CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Multiple Myeloma / Plasma Cell Leukemia Pre-HSCT Data

Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number:

CIBMTR Recipient ID:

Today's Date: Month Day Year (2 0 __ __)

Date of HSCT for which this form is being completed: 🕮 Month Day Year (2 0 __ __)

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. Specify date of diagnosis: Month Day Year
   2 ☐ no

3. Plasma cell leukemia (PCL)
   1 ☐ yes → 4. Specify date of diagnosis: Month Day Year
   2 ☐ no

5. Solitary plasmacytoma (in absence of bone marrow findings diagnostic for multiple myeloma or PCL)
   1 ☐ yes → 6. Specify date of diagnosis: Month Day Year ☐ date unknown
   2 ☐ no

7. Monoclonal gammopathy of unknown significance (MGUS) prior to diagnosis for multiple myeloma or PCL
   1 ☐ yes → 8. Specify date of diagnosis: Month Day Year ☐ date unknown
   2 ☐ no

9. Amyloidosis (at any time) 🕮
   1 ☐ yes → 10. Specify date of diagnosis: Month Day Year ☐ date unknown
   2 ☐ no

CIBMTR Form 2016 (MYE) v1.0 (1–8) July 2007

For internal use only: Document F00504 version 1.0 Replaces: n/a

Mail this form to your designated campus (Milwaukee or Minneapolis). Retain the original at the transplant center.

CIBMTR Center Number: ☐☐☐☐☐ CIBMTR Recipient ID: ☐☐☐☐☐☐☐☐☐☐

Laboratory Studies at Diagnosis

Report values prior to first treatment for multiple myeloma / PCL.

11. *For PCL only:* Plasma cells in blood:
    1 ☐ known → ☐☐ %
    2 ☐ not known

12. *For PCL only:* Absolute number of plasma cells in blood:
    1 ☐ known → ☐☐☐☐☐.☐☐
    2 ☐ not known
    Specify units:
    1 ☐ x 10^9/L (x 10^3/mm^3)
    2 ☐ x 10^6/L

13. Immunochemical type:
    1 ☐ secretory →
    2 ☐ non-secretory

    Specify paraproteins present: *(IFE results; see quantification at question 35.)*

	Chain type					Source	
	IgG	IgA	IgM 🕮	IgD	IgE	Serum	Urine
14. Heavy chain 1	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	15. 1 ☐	2 ☐
16. Heavy chain 2	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	17. 1 ☐	2 ☐

	Chain type		Source	
	κ (kappa)	λ (lambda)	Serum	Urine
18. Light chain 1	1 ☐	2 ☐	19. 1 ☐	2 ☐
20. Light chain 2	1 ☐	2 ☐	21. 1 ☐	2 ☐

22. WBC:
    1 ☐ known → ☐☐☐☐☐☐.☐
    2 ☐ not known
    1 ☐ x 10^9/L (x 10^3/mm^3)
    2 ☐ x 10^6/L

23. Hemoglobin:
    1 ☐ known → ☐☐☐☐.☐☐
    2 ☐ not known
    1 ☐ g/dL
    2 ☐ g/L
    3 ☐ mmol/L
    → 24. Was RBC transfused in the prior 30 days?
    1 ☐ yes
    2 ☐ no

25. Platelets:
    1 ☐ known → ☐☐☐☐☐☐☐
    2 ☐ not known
    1 ☐ x 10^9/L (x 10^3/mm^3)
    2 ☐ x 10^6/L
    → 26. Were platelets transfused in the prior 7 days?
    1 ☐ yes
    2 ☐ no

27. Plasma cells in bone marrow aspirate:
    1 ☐ known → ☐☐☐ %
    2 ☐ not known

28. Plasma cells in bone marrow biopsy:
    1 ☐ known → ☐☐☐ %
    2 ☐ not known

29. Plasma cells in bone marrow, sample source unknown:
    1 ☐ known → ☐☐☐ %
    2 ☐ not known

30. Serum albumin: 🕮
    1 ☐ known → ☐☐.☐
    2 ☐ not known
    1 ☐ g/dL
    2 ☐ g/L

31. Serum β_2 microglobulin:
    1 ☐ known → ☐☐☐.☐☐☐
    2 ☐ not known
    1 ☐ µg/dL
    2 ☐ mg/L
    3 ☐ nmol/L

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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 ($ß_2$-microglobulin < 3.5 mg/dL, albumin ≥ 3.5 g/dL)
- 2 ☐ Stage II ($ß_2$-microglobulin < 3.5 and albumin < 3.5; or $ß_2$-microglobulin between 3.5 and 5.5)
- 3 ☐ Stage III: ($ß_2$-microglobulin > 5.5)
- 4 ☐ unknown

