

# ERROR CORRECTION FORM

Sequence Number:

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CIBMTR Recipient ID:

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Initials:

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Today's Date:

		2	0		
Month	Day	Year			

Infusion Date:

		2	0		
Month	Day	Year			

CIBMTR Center Number:

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## Multiple Myeloma / Plasma Cell Leukemia Pre-HSCT Data

### Registry Use Only

Sequence Number:

Date Received:


CIBMTR Center Number:

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CIBMTR Recipient ID:

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Today's Date:

				2	0		
Month	Day	Year					

Date of HSCT for which this form is being completed:

				2	0		
Month	Day	Year					

HSCT type:  autologous  allogeneic, unrelated  allogeneic, related  syngeneic (identical twin)

Product type:  marrow  PBSC  cord blood  other product, specify: \_\_\_\_\_

This form must be accompanied by Form 2000 – Recipient Baseline Data. All information in the box above, including the date, should be identical with the corresponding Form 2000. Information should come from an actual examination by the Transplant Center physician, or the physician who is following the recipient pre-HSCT, or abstraction of the recipient's medical records.

Questions followed by the symbol indicate additional information necessary to complete the question is referenced in the forms instruction manual.

If this is a report of a second or subsequent transplant, check here  and continue with question 132.

## Disease Assessment at Diagnosis

Specify the disease diagnoses:

1. Multiple myeloma

- 1  yes  
2  no

2. Specify date of diagnosis:

Month	Day	Year					

3. Plasma cell leukemia (PCL)

- 1  yes  
2  no

4. Specify date of diagnosis:

Month	Day	Year					

5. Solitary plasmacytoma (in absence of bone marrow findings diagnostic for multiple myeloma or PCL)

- 1  yes  
2  no

6. Specify date of diagnosis:

								<input type="checkbox"/> date unknown
Month	Day	Year						

7. Monoclonal gammopathy of unknown significance (MGUS) prior to diagnosis for multiple myeloma or PCL

- 1  yes  
2  no

8. Specify date of diagnosis:

								<input type="checkbox"/> date unknown
Month	Day	Year						

9. Amyloidosis (at any time)

- 1  yes  
2  no

10. Specify date of diagnosis:

								<input type="checkbox"/> date unknown
Month	Day	Year						



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32. If questions 30 and 31 are "not known," what was the International Staging System (ISS) stage at diagnosis?

- 1  Stage I ( $\beta_2$ -microglobulin < 3.5 mg/dL, albumin  $\geq$  3.5 g/dL)
- 2  Stage II ( $\beta_2$ -microglobulin < 3.5 and albumin < 3.5; or  $\beta_2$ -microglobulin between 3.5 and 5.5)
- 3  Stage III: ( $\beta_2$ -microglobulin > 5.5)
- 4  unknown

33. Serum calcium:

- 1  known  $\rightarrow$    .
- 2  not known

Specify units:

- 1  mg/dL
- 2  mmol/L
- 3  mEq/L

34. Serum creatinine:

- 1  known  $\rightarrow$      .
- 2  not known
- 3  non-secretory

- 1  mg/dL
- 2  mmol/L
- 3   $\mu$ mol/L

35. Upper limit of normal for serum creatinine:





36. Serum monoclonal Ig: (only from electrophoresis) (monoclonal (M-spike) protein level) (This value will be used to calculate the best response to HSCT if question 131 is answered as option 1.)

