2013: CLL Pre-HCT

The Chronic Lymphocytic Leukemia Pre-HCT Data Form is one of the Comprehensive Report Forms. This form captures CLL-specific pre-HCT data such as: disease assessment at diagnosis, laboratory studies at diagnosis, pre-HCT treatment for CLL, most recent disease assessment prior to the start of the preparative regimen, laboratory studies prior to the preparative regimen, and disease status at the last assessment prior to the preparative regimen.

This form must be completed for all recipients whose primary disease, reported on Form 2000 question 9, is chronic lymphocytic leukemia (CLL), B-cell/small lymphocytic leukemia (SLL), hairy cell leukemia, or prolymphocytic leukemia (PLL). Both Form 2013 (Chronic Lymphocytic Leukemia Pre-HCT Data) and Form 2018 (Hodgkin and Non-Hodgkin Lymphoma Pre-HCT Data), must be completed if the recipient had a Richter's transformation from CLL to diffuse large B-cell lymphoma prior to transplant.

Subsequent Transplant

If this is a report of a second or subsequent transplant for the same disease subtype and **this baseline disease insert was not completed for the previous transplant** (e.g., patient was on TED track for the prior HCT, prior HCT was autologous with no consent, etc.), begin at question 1.

If this is a report of a second or subsequent transplant for a **different disease** (e.g., patient was previously transplanted for a disease other than CLL), begin the form at question 1.

If this is a report of a second or subsequent transplant for the **same disease and this baseline disease insert has previously been completed**, check the indicator box and continue with question 138.

Manual Updates:
Sections of the Forms Instruction Manual are frequently updated. The most recent updates to the manual can be found below. For additional information, select the manual section and review the updated text.

If you need to reference the historical Manual Change History for this form, please click here or reference the retired manual section on the Retired Forms Manuals webpage.

Date	Manual Section	Add/Remove/ Modify	Description
7/18/16	2013: CLL Pre-HCT	Modify	Updated all question numbers to match the current version of the CLL Pre-HCT Disease Insert

Q1-25: Disease Assessment at Diagnosis

Question 1: What was the date of diagnosis of Chronic Lymphocytic Leukemia?

Report the date of the first pathological diagnosis (e.g., bone marrow biopsy) of CLL, SLL, Hairy Cell Leukemia, or PLL. Enter the date the sample was collected for examination. If the diagnosis was determined at an outside center and no documentation of a pathological or laboratory assessment is available, the dictated date of diagnosis within a physician's note may be reported. Do not report the date symptoms first appeared. The date of diagnosis is important because the interval between diagnosis and HCT is often a significant indicator for the recipient's prognosis post-HCT.

If the exact pathological diagnosis date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

Question 2: What was the disease histology at diagnosis?

Indicate if the disease histology resembled chronic lymphocytic leukemia (CLL) or prolymphocytic leukemia (PLL) at diagnosis. If this is unclear from a pathology report, consult with a physician and have her/him document the histology at diagnosis.

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

Indicate if a copy of the pathology report used for diagnosis is attached. Use the Log of Appended Documents (Form 2800) to attach a copy of the pathology report. Attaching a copy of the report may prevent additional queries.

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

Histologic transformation may occur after CLL diagnosis. Indicate if CLL transformed into another disease, such as diffuse large B-cell lymphoma (known as Richter's transformation or Richter's syndrome). If CLL transformed, select "yes" and continue with question 5. If CLL did not transform, select "no" and continue with question 9.

Question 5: Date of transformation

Enter the date of assessment that determined the disease transformation. Report the date of the pathological evaluation (e.g., lymph node biopsy). Enter the date the sample was collected for pathological and laboratory evaluations.
If the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

Questions 6-7: New Histology

Indicate if the new histology is prolymphocytic leukemia, diffuse large B-cell lymphoma, or other histology.

Richter's Syndrome occurs when CLL transforms into diffuse large B-cell lymphoma. If the recipient transforms to diffuse large cell lymphoma, report Non-Hodgkin Lymphoma (NHL) on question 9 of Form 2000 as the primary disease for HCT. Specify the subtype as diffuse large B-cell lymphoma using option 10 under question 9 on Form 2000. In addition to this form, Form 2018 (Hodgkin and Non-Hodgkin Lymphoma Pre-HCT Data) must be completed.

In rare cases, CLL may transform into other histologies such as ALL. If CLL transforms into another histology, specify using question 7.

Question 8: Is a copy of the pathology report attached?

