POC/QOC DATA ACQUISITION MANUAL

2014 DIAGNOSIS

MULTIPLE MYELOMA
STAGE IV COLON CANCER
CHRONIC LYMPHOCYTIC/SMALL CELL LEUKEMIA

POC DATA ACQUISITION MANUAL

SECTION II

PATIENT ELIGIBILITY

SECTION II - PATIENT ELIGIBILITY

CONTENTS

PATIENT ELIGIBILITY

In addition to using a common set of data items and codes, it is also important that the registries involved in this study adopt a uniform policy by which patients are selected for inclusion. This will ensure that the descriptions of the patient populations are comparable. Analyses will include the comparison of data collected for chronic lymphocytic leukemia, ~~and~~ multiple myeloma and for stage IV colon cancer patients diagnosed in 2014. It is important that the populations be comparable over time.

1. PATIENT SELECTION

1.1 The sampling procedures and the proportion of cases to be sampled are outlined below.

1.1.1 Sampling will be of men and women with stage IV colon cancer (TNM and Collaborative Stage defined below) diagnosed between January 1, 2014 and December 31, 2014 by sex and race/ethnicity.

1.1.2 Men and women with chronic lymphocytic leukemia/small lymphocytic lymphoma diagnosed between January 1, 2014 and December 31, 2014 will be sampled by sex and race/ethnicity.

1.1.3 Men and women diagnosed with multiple myeloma between January 1, 2014 and December 31, 2014 will be sampled by age group, sex and race/ethnicity.

2. SAMPLING

2.1 Each registry will select cases from their database according to the sampling plan below. Cases will be sampled approximately proportionate to the registry size. Non-Hispanic blacks, Hispanics, Asian/Pacific Islander and Native Alaskan/American Indians will be over-sampled to provide more stable estimates.

2.2. To sample cases, assign a random number between 0 and 1 to all eligible cases of the cancer of interest in your registry for the time period January 1, 2014 through December 31, 2014. The number of cases to be sampled divided by the total number of eligible cases will be your *sampling fraction*. If the case has a number less than or equal to your sampling fraction, X, the case will be included in the study. If the random number assigned is greater than your sampling fraction, the case will not be abstracted for the Patterns of Care study. For example, the sampling fraction for non-Hispanic black stage IV colon cancer is 0.63. All non-Hispanic black stage IV colon cancer cases eligible for inclusion in the study would have a random number between 0 and 1 assigned. If case 10100001 were given the random number of 0.594, it would be included in the study. Its number is less than the sampling fraction number of 0.63. If case 10100001 were assigned the random number of 0.654, it would not be abstracted for this study because its number is greater than the 0.63 sampling fraction.

2.3 At some point during the study, it is likely that cases will be added to the registry's database for a time period for which sampling has already been completed. In order to give these additional cases an opportunity to be included in the study, the registries should identify such patients, add them to the appropriate Sampling File, and assign them random numbers between 0 and 1. All cases found after the initial sampling **MUST** be sampled in this way. These additional cases will not modify the sampling fractions already obtained for a given time interval. The basis for selection of these patients into the study will be the sampling fractions (i.e., if the fraction for a cancer site group or subgroup is 0.49, a patient will be added to the appropriate SEER Patterns of Care file if his/her assigned random number is 0.49 or less). **In the event that one or more of these additional cases is found to be ineligible after selection into the study, do not replace them with another case. If there are a large number of cases found to be ineligible, please discuss with NCI whether additional cases should be sampled.**

3. REPORTABLE CASES

3.1 Reportable cases are to be drawn from all cancer patients who are registered to the SEER program.

3.2 A reportable case is one that fits the following criteria:

3.2.1 Patient must have a pathologically confirmed diagnosis of cancer of one of the following: colon stage IV, chronic lymphocytic leukemia/small lymphocytic lymphoma, or multiple myeloma.

3.2.2 Patient must have been initially diagnosed between January 1, 2014 and December 31, 2014.

3.2.3 Malignant neoplasms arising in the ICD-O Topography sites listed below are reportable to SEER POC study. See **SEER Program Coding and Staging Manual 2014** for a list of reportable terms.

3.2.4 This must be the first cancer diagnosed for this patient.

4. STAGE IV COLON CANCER CASES

4.1 Reportable colon cases

4.1.1 Primary site topography codes

C18.0 Cecum
Ileocecal valve
Ileocecal junction
C18.2 Ascending colon
Right colon
C18.3 Hepatic flexure of colon
C18.4 Transverse colon
C18.5 Splenic flexure of colon
C18.6 Descending colon
Left colon
C18.7 Sigmoid colon
Sigmoid flexure
Sigmoid, NOS
Pelvic colon
C18.8 Overlapping lesion of the colon
C18.9 Colon, NOS
Large intestine (excluding Rectum, NOS, C20.9 and Rectosigmoid junction, C19.9)
Large bowel, NOS

4.1.2 Include cases meeting the following criteria:

Derived Stage IV, 7th Edition (from CS coded fields): Tumor has spread to distant sites and/or lymph nodes.
Patients with first primaries only
Behavior codes: 3
Diagnostic confirmation codes 1-4

4.1.3 Exclude cases meeting any of the following criteria:

Derived AJCC stage I-III, 7th Edition (from CS coded fields)
Previous diagnosis of cancer
Simultaneously diagnosed with another cancer
Lymphoma of colon (histology codes 9590-9989)
Diagnosed at autopsy or on death certificate only

4.2 Patients will be sampled separately by sex and race/ethnicity.

5. CHRONIC LYMPHOCYTIC LEUKEMIA / SMALL LYMPHOCYTIC LYMPHOMA CASES

5.1 Reportable chronic lymphocytic leukemia/small lymphocytic lymphoma:

5.1.1 Include cases meeting the following criteria:

ICD-O-3 Histology codes: M-9823
Diagnostic confirmation codes 1-4

5.1.2 Exclude cases meeting any of the following criteria:

Previous diagnosis of cancer
Simultaneous diagnosis with second primary cancer
Diagnosed at autopsy or on death certificate only

5.2 Patients will be sampled separately by sex and race/ethnicity.

6. MULTIPLE MYELOMA CASES

6.1 Reportable multiple myeloma:

6.1.1 Include only cases meeting the following criteria:

ICD-O-3 Histology codes: M-9731-9732
Include only cases IDC-O-3 topography code: C42.1
Diagnostic confirmation codes 1-5

6.1.2 Exclude cases meeting any of the following criteria:

Previous diagnosis of cancer
Simultaneous diagnosis with second primary cancer
Patients diagnosed at autopsy or on death certificate only

6.2 Patients will be sampled separately by age, sex, and race/ethnicity.

7. GENERAL NON-REPORTABLE CASES AND MALIGNANCIES

Cases which are not reportable to SEER POC/QOC study are those with:

- Previous malignancies (except basal cell or squamous cell carcinoma of the skin)
- Simultaneously diagnosed cancers of more than one site 60 days or less apart (e.g., a patient simultaneously diagnosed with primary breast cancer and primary lung cancer within 60 days)
- Non-histologically proven carcinoma (clinical diagnosis)
- Lymphomas of the colon

