

# ERROR CORRECTION FORM

Sequence Number:

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CIBMTR Recipient ID:

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Initials:

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Today's Date:

				2	0		
Month	Day	Year					

Infusion Date:

				2	0		
Month	Day	Year					

CIBMTR Center Number:

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## Amyloidosis Pre-HSCT Data

Registry Use Only

Sequence Number:

Date Received:

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CIBMTR Center Number:

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Today's Date:

				2	0		
Month	Day	Year					

Date of HSCT for which this form is being completed: ☞

				2	0		
Month	Day	Year					

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.

For recipients with amyloid in the presence of multiple myeloma (> 10% plasma cells on bone marrow biopsy), complete a From 2016 MYE insert. ☞

If this is a report of a second or subsequent transplant, check here  and continue with question 120.

## Disease Status at Diagnosis

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

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 date unknown  
Month Day Year

Specify the paraproteins present at diagnosis:

2. Serum heavy chain

- 1  yes →  
2  no  
3  unknown

Specify serum heavy chain type(s) present:

3. 1  yes 2  no 3  unknown IgG  
4. 1  yes 2  no 3  unknown IgA  
5. 1  yes 2  no 3  unknown IgD  
6. 1  yes 2  no 3  unknown IgE  
7. 1  yes 2  no 3  unknown IgM  
8. 1  yes 2  no 3  unknown heavy chain present, type unknown

9. Serum light chain

- 1  yes →  
2  no  
3  unknown

10. Specify the serum light chain type:

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

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Month Day Year

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11. Heavy chain detected in urine

- 1  yes  
2  no  
3  unknown

Specify urine heavy chain type(s) present:

12. 1  yes 2  no 3  unknown IgG  
13. 1  yes 2  no 3  unknown IgA  
14. 1  yes 2  no 3  unknown IgD  
15. 1  yes 2  no 3  unknown IgE  
16. 1  yes 2  no 3  unknown IgM  
17. 1  yes 2  no 3  unknown heavy chain present, type unknown

18. Light chain detected in urine

- 1  yes  
2  no  
3  unknown

19. Specify the urine light chain type:

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

## Organ Involvement Prior to First Treatment for Amyloidosis

### Renal Involvement

20. Specify the total 24-hour urinary protein excretion:

- 1  known  .  g/24 hours  
2  not known

21. Was a renal biopsy performed?

- 1  yes  
2  no  
3  unknown

22. Specify the 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

24. Specify the level of serum alkaline phosphatase: Specify units:

- 1  known  .  1  IU/L  
2  not known 2  μkat/L

25. Specify your institution's upper limit of normal for serum alkaline phosphatase:

- 1  known  .  1  IU/L  
2  not known 2  μkat/L

26. Was a liver biopsy performed?

- 1  yes  
2  no  
3  unknown

27. Specify the liver biopsy results:

- 1  positive for amyloid involvement  
2  negative  
3  unknown

# ERROR CORRECTION FORM

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Initials:

Today's Date:

 /  /   
Month Day Year

Infusion Date:

 /  /   
Month Day Year

CIBMTR Center Number:

CIBMTR Center Number:

CIBMTR Recipient ID:

## 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

## Gastrointestinal 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

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45. Was a gastrointestinal biopsy performed?

- 1  yes  
2  no  
3  unknown

Specify site(s) of GI biopsy:

46. Rectal

- 1  yes  
2  no  
3  unknown

47. Specify the rectal biopsy results:

- 1  positive for amyloid involvement  
2  negative  
3  unknown

48. Is a copy of the rectal biopsy report attached?

- 1  yes  
2  no

49. Other site

- 1  yes  
2  no  
3  unknown

50. Specify other GI biopsy site: \_\_\_\_\_

51. Specify the biopsy results:

- 1  positive for amyloid involvement  
2  negative  
3  unknown

52. Is a copy of the biopsy report attached?

- 1  yes  
2  no

## Peripheral Neuropathy

53. Was a sensory / motor exam performed?

- 1  yes  
2  no  
3  unknown

54. Specify the exam results:

- 1  normal  
2  abnormal  
3  unknown

55. Was an electromyograph (EMG) and/or nerve conduction velocity (NCV) test performed?

- 1  yes  
2  no  
3  unknown

56. Specify EMG / NCV results:

- 1  normal  
2  abnormal  
3  unknown

57. Was a nerve biopsy performed?

- 1  yes  
2  no  
3  unknown

Specify site(s) of nerve biopsy:

58. Sural

- 1  yes  
2  no  
3  unknown

59. Specify the sural nerve biopsy results:

- 1  positive for amyloid involvement  
2  negative  
3  unknown

60. Other site

- 1  yes  
2  no  
3  unknown

61. Specify other nerve biopsy site: \_\_\_\_\_

62. Specify the nerve biopsy results:

- 1  positive for amyloid involvement  
2  negative  
3  unknown

CIBMTR Form 2017 (AMY) v1.0 (4-9) July 2007  
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Fax this form to your designated campus (Milwaukee 414-456-6165 or Minneapolis 612-627-5895).