- 1  known  $\rightarrow$      .
- 2  not known
- 3  non secretory

- 1  mg/dL
- 2  g/dL
- 3  g/L

37. Urinary monoclonal light chains:

- 1  known  $\rightarrow$      .  g / 24 hours
- 2  not known

38. Serum free light chains —  $\kappa$  (kappa):

- 1  known  $\rightarrow$      .
- 2  not known

- 1  mg/dL
- 2  mg/L

39. Upper limit of normal for  $\kappa$  free light chain:





- 1  mg/dL
- 2  mg/L

40. Serum free light chains —  $\lambda$  (lambda):

- 1  known  $\rightarrow$      .
- 2  not known

- 1  mg/dL
- 2  mg/L

41. Upper limit of normal for  $\lambda$  free light chain:





- 1  mg/dL
- 2  mg/L

42. LDH:

- 1  known  $\rightarrow$        .
- 2  not known

- 1  U/L
- 2   $\mu$ kat/L

43. Upper limit of normal for LDH:





- 1  U/L
- 2   $\mu$ kat/L

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

44. IgG:

- 1  known  $\rightarrow$        .
- 2  not known

- 1  mg/dL
- 2  g/dL
- 3  g/L

45. Upper limit of normal for IgG:       .

46. Lower limit of normal for IgG:       .

47. IgA:

- 1  known  $\rightarrow$        .
- 2  not known

- 1  mg/dL
- 2  g/dL
- 3  g/L

48. Upper limit of normal for IgA:       .

49. Lower limit of normal for IgA:       .

50. IgM:

- 1  known  $\rightarrow$        .
- 2  not known

- 1  mg/dL
- 2  g/dL
- 3  g/L

51. Upper limit of normal for IgM:       .

52. Lower limit of normal for IgM:       .

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## Pre-HSCT Treatment for Plasma Cell Disorders

53. Was therapy given between diagnosis and the start of the preparative regimen?

- 1  yes →  
2  no

Line of Therapy:	1st Line of Therapy	2nd Line of Therapy																				
<b>Systemic Therapy:</b>	54. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with q. 78	92. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with q. 116																				
Date therapy started:	55. <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr><tr><td>Month</td><td>Day</td><td>Year</td><td>Year</td><td></td></tr></table>						Month	Day	Year	Year		93. <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr><tr><td>Month</td><td>Day</td><td>Year</td><td>Year</td><td></td></tr></table>						Month	Day	Year	Year	
Month	Day	Year	Year																			
Month	Day	Year	Year																			
Date therapy stopped:	56. <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr><tr><td>Month</td><td>Day</td><td>Year</td><td>Year</td><td></td></tr></table>						Month	Day	Year	Year		94. <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr><tr><td>Month</td><td>Day</td><td>Year</td><td>Year</td><td></td></tr></table>						Month	Day	Year	Year	
Month	Day	Year	Year																			
Month	Day	Year	Year																			
Number of cycles:	57. <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table> <input type="checkbox"/> unknown/not applicable			95. <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table> <input type="checkbox"/> unknown/not applicable																		
bortezomib (Velcade)	58. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	96. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
carmustine (BCNU, Gliadel)	59. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	97. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
cisplatin (Platinol, CDDP)	60. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	98. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
clarithromycin (Biaxin)	61. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	99. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
corticosteroids	62. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	100. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
cyclophosphamide (Cytosan)	63. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	101. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
cytarabine (Ara-C)	64. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	102. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
doxorubicin (Adriamycin)	65. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	103. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
doxorubicin liposomal (Doxil)	66. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	104. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
etoposide (VP-16, VePesid)	67. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	105. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
idarubicin (Idamycin)	68. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	106. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
interferon (Intron, Roferon) (includes PEG)	69. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	107. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
lenalidomide (Revlimid)	70. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	108. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
melfalan (L-PAM, Alkeran)	71. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	109. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
mitoxantrone (Novantrone)	72. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	110. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
rituximab (anti-CD20, Rituxan)	73. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	111. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
thalidomide (Thalomid)	74. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	112. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
vincristine (VCR, Oncovin)	75. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	113. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
other systemic therapy	76. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	114. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
specify other therapy	77. _____	115. _____																				
<b>Supportive Care:</b>	78. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with q. 84	116. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with q. 122																				
bisphosphonates (pamidronate [Aredia], zoledronic acid [Zometa])	79. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	117. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
erythroid stimulants (epoetin [EPO, Procrit], darbepoetin [Aranesp])	80. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	118. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
kyphoplasty	81. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	119. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
vertebroplasty	82. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	120. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
specify number of vertebrae	83. <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>			121. <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td></tr></table>																		
<b>Radiation Therapy:</b>	84. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with q. 87	122. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with q. 125																				
Date therapy started:	85. <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr><tr><td>Month</td><td>Day</td><td>Year</td><td>Year</td><td></td></tr></table>						Month	Day	Year	Year		123. <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr><tr><td>Month</td><td>Day</td><td>Year</td><td>Year</td><td></td></tr></table>						Month	Day	Year	Year	
Month	Day	Year	Year																			
Month	Day	Year	Year																			
Date therapy stopped:	86. <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr><tr><td>Month</td><td>Day</td><td>Year</td><td>Year</td><td></td></tr></table>						Month	Day	Year	Year		124. <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr><tr><td>Month</td><td>Day</td><td>Year</td><td>Year</td><td></td></tr></table>						Month	Day	Year	Year	
Month	Day	Year	Year																			
Month	Day	Year	Year																			
Was this line of therapy given for stem cell priming?	87. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	125. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
<b>Best Response to Line of Therapy:</b> (see page 8 for definitions)	88. 1 <input type="checkbox"/> sCR 2 <input type="checkbox"/> CR 3 <input type="checkbox"/> VGPR 4 <input type="checkbox"/> PR 5 <input type="checkbox"/> SD 6 <input type="checkbox"/> PD 7 <input type="checkbox"/> unknown	126. 1 <input type="checkbox"/> sCR 2 <input type="checkbox"/> CR 3 <input type="checkbox"/> VGPR 4 <input type="checkbox"/> PR 5 <input type="checkbox"/> SD 6 <input type="checkbox"/> PD 7 <input type="checkbox"/> unknown																				
Date response established:	89. <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr><tr><td>Month</td><td>Day</td><td>Year</td><td>Year</td><td></td></tr></table>						Month	Day	Year	Year		127. <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr><tr><td>Month</td><td>Day</td><td>Year</td><td>Year</td><td></td></tr></table>						Month	Day	Year	Year	
Month	Day	Year	Year																			
Month	Day	Year	Year																			
Did disease relapse/progress following this line of therapy?	90. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	128. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no																				
Date of relapse/progression:	91. <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr><tr><td>Month</td><td>Day</td><td>Year</td><td>Year</td><td></td></tr></table>						Month	Day	Year	Year		129. <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td><td style="width: 20px;"></td></tr><tr><td>Month</td><td>Day</td><td>Year</td><td>Year</td><td></td></tr></table>						Month	Day	Year	Year	
Month	Day	Year	Year																			
Month	Day	Year	Year																			