- Death certificate diagnosis ONLY
- Autopsy diagnosis ONLY
- Patient younger than adult (adult is 20+ years old)

8. REPORTABILITY SUMMARY

8.1 Colon

Include:
Behavior code 3
Stage IV
Diagnostic confirmation codes 1-4
Exclude:
Patients with previous diagnosis of cancer
Stage I-III
Simultaneous diagnosis with second primary cancer
Histology codes 9590-9989 (Lymphoma of colon)
Patients diagnosed at autopsy or on death certificate only

8.2 Chronic lymphocytic leukemia/small lymphocytic lymphoma

Include:
ICD-O-3 Histology codes: M-9823
Diagnostic confirmation codes 1-4
Exclude:
Histology: All others
Patients with previous diagnosis of cancer
Simultaneous diagnosis with second primary cancer
Patients diagnosed at autopsy or on death certificate only

8.3 Multiple Myeloma

Include:
ICD-O-3 Histology codes: M-9731-9732
IDC-O-3 Site code: C42.1 only
Diagnostic confirmation codes 1-5
Exclude:
Histology: All others
Patients with previous diagnosis of cancer
Simultaneous diagnosis with second primary cancer
Any site other than C42.1
Patients diagnosed at autopsy or on death certificate only

POC DATA ACQUISITION MANUAL

SECTION III

COMMON DATA SET

SECTION III - COMMON DATA SET

CONTENTS

SEER PARTICIPANT

ITEM A-1

1. Code: 2 digits

2. Description:

2.1 The SEER Institution Number consists of the 2-digit SEER PARTICIPANT Code used for annual submissions to NCI.

CASE NUMBER

ITEM A-2

1. Code: 8 digits

2. Description:

2.1 The CASE NUMBER is the SEER patient identification number used on the files submitted to the National Cancer Institute.

2.2 The CASE NUMBER is used for administrative purposes by NCI and for communication with the SEER Registry concerning the case. Patient name and number assignment lists will be available only at the SEER Registry.

2.3 If you do not have a full eight digits, please code this exactly as you would for your routine SEER submissions.

QUALITY CONTROL

ITEM A-3

1. Code: 0 = No
1 =Yes

2. Description:

2.1 For each cancer site, a random 5% sample of cases to be re-abstracted should be selected by the registry. The procedure used by each registry for selecting this sample should be available if questions arise. Quality Control activities should be conducted as data abstracting progresses, rather than waiting until the end of the data collection.

2.2 Code "0" if this is not a re-abstracted QUALITY CONTROL case and "1" if it is.

2.3 Quality control is to be done as the abstracting proceeds. **The goal of QC is to correct mistakes being made as the study progresses rather than waiting until all of the data have been incorrectly collected**. Therefore, a comparison between the original abstract and the quality control abstract should be made at the time of completion of the QC form by the quality control expert. Any discrepancies should be immediately addressed with the abstractor and it should be determined whether the abstractor or the quality control person is correct. Once this is determined the appropriate correction should be made to the abstract form and a full discussion should take place to be certain that the data is being accurately abstracted and coded.

2.4 Steps to be taken:
Original abstract completed
QC abstract completed
Immediate comparison of the original and QC forms
Identification of differences between the original and QC
Determination of correct item or code
Discussion of correct abstracting or coding
Correction of original or QC abstract

TUMOR RECORD NUMBER

ITEM A-4

1. Code: 2-digit code

01	First record for a case
02	Second record for a case
..	
..	
..	
nn	Last of nn records for a case.

2. Description:

2.1 This is the unique sequential number as assigned to SEER participants.

2.2 This is the number that refers to the order in which the cancer was registered in SEER. This data item will not be edited, is for registry use only, can be blank if not needed.

SEQUENCE NUMBER

ITEM A-5

1. Code: 2 digits

2. Description:

2.1 The SEQUENCE NUMBER is the number of this primary in the life history of the patient. This is the SEQUENCE NUMBER as assigned for SEER submissions.

2.2 For this study, only “00” and “01” will be eligible, since these are to be first primary cancers.

PRIMARY SITE

ITEM A-6

1. Code: 4-digit code

2. Description:

2.1 The Topography section of the *International Classification of Disease for Oncology*, Third edition (ICD-O-3, 2001) is used for coding the primary site of all solid tumors.

2.2 The Hematopoietic and Lymphoid Neoplasm Database and Coding Manual is used for coding primary site for hematopoietic and lymphoid neoplasms diagnosed 1/1/2010 and later.

2.3 The coding of primary site is to be completed as described in *The SEER Program Coding and Staging Manual 2014* Section IV, Primary Site.

MORPHOLOGY

ITEM A-7

1. Code: 6 digits

1.1	Histology	4 digits
1.2	Behavior	1 digit
1.3	Grade	1 digit

2. Description:

2.1 All pathology reports related to this cancer for the case should be examined. Usually the final pathologic diagnosis is coded. However, if the final diagnosis is carcinoma NOS, and a more specific detailed HISTOLOGY is found in the microscopic description or in a comment, code the more specific description.

2.2 Use the SEER Program Coding and Staging Manual 2014 for morphology coding instructions. For hematopoietic and lymphoid neoplasms, use the Hematopoietic and Lymphoid Neoplasm Database and Coding Manual.

2.3 The BEHAVIOR codes are those used in ICD-O-3 and as described in The SEER Program and Coding and Staging Manual 2014.

2.4 For a complete description of coding of GRADE/differentiation, see Section IV, Grade, Differentiation or Cell Indicator of *The SEER Program Coding and Staging Manual 2014*. This is histologic grade.

2.5 Grade should be coded “6-B-Cell” for Multiple Myeloma and CLL/SLL (see Hematopoietic Database).

DIAGNOSTIC CONFIRMATION

ITEM A-8

1. Code: Microscopically Confirmed
1 = Positive histology
2 = Positive cytology
3 = Positive histology PLUS positive immunophenotyping and/or positive genetic studies (for hematopoietic and lymphoid neoplasms only)
4 = Positive microscopic confirmation, method not specified

Not Microscopically Confirmed
5 = Positive laboratory test/marker study
6 = Direct visualization without microscopic confirmation
7 = Radiology and other imaging techniques without microscopic confirmation
8 = Clinical diagnosis only (other than 5, 6, or 7)

Confirmation Unknown
9 = Unknown whether or not microscopically confirmed; death certificate only

2. Description:

2.1 Eligible codes include only microscopically confirmed diagnosis codes 1, 2, 3, 4 and 5 (myeloma only). These cases must have their cancers microscopically confirmed.

2.2 Code diagnostic confirmation as described in the SEER Program Coding and Staging Manual 2014, Section IV and the Hematopoietic and Lymphoid Neoplasm Database and Coding Manual

2.3 No case diagnosed at autopsy or by death certificate only would be eligible.

HOSPITAL CODE

ITEM A-9

1. Code: 3 digits

2. Description:

2.1 This item number will be assigned by the SEER site to the hospital of most definitive surgery or, if no surgery, the most definitive therapy. The codes are used to describe the hospital characteristics. The codes are provided to each registry by NCI. Bed size, residency training program and hospital classification are provided by the American Hospital Association Guidebook[1].

