Amyloidosis Pre-HSCT Data

Registry Use Only

Date of biopsy-proven diagnosis of Amyloidosis:

Month Day Year

Specify serum heavy chain type(s) present:

1. yes
2. no
3. unknown

Specify serum heavy chain type(s) present:

1. yes
2. no
3. unknown

Serum heavy chain

Serum light chain

Specify serum light chain type:

1. κ (kappa)
2. λ (lambda)
3. light chain present, type unknown

Disease Status at Diagnosis

1. What was the date of biopsy-proven diagnosis of Amyloidosis? □ date unknown

Month Day Year

Specify the paraproteins present at diagnosis:

2. Serum heavy chain

3. □ yes □ no □ unknown

4. □ yes □ no □ unknown

5. □ yes □ no □ unknown

6. □ yes □ no □ unknown

7. □ yes □ no □ unknown

8. □ yes □ no □ unknown

9. Serum light chain

10. Specify the serum light chain type:

□ κ (kappa)

□ λ (lambda)

□ light chain present, type unknown

Mail this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).
Organ Involvement Prior to First Treatment for Amyloidosis

Renal Involvement

20. Specify the total 24-hour urinary protein excretion:
   - 1 □ known
   - 2 □ not known

21. Was a renal biopsy performed?
   - 1 □ yes
   - 2 □ no
   - 3 □ unknown

Specify renal biopsy results:
   - 1 □ positive for amyloid involvement
   - 2 □ negative
   - 3 □ unknown

Hepatic Involvement

23. Was hepatomegaly (liver span > 15 cm) present on examination or on radiographic imaging?
   - 1 □ yes
   - 2 □ no
   - 3 □ unknown

Specify liver biopsy results:
   - 1 □ positive for amyloid involvement
   - 2 □ negative
   - 3 □ unknown

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).
Cardiac Involvement

28. Was a cardiographic imaging procedure performed?
1 ☐ yes
2 ☐ no
3 ☐ unknown

29. Was the left ventricular ejection fraction measured?
1 ☐ yes
2 ☐ no
3 ☐ unknown

30. Specify the left ventricular ejection fraction: %

31. Specify the method used to determine the left ventricular ejection fraction:
1 ☐ echocardiogram
2 ☐ multiple gated acquisition (MUGA) scan
3 ☐ unknown

32. Was diastolic dysfunction present?
1 ☐ yes
2 ☐ no
3 ☐ unknown

33. Specify the interventricular septal wall thickness measured by echocardiogram:
1 ☐ known mm
2 ☐ not known

34. Was a cardiac biopsy performed?
1 ☐ yes
2 ☐ no
3 ☐ unknown

35. Specify the cardiac biopsy results:
1 ☐ positive for amyloid involvement
2 ☐ negative
3 ☐ unknown

36. Were any cardiac biomarkers assessed?
1 ☐ yes
2 ☐ no
3 ☐ unknown

Specify the cardiac biomarkers assessed:
37. 1 ☐ yes 2 ☐ no brain natriuretic peptide (BNP) and/or N-terminal prohormone brain natriuretic peptide (NT-proBNP)

38. Specify the BNP / NT-proBNP level: pg/mL

39. 1 ☐ yes 2 ☐ no troponin

40. Specify the troponin level: µg/L

Gastrintestinal Involvement

41. Was there clinical suspicion of gastrointestinal (GI) involvement?
1 ☐ yes
2 ☐ no
3 ☐ unknown

Specify the site(s) of GI involvement:
42. 1 ☐ yes 2 ☐ no upper GI tract
43. 1 ☐ yes 2 ☐ no lower GI tract

