

ERROR CORRECTION FORM

Sequence Number:

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CIBMTR Recipient ID:

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Visit:

100 day
 6 month

 year

Today's Date:

Month	Day	20		Year															

Infusion Date:

Month	Day	20		Year															

CIBMTR Center Number:

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Initials:

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Multiple Myeloma / Plasma Cell Leukemia Post-HSCT Data

Registry Use Only

Sequence Number:

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Date Received:

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CIBMTR Center Number:

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CIBMTR Recipient ID:

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Today's Date:

Month	Day	20		Year															

Date of HSCT for which this form is being completed:

Month	Day	Year																	

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

Product type: marrow PBSC cord blood other product, specify: _____

Visit: 100 day 6 month 1 year 2 years > 2 years, specify:

To be completed in conjunction with a Form 2100 – 100 Days Post-HSCT Data, Form 2200 – Six Months to Two Years Post-HSCT Data, or Form 2300 – Yearly Follow-Up for Greater Than Two Years Post-HSCT Data. Information reported here should reflect the date of last contact as reported in the post-HSCT data collection form, or immediately prior to death.

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

Disease Assessment at the Time of Best Response to HSCT

Best response is based on response to the HSCT, but does NOT include response to any therapy given for disease relapse or progression post-HSCT. If the HSCT was planned as part of initial therapy for a recipient with no disease progression or relapse at any time prior to HSCT, (see Form 2016, question 131, option 1), determine the best response by comparing to the disease status at the time of initial diagnosis. If the HSCT was performed later in the disease course for a recipient with disease relapse or progression at any time prior to HSCT (see Form 2016, question 131, option 2), determine best response by comparing to the disease status immediately prior to the start of the preparative regimen. This comparison is meant to capture the best disease status in response to HSCT that occurred in the reporting interval, even if a subsequent disease relapse or progression occurred during the same reporting interval. If a recipient already achieved their best response in a previous reporting interval, confirm the best response and check the box to indicate "date previously reported."

1. Compared to the disease status prior to the preparative regimen, what was the best response to HSCT since the date of the last report? (see definitions on page 6)

- 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) —————>

2. Specify the date the best response first began:

Month	Day	20		Year															

date previously reported —————> **Continue with question 20**

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100 day
 6 month
 year

Today's Date:

Month Day Year

Infusion Date:

Month Day Year

CIBMTR Center Number:

Initials:

CIBMTR Center Number:

CIBMTR Recipient ID:

Laboratory Studies at the Time of Best Response to HSCT

3. Plasma cells in bone marrow aspirate:

1 known → %

2 not known

4. Plasma cells in bone marrow biopsy:

1 known → %

2 not known

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

1 known → %

2 not known

6. Serum monoclonal Ig: (only from electrophoresis)

1 known → . mg/dL

2 not known

3 non secretory

1 mg/dL

2 g/dL

3 g/L

7. Serum immunofixation:

1 known →

2 not known

8. Specify monoclonal immunoglobulin result:

1 present / positive →

2 absent / negative

Specify bands currently present:

9. 1 yes 2 no Original monoclonal bands

10. 1 yes 2 no New monoclonal bands

11. Urinary monoclonal light chains:

1 known → . g/24 hours

2 not known

12. Urinary immunofixation:

1 known →

2 not known

13. Specify monoclonal immunoglobulin result:

1 present / positive →

2 absent / negative

Specify bands currently present:

14. 1 yes 2 no Original monoclonal bands

15. 1 yes 2 no New monoclonal bands

16. Serum free light chains — κ (kappa):

1 known → . mg/dL

2 not known

1 mg/dL

2 mg/L

17. Upper limit of normal for κ free light chain:

. mg/dL

2 mg/L

18. Serum free light chains — λ (lambda):

1 known → . mg/dL

2 not known

1 mg/dL

2 mg/L

19. Upper limit of normal for λ free light chain:

. mg/dL

2 mg/L

ERROR CORRECTION FORM

Sequence Number:

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Visit:

100 day

6 month

year

Today's Date:

Month Day Year

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Month Day Year

CIBMTR Center Number:

Initials:

CIBMTR Center Number:

CIBMTR Recipient ID:

Post-HSCT Treatment for Multiple Myeloma / Plasma Cell Leukemia

20. Was planned treatment per protocol given since the date of the last report? (Include any maintenance therapy, but exclude any treatment for relapse or progressive disease.)