Indicate if a copy of the pathology report used to detect transformation is attached. Use the Log of Appended Documents (Form 2800) to attach a copy of the pathology report. Attaching a copy of the report may prevent additional queries.

Questions 9-13: Autoimmune disorder(s) at diagnosis

Indicate if each autoimmune disorder was present at diagnosis.
Immune hemolytic anemia is the destruction of red blood cells by the immune system.

Immune thrombocytopenia is the destruction of platelets by the immune system.
The Coombs' test detects antibodies that bind to red blood cells. A direct Coombs' test indicates if antibodies are bound to red blood cells. An indirect Coombs' test indicates if antibodies are present in the blood, but not yet bound to the red blood cells. This binding causes premature destruction of red blood cells. These tests may also be called "Direct Antiglobulin Test" or "Indirect Antiglobulin Test."

If recipient had an autoimmune disorder not listed above at diagnosis, specify the disorder using question 13.

Question 14: What was the Rai stage at diagnosis?

Using the criteria below, indicate the Rai stage at diagnosis. If the Rai stage is not clear at diagnosis, consult with a physician and have her/him document the stage. If the Rai stage at diagnosis is unknown, check "unknown" and continue with question 15.

Table 1. Rai Stage

Stage	Risk	Description
Stage 0	*Low Risk*	Lymphocytosis (>15,000 × 10^9/L in blood or bone marrow **only**
Stage I	*Intermediate Risk*	Lymphocytosis plus enlarged lymph nodes (lymphadenopathy)
Stage II	*Intermediate Risk*	Lymphocytosis plus enlarged liver or spleen with or without lymphadenopathy
Stage III	*High Risk*	Lymphocytosis plus anemia (hemoglobin < 11 g/dL) with or without enlarged liver, spleen, or lymph nodes
Stage IV	*High Risk*	Lymphocytosis plus thrombocytopenia (platelet count < 100 × 10^9/L) with or without anemia or enlarged liver, spleen, or lymph nodes

Question 15: What was the Binet stage at diagnosis?

Using the criteria below, indicate the Binet stage at diagnosis. If the Binet stage is not clear at diagnosis, consult with a physician and have her/him document the stage. If the Binet stage at diagnosis is unknown, check “unknown” and continue with question 16.

The Binet staging focuses on lymphoid bearing areas: axillary, cervical, inguino-femoral, liver, and spleen.

Table 2. Binet Stage

Stage	Description
Stage A	Two or fewer lymphoid bearing areas enlarged, without anemia thrombocytopenia
Stage B	Three or more lymphoid bearing areas enlarged, without anemia or thrombocytopenia
Stage C	Presence of anemia (hemoglobin < 10.0 g/dL) or thrombocytopenia (platelet count < 100 × 10^9/L or 100,000/µL)

Question 16: What were the disease symptoms at diagnosis?

Using the criteria below, indicate if the recipient had “B” symptoms (also known as systemic or constitutional symptoms). If the symptoms at diagnosis are not clear at diagnosis, consult with a physician and have her/him document the presence or absence of “B” symptoms. If the symptomology at diagnosis is unknown, check “unknown” and continue with question 17.

Table 3. Systemic Symptoms

Symptoms	Description
A	None of the symptoms listed in B below
B	• Unexplained fever > 38° C (100.4° F); • Night sweats; or, • Unexplained weight loss of > 10% of body weight in six months before treatment

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

Extramedullary or extranodal involvement refers to the presentation of disease outside of the bone marrow, blood, and/or lymph nodes. Common areas of extranodal involvement include the central nervous system, liver, and lungs. Splenic involvement is evidenced by enlargement of the spleen, referred to as splenomegaly. Splenic or other extranodal involvement is most often detected utilizing imaging techniques or pathological findings.

If there was extramedullary or extranodal involvement at diagnosis, indicate “yes” and complete questions 18-24.
If there was no evidence of extramedullary disease, select “no” and continue with question 25.

If evidence of extramedullary involvement at diagnosis is unknown, select “unknown” and continue with question 25.

Questions 18-24: Specify site(s) of involvement

Specify the site(s) of involvement. If there is splenic involvement, specify how far the spleen extends below the costal margin (in centimeters) using question 22. If “Other site(s),” specify in question 24.

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

The CIBMTR uses the Karnofsky/Lansky scale to determine the functional status of the recipient at time of diagnosis. The Karnofsky Scale is designed for recipients aged 16 years and older, and is not appropriate for children under the age of 16. The Lansky Scale is designed for recipients less than 16 years old.