2.2 A patient seen in more than one institution/hospital should be assigned only one HOSPITAL CODE, that of the hospital providing the most definitive treatment as described above.

2.3 The HOSPITAL CODE is used to describe the characteristics of the hospitals/institutions while maintaining the confidentiality of each.

2.4 The HOSPITAL CODE is comprised of the three components below.

Bed size code:

1 = 1 - 49 beds
2 = 50 - 99 beds
3 = 100 - 199 beds
4 = 200 - 299 beds
5 = 300 - 399 beds
6 = 400 - 499 beds
7 = 500 or more beds
8 = OPD, including doctor's office only
9 = Unknown

Approved Residency training

0 = No
1 = Yes (MD or DO training program)
9 = Unknown

Residency training approval by the Accreditation Council for Graduate Medical Education. A physician's office should be coded "0- No."

HOSPITAL CODE (continued)

ITEM A-9

Hospital Classification code:

1 = Government, nonfederal (state, county, city, city/county, hospital district/hospital authority)

2 = Non-government, not-for-profit (church-operated, other not-for-profit)

3 = Non-government, for-profit (individual, partnership, corporation); physician office

4 = Government, Federal (Air force, Army, Navy, Public Health Service, Veterans Administration, Public Health Service Indian Service, Department of Justice, other Federal facilities)

9 = Unknown

2.5 These items are taken directly from the American Hospital Association Annual Survey of Hospitals. This survey is completed by all accredited hospitals in the U.S. Therefore, the information should be available from all hospital administrations.

2.6 Each hospital will have a three-digit code that will include one code for each of these items above. These codes will be assigned by the registry. For example, a 300 bed, non-profit, State University Hospital with an approved residency program would be coded as:

5 1 1

2.7 There will be one code for each hospital/institution. However, these codes will not necessarily be unique. Your registry area may have several hospitals with the same characteristics. It is possible that there may be several non-government, non-profit hospitals of 100-199 beds with no residency training program. The 3-digit code for all of these hospitals would be:

3 02

2.8 If a patient is seen only in a physician's office and is never hospitalized, code the bed size as 8, OPD. The code would be:

8 0 3

[1]American Hospital Association. American Hospital Association Guide to the Health Care Field. Chicago, IL.

INSURANCE STATUS

ITEM A-10

1. Code: 0 = No
1 = Yes
9 = Unknown

No insurance/Self pay
Medicare
Medicaid/Medicaid pending
Private Insurance/HMO Plan/IPA PLAN/Managed Care
Tricare/VA/Other Military
IHS (Indian Health Service)
Other (specify) _____

2. Description:

2.1 This item is used to code information on ***all*** insurance coverage reported by the patient at diagnosis or treatment. Code all appropriate insurance carriers on the abstract form. Code all insurance carriers from each hospital from date of diagnosis through treatment. Please try to determine insurance status because we know this influences selection of therapy for cancer patients.

2.2 Code "1 – Yes" for No Insurance when it is stated in the medical record that a patient has no insurance coverage or is a self-pay. All other insurance variables should be coded "0 – No" when No Insurance/Self-Pay is coded "1 – Yes."

2.3 Code "1 – Yes" for private insurance when the patient is reported to have a private insurance carrier such as Blue Cross, Travelers, Aetna, etc. or is in an HMO or managed care program, including an IPA.

2.4 Some patients may have Indian Health Service Insurance. This will be the exception, although we are oversampling American Indians and Alaskan Natives. Code "1 – Yes" when the patient has IHS insurance.

2.5 Code "9 - Unknown, not stated" to all when there is no insurance carrier information in the patient's medical record.

INSURANCE STATUS (continued)

ITEM A-10

3. Specifics:

3.1 Medicaid is insurance provided by the state and supplemented by the federal government for those who are on welfare or are medically indigent (i.e., cannot afford to pay their medical bills although they are not on welfare). Some states may use a term other than Medicaid for their program: e.g., California has a program called "MediCal." Please verify the name of the Medicaid program in your state. If the hospital has noted that "Medicaid is pending," code Medicaid as "1 – Yes." Patients with Medicaid do not usually have any other insurance, with the exception of some patients on Medicare. If Medicaid is coded "1 – Yes," then No Insurance and probably all other insurance variables (with the exception of possibly Medicare) will be coded "0 – No."

3.2 Blue Cross/ Blue Shield is one of the most common non-governmental insurance carriers. In many states Blue Cross covers only inpatient care; however, this is not universally true. Blue Shield is a carrier that covers physician's services and outpatient care. It is often linked with Blue Cross coverage. Code "1 – Yes" to private insurance if either is noted in the medical record. There are many other similar companies, such as Aetna, Prudential, Travelers, etc.

3.3 HMO Plans are insurance plans in which health care agencies (Health Maintenance Organizations) offer services on a prepaid basis. These are also referred to as managed care. Patients may subscribe individually or employers may pay the annual subscription fee. Medicare patients may join as part of "Medicare Advantage." Included in this code are IPA (Independent Practice Association) plans and other managed care providers. These are also prepaid plans. Code "1 – Yes" if the patient has any type of managed care coverage.

3.4 Tricare, VA, Other Military: Tricare is a comprehensive insurance plan provided by the federal government for retired military and diplomatic personnel and their dependents. This form of health insurance was previously known as CHAMPUS. VA and other military insurance entitles patients to treatment at no cost at VA hospitals. Patients with this coverage may be also be treated in non-VA hospitals. Code "1 – Yes" if the patient has this type of insurance.

INSURANCE STATUS (continued)

ITEM A-10

4. Examples:

4.1 Patient with Medicare and Blue Cross/ Blue Shield: Code "1 – Yes" to Medicare and to private insurance.

4.2 Patient who has documentation in the record that no insurance coverage is available: Code "1 – Yes" to no insurance and code all others "0 – No."

4.3 Patient who has no information available in the record regarding insurance coverage: Code "9 – Unknown" to all types of insurance.

4.4 If Medicaid pending is coded as yes, it is unlikely that the patient has insurance other than, perhaps, Medicare.

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

TREATMENT PROTOCOL REGISTRATION

ITEM A-11

1. Code: 0 = Not registered on treatment protocol
1 = Registered on treatment protocol
7 = Patient or patient's guardian refused treatment protocol
8 = Treatment protocol participation recommended, unknown if registered
9 = Unknown, not stated

2. Description:

2.1 Code whether the patient was registered on a treatment protocol during the first course of therapy. This includes treatment protocols sponsored by cooperative groups, clinical cancer centers, comprehensive cancer centers, and drug companies.

2.2 If a patient is registered on a non-therapeutic protocol (pain control, for instance, cancer control, or other protocol), but is not participating in a treatment protocol, code Item A-11 as "0 - Not registered on treatment protocol."

2.3 Code "0 - Not registered on a treatment protocol" when it is known that the patient was not registered on a treatment protocol during the first course of therapy.

2.4 Code "1 - Registered on treatment protocol" when the patient was registered on a treatment protocol during the first course of therapy.

