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)
   - 3. other histology

7. Specify histology:

8. Is a copy of the pathology report attached?
   - 1. yes
   - 2. no

Also complete a Form 2018 LYM

CIBMTR Form 2013 (CLL) v1.0 (1–8) July 2007
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Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).
Autoimmune disorder(s) at diagnosis:
9. ☐ yes ☐ no ☐ unknown Immune hemolytic anemia  
10. ☐ yes ☐ no ☐ unknown Immune thrombocytopenia  
11. ☐ yes ☐ no ☐ unknown Positive Coombs’ test  
12. ☐ yes ☐ no ☐ unknown Other

What was the Rai stage at diagnosis?
1. ☐ low risk — stage 0 — lymphocytosis (> 15,000 x 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 x 10^9/L) with or without anemia or enlarged liver, spleen, or lymph nodes  
6. ☐ unknown

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 x 10^9/L)  
4. ☐ unknown

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° C; or, night sweats  
3. ☐ unknown

Was there extramedullary and/or extranodal involvement at diagnosis?
1. ☐ yes  
2. ☐ no  
3. ☐ unknown

Specify site(s) of involvement:
18. ☐ yes ☐ no Central nervous system (CNS)  
19. ☐ yes ☐ no Liver  
20. ☐ yes ☐ no Lung  
21. ☐ yes ☐ no Spleen  
22. Specify centimeters below costal margin:

Specify site:
23. ☐ yes ☐ no Other site  
24. Specify site:

Enter age-appropriate Karnofsky or Lansky score at diagnosis:

(See complete scale on page 11 of Form 2000 — Recipient Baseline Data)
### Laboratory Studies at Diagnosis

26. Lymphocytes in bone marrow:
   1. known
   2. not known

### Peripheral Blood Studies at Diagnosis

27. WBC:
   1. known
   2. not known

28. Lymphocytes:
   1. known
   2. not known

29. Prolymphocytes:
   1. known
   2. not known

30. LDH:
   1. known
   2. not known

31. Upper limit of normal for LDH:

32. $\beta_2$ microglobulin:
   1. known
   2. not known

33. Upper limit of normal for $\beta_2$:

34. IgG:
   1. known
   2. not known

35. Lower limit of normal for IgG:

36. IgA:
   1. known
   2. not known

37. Lower limit of normal for IgA:

38. IgM:
   1. known
   2. not known

39. Lower limit of normal for IgM:

40. Leukemia cell type: *(may be determined at any time after diagnosis)*
   1. B cell
   2. T cell
   3. unknown

### Immunophenotype: *(may be determined at any time after diagnosis)*

41. 1. yes 2. no 3. unknown CD5+
42. 1. yes 2. no 3. unknown CD19+
43. 1. yes 2. no 3. unknown CD20+
44. 1. yes 2. no 3. unknown CD23+
45. 1. yes 2. no 3. unknown CD38+
46. 1. yes 2. no 3. unknown slg weakly expressed

47. Did hypercalcemia occur at any time?
   1. yes
   2. no
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

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

Specify abnormalities identified:

<table>
<thead>
<tr>
<th>Cytogenetic abnormality</th>
<th>At diagnosis</th>
<th>Any test result between diagnosis and preparative regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trisomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+12</td>
<td>51. yes</td>
<td>61. yes</td>
</tr>
<tr>
<td>Translocation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>t(11;14)</td>
<td>52. yes</td>
<td>62. yes</td>
</tr>
<tr>
<td>any translocation of 14</td>
<td>53. yes</td>
<td>63. yes</td>
</tr>
<tr>
<td>Deletion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>del(11q)/11q– (ATM)</td>
<td>54. yes</td>
<td>64. yes</td>
</tr>
<tr>
<td>del(13q)/13q–</td>
<td>55. yes</td>
<td>65. yes</td>
</tr>
<tr>
<td>del(17p)/17(p53)–</td>
<td>56. yes</td>
<td>66. yes</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>abnormal 6</td>
<td>57. yes</td>
<td>67. yes</td>
</tr>
<tr>
<td>abnormal 8</td>
<td>58. yes</td>
<td>68. yes</td>
</tr>
<tr>
<td>Other abnormality</td>
<td>59. yes</td>
<td>69. yes</td>
</tr>
<tr>
<td>Specify other abnormality</td>
<td>60. yes</td>
<td>70. yes</td>
</tr>
</tbody>
</table>