Copy this page to report more than 2 lines of therapy; check here  if additional pages are attached.

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Initials:

Today's Date:

 /  /   
Month Day Year

Infusion Date:

 /  /   
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130. Specify the sensitivity of myeloma to chemotherapy prior to the preparative regimen:

(Treatment must have been completed  $\leq$  6 months prior to HSCT.)

- 1  sensitive —  $\geq$  50% reduction in Ig level, or  $\geq$  90% reduction in urinary light chains in light chain only disease, or  $\geq$  50% reduction of plasma cells in bone marrow for nonsecretory myeloma (includes disease status of sCR, CR, VGPR and PR)
- 2  resistant —  $<$  50% reduction of Ig level, or  $<$  90% reduction in urinary light chains in light chain only disease, or  $<$  50% reduction of plasma cells in bone marrow for nonsecretory myeloma (includes disease status of SD and PD)
- 3  not applicable — no chemotherapy, or chemotherapy ended more than 6 months prior to the preparative regimen
- 4  unknown

131. At what point in the disease course was the HSCT performed?

- 1  as part of *initial therapy* for a recipient with *no disease progression* at any time prior to HSCT
- 2  *later* in the disease course for a recipient *with disease progression* at any time prior to HSCT

## Laboratory Studies Prior to the Start of the Preparative Regimen

132. Plasma cells in bone marrow aspirate:

- 1  known  $\longrightarrow$   %
- 2  not known

133. Plasma cells in bone marrow biopsy:

- 1  known  $\longrightarrow$   %
- 2  not known

134. Plasma cells in bone marrow, sample source unknown:

- 1  known  $\longrightarrow$   %
- 2  not known

135. Serum albumin:

- 1  known  $\longrightarrow$   .  Specify units: 1  g/dL
- 2  not known 2  g/L

136. Serum  $\beta_2$  microglobulin:

- 1  known  $\longrightarrow$   .  1   $\mu$ g/dL
- 2  not known 2  mg/L
- 3  nmol/L

137. Serum monoclonal Ig: (only from electrophoresis) (This value will be used to calculate the best response to HSCT.) (This value will be used to calculate the best response to HSCT if question 131 is answered as option 2.)

- 1  known  $\longrightarrow$   .  1  mg/dL
- 2  not known 2  g/dL
- 3  g/L

138. For recipients with PCL only: Are circulating plasma cells currently present?

- 1  yes
- 2  no

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139. Were cytogenetics tested (conventional or FISH)?