44. Specify the 24-hour fecal fat result:
1 ☐ known g/24 hours
2 ☐ not known
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>45. Was a gastrointestinal biopsy performed?</td>
<td>1 yes  2 no  3 unknown</td>
</tr>
<tr>
<td>Specify site(s) of GI biopsy:</td>
<td></td>
</tr>
<tr>
<td>46. Rectal</td>
<td>1 yes  2 no  3 unknown</td>
</tr>
<tr>
<td><strong>Specify the rectal biopsy results:</strong></td>
<td></td>
</tr>
<tr>
<td>47. positive for amyloid involvement</td>
<td></td>
</tr>
<tr>
<td>48. negative</td>
<td></td>
</tr>
<tr>
<td>49. Other site</td>
<td>1 yes  2 no  3 unknown</td>
</tr>
<tr>
<td>50. Specify other GI biopsy site:</td>
<td></td>
</tr>
<tr>
<td>51. Specify the biopsy results:</td>
<td></td>
</tr>
<tr>
<td>52. Is a copy of the biopsy report attached?</td>
<td>1 yes  2 no</td>
</tr>
<tr>
<td>Peripheral Neuropathy</td>
<td></td>
</tr>
<tr>
<td>53. Was a sensory / motor exam performed?</td>
<td>1 yes  2 no  3 unknown</td>
</tr>
<tr>
<td>Specify the exam results:</td>
<td></td>
</tr>
<tr>
<td>54. normal</td>
<td></td>
</tr>
<tr>
<td>55. Was an electromyograph (EMG) and/or nerve conduction velocity (NCV) test performed?</td>
<td>1 yes  2 no  3 unknown</td>
</tr>
<tr>
<td>Specify EMG / NCV results:</td>
<td></td>
</tr>
<tr>
<td>56. normal</td>
<td></td>
</tr>
<tr>
<td>57. Was a nerve biopsy performed?</td>
<td>1 yes  2 no  3 unknown</td>
</tr>
<tr>
<td>Specify site(s) of nerve biopsy:</td>
<td></td>
</tr>
<tr>
<td>58. Sural</td>
<td>1 yes  2 no  3 unknown</td>
</tr>
<tr>
<td><strong>Specify the sural nerve biopsy results:</strong></td>
<td></td>
</tr>
<tr>
<td>59. positive for amyloid involvement</td>
<td></td>
</tr>
<tr>
<td>60. Other site</td>
<td>1 yes  2 no  3 unknown</td>
</tr>
<tr>
<td>61. Specify other nerve biopsy site:</td>
<td></td>
</tr>
<tr>
<td>62. Specify the nerve biopsy results:</td>
<td></td>
</tr>
<tr>
<td>63. positive for amyloid involvement</td>
<td></td>
</tr>
</tbody>
</table>

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).
63. Did the recipient display any other evidence of peripheral nerve involvement for amyloidosis?
   1 □ yes  
   2 □ no  
   3 □ unknown

64. Specify other evidence: ______________________

Autonomic Neuropathy

65. Did the recipient display symptomatic orthostatic hypotension not attributable to medications or volume depletion?
   1 □ yes  
   2 □ no  
   3 □ unknown

66. Did the recipient display any other evidence of autonomic neuropathy involvement (pseudo-obstruction or intractable diarrhea)?
   1 □ yes  
   2 □ no  
   3 □ unknown

67. Specify other evidence: ______________________

Other Site(s)

68. Was an abdominal fat aspirate performed?
   1 □ yes  
   2 □ no  
   3 □ unknown

69. Specify the aspirate results:
   1 □ positive for amyloid involvement  
   2 □ negative  
   3 □ unknown

70. Did the recipient display any other clinical organ involvement?
   1 □ yes  
   2 □ no  
   3 □ unknown

71. 1 □ yes 2 □ no arthropathy
72. 1 □ yes 2 □ no lung
73. 1 □ yes 2 □ no soft tissue
74. 1 □ yes 2 □ no tongue (macroglossia)
75. 1 □ yes 2 □ no other organ involvement

76. Specify other organ: ______________________

77. Was a biopsy performed?
   1 □ yes  
   2 □ no  
   3 □ unknown

78. Specify the biopsy results:
   1 □ positive for amyloid involvement  
   2 □ negative  
   3 □ unknown
Laboratory Values at Diagnosis of Amyloidosis

79. WBC:
1. [ ] known
2. [ ] not known

Specify units:
1. \( \times 10^9/L \) (\( \times 10^3/mm^3 \))
2. \( \times 10^6/L \)

