



Chronic Lymphocytic Leukemia (CLL) Pre-HSCT Data

Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number:

CIBMTR Recipient ID:

Today's Date: / / 20

Date of HSCT for which this form is being completed: / / 20

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.

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

If this is a report of a second or subsequent transplant, check here and continue with question 170.

Disease Assessment at Diagnosis

1. What was the date of diagnosis of Chronic Lymphocytic Leukemia?

 / /

Month Day Year

2. What was the disease histology at diagnosis?

- 1 chronic lymphocytic leukemia (CLL)
- 2 prolymphocytic leukemia (PLL)

3. Is a copy of the pathology report used for diagnosis attached?

- 1 yes
- 2 no

4. Did a histologic transformation occur at any time after CLL diagnosis?

- 1 yes
- 2 no

5. Date of transformation:

 / /

Month Day Year

6. New histology:

- 1 prolymphocytic syndrome (PLL)
- 2 Richter syndrome (diffuse large cell lymphoma) → **Also complete a Form 2018 LYM**
- 3 other histology →

7. Specify histology: _____

8. Is a copy of the pathology report attached?

- 1 yes
- 2 no

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

CIBMTR Center Number:

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Autoimmune disorder(s) at diagnosis:

9. 1 yes 2 no 3 unknown Immune hemolytic anemia
10. 1 yes 2 no 3 unknown Immune thrombocytopenia
11. 1 yes 2 no 3 unknown Positive Coombs' test
12. 1 yes 2 no 3 unknown Other →

13. Specify other autoimmune disorder:

14. What was the Rai stage at diagnosis?

- 1 low risk — stage 0 — lymphocytosis ($> 15,000 \times 10^9/L$) in blood or bone marrow only
2 intermediate risk — stage I — lymphocytosis plus enlarged lymph nodes (lymphadenopathy)
3 intermediate risk — stage II — lymphocytosis plus enlarged liver or spleen with or without lymphadenopathy
4 high risk — stage III — lymphocytosis plus anemia (Hgb < 11 g/dL) with or without enlarged liver, spleen, or lymph nodes
5 high risk — stage IV — lymphocytosis plus thrombocytopenia (platelet count $< 100 \times 10^9/L$) with or without anemia or enlarged liver, spleen, or lymph nodes
6 unknown

15. What was the Binet stage at diagnosis?

(Five lymphoid bearing areas are possible: axillary, cervical, inguino-femoral, liver, and spleen.)

- 1 stage A — two or fewer lymphoid bearing areas enlarged, without anemia or thrombocytopenia
2 stage B — three or more lymphoid bearing areas enlarged, without anemia or thrombocytopenia
3 stage C — presence of anemia (Hgb < 10.0 g/dL) or thrombocytopenia (platelet count $< 100 \times 10^9/L$)
4 unknown

16. What were the disease symptoms at diagnosis?

- 1 A — none of the symptoms listed in B below
2 B — unexplained weight loss of $> 10\%$ of body weight in six months before treatment; unexplained fever $> 38^\circ C$; or, night sweats
3 unknown

17. Was there extramedullary and/or extranodal involvement at diagnosis?

- 1 yes →
2 no
3 unknown

Specify site(s) of involvement:

18. 1 yes 2 no Central nervous system (CNS)

19. 1 yes 2 no Liver

20. 1 yes 2 no Lung

21. 1 yes 2 no Spleen →

22. Specify centimeters below costal margin:

23. 1 yes 2 no Other site →

24. Specify site:

25. Enter age-appropriate Karnofsky or Lansky score at diagnosis:

(See complete scale on page 11 of Form 2000 — Recipient Baseline Data)

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48. Were cytogenetics tested (conventional or FISH)?

- 1 yes →
- 2 no
- 3 unknown

49. Results of test at diagnosis:

- 1 yes abnormalities identified →
- 2 no evaluable metaphases
- 3 no abnormalities

Complete questions 51–60 in the table below

50. Results of tests after diagnosis to prior to the preparative regimen:

- 1 yes abnormalities identified →
- 2 no evaluable metaphases on any tests
- 3 no abnormalities on any tests after diagnosis and before the preparative regimen

Complete questions 61–70 in the table below

Specify abnormalities identified:

| Cytogenetic abnormality | At diagnosis | Any test result between diagnosis and preparative regimen |
|---|--|--|
| Trisomy +12 | 51. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 61. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| Translocation t(11;14) any translocation of 14 | 52. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 53. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 62. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no 63. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| Deletion del(11q) / 11q– (ATM) | 54. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 64. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| del(13q) / 13q– | 55. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 65. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| del(17p) / 17(p53)– | 56. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 66. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| Other abnormal 6 | 57. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 67. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| abnormal 8 | 58. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 68. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| Other abnormality | 59. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 69. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| Specify other abnormality: | 60. _____ | 70. _____ |