Recipient performance status is a critical data field that has been determined to be essential for all outcome-based studies. If a Karnofsky/Lansky score is not documented in the source documentation (e.g., inpatient progress note, physician’s clinic note), data management professionals **should not** assign a performance score based on analysis of available documents. Rather, a physician should provide documentation of the performance score.

The CIBMTR recognizes that some transplant centers prefer to assign and use the ECOG performance score as opposed to the Karnofsky/Lansky score. Although the ECOG and Karnofsky/Lansky performance

score systems are based on similar principles, the scales are not the same. The Karnofsky/Lansky scale is described in 10 categories, whereas the ECOG performance status is reported in six categories. Due to the overlap between the two systems, an ECOG score of “one” can represent either “80” or “90” on the Karnofsky/Lansky scale; whereas a Karnofsky/Lansky score of “80” or “90” is converted directly to an ECOG score of “one.” Therefore, the Karnofsky/Lansky scale can be more accurately converted into ECOG.

However, for centers that collect only an ECOG performance score, CIBMTR will make the following accommodations when auditing the source data:

- Centers assigning ECOG scores should do so using standard practices to ensure accuracy.
- For the purposes of CIBMTR reporting, conversion of ECOG to Karnofsky/Lansky should follow a standard and consistent practice to account for the lack of direct mapping. This practice should be clear and reproducible.

Select the appropriate performance scale, Karnofsky or Lansky, based on the recipient’s age. Using this scale, select the score (10-100) that best represents the recipient’s activity status at the time of diagnosis. The only valid scores are 10-100. The Karnofsky/Lansky scale can be found in Appendix L.

Q26-80: Laboratory Studies at Diagnosis

Report findings prior to any treatment of the primary disease for which the HCT is being performed.

Question 26-27: Lymphocytes in bone marrow

Indicate whether the percentage of lymphocytes in the bone marrow is “known” or “not known” at the time of CLL diagnosis. If “known,” report the laboratory value documented on the laboratory report. If “not known,” continue with question 28.

Question 28-29: WBC

Indicate whether the white blood count (WBC) in the peripheral blood is “known” or “not known” at the time of CLL diagnosis. If “known,” report the laboratory value and unit of measure documented on the laboratory report. If “not known,” continue with question 30.

Question 30-31: Lymphocytes

Indicate whether the percentage of lymphocytes in the peripheral blood is “known” or “not known” at the time of CLL diagnosis. If “known,” report the laboratory value documented on the laboratory report. If “not known,” continue with question 32.

The percentage of lymphocytes in the bone marrow is reported in Question 27.

Question 32-33: Prolymphocytes

Indicate whether the percentage of prolymphocytes in the peripheral blood is “known” or “not known” at the time of CLL diagnosis. If “known,” report the laboratory value documented on the laboratory report. If “not known,” continue with question 34.

Question 34-35: LDH

Indicate whether the lactate dehydrogenase (LDH) value is “known” or “not known” at the time of CLL diagnosis. If “known,” report the laboratory value and unit of measure documented on the laboratory report. If “not known,” continue with question 37.

Question 36: Upper limit of normal for LDH

Indicate the upper limit of normal for LDH at your institution.

Question 37-38: β2 macroglobulin

Indicate whether the β2 microglobulin is “known” or “not known” at the time of CLL diagnosis. If “known,” report the laboratory value and unit of measure documented on the laboratory report. If “not known,” continue with question 40.

Question 39: Upper limit of normal for β2 microglobulin

Indicate the upper limit of normal for β2 microglobulin at your institution.

Question 40: IgG

Indicate whether the IgG level is “known” or “not known” at the time of CLL diagnosis. If “known,” report the laboratory value and unit of measure documented on the laboratory report. If “not known,” continue with question 43.

Question 42: Lower limit of normal for IgG

Indicate the lower limit of normal for IgG at your institution.

Question 43-44: IgA

Indicate whether the IgA level is “known” or “not known” at the time of CLL diagnosis. If “known,” report the laboratory value and unit of measure documented on the laboratory report. If “not known,” continue with question 46.

Question 45: Lower limit of normal for IgA

Indicate the lower limit of normal for IgA at your institution.

Question 46-47: IgM

Indicate whether the IgM level is “known” or “not known” at the time of CLL diagnosis. If “known,” report the laboratory value and unit of measure documented on the laboratory report. If “not known,” continue with question 49.

