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

**Cardiac**

1. Specify the recipient’s best cardiac response to the HSCT:
   - ☐ cardiac response — requires any of the following: • ≥ 2 mm decrease in mean interventricular septal wall thickness by echocardiogram • ≥ 20% increase in left ventricular ejection fraction • ≥ 2 grade decrease in New York Heart Association functional class without an increase in diuretic use • no increase in wall thickness
   - ☐ no response / stable disease — does not meet criteria for cardiac response nor progressive disease
   - ☐ progressive disease — requires any of the following: • ≥ 2 mm increase from baseline in interventricular septal wall thickness by echocardiogram • ≥ 10% decrease in left ventricular ejection fraction • ≥ 1 grade increase in New York Heart Association functional class
   - ☐ cardiac best response not assessed
   - ☐ cardiac best response not evaluable

2. Specify reason: __________________________

3. Date best cardiac response was first documented:
   - ☐ known
   - ☐ unknown

4. Date of HSCT for which this form is being completed:
   - Month __ Day __ Year

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

6. Product type: ☐ marrow ☐ PBSC ☐ cord blood ☐ other product, specify: __________________________

### Gastrointestinal

4. Was there clinical improvement in GI involvement in response to the HSCT?
   - ☐ yes
   - ☐ no
   - ☐ unknown

5. Date best GI response was first documented:
   - ☐ known
   - ☐ unknown

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**Registry Use Only**

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<thead>
<tr>
<th>Registry Use Only</th>
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<tbody>
<tr>
<td><strong>Sequence Number:</strong></td>
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<td><strong>Date Received:</strong></td>
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**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.**

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

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).
6. Specify the recipient’s best hepatic response to the HSCT:
   1. hepatic response — requires all of the following: • ≥ 2 cm decrease in liver span if hepatomegaly present (liver span > 15 cm) • ≥ 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: • ≥ 50% increase in serum alkaline phosphatase level
   4. hepatic best response not assessed
   5. hepatic best response not evaluable

8. Date best hepatic response was first documented:
   1. known
   2. not known

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

11. Date best autonomic neuropathy response was first documented:
    1. known
    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

14. Date best peripheral neuropathy response was first documented:
    1. known
    2. not known
### 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: ≥ 50% reduction in current serum monoclonal protein levels > 0.5 g/dL, ≥ 50% reduction in current urine light chain levels > 100 mg/day with a visible peak, ≥ 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 or 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, ≥ 50% increase in serum M protein to > 0.5 g/dL, or ≥ 50% increase in urine M protein to > 200 mg/day with visible peak present, free light chain increase of ≥ 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
- [ ] 2 not known

Month Day Year

### Renal

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

1. **Renal response** — ≥ 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 ≥ 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: ≥ 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
- [ ] 2 not known

Month Day Year

### Other system

21. Did any other system respond to the HSCT?

- [ ] Yes
- [ ] 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
- [ ] 2 not known

Month Day Year
26. Plasma cells in bone marrow aspirate:
   1. known %
   2. not known

27. Plasma cells in bone marrow biopsy:
   1. known %
   2. not known

28. Serum monoclonal Ig: (only from electrophoresis)
   1. known
   2. not known

29. Serum free light chain, κ (kappa)
   1. known
   2. not known

30. Serum free light chain, λ (lambda)
   1. known
   2. not known

31. Urinary monoclonal light chains:
   1. known
   2. not known

32. Was any planned treatment per protocol (not for progressive disease) given since the date of the last report?
   1. yes
   2. no
   3. unknown

   Specify treatment(s) given:
   33. 1 yes 2 no bortezomib (Velcade)
   34. 1 yes 2 no corticosteroids
   35. 1 yes 2 no cyclophosphamide
   36. 1 yes 2 no lenalidomide (Revlimid)
   37. 1 yes 2 no melphalan (LPAM)
   38. 1 yes 2 no thalidomide
   39. 1 yes 2 no other treatment

40. Specify:

Current Status of Amyloidosis

41. Specify the date the current disease status was determined: Month Day Year

Specify the recipient’s current disease status for each of the following hematologic and organ systems:

Cardiac

42. Specify the recipient’s current cardiac status:
   1. cardiac response — requires any of the following: • ≥ 2 mm decrease in mean interventricular septal wall thickness by echocardiogram • ≥ 20% increase in left ventricular ejection fraction • ≥ 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: • ≥ 2 mm increase from baseline in interventricular septal wall thickness by echocardiogram • ≥ 10% decrease in left ventricular ejection fraction • ≥ 1 grade increase in New York Heart Association functional class

43. Specify reason:

44. Date current cardiac status was first documented: Month Day Year
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
2 not known

Hepatic
47. Specify the recipient’s current hepatic status:
1 hepatic response — requires all of the following: • ≥ 2 cm decrease in liver span if hepatomegaly present (liver span > 15 cm) • ≥ 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: • ≥ 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
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
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
2 not known
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: • ≥ 50% reduction in current serum monoclonal protein levels > 0.5 g/dL • ≥ 50% reduction in current urine light chain levels > 100 mg/day with a visible peak • ≥ 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, ≥ 50% increase in serum M protein to > 0.5 g/dL, or ≥ 50% increase in urine M protein to > 200 mg/day with visible peak present • free light chain increase of ≥ 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
   2 □ not known

Renal

59. Specify the recipient’s current renal status:
   1 □ renal response — ≥ 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 ≥ 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: • ≥ 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
   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
   2 □ not known
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: ________________________________________________________