71. Is a copy of the cytogenetic or FISH report attached?

- 1 yes
- 2 no

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Pre-HSCT Treatment for CLL

72. Was therapy given between diagnosis and the start of the preparative regimen?

- 1 yes →
- 2 no
- 3 unknown

| | 1st Line of Therapy | 2nd Line of Therapy |
|--|--|--|
| Line of Therapy: | 1st Line of Therapy | 2nd Line of Therapy |
| Systemic Therapy: | 73. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with q. 98 | 114. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with q. 139 |
| Date therapy started: | 74. <input type="text"/> / <input type="text"/> / <input type="text"/> | 115. <input type="text"/> / <input type="text"/> / <input type="text"/> |
| Date therapy stopped: | 75. <input type="text"/> / <input type="text"/> / <input type="text"/> | 116. <input type="text"/> / <input type="text"/> / <input type="text"/> |
| Number of cycles: | 76. <input type="text"/> <input type="checkbox"/> unknown/not applicable | 117. <input type="text"/> <input type="checkbox"/> unknown/not applicable |
| Monoclonal antibodies: | | |
| alemtuzumab (Campath) | 77. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 118. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| ibritumomab tiuxetan (Zevalin) | 78. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 119. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| rituximab (anti-CD20, Rituxan) | 79. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 120. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| tositumomab (Bexxar) | 80. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 121. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| other monoclonal antibody | 81. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 122. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| specify other antibody | 82. _____ | 123. _____ |
| chlorambucil (Leukeran) | 83. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 124. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| cladribine (2-CdA, Leustatin) | 84. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 125. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| corticosteroids <input type="checkbox"/> | 85. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 126. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| cyclophosphamide (Cytosan) | 86. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 127. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| cytarabine (Ara-C) | 87. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 128. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| doxorubicin (Adriamycin) | 88. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 129. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| etoposide (VP-16, VePesid) | 89. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 130. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| fludarabine (Fludara) | 90. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 131. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| gemcitabine (Gemzar) | 91. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 132. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| ifosfamide (Ifex) | 92. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 133. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| nitrogen mustard (mustine) | 93. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 134. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| pentostatin (Nipent) | 94. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 135. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| vincristine (VCR, Oncovin) | 95. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 136. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| other treatment | 96. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 137. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| specify other treatment | 97. _____ | 138. _____ |
| Radiation Therapy: | 98. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with 104 | 139. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with q. 145 |
| Date therapy started: | 99. <input type="text"/> / <input type="text"/> / <input type="text"/> | 140. <input type="text"/> / <input type="text"/> / <input type="text"/> |
| Date therapy stopped: | 100. <input type="text"/> / <input type="text"/> / <input type="text"/> | 141. <input type="text"/> / <input type="text"/> / <input type="text"/> |
| mediastinum | 101. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 142. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| other site(s) | 102. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 143. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| specify other site(s) | 103. _____ | 144. _____ |
| Surgery: | 104. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with 109 | 145. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no → cont. with q. 150 |
| Date of surgery: | 105. <input type="text"/> / <input type="text"/> / <input type="text"/> | 146. <input type="text"/> / <input type="text"/> / <input type="text"/> |
| splenectomy | 106. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 147. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| other site(s) | 107. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 148. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| specify other site(s) | 108. _____ | 149. _____ |
| Was this line of therapy given for stem cell priming? | 109. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 150. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| Best Response to Line of Therapy: | 110. 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> NPR 3 <input type="checkbox"/> PR 4 <input type="checkbox"/> SD 5 <input type="checkbox"/> Prog 6 <input type="checkbox"/> NA 7 <input type="checkbox"/> unknown | 151. 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> NPR 3 <input type="checkbox"/> PR 4 <input type="checkbox"/> SD 5 <input type="checkbox"/> Prog 6 <input type="checkbox"/> NA 7 <input type="checkbox"/> unknown |
| (see definitions at q. 187) | | |
| Date response established: | 111. <input type="text"/> / <input type="text"/> / <input type="text"/> | 152. <input type="text"/> / <input type="text"/> / <input type="text"/> |
| Did disease relapse/progress following this line of therapy? | 112. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | 153. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| Date of relapse/progression: | 113. <input type="text"/> / <input type="text"/> / <input type="text"/> | 154. <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.

CIBMTR Center Number:

CIBMTR Recipient ID:

Most Recent Disease Assessment Prior to the Start of the Preparative Regimen

155. What was the Rai stage immediately prior to the preparative regimen?

- 1 complete remission
- 2 low risk — stage 0 — lymphocytosis ($> 15,000 \times 10^9/L$) in blood or bone marrow only
- 3 intermediate risk — stage I — lymphocytosis plus enlarged lymph nodes (lymphadenopathy)
- 4 intermediate risk — stage II — lymphocytosis plus enlarged liver or spleen with or without lymphadenopathy
- 5 high risk — stage III — lymphocytosis plus anemia (Hgb < 11 g/dL) with or without enlarged liver, spleen, or lymph nodes
- 6 high risk — stage IV — lymphocytosis plus thrombocytopenia (platelet count $< 100 \times 10^9/L$) with or without anemia or enlarged liver, spleen, or lymph nodes
- 7 unknown

156. What was the Binet stage immediately prior to the preparative regimen?

(Five lymphoid bearing areas are possible: axillary, cervical, inguino-femoral, liver, and spleen.)