Question 48: Lower limit of normal for IgM

Indicate the lower limit of normal for IgM at your institution.

Question 49: Leukemia cell type

Indicate the leukemic cell type: B-cell or T-cell. Cell type can be determined using immunophenotyping techniques such as flow cytometry. The cell type may be determined at any time after diagnosis and prior to HCT. If the leukemic cell type is unknown, select “unknown” and continue with question 50.

Questions 50-55: Immunophenotype

Indicate if any of the surface markers in questions 50-55 were expressed by cells at any time following diagnosis prior to the preparative regimen. These markers are often detected by immunophenotyping/flow cytometry. Do not leave any response blank.

Question 56: Did hypercalcemia occur at any time?

Indicate if hypercalcemia occurred at any time between diagnosis and immediately prior to the HCT. Hypercalcemia is the elevation of blood calcium levels above the upper normal limit at your center.

Question 57: Were cytogenetics tested (conventional or FISH)?

Cytogenetic assessment involves testing blood or bone marrow for the presence of a known chromosomal abnormality that reflects the recipient’s disease. FISH is categorized with cytogenetics.

Indicate if chromosome studies (cytogenetics) were obtained at the time the recipient was diagnosed with CLL (prior to the start of any treatment) and/or any time prior to the start of the preparative regimen.

If cytogenetic studies were obtained at either time point, check “yes” and continue with question 58.

If cytogenetic studies were obtained but there were not adequate cells (metaphases) to determine the results, check “yes,” and specify “no evaluable metaphases” in questions 57 and/or 58.

If no cytogenetic studies were obtained or it is unknown if chromosome studies were performed, indicate “no” or “unknown” and continue with question 81.

Question 58: Results of test at diagnosis

Indicate if any chromosomal abnormalities were identified at the time the recipient was diagnosed with CLL.

If “yes abnormalities identified,” continue with questions 59-68.

If “no evaluable metaphases” or “no abnormalities,” continue with question 69 and leave questions 59-68 blank.

Question 69: Results of tests after diagnosis to prior to the preparative regimen

Indicate if any chromosomal abnormalities were identified at any time after CLL diagnosis and prior to the start of the preparative regimen.

If “yes abnormalities identified,” complete questions 70-79.

If “no evaluable metaphases” or “no abnormalities,” continue with question 80 and leave questions 70-79 blank.

Questions 59-79: Specify abnormalities identified

Questions 59-68: Indicate “yes” or “no” for each cytogenetic abnormality identified at the time of CLL diagnosis prior to the start of treatment. If “Other abnormality” is selected, specify using question 68. Do not leave any response blank.

Questions 70-79: Indicate “yes” or “no” for each cytogenetic abnormality identified at any time after CLL diagnosis and prior to the start of the preparative regimen. If “Other abnormality” is selected, specify using question 79. Do not leave any response blank.

For more information regarding cytogenetic terminology and nomenclature, see Appendix R, Cytogenetic Abbreviations and Terminology.

Question 80: Is a copy of the cytogenetic or FISH report attached?

Indicate if a copy of the cytogenetic or FISH report is attached. Use the **Add Attachment** feature in FormsNet to attach a copy of the cytogenetic or FISH report. Additional information about using the Add Attachment feature in FormsNet can be found in the FormsNet3 Training Guide. Attaching a copy of the report may prevent additional queries.

Q81-122: Pre-HCT Treatment for CLL

When submitting the paper version of the form for more than two lines of therapy, copy the "Pre-HCT Treatment for Chronic Lymphocytic Leukemia" section and complete a "Line of Therapy" section for each line of therapy administered. The FormsNet™ application allows multiple lines of therapy to be reported. Complete a "Line of Therapy" section for each line of therapy administered prior to the start of the preparative regimen.

Question 81: Was therapy given between diagnosis and the start of the preparative regimen?

Indicate if the recipient received treatment for CLL between the time of diagnosis and the start of the preparative regimen. If "yes," continue with question 82. If "no" or "unknown," continue with question 123.

Question 82: Systemic Therapy

Systemic therapy is delivered to the whole body and may be injected into a vein or given orally. These drugs enter the bloodstream and reach all areas of the body. Systemic therapies used to treat CLL include chemotherapy and monoclonal antibodies.

Indicate "yes" if systemic therapy was administered, and continue with question 83.

Indicate "no" if systemic therapy was not administered, and continue with question 107.

Question 83: Date therapy started

Enter the date the recipient started receiving the line of therapy.