80. Hemoglobin (untransfused):
1. [ ] known
2. [ ] not known

1. [ ] g/dL
2. [ ] g/L
3. [ ] mmol/L

81. Platelets (untransfused):
1. [ ] known
2. [ ] not known

1. [ ] g/dL
2. [ ] g/L
3. [ ] mmol/L

82. Plasma cells in bone marrow aspirate:
1. [ ] known
2. [ ] not known

[ ] %
[ ] source (aspirate vs. biopsy) unknown

83. Plasma cells in bone marrow biopsy:
1. [ ] known
2. [ ] not known

[ ] %
[ ] source (aspirate vs. biopsy) unknown

84. Was there evidence of amyloid involvement in the bone marrow?
1. [ ] yes
2. [ ] no

85. Serum albumin:
1. [ ] known
2. [ ] not known

1. [ ] g/dL
2. [ ] g/L

86. Serum \( \beta_2 \) microglobulin:
1. [ ] known
2. [ ] not known

1. [ ] µg/dL
2. [ ] mg/L
3. [ ] mmol/L

87. Serum creatinine:
1. [ ] known
2. [ ] not known

1. [ ] mg/dL
2. [ ] mmol/L
3. [ ] µmol/L

88. Serum monoclonal Ig: (only from electrophoresis)
1. [ ] known
2. [ ] not known

1. [ ] mg/dL
2. [ ] g/dL
3. [ ] g/L

89. Serum free light chain, \( \kappa \) (kappa)
1. [ ] known
2. [ ] not known

1. [ ] mg/dL
2. [ ] g/dL
3. [ ] g/L

90. Serum free light chain, \( \lambda \) (lambda)
1. [ ] known
2. [ ] not known

1. [ ] mg/dL
2. [ ] g/dL
3. [ ] g/L

91. Urinary monoclonal light chains:
1. [ ] known
2. [ ] not known

1. [ ] g/24 hours
2. [ ] mg/24 hours

92. LDH:
1. [ ] known
2. [ ] not known

1. [ ] U/L
2. [ ] µkat/L

93. Upper limit of normal for LDH:

[ ]
Treatment for Amyloidosis

94. Was chemotherapy given to treat amyloidosis prior to the preparative regimen?

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

95. Specify the total number of chemotherapy regimens given prior to the preparative regimen:

<table>
<thead>
<tr>
<th></th>
<th>known</th>
<th>not known</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Line of Therapy</th>
<th>1st Line of Therapy</th>
<th>2nd Line of Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>bortezomib (Velcade)</td>
<td>96.</td>
<td>1</td>
</tr>
<tr>
<td>corticosteroids</td>
<td>97.</td>
<td>1</td>
</tr>
<tr>
<td>cyclophosphamide</td>
<td>99.</td>
<td>1</td>
</tr>
<tr>
<td>lenalidomide (Revlimid)</td>
<td>101.</td>
<td>1</td>
</tr>
<tr>
<td>melphalan (LPM)</td>
<td>103.</td>
<td>1</td>
</tr>
<tr>
<td>other systemic therapy</td>
<td>105.</td>
<td>1</td>
</tr>
<tr>
<td>specify other therapy</td>
<td>107.</td>
<td>1</td>
</tr>
</tbody>
</table>

Organ Involvement Immediately Prior to the Preparative Regimen

Renal Involvement

120. Specify the total urinary protein excretion:

<table>
<thead>
<tr>
<th></th>
<th>known</th>
<th>not known</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>g/24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

121. Specify the 24-hour creatinine clearance value:

<table>
<thead>
<tr>
<th></th>
<th>known</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>mL/minute (cc/minute)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Hepatic Involvement

122. Was hepatomegaly (liver span > 15 cm) present on examination or on radiographic imaging?

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
<th>unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

123. Specify the level of serum alkaline phosphatase:

<table>
<thead>
<tr>
<th></th>
<th>known</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>I/U/L</th>
<th>µkat/L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

124. Specify your institution’s upper limit of normal for serum alkaline phosphatase:

<table>
<thead>
<tr>
<th></th>
<th>known</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).
Cardiac Involvement

125. Was a cardiographic imaging procedure performed?
1. yes
2. no
3. unknown

126. Was the left ventricular ejection fraction measured?
1. yes
2. no
3. unknown

127. Specify the left ventricular ejection fraction: __ %

128. Specify the method used to determine the ejection fraction:
1. echocardiogram
2. multiple gated acquisition (MUGA) scan
3. unknown

129. Specify the interventricular septal wall thickness measured by echocardiogram:
1. known mm
2. not known

130. Specify the recipient's New York Heart Association functional classification of heart failure: (Symptoms may include dyspnea, chest pain, fatigue, and palpitations; activity level should be assessed with consideration for patient's age-group.)
1. Class I — Able to perform ordinary activities without symptoms; no limitation of physical activity
2. Class II — Ordinary physical activity produces symptoms; slight limitation of physical activity
3. Class III — Less-than-ordinary physical activity produces symptoms; moderate limitation of physical activity
4. Class IV — Symptoms present even at rest; severe limitation of physical activity
5. unknown