- 1 complete remission
- 2 stage A — two or fewer lymphoid bearing areas enlarged
- 3 stage B — three or more lymphoid bearing areas enlarged
- 4 stage C — presence of anemia (Hgb < 10.0 g/dL) or thrombocytopenia (platelet count $< 100,000 / \mu L$)
- 5 unknown

157. Did the recipient have known nodal involvement immediately prior to the preparative regimen?

- 1 yes →
- 2 no

158. Specify the total number of nodes involved:

- 1 one node
- 2 two or more nodes

159. Specify the size of the largest nodal mass: cm x cm

160. Did the recipient have known extramedullary and/or extranodal involvement immediately prior to the preparative regimen?

- 1 yes →
- 2 no

Specify site(s) of involvement:

161. 1 yes 2 no Central nervous system (CNS)

162. 1 yes 2 no Liver

163. 1 yes 2 no Lung

164. 1 yes 2 no Spleen →

165. Specify centimeters below costal margin:

166. 1 yes 2 no Other site →

167. Specify site: _____

168. Was a direct or indirect Coombs' test performed?

- 1 yes →
- 2 no

169. Specify the Coombs' test results:

- 1 negative (normal, no agglutination)
- 2 positive (abnormal, antibodies present)

CIBMTR Center Number:

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Laboratory Studies Prior to the Start of the Preparative Regimen

170. Lymphocytes in bone marrow:

- 1 known → %
2 not known

171. LDH:

- 1 known → .
2 not known

Specify units:

- 1 U/L
2 μ kat/L

172. Upper limit of normal for LDH:
 .

173 β_2 microglobulin:

- 1 known → .
2 not known

- 1 μ g/dL
2 mg/L
3 nmol/L

174. Upper limit of normal for β_2 :
 .

175. IgG:

- 1 known → .
2 not known

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

176. Lower limit of normal for IgG:
 .

177. IgA:

- 1 known → .
2 not known

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

178. Lower limit of normal for IgA:
 .

179. IgM:

- 1 known → .
2 not known

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

180. Lower limit of normal for IgM:
 .

181. Was molecular testing / immunophenotyping performed at the time of disease assessment prior to the preparative regimen?

- 1 yes →
2 no

Specify the testing method(s) used:

182. Immunophenotyping (4 color flow cytometry)

- 1 yes →
2 no

183. Specify the date immunophenotyping was performed:

/ /
Month Day Year

184. Was disease detected?

- 1 yes
2 no

185. Heavy chain gene rearrangement (ASO-PCR)

- 1 yes →
2 no

186. Specify the date the heavy chain gene rearrangement testing was performed:

/ /
Month Day Year

187. Was disease detected?

- 1 yes
2 no

CIBMTR Center Number:

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Disease Status at the Last Assessment Prior to the Preparative Regimen

188. What was the disease status at the last evaluation prior to the preparative regimen?

- 1 complete response (CR) — no lymphadenopathy; no organomegaly; neutrophils $> 1.5 \times 10^9/L$; platelets $> 100 \times 10^9/L$; hemoglobin $> 11g/dL$; lymphocytes $< 4 \times 10^9/L$; bone marrow $< 30\%$ lymphocytes; absence of constitutional symptoms
- 2 nodular partial response (NPR) — complete response with persistent lymphoid nodules in bone marrow
- 3 partial response (PR) — $\geq 50\%$ decrease in peripheral blood lymphocyte count from pretreatment value; $\geq 50\%$ reduction in lymphadenopathy if present pretreatment; $\geq 50\%$ reduction in liver and spleen size if enlarged pretreatment; one or more of the following: neutrophils $\geq 1.5 \times 10^9/L$ or 50% improvement over baseline, platelets $> 100 \times 10^9/L$ or 50% improvement over baseline, hemoglobin $> 11.0 g/dL$ or 50% improvement over baseline
- 4 stable disease (SD) — no change; not complete response, partial response, nor progressive disease
- 5 progressive disease (Prog) — one or more of the following: $\geq 50\%$ increase in the sum of the products of ≥ 2 lymph nodes (≥ 1 node must be ≥ 2 cm) or new nodes; $\geq 50\%$ increase in liver or spleen size, or new hepatomegaly or splenomegaly; $\geq 50\%$ increase in absolute lymphocyte count to $\geq 5 \times 10^9/L$; transformation to a more aggressive histology
- 6 untreated — no chemotherapy given in the 6 months prior to HSCT
- 7 not assessed (NA)

189. Date of the most recent assessment for disease status prior to the preparative regimen:

| | | | | | |
|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Month | | Day | | Year | |

190. Signed: _____

Person completing form

Please print name: _____

Phone: (_____) _____

Fax: (_____) _____

E-mail address: _____