If the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

Question 84: Date therapy ended

Enter the date the recipient started the last cycle for this line of therapy.

If the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

Question 85: Number of cycles

Chemotherapy is usually administered in cycles with rest periods in between. This allows cancer cells to be attacked at vulnerable times and provides healthy cells adequate time to recover from the damage. A cycle can last one or more days and may repeat weekly, bi-weekly, or monthly. A chemotherapy course may consist of multiple cycles. Enter the number of chemotherapy cycles the recipient received during the line of therapy being reported or check “unknown/not applicable.”

Questions 86-106: Treatment

Treatments vary based on protocol and may be administered in inpatient or outpatient settings. A treatment may consist of a single drug or a combination of drugs. Additionally, the drugs may be administered on one day, over consecutive days, or continuously. Indicate “yes” or “no” for each chemotherapy treatment drug administered for the line of therapy being reported. Do not leave any responses blank. If the recipient received a chemotherapy treatment that is not listed, check “yes” for “other treatment” and specify the treatment in question 106.

Question 107: Radiation Therapy

Radiation therapy utilizes high-energy radiation to kill cancer cells. For CLL, radiation therapy may be used to kill cells that have invaded other tissues and lymph nodes. Indicate if the recipient received radiation therapy between the time of diagnosis and the start of the preparative regimen. If “yes,” continue with question 108. If “no,” continue with question 109.

Question 108: Date therapy started

Enter the date the line of radiation therapy began.

If the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

Question 109: Date therapy stopped

Enter the date the line of radiation therapy ended.

If the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

Questions 110-112: Specify site(s) of radiation therapy

Radiation may be used to kill leukemic cells in mediastinal masses or in other tissues. Indicate if radiation therapy was used on the mediastinum or another site after diagnosis prior to the start of the preparative regimen. If “Other site(s),” specify using question 112.

Question 113: Surgery

Indicate if the recipient received surgery after diagnosis and prior to the start of the preparative regimen. If “yes,” continue with question 114. If “no,” continue with question 118.

Question 114: Date of surgery

Enter the date of surgery.

If the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

Questions 114-117: Specify surgery

Indicate if the recipient had a splenectomy or surgery on another site. If “other site(s),” specify using question 117.

Question 118: Was this line of therapy given for stem cell priming?

The release of stem cells from the bone marrow into the peripheral blood is called stem cell priming (i.e., mobilization). Chemotherapy agents (e.g., cyclophosphamide) are often used to stimulate the mobilization of these stem cells for future collection.

Questions 118 refers to the line of chemotherapy indicated in questions 86-106. Indicate “yes” if the line of therapy was given for stem cell priming. Indicate “no” if the line of therapy was not given for stem cell priming.

Question 119: Best Response to Line of Therapy

Indicate the best response to the line of therapy. **See CLL Response Criteria for disease status definitions.** The best response is determined by a disease assessment, such as hematologic test, pathology study, and/or physician assessment.

If the best response to the line of therapy is unknown, check “unknown.”

Question 120: Date response established

Enter the date the best response to the line therapy was established. Report the date of the pathological evaluation (e.g., bone marrow biopsy) or blood/serum assessment (e.g., CBC, peripheral blood smear). Enter the date the sample was collected for pathological and/or laboratory evaluations. If no pathological, radiographic, or laboratory assessment was performed to establish the best response to the line of therapy, report the office visit in which the physician clinically assessed the recipient's response.

If the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

Question 121: Did disease relapse/progress following this line of therapy?

Relapse is the recurrence of disease after CR. Relapse is demonstrated by the reappearance of disease as based on one or more diagnostic tests.

Progression of CLL is a worsening of the disease following nPR, PR, or SD and requires ***one or more*** of the following:

- ≥ 50% increase in the sum of the products of ≥ 2 lymph nodes (≥ 1 lymph 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 ≥ 5×10^9/L
- Transformation to a more aggressive histology

Question 122: Date of relapse/progression

Enter the assessment date that relapse or progression was established following the line of therapy. Report the date of the pathological evaluation (e.g., bone marrow) or blood/serum assessment (e.g., CBC, peripheral blood smear). Enter the date the sample was collected for pathological and laboratory evaluations. If extramedullary disease is detected upon radiographic examination (e.g., X-rays, CT scans, MRI scans, PET scans), enter the date the imaging took place. If the physician determines evidence of relapse following a clinical assessment during an office visit, report the date of assessment.