2.5 Code "7 - Patient or patient's guardian refused protocol" when registration on a treatment protocol was recommended, but the patient was never registered because of patient/guardian refusal.

2.6 Code "8 - Treatment protocol participation recommended, unknown if registered" when a treatment protocol was recommended, but it is unknown whether the patient was actually registered.

2.7 Code "9 - Unknown, not stated" when there is no documentation regarding registration on a treatment protocol.

TREATMENT PROTOCOL SPONSOR AND NUMBER

ITEM A-12

1. Code: 1 to 12 characters representing the Treatment Protocol Sponsor such as cooperative group, research base, Clinical Cancer Center, or Comprehensive Cancer Center and the Protocol Number.

2. Description:

2.1 "Treatment Protocol Sponsor" identifies the research base or cooperative group that is conducting the clinical trial. When the patient was entered through an intermediate research base, the actual sponsoring group should be recorded. "Treatment Protocol Number" identifies the specific treatment protocol.

2.2 Code letters and digits only, eliminating all punctuation such as hyphens, slashes, periods, and spaces.

2.3 If a patient was not registered on a treatment protocol, record "9" in the first (left) code box on the form. If A-11 is coded “0”, “7”, “8”, or “9”, then A-12 should be coded with a single “9” in the left most box and the other boxes in A-12 should be left blank.

2.4 The Treatment Protocol Sponsor and Number should be left-justified and the remaining code spaces left blank.

2.5 If a patient is registered on a local treatment protocol, record "LOCAL."

2.6 If a patient is registered on a drug company treatment protocol, record the name of the drug company.

2.7 If the protocol sponsor and number are unknown then A-12 should be coded with a single “9” in the left most box and the other boxes in A-12 should be left blank.

TREATMENT PROTOCOL SPONSOR AND NUMBER (continued)

ITEM A-12

3. Examples:

3.1 SWOG 8711 is coded:

A-12 S W O G 8 7 1 1 _ _ _ _

Sponsor: SWOG

Number: 8711

3.2 Local protocol is coded:

A-12 L O C A L _ _ _ _ _ _ _

3.3 Drug company protocol is coded:

A-12 B A X T E R T R A V E N

Sponsor: Baxter Travenol

THERAPY VERIFIED WITH PHYSICIAN

ITEM A-13

1. Code: 0 = No verification of therapy
1 = Yes, physician office
2 = Unified record review
3 = No, hospital record only

2. Description:

2.1 This item will allow investigators to determine whether the treatment recorded has been verified by a source other than the hospital medical record.

2.2 If the therapy was not verified by the physician, by reviewing the patient's unified record, or by reviewing the patient's hospital record, then code this item as "0 – No verification of therapy." This might be the case if the hospital medical record cannot be found. Also use code "0" if the individual was a "VA patient only" and access to the medical records has been denied by the VA. This is not always the case; some registries are allowed access while other VA systems will not provide information to the registry. Please document in the "comment" column of the POC abstracting software if you were not allowed access.

2.3 If the therapy was not verified by the physician or by reviewing a unified record and/or the only information available is from the hospital medical record, then code "3 – No, hospital record only."

2.4 If the therapy was verified through contact with the physician code this "1 – Yes, physician office." The contact may be the physician's response to a letter, a telephone contact with the physician or his/her office staff, or a review of the physician's office records.

2.5 In the case of facilities such as HMOs or hospitals with consolidated inpatient and outpatient records where there is a unified record, reviewing this record would be equivalent to reviewing the physician's office records. Code "2 – Unified record review."

CO-MORBID CONDITIONS

Item C

1. Code: List all co-morbid conditions noted on the record at the time of initial diagnosis and during first course of treatment. These may be noted on the face sheet, discharge summary, nurse's notes, physician notes and/or the history and physical. Please check the entire record. Side-effects from cancer treatment are not considered co-morbid conditions.

2. Description:

2.1 Co-morbid conditions: List all medical conditions, including histories of disease or health problems.

2.2 If more than 20 different co-morbid conditions are found, list the others in the abstractor's comments.

2.3 If the condition was reported as a history of, be certain that "HISTORY" is recorded with the condition.

2.4 ***Do not complete the ICD codes next to the Co-morbid conditions.*** To assure comparability across registries, the co-morbid conditions will be coded by NCI.

2.5 This item is to record co-morbidities, not side effects of treatment. A medical condition that is related to the cancer or cancer therapy should not be included. For example, ascites would not be a co-morbid condition for a patient diagnosed with advanced ovarian cancer.

CODER ID

1. **Code:** Provide the coder ID assigned.

DATE ABSTRACTED

1. Code: month | day | year

2. Description:

2.1 Code the month, day and year that the final abstracting was completed. This might be the final abstracting of the hospital medical record, or it might be the date the physician verification form was completed.

2.2 We are collecting treatment data, so it is important to know how long the patient was followed. For example, we are much less likely to find much treatment information for a patient whose DATE ABSTRACTED was 1 month following diagnosis. Compare this to an individual whose abstract was completed 18 months following diagnosis. This patient is much more likely to have been treated, perhaps with several regimens - e.g., chemotherapy and radiation.

2.3 This is NOT the date the abstract form was completed or consolidated at the registry. **This date is the date the final medical record review was completed or the date of the physician verification form was completed or the office visited**.

POC DATA ACQUISITION MANUAL

SECTION IV

MULTIPLE MYELOMA DATA SET

SECTION V – MUTLIPLE MYELOMA DATA SET

CONTENTS

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

OVERT VS. SMOLDERING MYELOMA

ITEM B-1

1. Code: 1 – Overt
2 – Smoldering
9 – Unknown

2. Description:

2.1 Patients who are newly diagnosed with myeloma can present with overt (symptomatic) or smoldering (asymptomatic) myeloma. Historically, patients with smoldering myeloma were just observed closely but recent studies have shown better outcomes if patients with smoldering myeloma are treated early.

2.2 Review the PVF (Q2) to determine if the physician indicated the patient had overt vs. smoldering myeloma at diagnosis. If overt is marked, then code “1-Overt”. If smoldering is marked, then code “2-smoldering”.

2.3 If no information is provided on Q2 of the PVF, then review the medical record and code whether the patient had overt or smoldering myeloma AT THE TIME OF DIAGNOSIS. Time of diagnosis includes 6 months (2 months prior to diagnosis, month of diagnosis, and 3 months after the month of diagnosis). If both “smoldering” and “overt” are on the medical record, then code “overt”.

2.4 If neither the PVF nor the medical record mention “smoldering” or “overt”, then code "9 – Unknown".

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

INTERNATIONAL STAGING SYSTEM

ITEM B-2

1. Code:
1 – I
2 – II
3 – III
9 – Unknown

2. Description:

2.1 The International Staging System (ISS) is the current standard for staging myeloma.

2.2 The criteria are:

Stage I Serum B2-microglobulin <3.5 mg/L
Serum albumin ≥ 3.5 g/dL

Stage II Not stage I or III

Serum B_2-microglobulin < 3.5 mg/L and serum albumin <3.5 g/dL
OR Serum B_2-microglobulin 3.5 to < 5.5 mg/L irrespective of serum albumin

Stage III Serum B_2-microglobulin ≥ 5.5 mg/L

2.3 Code the ISS as reported in the medical record or the PVF. If the two sources disagree, use the most advanced stage reported. Do not stage the patients yourself. Information collected about albumin levels and B2-microglobulin can be used by researchers to calculate ISS.