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

1. yes
2. no
Pre-HSCT Treatment for CLL

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

<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>Systemic Therapy:</td>
<td>Date therapy started:</td>
<td>Date therapy stopped:</td>
</tr>
<tr>
<td>Monoclonal antibodies:</td>
<td>Number of cycles:</td>
<td>Monoclonal antibodies:</td>
</tr>
<tr>
<td>Rituximab (anti-CD20, Rituxan)</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Bortezomib (Velcade)</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Chlorambucil (Leukeran)</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Cyclophosphamide (Cytoxan)</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Cytarabine (Ara-C)</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Doxorubicin (Adriamycin)</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Etoposide (VP-16, Vepesid)</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Fludarabine (Fludara)</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Gemcitabine (Gemzar)</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Ilosfamide (flex)</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Nitrogen mustard (mustine)</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Pentostatin (Neupogen)</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Vincristine (VCR, Oncovin)</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Other treatment</td>
<td>1 yes 2 no</td>
<td>1 yes 2 no</td>
</tr>
<tr>
<td>Radiation Therapy:</td>
<td>Date therapy started:</td>
<td>Date therapy stopped:</td>
</tr>
<tr>
<td>Surgery:</td>
<td>Date of surgery:</td>
<td>Date of surgery:</td>
</tr>
<tr>
<td>Splenectomy</td>
<td>Date response established:</td>
<td>Date of relapse/progression:</td>
</tr>
</tbody>
</table>

Copy this page to report more than 2 lines of therapy; check here if additional pages are attached.
**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 x 10⁹/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 x 10⁹/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 / µL)
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?

Specify site(s) of involvement:

161. Central nervous system (CNS)
162. Liver
163. Lung
164. Spleen

165. Specify centimeters below costal margin: __

166. 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)
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:

172. Upper limit of normal for LDH:
   1. U/L
   2. µkat/L

173. β2 microglobulin:
   1. known: 
   2. not known:

174. Upper limit of normal for β2:
   1. µg/dL
   2. mg/L
   3. mmol/L

175. IgG:
   1. known: 
   2. not known:

176. Lower limit of normal for IgG:
   1. mg/dL
   2. g/dL
   3. g/L

177. IgA:
   1. known: 
   2. not known:

178. Lower limit of normal for IgA:
   1. mg/dL
   2. g/dL
   3. g/L

179. IgM:
   1. known: 
   2. not known:

180. Lower limit of normal for IgM:
   1. mg/dL
   2. g/dL
   3. g/L

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
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 x 10^9/L; platelets > 100 x 10^9/L; hemoglobin > 11 g/dL; lymphocytes < 4 x 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)** — ≥ 50% decrease in peripheral blood lymphocyte count from pretreatment value; ≥ 50% reduction in lymphadenopathy if present pretreatment; ≥ 50% reduction in liver and spleen size if enlarged pretreatment; one or more of the following: neutrophils ≥ 1.5 x 10^9/L or 50% improvement over baseline, platelets > 100 x 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: ≥ 50% increase in the sum of the products of ≥ 2 lymph nodes (≥ 1 node must be ≥ 2 cm) or new nodes; ≥ 50% increase in liver or spleen size, or new hepatomegaly or splenomegaly; ≥ 50% increase in absolute lymphocyte count to ≥ 5 x 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: [Month] [Day] [Year]

190. Signed: ______________________________________  [Person completing form]

Please print name: ______________________________________

Phone: (__________) ______________________________________

Fax: (__________) ______________________________________

E-mail address: ______________________________________

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