If the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

Q123-137: Most Recent Disease Assessment Prior to the Start of the Preparative Regimen

Question 123: What was the Rai stage immediately prior to the preparative regimen?

Using Table 1, indicate the Rai stage immediately prior to the preparative regimen. If the Rai stage is not clear, consult with a physician and have her/him document the stage. If the Rai stage is unknown, check "unknown" and continue with question 124.

Question 124: What was the Binet stage immediately prior to the preparative regimen?

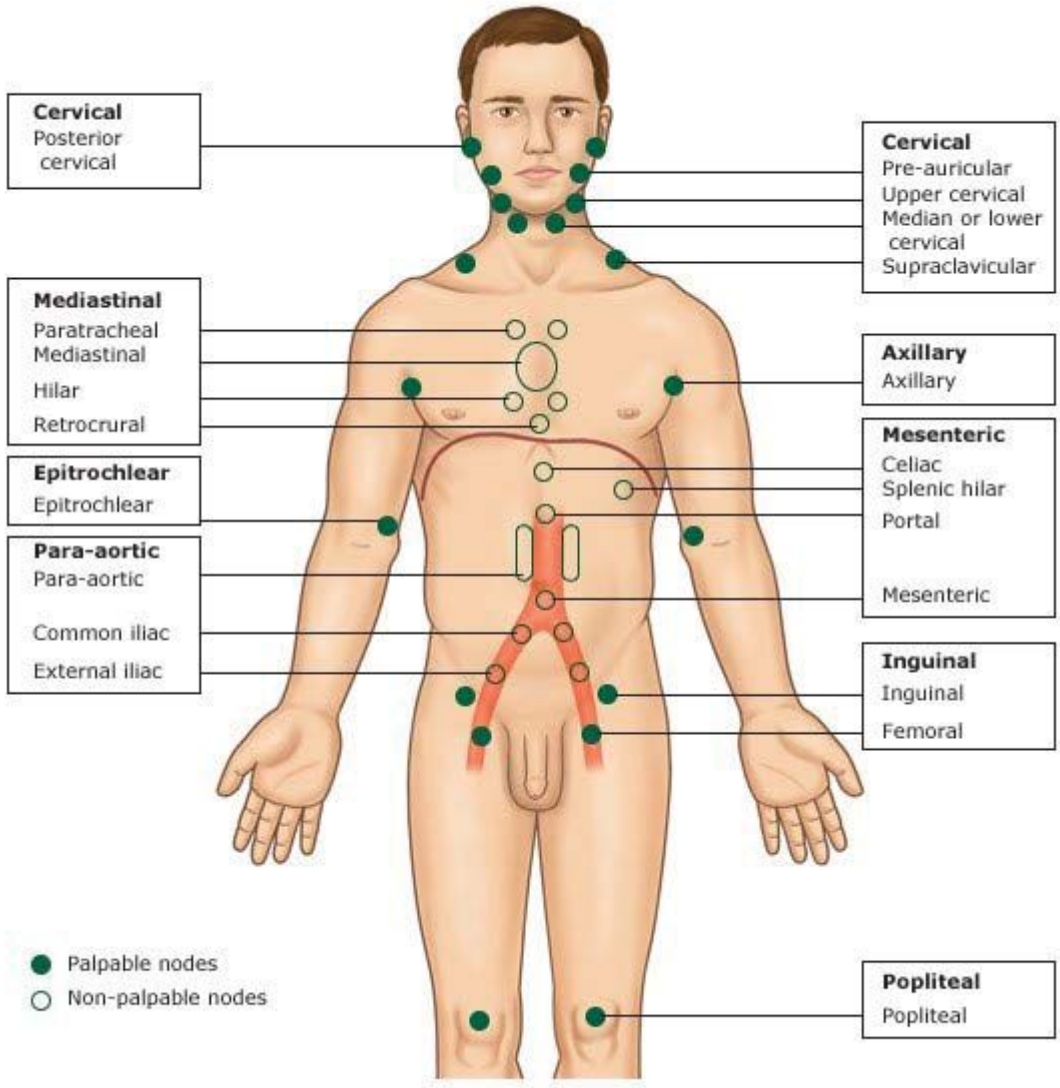
Using Table 2, indicate the Binet stage immediately prior to the preparative regimen. If the Binet stage is not clear, consult with a physician and have her/him document the stage. If the Binet stage is unknown, check "unknown" and continue with question 125.