Gastrointestinal Involvement

131. Did the recipient display any new evidence of gastrointestinal involvement with amyloidosis since diagnosis?
1. yes
2. no
3. unknown

132. Specify new evidence:

Peripheral Neuropathy

133. Was a sensory / motor exam performed?
1. yes
2. no
3. unknown

134. Specify the exam results:
1. normal
2. abnormal
3. unknown

135. Was an electromyograph (EMG) and/or nerve conduction velocity (NCV) test performed?
1. yes
2. no
3. unknown

136. Specify EMG / NCV results:
1. normal
2. abnormal
3. unknown

137. Did the recipient display any new evidence of peripheral nerve involvement with amyloidosis since diagnosis?
1. yes
2. no
3. unknown

138. Specify new evidence:

Autonomic Neuropathy

139. Did the recipient display any new evidence of autonomic neuropathy involvement (pseudo-obstruction or intractable diarrhea) since diagnosis?
1. yes
2. no
3. unknown

140. Specify new evidence:
CIBMTR Form 2017 (AMY) v1.0 (9–9) July 2007
Copyright © 2007 National Marrow Donor Program and The Medical College of Wisconsin, Inc. All rights reserved.
For internal use only: Document F00506 version 1.0 Replaces: n/a

### Other Sites

141. Did the recipient display any clinical evidence of other new organ involvement since diagnosis?

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
<th>unknown</th>
</tr>
</thead>
</table>
1 |     | 2  | 3       |

Specify the evidence of other organ involvement:

142. 1 □ yes 2 □ no arthropathy
143. 1 □ yes 2 □ no lung
144. 1 □ yes 2 □ no soft tissue
145. 1 □ yes 2 □ no tongue (macroglossia)
146. 1 □ yes 2 □ no other evidence

147. Specify other evidence: ____________________________

### Hematologic and Clinical Parameters Immediately Prior to the Preparative Regimen

148. Plasma cells in bone marrow aspirate:

<table>
<thead>
<tr>
<th></th>
<th>known</th>
<th>not known</th>
<th>source (aspirate vs. biopsy) unknown</th>
</tr>
</thead>
</table>
1 |     | 2         |                                     |

149. Plasma cells in bone marrow biopsy:

<table>
<thead>
<tr>
<th></th>
<th>known</th>
<th>not known</th>
<th>source (aspirate vs. biopsy) unknown</th>
</tr>
</thead>
</table>
1 |     | 2         |                                     |

150. Was there evidence of amyloid involvement in the bone marrow?

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
</table>
1 |     | 2  |

Specify units:

1 □ g/dL 2 □ g/L

151. Serum albumin:

<table>
<thead>
<tr>
<th></th>
<th>known</th>
<th>not known</th>
</tr>
</thead>
</table>
1 |     | 2         |

152. Serum β2 microglobulin:

<table>
<thead>
<tr>
<th></th>
<th>known</th>
<th>not known</th>
<th>1 □ µg/dL 2 □ mg/L 3 □ nmol/L</th>
</tr>
</thead>
</table>
1 |     | 2         |                                  |

153. Serum monoclonal Ig: (only from electrophoresis)

<table>
<thead>
<tr>
<th></th>
<th>known</th>
<th>not known</th>
<th>1 □ mg/dL 2 □ g/dL 3 □ g/L</th>
</tr>
</thead>
</table>
1 |     | 2         |                               |

154. Serum free light chain, κ (kappa)

<table>
<thead>
<tr>
<th></th>
<th>known</th>
<th>not known</th>
<th>1 □ mg/dL 2 □ g/dL 3 □ g/L</th>
</tr>
</thead>
</table>
1 |     | 2         |                               |

155. Serum free light chain, λ (lambda)

<table>
<thead>
<tr>
<th></th>
<th>known</th>
<th>not known</th>
<th>1 □ mg/dL 2 □ g/dL 3 □ g/L</th>
</tr>
</thead>
</table>
1 |     | 2         |                               |

156. Urinary monoclonal light chains:

<table>
<thead>
<tr>
<th></th>
<th>known</th>
<th>not known</th>
<th>1 □ g/24 hours 2 □ mg/24 hours</th>
</tr>
</thead>
</table>
1 |     | 2         |                               |

Please print name: __________________________________________

Phone: (_________) ___________________________________________

Fax: (_________) ___________________________________________

E-mail address: ____________________________________________

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).