2.4 If the ISS cannot be determined, code "9 – Unknown".

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

PRIOR MGUS

ITEM B-3

1. Code: 0 – No prior MGUS
1 – Yes, prior MGUS
9 – Unknown

2. Description:

2.1 Monoclonal gammopathy of unknown significance, MGUS (or benign monoclonal gammopathy, BMG) falls under the category of plasma cell disorders in which an abnormal amount of a single immunoglobulin is present in the serum. This monoclonal spike, or M component, is seen in multiple myeloma, Waldenstrom's macroglobulinemia, primary amyloidosis and various rare heavy chain diseases (true public health hazards). MGUS probably represents the common manifestation of multiple disorders and normal variants but it is considered a distinct entity from malignant disorders like non-plasma cell leukemias and lymphomas which occasionally produce an M-spike. Studies have shown a risk of malignant transformation to be 4% at 5 years, 15% at 10 years and 26% at 15 years.

2.2 This information is requested from the physician, but may also be noted in the medical record. If the physician does not provide this information, but it is found in the medical record, please record the information from the medical record.

2.3 Code "0-No prior MGUS" if there is no indication of MGUS.

2.4 If the physician indicates that there was a history of MGUS, code "1-Yes, prior MGUS".

2.5 If the physician does not know whether there was a prior history and/or there is no information in the medical record, code "9-Unknown".

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

TYPE OF IMAGING PERFORMED AT DIAGNOSIS

ITEM B-4

1. Code: 0—No
1—Yes
7—Patient or patient's guardian refused
8—Recommended, Unknown if performed
9—Unknown

- CT scan
- MRI scan
- PET scan
- Bone scan

2. Description:

2.1 The diagnosis and treatment of multiple myeloma has been based in part on bone involvement. Advanced imaging, namely CT, MRI or PET scan, is used to assess the level of bone involvement.

2.2 Review the medical record and the PVF to determine whether the patient had an advanced imaging performed at the time of diagnosis. Time of diagnosis includes 6 months (2 months prior to diagnosis, month of diagnosis, and 3 months after the month of diagnosis). Patients can undergo multiple types of scan, so code all types of scans reported on either source.

2.3 From the medical record, include only those scans reported 2 months prior to diagnosis, month of diagnosis, and 3 months after the month of diagnosis

2.4 Code "7 – Patient or patient's guardian refused" when imaging was recommended, but not performed due to patient or guardian refusal.

2.5 Code "8– Recommended, unknown if performed" if an advanced imaging was recommended, but it cannot be determined whether the patient received it.

2.6 Code "9-Unknown" if it cannot be determined whether the patient had an advanced imaging.

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

TRANSPLANT DATE

ITEM B-5

1. Code: MM-DD-YYYY
00-00-0000 - No transplant

Month	Day	Year
01 - January	01	Use 4-digit Year
02 - February	02	
.	.	
.	.	
12 - December	31	
77	77	7777 – Patient or guardian refused
96	96	9696 – Recommended, unknown if performed
97	97	9797 – Unknown if performed
99 - Month Unknown	99 - Day Unknown	9999 – Year Unknown

2. Description:

2.1 Record the transplant date for the patient NO MATTER HOW LONG AFTER THE DIAGNOSIS OF MULTIPLE MYELOMA.

2.2 If there is no transplant or no mention of a transplant, then code "00-00-0000 – No transplant".

2.3 If it cannot be determined whether the patient had a transplant, then code "97-97-9797".

2.4 Code "77-77-7777 – Patient or patient's guardian refused transplant" when a transplant was recommended, but not performed due to patient or guardian refusal.

2.5 If the exact date of the transplant is unknown, code an estimate (e.g., if in history and physical, the physician states the patient had a transplant two weeks ago, code date as 14 days prior to date of admission). If the record states that the transplant was performed recently, then code the month and year, but code the day as "99". Coding closest approximation is preferable to coding unknown.

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

DATE RADIATION BEGAN

ITEM B-6

1. Code: MM-DD-YYYY
00-00-0000 - No radiation

Month	Day	Year
00	00	0000 – No radiation given
01 - January	01	Use 4-digit year
02 - February	02	
.	.	
.	.	
.	.	
12 - December	31	
77	77	7777 – Patient or guardian refused
96	96	9696 – Recommended, unknown if given
97	97	9797 – Unknown if given
99 - Month Unknown	99 - Day Unknown	9999 – Year Unknown

2. Description:

2.1 Enter the date of first radiation to any site is given. Radiation refers to treatment of specific site, not whole body radiation. RECORD THE DATE OF RADIATION NO MATTER HOW LONG AFTER DIAGNOSIS IT WAS GIVEN.

2.2 Code "00-00-0000" if there was no radiation given or recommended.

2.3 Code "77-77-7777" if the patient and/or guardian refused recommended radiation.

2.4 Code "96-96-9696 - Recommended, unknown if given" when a patient was recommended to receive radiation, but it is unknown if it was actually received.

2.5 Code "97-97-9797 - Unknown" if it is unknown whether radiation was performed.

2.6 If the exact date of radiation is unknown, then code an estimate. For example, if in history and physical, the physician states the patient had radiation two weeks ago, code date of radiation as 14 days prior to date of admission. Coding the closest approximation is preferable to coding unknown. If it states the radiation was performed “recently”, then estimate the month and code the day as “99”.

CREATININE

ITEM B-7

1. Code: 0 – Normal
1 – Elevated
9 – Unknown

2. Description:

2.1 Elevated creatinine is a prognostic indicator for multiple myeloma. Persistent elevated creatinine indicates poorer prognosis. High levels of creatinine suggest failing kidneys.

2.2 Review the medical record to determine whether the patient had an elevated creatinine level **PRIOR** to the initiation of treatment. If the creatinine level was within normal limits, then code "0 - Normal". Normal creatinine levels vary among laboratories. The "normal" range is usually given along with the patient's values. A "usual" normal value is 0.8 to 1.4 mg/dl. Females have a lower creatinine than males, due to less muscle mass. Creatinine is measured in mg/dl = milligrams per deciliter. Code "0 – Normal" includes normal and levels of creatinine below normal.

2.3 If the patient had an elevated creatinine level, code "1 - Yes."

2.4 If it cannot be determined whether the patient had an elevated or normal creatinine level, code "9 - Unknown". If you cannot determine the "normal" range for the particular laboratory, it is better to use the "usual" normal of 0.8-1.4 mg/dl or less than to code the creatinine as unknown.

PERSISTENT ELEVATED CREATININE

ITEM B-8

1. Code: 0 – No
1 – Only one test performed
2 – Yes
9 – Unknown

2. Description:

2.1 Elevated creatinine is a prognostic indicator for multiple myeloma. Persistent elevated creatinine indicates poor prognosis. High levels of creatinine indicate failing kidneys.