The Binet staging focuses on lymphoid bearing areas. Five lymphoid bearing areas are possible: auxiliary, cervical, inguino-femoral, liver, and spleen.

Question 125: Did the recipient have known nodal involvement prior to the preparative regimen?

Refer to Graphic 1 for identification of nodal areas. Nodal involvement may be assessed by a physician palpating lymph nodes, pathology from a lymph node biopsy, or radiological assessment (e.g., PET or CT imaging). If evidence of nodal involvement is indicated prior to the start of the preparative regimen, select "yes," and continue with Question 126. If there is no evidence of nodal involvement upon assessment, select "no," and continue with Question 128.

Graphic 1. Nodal Regions[1]



[1] "Lymphadenopathy." Web log post. *Horses and Zebras*. Morning Report at Toronto General Hospital, 20 July 2010. Web. 2 May 2012. http://morningreporttgh.blogspot.com/2010/07/lymphadenopathy.html

Question 126: Specify the total number of nodes involved

Lymph node regions or groups occur above and below the diaphragm. Nodal regions include cervical (neck), axillary (underarm), mediastinal (thoracic), mesenteric (abdominal), para-aortic (pelvic), inguinal (groin), epitrochlear (inside of arm just above elbow), and popliteal (back of knee). Refer to Graphic 1 for specific nodes within each nodal region. Indicate the total number of nodal regions with evidence of lymphoma involvement.

Question 127: Specify the size of the largest nodal mass

Report the size (measured in centimeters) of the largest known nodal mass.

Question 128: Did the recipient have known extramedullary and/or extranodal involvement immediately prior to the preparative regimen?

Extramedullary or extranodal involvement refers to the presentation of disease outside of the bone marrow, blood, and/or lymph nodes. Common areas of extranodal involvement may include the central nervous system, liver, and lungs. Splenic involvement is evidenced by enlargement of the spleen, referred to as splenomegaly. Splenic or other extranodal involvement is most often detected utilizing imaging techniques or pathological findings.

If there was extramedullary or extranodal involvement immediately prior to the preparative regimen, indicate “yes” and complete questions 129-135.

If no extramedullary or extranodal involvement was identified, or if evidence of extramedullary or extranodal involvement was unknown prior to the start of the preparative regimen, indicate “no” and continue with question 136.

Questions 129-135: Specify site(s) of involvement

Answer each question “yes” or “no.” Do not leave any question unanswered. If there is splenic involvement, specify how far the spleen extends below the costal margin (in centimeters) using question 133. If “Other site(s),” specify the sites in question 135.

Question 136: Was a direct or indirect Coombs’ test performed?

The Coombs’ test detects antibodies that bind to red blood cells. A direct Coombs’ test indicates if antibodies are bound to red blood cells. An indirect Coombs’ test indicates if antibodies are present in the blood, but not yet bound to the red blood cells. This binding causes premature destruction of red blood cells. These tests may also be called “Direct Antiglobulin Test” or “Indirect Antiglobulin Test.” Indicate if the recipient had a Coombs’ test performed prior to the start of the preparative regimen. If the test was not performed, select “no” and continue with question 138.

Question 137: Specify the Coombs’ test results

Indicate the results of the Coombs’ test. A positive test is evidenced by the clumping (or agglutination) of red blood cells, indicating that antibodies against the body’s red blood cells are present.

Q138-161: Laboratory Studies Prior to the Start of the Preparative Regimen

If multiple tests were done prior to transplant, report the results of the most recent assessment.

Question 138: Lymphocytes in bone marrow

Indicate whether the percentage of lymphocytes in the bone marrow is “known” or “not known” prior to the start of the preparative regimen. If “known,” report the laboratory value documented on the laboratory report. If “not known,” continue with question 140.

Question 140-141: LDH

Indicate whether the lactate dehydrogenase (LDH) value is “known” or “not known” prior to the start of the preparative regimen. If “known,” report the laboratory value and unit of measure documented on the laboratory report. If “not known,” continue with question 143.

Question 142: Upper limit of normal for LDH

Indicate the upper limit of normal for LDH at your institution.

Question 143-144: β2 microglobulin

Indicate whether the β2 microglobulin is “known” or “not known” prior to the start of the preparative regimen. If “known,” report the laboratory value and unit of measure documented on the laboratory report. If “not known,” continue with question 146.

Question 145: Upper limit of normal for β2 microglobulin

Indicate the upper limit of normal for β2 microglobulin at your institution.