- 1  yes  
 2  no  
 3  unknown

140. Results of test at diagnosis:

- 1  yes abnormalities identified → **Complete questions 142–160 in the table below**  
 2  no evaluable metaphases  
 3  no abnormalities

141. Results of tests after diagnosis to prior to the preparative regimen:

- 1  yes abnormalities identified → **Complete questions 161–179 in the table below**  
 2  no evaluable metaphases on any tests  
 3  no abnormalities on any tests after diagnosis and before the preparative regimen

Specify abnormalities identified:

Cytogenetic abnormality	At diagnosis	Any test result between diagnosis and preparative regimen
Monosomy		
–13	142. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	161. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
Trisomy		
+3	143. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	162. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
+5	144. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	163. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
+7	145. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	164. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
+9	146. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	165. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
+11	147. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	166. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
+15	148. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	167. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
+19	149. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	168. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
Translocation		
t(4;14)	150. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	169. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
t(6;14)	151. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	170. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
t(11;14)	152. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	171. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
t(14;16)	153. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	172. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
Deletion		
del 13/13q–	154. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	173. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
del 17/17p–	155. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	174. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
Other		
hyperdiploid (> 50)	156. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	175. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
hypodiploid (< 46)	157. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	176. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
any abnormality at 1q	158. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	177. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
other abnormality	159. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	178. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
specify other abnormality:	160. _____	179. _____

180. Is a copy of the cytogenetic or FISH report attached?

- 1  yes  
 2  no

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## Disease Status at the Last Evaluation Prior to the Preparative Regimen

181. What was the disease status prior to the preparative regimen?

(Report the most recent disease assessment prior to the preparative regimen.) (see page 8 for definitions)

- 1  stringent complete response (sCR) →
- 2  complete response (CR) →
- 3  very good partial response (VGPR) →
- 4  partial response (PR) →
- 5  stable disease (SD)
- 6  progressive disease (PD) →
- 7  relapse from CR (Rel) (untreated) →
- 8  disease status unknown

182. Specify the date of the most recent assessment for disease status prior to the preparative regimen: ☞

		2	0		
Month	Day	Year			

183. Signed: \_\_\_\_\_

*Person completing form*

Please print name: \_\_\_\_\_

Phone: (\_\_\_\_\_) \_\_\_\_\_

Fax: (\_\_\_\_\_) \_\_\_\_\_

E-mail address: \_\_\_\_\_

# ERROR CORRECTION FORM

Sequence Number:

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CIBMTR Recipient ID:

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Initials:

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Today's Date:

		2	0		
Month	Day	Year			

Infusion Date:

		2	0		
Month	Day	Year			

CIBMTR Center Number:

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## Response Codes

**Stringent complete response (sCR)** — CR as defined below, plus:

- normal free light chain ratio, and
- absence of clonal cells in the bone marrow by immunohistochemistry or immunofluorescence (confirmation with repeat bone marrow biopsy not needed). (Presence and/or absence of clonal cells is based upon the  $\kappa/\lambda$  ratio. An abnormal  $\kappa/\lambda$  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  $\kappa/\lambda$  of  $> 4:1$  or  $< 1:2$ .)

sCR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy sCR requirements.

**Complete response (CR)** — negative immunofixation on serum and urine samples, and disappearance of any soft tissue plasmacytomas, and  $\leq 5\%$  plasma cells in the bone marrow (confirmation with repeat bone marrow biopsy not needed).

CR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy CR requirements.

**Very good partial response (VGPR)** — serum and urine M-protein detectable by immunofixation but not on electrophoresis, or  $\geq 90\%$  reduction in serum M-protein and urine M-protein level  $< 100$  mg/24 hours

VGPR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy VGPR requirements.

**Partial response (PR)** —  $\geq 50\%$  reduction in serum M-protein, and reduction in 24-hour urinary M-protein by  $\geq 90\%$  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  $\geq 1$  g/dL

• urine M-protein  $\geq 200$  mg/24 hours • serum free light chain assay shows involved level  $\geq 10$  mg/dL, provided serum free light chain ratio is abnormal), a  $\geq 50\%$  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  $\geq 50\%$  reduction in plasma cells is required in place of M-protein, provided the baseline bone marrow plasma cell percentage was  $\geq 30\%$ . In addition to the above listed criteria, a  $\geq 50\%$  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  $\geq 25\%$  from baseline in:

- serum M-component and/or (absolute increase  $\geq 0.5$  g/dL) (for progressive disease, serum M-component increases of  $\geq 1$  g/dL are sufficient to define relapse if the starting M-component is  $\geq 5$  g/dL)
- urine M-component and/or (absolute increase  $\geq 200$  mg/24 hours)
- for recipients without measurable serum and urine M-protein levels: the difference between involved and uninvolved free light chain levels (absolute increase  $> 10$  mg/dL)
- bone marrow plasma cell percentage (absolute percentage  $\geq 10\%$ ) (relapse from CR has a 5% cutoff vs. 10% for other categories of relapse)
- 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)** — requires one or more of the following:

- reappearance of serum or urine M-protein by immunofixation or electrophoresis
- development of  $\geq 5\%$  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.