2.2 Review the medical record to determine whether the patient had persistent elevated creatinine levels defined as more than one occasion at least two weeks apart prior to the initiation of treatment. If the creatinine levels were within normal limits, code "0 - No". Normal creatinine levels vary by laboratories. The "normal" range is usually given along with the patient's values. A "usual" normal value is 0.8 to 1.4 mg/dl. Females have a lower creatinine than males, due to less muscle mass. Creatinine is measured in mg/dl = milligrams per deciliter.

2.3 If the patient had persistently elevated creatinine levels, code "2 - Yes".

2.4 If it cannot be determined whether the patient had persistently elevated creatinine levels, code "9 - Unknown". If you cannot determine the "normal" range for the particular laboratory it is better to use the "usual" normal of 0.8-1.4 mg/dl or less than to code the creatinine as unknown.

ALBUMIN

ITEM B-9

1. Code:

0 – < 3.5
1 – ≥3.5
3 – Low
4 – Normal
9 – Unknown

2. Description:

2.1 Albumin is an important blood protein that is made by the liver and excreted by the kidneys. Because albumin is synthesized by the liver, decreased serum albumin may result from liver disease. It can also result from kidney disease, which allows albumin to escape into the urine. This data will be found in the laboratory reports or in the physicians' notes. Low serum albumin levels indicate poorer prognosis. Record the albumin **PRIOR** to administration of therapy.

2.2 Code "0– < 3.5" if the albumin was less than 3.5. This is a low albumin level.

2.3 If the patient had an albumin of 3.5 or greater, then code "1 - ≥3.5".

2.4 If it cannot be determined what the level of albumin was, review the record for references to low or normal serum albumin levels. Code "3-Low" if there is a note in the record that indicates the patient had a low serum albumin level.

2.5 Code "4-Normal" if the records indicate that serum albumin was normal. This is preferable to coding the level as unknown.

2.6 If there is no information about the serum albumin level in the chart, code "9-Unknown".

B2 MICROGLOBULIN

ITEM B-10

1. Code:
1 – <3.5
2 – 3.5-5.5
3 – >5.5
4 – Normal
5 – Elevated
6 – Equivocal or indeterminable
9 – Unknown

2. Description:

2.1 The level of beta-2-microglobulin in the blood may further influence the prognosis of multiple myeloma. Beta-2-microglobulin is a protein produced by myeloma cells. High levels of the protein indicate that cancer cells are present in large numbers. Record the microglobulin **PRIOR** to administration of therapy.

2.2 This information should be found in a laboratory report or in the physician's notes.

2.3 Use code "1" if the level is less than 3.5.

2.4 Use code "2" if the level is between 3.5 and 5.5.

2.5 Use code "3" if the level is greater than 5.5.

2.6 A value is preferred, but if there is only a note that indicates the beta-2-microglobulin was normal, code "4– Normal". If the notes indicate that it was elevated, code "5– Elevated".

2.7 If it cannot be determined what the value was and there is no indication that it was normal or elevated, code "9 – Unknown".

BONE MARROW CYTOGENETICS

ITEM B-11

1. Code: 0 – Not performed
1 – Performed
9 – Unknown

2. Description:

2.1 Cytogenetics is the study of chromosomes and the related disease states caused by numerical and structural chromosome abnormalities. A variety of cell or tissue types can be used to perform these studies. This item refers to an examination that requires a bone marrow biopsy and special tests to determine whether the cells within the bone marrow are genetically altered. The question in this item is concerned only with whether or not the test was performed, not the test results.

2.2 Code "1 – Performed" if the bone marrow cytogenetics were performed at the time of diagnosis. Time of diagnosis includes 6 months (2 months prior to diagnosis, month of diagnosis, and 3 months after the month of diagnosis). There should be a report within the record.

2.3 Code "0 – Not performed" if there is *no record or no mention* of bone marrow cytogenetic tests being performed.

2.4 Code "9 – Unknown" if it cannot be determined whether the bone marrow cytogenetics test was performed.

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

SYSTEMIC AGENTS

ITEMS B-12-B-28

1. Code: MM-DD-YYYY
00-00-0000 - No systemic therapy

Month	Day	Year
00	00	0000 – Not given
01 - January	01	Use 4-digit year
02 - February	02	
.	.	.
.	.	.
12 - December	31	
77	77	7777 – Patient/guardian refused
96	96	9696 – Recommended, unknown if given
97	97	9797 – Unknown if given
99 - Month Unknown	99 - Day Unknown	9999 – Year unknown

B-12 Bisphosphonates (Etidronate , Clodronate, Tiludronate, Pamidronate, Alendronate, Ibandronate, Risedronate, Zoledronic acid)

B-13 Bortezomib (Velcade)

B-14 Carfilzomib (Kyprolis)

B-15 Cyclophosphamide (Cytoxan)

B-16 Doxorubicin (Adriamycin)

B-17 Liposomal Doxorubicin

B-18 Etoposide

B-19 Lenalidomide (Revlimid)

B-20 Melphalan

B-21 Pomalidomide (Pomalyst)

B-22 Thalidomide (Kevadon)

B-23 Vincristine

B-24 Dexamethasone (Decadron)

B-25 Prednisone – corticosteroid

B-26 Epoetin (Epogen, Procrit)

B-27 Granulocyte Colony Stimulating Factor (G-CSF, Filgrastim, Neupogen)

B-28 Other, specify: _____

Examples of other systemic agents which might have been given are:
Thiotepa
Vinblastine (Velban)
Mitoxantrone (Novantrone)

This list is by no means complete and if other agents are found, please list them as well.

2. Description:

2.1 Enter the first date the systemic agent was given NO MATTER HOW LONG AFTER THE DIAGNOSIS OF MULTIPLE MYELOMA.

2.2 Code "00-00-0000 - Not given" when the patient did not receive systemic therapy following the diagnosis of multiple myeloma.

2.3 If no systemic therapy was given, all agents must be coded "00-00-0000", unless the patient or patient's guardian refused (see also code "7 - Patient or patient's guardian refused").

2.4 Code "the month, day and year" when a particular systemic agent was given following the diagnosis of multiple myeloma.

2.5 Code "77-77-7777 - Patient or patient's guardian refused" when chemotherapy was recommended, but not administered because of patient or guardian refusal. If the patient refused systemic therapy, but it is not known which specific agent was refused, all agents not known to have been given should be coded "77-77-7777".

SYSTEMIC AGENTS (continued)

ITEM B-12-B-28

2.6 Code "96-96-9696 - Recommended, unknown if given" when a patient was recommended to receive a systemic agent, but it is unknown if it was actually received. When systemic therapy was recommended, but the agents used were not documented, all agents must be coded "96-96-9696 - Unknown if given".

2.7 Code "97-97-9797 - Unknown" when there is no documentation regarding systemic therapy in the medical records reviewed and there is no information about the systemic therapy from the treating physician.

2.8 Code "99-99-9999" if it is known that the patient had the agent, but the date given cannot be determined. If the exact date of the first administration is unknown, code an estimate (e.g., if in history and physical, the physician states the patient had Methotrexate beginning two weeks ago, code date of first Methotrexate as 14 days prior to that date). If the record state that the Methotrexate was given recently, code the month and year, but code the day as "99." Coding closest approximation is preferable to coding unknown.

SEER POC DATA ACQUISITION MANUAL

SECTION V

STAGE IV COLON DATA SET

SECTION V – STAGE IV COLON DATA SET

CONTENTS

PERFORATION

ITEM B-1

1. Code:
0 – No bowel perforation
1 – Bowel perforation present in operative or pathology report(s) only
2 – Bowel perforation clinically evident only, not found at surgery or no surgery
3 – Bowel perforation on clinical report and operative or pathology report(s)
9 – Unknown

2. Description:

2.1 Information on the presence of a bowel perforation should come from the operative report or pathology report and clinical records. Examine these records carefully for statements about the presence or absence of a bowel perforation.

2.2 Code "0 – No bowel perforation" when the operative or pathological record states there was no bowel perforation present or when there is no mention of perforation in the operative or pathological records and there is no clinical evidence of perforation.

2.3 Code "1 – Bowel perforation present in operative or pathology report(s) only" when there is evidence from either of these reports that there was perforation of the bowel.

2.4 A tumor is sometimes said in a path report to have 'perforated the full thickness of the bowel wall' microscopically, that is, T3 -- **but this doesn't correspond to gross perforation and does not carry the same poor prognosis**. Be certain that you distinguish between these two meanings.

2.5 Code "2 – Bowel perforation clinically evident only" when there is evidence of bowel perforation, such as peritoneal signs that a tumor might have perforated the bowel and breached its integrity, thereby releasing bacteria and tumor cells into the peritoneal cavity. This might sometimes be suspected pre-op and then no evidence is found for it at surgery or the patient does not have surgery. Also use this code when the history and physical record states there was bowel perforation, but this is not confirmed in either the operative report or the pathology report.

2.6 Code "3 – Bowel perforation on clinical report and operative or pathology report(s)" when there is clinical evidence of perforation and evidence of perforation on the operative or pathological records.

2.7 Code "9 - unknown" when it is unclear from the operative or pathological record if there was a bowel perforation.

OBSTRUCTION

ITEM B-2

1. Code:
0 – No bowel obstruction
1 – Partial bowel obstruction
2 – Complete bowel obstruction
3 – Partial or complete obstruction is not specified
9 – Unknown

2. Description:

2.1 Information on the presence of a **bowel obstruction should come from the operative or pathology reports only**. Examine the record carefully for statements about the presence or absence of a bowel obstruction.

2.2 Code "0 – No bowel obstruction" when the operative or pathology record states there is no bowel obstruction or if there is no statement in the operative or pathology records about the presence or absence of an obstruction.

2.3 Code "2- Complete bowel obstruction" when a separate operation for decompressing colostomy was performed prior to the procedure to resect the tumor.

2.4 Code "3 – Partial or complete obstruction is not specified" when the operative or pathology record states the patient has a bowel obstruction, but it is not clear whether the obstruction was partial or complete.

2.5 Code "9 – Unknown" when the presence or absence of bowel obstruction cannot be determined from the statements contained in the operative or pathology reports.

3. Specifics:

3.1 If there is a statement about bowel obstruction in anything other than the operative report or the pathology report, and it is not confirmed in these reports, then it is unlikely to be an obstruction. Code "0 - No bowel obstruction" should be used.

KRAS MUTATIONS and DATES

ITEM B-3

1. Code: KRAS exon 2
KRAS non-exon 2
KRAS, NOS

0 – Test not performed
1 – Negative for mutation
2 – Positive for mutations
3 – Performed, results unknown
8 – Test type known (FOR KRAS, NOS ONLY)
9 – Unknown if performed

Dates each test
MM-DD-YYYY
00-00-0000 – Test not performed

Month	Day	Year
01 - January	01	Use 4-digit year
02 - February	02	
.	.	
.	.	
.	.	
77	77	7777 - Patient/guardian refused
96	96	9696 - Recommended, unknown if performed
97	97	9797 - Unknown if performed
99 - Month Unknown	99 - Day Unknown	9999 - Year Unknown

2. Description:

2.1 KRAS is a gene that encodes proteins in the epidermal growth factor receptor (EGFR) signaling pathway and is important for the development and progression of cancer. The KRAS status of a tumor, identified as normal (wild-type) or mutated, may indicate the prognosis and response of the tumor to therapeutic drugs. The first of the KRAS mutations to be associated with EGFR targeted monoclonal antibodies was the KRAS exon 2. Subsequently, KRAS non-exon 2 mutations have been assayed. The presence of KRAS mutations is recognized as a predictor of resistance to EGFR monoclonal antibodies.

KRAS MUTATIONS and DATES (continued)

ITEM B-3

2.2 Information on the presence of a **normal or mutated KRAS gene should come from the medical record.** Examine the record carefully for statements about KRAS mutations or abnormalities on both exon 2 and non-exon 2.

2.3 Code "0 – Test not performed" in all boxes when there is no statement in the medical record about any KRAS testing being performed.

2.4 Code "1- Negative for mutation" when the medical records indicate the KRAS exon 2 and/or KRAS non-exon 2 test was performed and results indicate the gene is negative for mutation. The medical record may also state that the KRAS status is normal or wild-type. If it is unclear whether the test performed was KRAS exon 2 or KRAS non-exon 2, then code KRAS, NOS as "1- Negative for mutation" and code KRAS exon 2 and KRAS non-exon 2 as "9 – Unknown if performed".

2.5 Code "2 – Positive for mutations" when the medical record states the KRAS test was performed and results indicate the gene is positive for mutation. The medical record may also state the KRAS status is abnormal or non-wild-type. If it is unclear whether the test performed was KRAS exon 2 or KRAS non-exon 2, then code KRAS, NOS "2 – Positive for mutations" and code KRAS exon 2 and KRAS non-exon 2 as "9 – Unknown if performed".

2.6 If it is known which KRAS test was performed, then code KRAS, NOS as "8-Test type known" and code the date as "00-00-0000".

2.7 Code "3—Performed, results unknown" when the KRAS test was performed, but it is not clear whether the results were positive or negative for mutation. If it is also unclear whether the test performed was KRAS exon 2 or KRAS non-exon 2, then code KRAS, NOS as "3—Performed, results unknown" and code KRAS exon 2 and KRAS non-exon 2 as "9 – Unknown if performed".

2.8 Code all KRAS tests as "9 – Unknown if performed" when it is unknown if the KRAS mutation test was performed.

2.9 Code "00-00-0000" if the KRAS was not recommended or performed. This may be coded "00-00-0000" for KRAS non-exon 2 while KRAS exon 2 might have been analyzed and the date of that test recorded. If the type of KRAS test (exon 2 and/or non-exon 2) are known, then KRAS, NOS will be coded "00-00-000."

KRAS MUTATION and DATES (continued)

ITEM B-3

2.10 Code "77-77-7777 – Patient/guardian refused KRAS" when the records indicate that the test was recommended, but the patient or guardian refused.

