

# 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:

|       |     |    |  |      |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Month | Day | 20 |  | Year |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

Infusion Date:

|       |     |    |  |      |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Month | Day | 20 |  | Year |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

CIBMTR Center Number:

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## Amyloidosis 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:

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| Month | Day | 20 |  | Year |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

Date of HSCT for which this form is being completed:

|       |     |  |  |      |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 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.

## Hematologic and Organ Parameters at the Time of Best Response

Specify the recipient's best response to the HSCT for each of the following hematologic and organ systems:

### Cardiac

1. Specify the recipient's best cardiac response to the HSCT:

- 1  cardiac response — requires any of the following: •  $\geq 2$  mm decrease in mean interventricular septal wall thickness by echocardiogram •  $\geq 20\%$  increase in left ventricular ejection fraction •  $\geq 2$  grade decrease in New York Heart Association functional class without an increase in diuretic use • no increase in wall thickness
- 2  no response / stable disease — does not meet criteria for cardiac response nor progressive disease
- 3  progressive disease — requires any of the following: •  $\geq 2$  mm increase from baseline in interventricular septal wall thickness by echocardiogram •  $\geq 10\%$  decrease in left ventricular ejection fraction •  $\geq 1$  grade increase in New York Heart Association functional class
- 4  cardiac best response not assessed
- 5  cardiac best response not evaluable → 



 2. Specify reason: \_\_\_\_\_

3. Date best cardiac response was first documented:

- 1  known →
- 2  not known

### Gastrointestinal

4. Was there clinical improvement in GI involvement in response to the HSCT?

- 1  yes
- 2  no
- 3  unknown

5. Date best GI response was first documented:

- 1  known →
- 2  not known

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CIBMTR Recipient ID:

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:

## Hepatic

6. Specify the recipient's best hepatic response to the HSCT:

- 1  hepatic response — requires all of the following: •  $\geq 2$  cm decrease in liver span if hepatomegaly present (liver span  $> 15$  cm) •  $\geq 50\%$  decrease and/or normalization of serum alkaline phosphatase level
- 2  no response / stable disease — does not meet criteria for hepatic response nor progressive disease
- 3  progressive disease — requires any of the following: •  $\geq 50\%$  increase in serum alkaline phosphatase level
- 4  hepatic best response not assessed
- 5  hepatic best response not evaluable →  7. Specify reason: \_\_\_\_\_

8. Date best hepatic response was first documented:

- 1  known →     
Month Day Year
- 2  not known

## Autonomic Nervous

9. Specify the best response of autonomic neuropathy to the HSCT:

- 1  autonomic neuropathy response — resolution of symptomatic orthostatic hypotension
- 2  no response / stable disease — does not meet criteria for autonomic neuropathy response nor progressive disease
- 3  progressive disease — worsening of symptomatic orthostatic hypotension not attributable to medications or blood volume depletion
- 4  autonomic neuropathy best response not assessed
- 5  autonomic neuropathy best response not evaluable →  10. Specify reason: \_\_\_\_\_

11. Date best autonomic neuropathy response was first documented:

- 1  known →     
Month Day Year
- 2  not known

12. Specify the best response of peripheral neuropathy to the HSCT:

- 1  peripheral neuropathy response — requires any of the following: • resolution of abnormal physical findings • resolution or improvement of abnormal EMG and/or NCV findings
- 2  no response / stable disease — does not meet criteria for peripheral neuropathy response nor progressive disease
- 3  progressive disease — requires any of the following: • worsening of physical findings • worsening of EMG and/or NCV findings
- 4  peripheral neuropathy best response not assessed
- 5  peripheral neuropathy best response not evaluable →  13. Specify reason: \_\_\_\_\_

14. Date best peripheral neuropathy response was first documented:

- 1  known →     
Month Day Year
- 2  not known

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  year

Today's Date:

/  /   
Month Day Year

Infusion Date:

/  /   
Month Day Year

CIBMTR Center Number:

Initials:

CIBMTR Center Number:

CIBMTR Recipient ID:

## Hematologic (Immunochemical)

15. Specify the recipient's best hematologic response to the HSCT:

- 1  complete response (CR) — requires all of the following: • serum and urine negative for monoclonal proteins by immunofixation • normal free light chain ratio • plasma cells in marrow < 5%
- 2  partial response (PR) — requires any of the following: •  $\geq 50\%$  reduction in current serum monoclonal protein levels > 0.5 g/dL •  $\geq 50\%$  reduction in current urine light chain levels > 100 mg/day with a visible peak •  $\geq 50\%$  reduction in current free light chain levels > 10 mg/dL
- 3  no response (NR) / stable disease (SD) — does not meet criteria for CR, PR nor progressive disease
- 4  progressive disease — requires any of the following: • if progressing from CR, any detectable monoclonal protein or abnormal free light chain ratio (light chain must double) • if progressing from PR or SD,  $\geq 50\%$  increase in serum M protein to > 0.5 g/dL, or  $\geq 50\%$  increase in urine M protein to > 200 mg/day with visible peak present • free light chain increase of  $\geq 50\%$  to > 10 mg/dL (100 mg/L)
- 5  hematologic best response not assessed
- 6  hematologic best response not evaluable → 16. Specify reason:

17. Date best hematologic (immunochemical) response was first documented:

- 1  known →  /  /   
Month Day Year
- 2  not known

## Renal

18. Specify the recipient's best renal response to the HSCT:

- 1  renal response —  $\geq 50\%$  decrease of at least 0.5 g/day in 24 hour urine protein of > 0.5 g/day pre-treatment — creatinine and creatinine clearance must not have worsened by  $\geq 25\%$  over baseline
- 2  no response / stable disease — does not meet criteria for renal response nor progressive disease
- 3  progressive disease — requires any of the following: •  $\geq 50\%$  increase of at least 1 g/day for urine protein to > 1 g/day • 25% worsening of serum creatinine or creatinine clearance
- 4  renal best response not assessed
- 5  renal best response not evaluable → 19. Specify reason:

20. Date best renal response was first documented:

- 1  known →  /  /   
Month Day Year
- 2  not known

## Other system

21. Did any other system respond to the HCST?

- 1  yes →
- 2  no

22. Specify other system:

23. Specify best response to HSCT for this system:

- 1  response
- 2  no response / stable disease
- 3  progressive disease
- 4  other system best response not evaluable → 24. Specify reason:

25. Date the best response for this system was first documented:

- 1  known →  /  /   
Month Day Year
- 2  not known



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 6 month  
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Today's Date:

/  /   
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/  /   
Month Day Year

CIBMTR Center Number:

Initials:

CIBMTR Center Number:

CIBMTR Recipient ID:

## Gastrointestinal

45. Was there clinical improvement in GI involvement since the date of the last report?

- 1  yes  
2  no  
3  unknown

46. Date current GI status was first documented:

- 1  known →  /  /   
Month Day Year  
2  not known

## Hepatic

47. Specify the recipient's current hepatic status:

- 1  hepatic response — requires all of the following: •  $\geq 2$  cm decrease in liver span if hepatomegaly present (liver span > 15 cm) •  $\geq 50\%$  decrease and/or normalization of serum alkaline phosphatase level  
2  no response / stable disease — does not meet criteria for hepatic response nor progressive disease  
3  progressive disease — requires any of the following: •  $\geq 50\%$  increase in serum alkaline phosphatase level  
4  hepatic current status not assessed  
5  hepatic current status not evaluable → 48. Specify reason:

49. Date current hepatic status was first documented:

- 1  known →  /  /   
Month Day Year  
2  not known

## Autonomic Nervous

50. Specify the current status of autonomic neuropathy:

- 1  autonomic neuropathy response — resolution of symptomatic orthostatic hypotension  
2  no response / stable disease — does not meet criteria for autonomic neuropathy response nor progressive disease  
3  progressive disease — worsening of symptomatic orthostatic hypotension not attributable to medications or blood volume depletion  
4  autonomic neuropathy current status not assessed  
5  autonomic neuropathy current status not evaluable → 51. Specify reason:

52. Date current autonomic neuropathy status was first documented:

- 1  known →  /  /   
Month Day Year  
2  not known

53. Specify the current status of peripheral neuropathy:

- 1  peripheral neuropathy response — requires any of the following: • resolution of abnormal physical findings • resolution or improvement of abnormal EMG and/or NCV findings  
2  no response / stable disease — does not meet criteria for peripheral neuropathy response nor progressive disease  
3  progressive disease — requires any of the following: • worsening of physical findings • worsening of EMG and/or NCV findings  
4  peripheral neuropathy current status not assessed  
5  peripheral neuropathy current status not evaluable → 54. Specify reason:

55. Date current peripheral neuropathy status was first documented:

- 1  known →  /  /   
Month Day Year  
2  not known

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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:

## Hematologic (Immunochemical)

56. Specify the recipient's current hematologic status:

- 1  complete response (CR) — requires all of the following: • serum and urine negative for monoclonal proteins by immunofixation • normal free light chain ratio • plasma cells in marrow < 5%
- 2  partial response (PR) — requires any of the following: •  $\geq 50\%$  reduction in current serum monoclonal protein levels > 0.5 g/dL •  $\geq 50\%$  reduction in current urine light chain levels > 100 mg/day with a visible peak •  $\geq 50\%$  reduction in current free light chain levels > 10 mg/dL
- 3  no response (NR) / stable disease (SD) — does not meet criteria for CR, PR nor progressive disease
- 4  progressive disease — requires any of the following: • if progressing from CR, any detectable monoclonal protein or abnormal free light chain ratio (light chain must double) • if progressing from PR or SD,  $\geq 50\%$  increase in serum M protein to > 0.5 g/dL, or  $\geq 50\%$  increase in urine M protein to > 200 mg/day with visible peak present • free light chain increase of  $\geq 50\%$  to > 10 mg/dL (100 mg/L)
- 5  hematologic current status not assessed
- 6  hematologic current status not evaluable → 57. Specify reason:

58. Date current hematologic status was first documented:

- 1  known →  /  /   
Month Day Year
- 2  not known

## Renal

59. Specify the recipient's current renal status:

- 1  renal response —  $\geq 50\%$  decrease of at least 0.5 g/day in 24 hour urine protein of > 0.5 g/day pre-treatment — creatinine and creatinine clearance must not have worsened by  $\geq 25\%$  over baseline
- 2  no response / stable disease — does not meet criteria for renal response nor progressive disease
- 3  progressive disease — requires any of the following: •  $\geq 50\%$  increase of at least 1 g/day for urine protein to > 1 g/day • 25% worsening of serum creatinine or creatinine clearance
- 4  renal best response not assessed
- 5  renal best response not evaluable → 60. Specify reason:

61. Date current renal status was first documented:

- 1  known →  /  /   
Month Day Year
- 2  not known

## Other system

62. Was any other system assessed for current status?

- 1  yes →
- 2  no

63. Specify other system:

64. Specify the current status of this system:

- 1  response
- 2  no response / stable disease
- 3  progressive disease
- 4  other system best response not evaluable →

65. Specify reason:

66. Date the current status of this system was first documented:

- 1  known →  /  /   
Month Day Year
- 2  not known

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67. Plasma cells in bone marrow aspirate:

1  known →  %  source (aspirate vs. biopsy) unknown  
2  not known

68. Plasma cells in bone marrow biopsy:

1  known →  %  source (aspirate vs. biopsy) unknown  
2  not known

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

1  known →  .  1  mg/dL  
2  not known 2  g/dL  
3  g/L

70. Serum free light chain, κ (kappa)

1  known →  .  1  mg/dL  
2  not known 2  g/dL  
3  g/L

71. Serum free light chain, λ (lambda)

1  known →  .  1  mg/dL  
2  not known 2  g/dL  
3  g/L

72. Urinary monoclonal light chains:

1  known →  .  1  g/24 hours  
2  not known 2  mg/24 hours

73. Signed: \_\_\_\_\_

*Person completing form*

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

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

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

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