33. Serum calcium:
- 1 ☐ known → ☐☐.☐☐
- 2 ☐ not known

Specify units:
- 1 ☐ mg/dL
- 2 ☐ mmol/L
- 3 ☐ mEq/L

34. Serum creatinine:
- 1 ☐ known → ☐☐☐.☐☐
- 2 ☐ not known
- 3 ☐ non-secretory

- 1 ☐ mg/dL
- 2 ☐ mmol/L
- 3 ☐ µmol/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 → ☐☐☐☐.☐
- 2 ☐ not known
- 3 ☐ non secretory

- 1 ☐ mg/dL
- 2 ☐ g/dL
- 3 ☐ g/L

37. Urinary monoclonal light chains:
- 1 ☐ known → ☐☐☐.☐ g / 24 hours
- 2 ☐ not known

38. Serum free light chains — κ (kappa):
- 1 ☐ known → ☐☐☐.☐☐
- 2 ☐ not known

- 1 ☐ mg/dL
- 2 ☐ mg/L

→ 39. Upper limit of normal for κ free light chain: ☐☐☐.☐☐
- 1 ☐ mg/dL
- 2 ☐ mg/L

40. Serum free light chains — λ (lambda):
- 1 ☐ known → ☐☐☐.☐☐
- 2 ☐ not known

- 1 ☐ mg/dL
- 2 ☐ mg/L

→ 41. Upper limit of normal for λ free light chain: ☐☐☐.☐☐
- 1 ☐ mg/dL
- 2 ☐ mg/L

42. LDH:
- 1 ☐ known → ☐☐☐☐☐.☐☐
- 2 ☐ not known

- 1 ☐ U/L
- 2 ☐ µkat/L

→ 43. Upper limit of normal for LDH: ☐☐☐☐☐.☐☐
- 1 ☐ U/L
- 2 ☐ µkat/L

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

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

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

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130. Specify the sensitivity of myeloma to chemotherapy prior to the preparative regimen:
(Treatment must have been completed ≤ 6 months prior to HSCT.)
1 ☐ sensitive — ≥ 50% reduction in 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 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 → | | | | %
2 ☐ not known

133. Plasma cells in bone marrow biopsy:
1 ☐ known → | | | | %
2 ☐ not known

134. Plasma cells in bone marrow, sample source unknown:
1 ☐ known → | | | | %
2 ☐ not known

135. Serum albumin:
1 ☐ known → | | . |
2 ☐ not known
Specify units:
1 ☐ g/dL
2 ☐ g/L

136. Serum β_2 microglobulin:
1 ☐ known → | | | . | | |
2 ☐ not known
1 ☐ µg/dL
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 → | | | | . |
2 ☐ not known
1 ☐ mg/dL
2 ☐ g/dL
3 ☐ g/L

138. *For recipients with PCL only:* Are circulating plasma cells currently present?
1 ☐ yes
2 ☐ no

CIBMTR Center Number: | | | | | | CIBMTR Recipient ID: | | | | | | | | | | |

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

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

1 ☐ yes
2 ☐ no

CIBMTR Center Number: | | | | | | CIBMTR Recipient ID: | | | | | | | | | | |

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: 🕮

Month | | Day | | Year 2 0 | |

183. Signed: _____
Person completing form

Please print name: _____

Phone: (_____) _____

Fax: (_____) _____

E-mail address: _____

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 κ/λ ratio. An abnormal κ/λ ratio by immunohistochemistry and/or immunofluorescence requires a minimum of 100 plasma cells for analysis. An abnormal ratio reflecting the presence of an abnormal clone is κ/λ of > 4:1 or < 1:2.)

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

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

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

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

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

Partial response (PR) — ≥ 50% reduction in serum M-protein, and reduction in 24-hour urinary M-protein by ≥ 90% or to < 200 mg/24 hours.

If the serum and urine M-protein are unmeasurable (i.e., do not meet any of the following criteria: • serum M-protein ≥ 1 g/dL • urine M-protein ≥ 200 mg/24 hours • serum free light chain assay shows involved level ≥ 10 mg/dL, provided serum free light chain ratio is abnormal), a ≥ 50% decrease in the difference between involved and uninvolved free light chain levels is required in place of the M-protein criteria. If serum and urine M-protein are unmeasurable, and serum free light assay is also unmeasurable, a ≥ 50% reduction in plasma cells is required in place of M-protein, provided the baseline bone marrow plasma cell percentage was ≥ 30%. In addition to the above listed criteria, a ≥ 50% reduction in the size of soft tissue plasmacytomas is also required, if present at baseline.

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

Stable disease (SD) — not meeting the criteria for CR, VGPR, PR or PD.

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

Progressive disease (PD) — requires any one or more of the following:

Increase of ≥ 25% from baseline in:
- serum M-component and/or (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)
- urine M-component and/or (absolute increase ≥ 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 ≥ 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 ≥ 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.