Question 146-147: IgG

Indicate whether the IgG level is “known” or “not known” prior to the start of the preparative regimen. If “known,” report the laboratory value and unit of measure documented on the laboratory report. If “not known,” continue with question 149.

Question 148: Lower limit of normal for IgG

Indicate the lower limit of normal for IgG at your institution.

Question 149-150: IgA

Indicate whether the IgA level is “known” or “not known” prior to the start of the preparative regimen. If “known,” report the laboratory value and unit of measure documented on the laboratory report. If “not known,” continue with question 152.

Question 151: Lower limit of normal for IgA

Indicate the lower limit of normal for IgA at your institution.

Question 152-153: IgM

Indicate whether the IgM level is “known” or “not known” prior to the start of the preparative regimen. If “known,” report the laboratory value and unit of measure documented on the laboratory report. If “not known,” continue with question 155.

Question 154: Lower limit of normal for IgM

Indicate the lower limit of normal for IgM at your institution.

Question 155: Was molecular testing/immunophenotyping performed at the time of disease assessment prior to the preparative regimen?

Molecular and immunophenotyping assessments are used to detect disease within the recipient. These methods can detect minimal residual disease (MRD) in the recipient’s blood, marrow, or tissue.

If molecular testing/immunophenotyping was performed at the time of disease assessment prior to the preparative regimen, select “yes” and continue with question 156.

If molecular testing/immunophenotyping was not performed, select “no” and continue with question 162.

Question 156: Immunophenotyping (4 color flow cytometry)

Immunophenotyping (flow cytometry) is a technique that can be performed on blood, bone marrow, or tissue preparations where cell surface markers can be detected on cellular material.

If immunophenotyping (flow cytometry) was performed at the time of disease assessment prior to the preparative regimen, select “yes” and continue with question 157.

If immunophenotyping (flow cytometry) was not performed, select “no” and continue with question 159.

Question 157: Specify the date immunophenotyping was performed

Enter the date the sample was collected for immunophenotyping at the time of disease assessment prior to the preparative regimen.

If the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

Question 158: Was disease detected?

Indicate if disease was detected by immunophenotyping. If this is not clear from the laboratory report, consult with a physician and have her/him document if evidence of disease is present.

Question 159: Heavy chain gene rearrangement (ASO-PCR)

Heavy chain gene rearrangement (ASO-PCR) testing is a molecular assessment that involves identifying a heavy chain rearrangement from diagnostic tissue (i.e., a molecular abnormality detected in the marrow, peripheral blood, or mass), creating an allele-specific oligonucleotide (ASO) (a “primer” unique to the recipient’s disease), and using polymerase chain reaction (PCR) to detect the disease.

Indicate “yes” if heavy chain gene rearrangement (ASO-PCR) testing was performed at the time of disease assessment prior to the preparative regimen.
If heavy chain gene rearrangement (ASO-PCR) was not performed, select “no” and continue with question 162.

Question 160: Specify the date the heavy chain gene rearrangement testing was performed

Enter the date the sample was collected for heavy chain gene rearrangement (ASO-PCR) testing at the time of disease assessment prior to the preparative regimen.

If the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.

Question 161: Was disease detected?

Indicate if disease was present based on heavy chain gene rearrangement (ASO-PCR) testing. If this is not clear from the laboratory report, consult with a physician and have her/him document if evidence of disease is present.

Q162-163: Disease Status at the Last Assessment Prior to the Preparative Regimen

Question 162: What was the disease status at the last evaluation prior to the preparative regimen?

Choose the correct disease status. **See CLL Response Criteria for disease status definitions.** When determining the disease status, compare the hematologic lab values, nodal, and extramedullary disease immediately prior to the preparative regimen to the assessments at baseline. “Baseline” is defined as the disease at diagnosis or at the time or relapse/progression.

Question 163: Date of the most recent assessment for disease status prior to the preparative regimen

Enter the date of the most recent assessment of disease status prior to the start of the preparative regimen. Report the date of the pathological evaluation (e.g., bone marrow biopsy), radiographic examination (e.g., X-rays, CT scans, MRI scans, PET scans), or blood/serum assessment (e.g., CBC, peripheral blood smear). Enter the date the sample was collected for pathological and laboratory evaluations; enter the date the imaging took place for radiographic assessments. If no pathological, radiographic, or laboratory assessment was performed within the pre-transplant work-up time period, report the most recent office visit in which the physician assessed the recipient’s disease status.

If the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, Guidelines for Completing Forms.