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Initials:

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Month	Day	Year			

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Month	Day	Year			

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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

Specify the evidence of other organ involvement:

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

78. Specify the biopsy results:

- 1  positive for amyloid involvement  
2  negative  
3  unknown

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Today's Date:

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20					
Month	Day	Year			

Infusion Date:

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Month	Day	Year			

CIBMTR Center Number:

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CIBMTR Center Number: 

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## Laboratory Values at Diagnosis of Amyloidosis

79. WBC:

1  known → 

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2  not known

Specify units:

1  x 10<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)  
2  x 10<sup>6</sup>/L

80. Hemoglobin (untransfused):

1  known → 

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2  not known

1  g/dL  
2  g/L  
3  mmol/L

81. Platelets (untransfused):

1  known → 

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2  not known

1  x 10<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)  
2  x 10<sup>6</sup>/L

82. Plasma cells in bone marrow aspirate:

1  known → 

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

 %  source (aspirate vs. biopsy) unknown

2  not known

83. Plasma cells in bone marrow biopsy:

1  known → 

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

 %  source (aspirate vs. biopsy) unknown

2  not known

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

1  yes  
2  no

85. Serum albumin:

1  known → 

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2  not known

1  g/dL  
2  g/L

86. Serum β<sub>2</sub> microglobulin:

1  known → 

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2  not known

1  μg/dL  
2  mg/L  
3  nmol/L

87. Serum creatinine:

1  known → 

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2  not known

1  mg/dL  
2  mmol/L  
3  μmol/L

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

1  known → 

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2  not known

1  mg/dL  
2  g/dL  
3  g/L

89. Serum free light chain, κ (kappa)

1  known → 

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2  not known

1  mg/dL  
2  g/dL  
3  g/L

90. Serum free light chain, λ (lambda)

1  known → 

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2  not known

1  mg/dL  
2  g/dL  
3  g/L

91. Urinary monoclonal light chains:

1  known → 

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2  not known

1  g/24 hours  
2  mg/24 hours

92. LDH:

1  known → 

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2  not known

1  U/L  
2  μkat/L

93. Upper limit of normal for LDH:

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## Treatment for Amyloidosis

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

- 1  yes →  
2  no

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

- 1  known →   
2  not known

Line of Therapy	1st Line of Therapy	2nd Line of Therapy
bortezomib (Velcade)	96. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	108. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown
corticosteroids	97. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	109. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown
cyclophosphamide	98. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	110. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown
lenalidomide (Revlimid)	99. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	111. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown
melphalan (LPAM)	100. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	112. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown
thalidomide	101. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	113. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown
other systemic therapy	102. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown	114. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 3 <input type="checkbox"/> unknown
specify other therapy	103. _____	115. _____
Used for stem cell priming?	104. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	116. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
Number of cycles:	105. <input type="text"/> <input type="checkbox"/> unknown / not applicable	117. <input type="text"/> <input type="checkbox"/> unknown / not applicable
Date started therapy:	106. <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> date started therapy unknown	118. <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> date started therapy unknown
Date stopped therapy:	107. <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> date stopped therapy unknown	119. <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> date stopped therapy unknown

Copy and complete this page to report more than 2 lines of therapy.

## Organ Involvement Immediately Prior to the Preparative Regimen

### Renal Involvement

120. Specify the total urinary protein excretion:

- 1  known →   g/24 hours  
2  not known

121. Specify the 24-hour creatinine clearance value:

- 1  known →   mL/minute (cc/minute)  
2  not known

### Hepatic Involvement

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

- 1  yes  
2  no  
3  unknown

123. Specify the level of serum alkaline phosphatase: Specify units:

- 1  known →    IU/L  
2  not known   $\mu$ kat/L

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

- 1  known →      
2  not known

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 20   
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CIBMTR Recipient ID:

## 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:

