptide (NT-proBNP)

yes no

340 Specify the NT-proBNP level: _____ pg/mL

341 Upper limit of normal for NT-proBNP: _____ pg/mL

342 Troponin I

yes no

343 Specify the troponin I level: _____ µg/L

344 Upper limit of normal for troponin I: _____ µg/L

345 Troponin T

yes no

346 Specify the troponin T level: _____ µg/L

347 Upper limit of normal for troponin T: _____ µg/L

348 High sensitivity troponin T

yes no

349 Specify the high sensitivity troponin T level: _____ µg/L

350 Upper limit of normal for high sensitivity troponin T: _____ µg/L

351 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

Hepatic Involvement

352 Hepatomegaly (liver edge palpable > 3 cm below right costal margin)

yes no Unknown

353 Specify the level of serum alkaline phosphatase

Known Unknown

354 _____ IU/L µkat/L

355 Upper limit of normal for serum alkaline phosphatase : _____ IU/L µkat/L

Peripheral Neuropathy

356 Was a sensory / motor exam performed?

yes no Unknown

357 Specify the exam results

Normal Abnormal Unknown

358 Did the recipient display any new evidence of peripheral nerve involvement with amyloidosis?

yes no Unknown

359 Specify other evidence: _____

Autonomic Neuropathy

360 Did the recipient display symptomatic orthostatic hypotension (not attributable to medications or volume depletion)?

yes no Unknown

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

yes no Unknown

362 Specify other evidence: _____

Disease Status at the Last Evaluation Prior to Start of Preparative Regimen(Conditioning)

Questions: 363 - 364

363 What was the disease status?

(Report the most recent disease assessment prior to the preparative regimen.)

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

364 Date assessed: __ __ __ __ - __ __- __ __

First Name: _____

Last Name: _____

E-mail address: _____

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