- 1 yes
2 no
3 unknown

Line of Therapy:	1st Line of Therapy	2nd Line of Therapy
Systemic Therapy:	21. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with q. 45	52. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with q. 76
Date therapy started:	22. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	53. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Date therapy stopped:	23. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	54. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Number of cycles:	24. <input type="text"/> <input type="text"/> <input type="checkbox"/> unknown/not applicable	55. <input type="text"/> <input type="text"/> <input type="checkbox"/> unknown/not applicable
bortezomib (Velcade)	25. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	56. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
carmustine (BCNU, Gliadel)	26. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	57. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
cisplatin (Platinol, CDDP)	27. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	58. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
clarithromycin (Biaxin)	28. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	59. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
corticosteroids <input type="checkbox"/>	29. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	60. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
cyclophosphamide (Cytoxan)	30. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	61. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
cytarabine (Ara-C)	31. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	62. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
doxorubicin (Adriamycin)	32. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	63. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
doxorubicin liposomal (Doxil)	33. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	64. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
etoposide (VP-16, VePesid)	34. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	65. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
idarubicin (Idamycin)	35. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	66. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
interferon (Intron, Roferon) (includes PEG)	36. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	67. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
lenalidomide (Revlimid)	37. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	68. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
melfhalan (L-PAM, Alkeran)	38. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	69. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
mitoxantrone (Novantrone)	39. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	70. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
rituximab (anti-CD20, Rituxan)	40. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	71. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
thalidomide (Thalomid)	41. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	72. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
vincristine (VCR, Oncovin)	42. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	73. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
other systemic therapy specify other therapy	43. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	74. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
	44. <input type="text"/>	75. <input type="text"/>
Radiation Therapy:	45. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with q. 48	76. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with q. 79
Date therapy started:	46. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	77. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Date therapy stopped:	47. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	78. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Best Response to Line of Therapy: (see definitions on page 6)	48. 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	79. 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:	49. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	80. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Did patient relapse/progress following this line of therapy?	50. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	81. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
Date of relapse/progression:	51. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	82. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

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

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

- 1 yes
2 no

84. Specify the date of disease relapse or progression:

Month Day Year

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Visit:

- 100 day
 6 month
 year

Today's Date:

Month Day Year

Infusion Date:

Month Day Year

CIBMTR Center Number:

Initials:

CIBMTR Center Number:

CIBMTR Recipient ID:

Disease Status at the Time of Evaluation for This Reporting Period

85. Plasma cells in bone marrow aspirate:

- 1 known → %

2 not known

86. Plasma cells in bone marrow biopsy:

- 1 known → %

2 not known

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

- 1 known → %

2 not known

88. Serum monoclonal Ig: (*only from electrophoresis*)

- 1 known → . 1 mg/dL

2 not known

3 non secretory

2 g/dL

3 g/L

89. Serum immunofixation:

- 1 known →

2 not known

90. Specify monoclonal immunoglobulin result:

- 1 present / positive →

2 absent / negative

Specify bands currently present:

91. 1 yes 2 no Original monoclonal bands

92. 1 yes 2 no New monoclonal bands

93. Urinary monoclonal light chains:

- 1 known → . g/24 hours

2 not known

94. Urinary immunofixation:

- 1 known →

2 not known

95. Specify monoclonal immunoglobulin result:

- 1 present / positive →

2 absent / negative

Specify bands currently present:

96. 1 yes 2 no Original monoclonal bands

97. 1 yes 2 no New monoclonal bands

98. Serum free light chains — κ (kappa):

- 1 known → .

2 not known

- 1 mg/dL

2 mg/L

99. Upper limit of normal for κ free light chain:

.

1 mg/dL

2 mg/L

100. Serum free light chains — λ (lambda):

- 1 known → .

2 not known

- 1 mg/dL

2 mg/L

101. Upper limit of normal for λ free light chain:

.

1 mg/dL

2 mg/L

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CIBMTR Recipient ID:

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Visit:

100 day

6 month

--	--

 year

Today's Date:

				2	0		
Month	Day	Year					

Infusion Date:

				2	0		
Month	Day	Year					

CIBMTR Center Number:

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Initials:

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CIBMTR Center Number:

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CIBMTR Recipient ID:

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102. What is the current disease status?

1 complete remission

2 not in complete remission

103. Date the current disease status was established in this reporting period:

				2	0		
Month	Day	Year					

104. Signed: _____
Person completing form

Please print name: _____

Phone number: (_____) _____

Fax number: (_____) _____

E-mail address: _____

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CIBMTR Recipient ID:

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Visit:

100 day
 6 month

--	--

 year

Today's Date:

		2	0		
Month	Day	Year			

Infusion Date:

		2	0		
Month	Day	Year			

CIBMTR Center Number:

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Initials:

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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 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 $\leq 5\%$ 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 ≥ 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 $\geq 50\%$ 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 ≥ 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 $\geq 10\%$) (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.