2.11 Code "96-96-9696 – Recommended, unknown if performed" if the records indicate that the KRAS was recommended, but it is unclear whether the patient had the test.

2.12 Code "97-97-9797 – Unknown if KRAS performed" if it is unknown whether KRAS testing was offered or performed.

2.13 If the exact date of the test is unknown, then estimate. For example, if the physician states the patient had KRAS assay two weeks ago, then code the date of surgery as 14 days prior to date of admission. Coding closest approximation is preferable to coding unknown. If an estimate cannot be made, then code "99-99-9999".

BRAF MUTATION

ITEM B-4

1. Code:
0 – Test not performed
1 – Negative for mutation
2 – Positive for mutations
8 – Performed, results unknown
9 – Unknown if performed

2. Description:

2.1 The BRAF gene belongs to a class of genes known as oncogenes and is responsible for regulating the growth and proliferation of cells. When mutated, the BRAF gene is continually active and may contribute to the growth of cancers by allowing abnormal cells to grow and divide uncontrollably. The BRAF gene may also be referred to as BRAF1, B-Raf proto-oncogene serine/threonine-protein kinase, the 94 kDa B-raf protein, Murine sarcoma viral (v-raf) oncogene homolog B1, the p94 gene or RAFB1.

2.2 Information on the presence of **a normal or mutated BRAF gene should come from the medical record.** Examine the record carefully for statements about BRAF mutations or abnormalities in the medical records.

2.3 Code "0 – Test not performed" when there is no statement in the medical record about the BRAF test being performed.

2.4 Code "1- Negative for mutation" when the medical records indicate the BRAF test was performed and results indicate the gene is negative for mutation. The medical record may also state that the BRAF status is normal.

2.5 Code "2 – Positive for mutations" when the medical record states the BRAF test was performed and results indicate the gene is positive for mutation. The medical record may also state the BRAF status is abnormal.

2.6 Code "8—Performed, results unknown" when the BRAF test was performed, but it is not clear whether the results were positive or negative for mutation.

2.7 Code "9 – Unknown if performed" when it is unknown if the BRAF test was performed.

MICROSATELLITE INSTABILITY

ITEM B-5

1. Code:
0 – Not performed
1 – Microsatellite stable (MSS); proficient mismatch repair (pMMR)
2 – Microsatellite unstable (MSI high); deficient mismatch repair (dMMR)
8 – Performed, results unknown
9 – Unknown if performed

2. Description:

2.1 Mutations in genes that repair damaged DNA cause regions called microsatellites to get longer or shorter, a phenomenon that scientists call microsatellite instability (MSI). Testing for microsatellite instability helps doctors determine whether a person is likely to have a gene mutation that causes hereditary nonpolyposis colorectal cancer (also known as HNPCC or Lynch Syndrome). Information on the presence of microsatellite instability **should come from the medical record.**

2.2 Code "0 – Not performed" when there is no statement in the medical record of a microsatellite instability test being performed.

2.3 Code "1- Microsatellite stable (MSS): proficient mismatch repair (pMMR)" when the medical records indicate the microsatellite test shows microsatellite stability (MSS) or proficient mismatch repair (pMMR).

2.4 Code "2 – Microsatellite unstable (MSI high): deficient mismatch repair (dMMR)" when the medical records indicate the microsatellite test shows unstability (MSI high) or deficient mismatch repair (dMMR).

2.5 Code "8—Performed, results unknown" when the microsatellite instability test was performed, but it is not clear whether the results were stable (proficient) or unstable (deficient).

2.6 Code "9 – Unknown if performed" when it is unknown if the microsatellite instability test was performed.

DATE OF CANCER-DIRECTED SURGERY TO PRIMARY SITE

ITEM B-6

1. Code: MM-DD-YYYY
00-00-0000 - No cancer-directed surgery to primary site

Month	Day	Year
01 - January	01	Use 4-digit year
02 - February	02	
.	.	
.	.	
.	.	
77	77	7777 - Patient/guardian refused surgery
96	96	9696 - Recommended, unknown if performed
97	97	9797 - Unknown if surgery performed
99 - Month Unknown	99 - Day Unknown	9999 - Year Unknown

2. Description:

2.1 Enter the date of the most definitive cancer-directed surgery to the primary site.

2.2 Code "00-00-0000" if no cancer-directed surgery was recommended or performed.

2.3 Code “77-77-7777 – Patient/guardian refused surgery” when the records indicate that surgery was recommended, but the patient or guardian refused.

2.4 Code “96-96-9696 – Recommended, unknown if performed” if the records indicate that the surgery was recommended, but it is unclear whether the patient had the surgery.

2.5 Code “97-97-9797 – Unknown if surgery performed” if it is unknown whether surgery was offered or performed.

2.6 If the exact date of the cancer-directed surgery is unknown, then estimate. For example, if the physician states the patient had surgery two weeks ago, then code the date of surgery as 14 days prior to date of admission. Coding closest approximation is preferable to coding unknown. If an estimate cannot be made, then code “99-99-9999”.

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

TYPE AND DATE RADIATION TO ***PRIMARY SITE*** BEGAN

ITEM B-7

1. Code: Type: 0 – No radiation given to primary site
1 – Conformal external beam
2 – Intensity modulated radiation therapy (IMRT)
3 – Brachytherapy
4 – External beam, not otherwise specified
7 – Patient or guardian refused
8 – Radiation given, type unknown
9 – Unknown if radiation given to the primary site

MM-DD-YYYY
00-00-0000 - No radiation given to the primary site

Month	Day	Year
01 - January	01	Use 4-digit year
02 - February	02	
.	.	
.	.	
.	.	
77	77	7777 - Patient/guardian refused radiation
96	96	9696 - Recommended, unknown if given
97	97	9797 - Unknown if offered/given
99 - Month Unknown	99 - Day Unknown	9999 - Year Unknown

2. Description:

2.1 Enter the date the patient was first given radiation to the ***primary site*** at any time following diagnosis.

2.2 Code "00-00-0000" if there was no radiation given to the primary site or recommended.

2.3 Code "77-77-7777 – Patient/guardian refused" when the patient or patient's guardian refused the recommended radiation to the primary site.

2.4 Code "96-96-9696 – Unknown" if it is unknown whether the recommended radiation to the primary site was performed.

2.5 If it cannot be determined whether radiation to the primary site was recommended and given, then code "97-97-9797 – Unknown if offered/given".

TYPE AND DATE RADIATION TO ***PRIMARY SITE*** BEGAN (continued)

ITEM B-7

2.6 If the exact date of radiation is unknown, then code an estimate. For example, if in history and physical, the physician states the patient had radiation two weeks ago, code date of radiation as 14 days prior to date of admission. Coding the closest approximation is preferable to coding unknown. If it states the radiation was performed "recently", then estimate the month and code the day as "99".

2.7 Code the type of radiation given. If the date is coded "96-96-9696" or "97-97-9797", then the type should be coded "9-Unknown if radiation given to primary site." If the date is coded "00-00-0000" or "77-77-7777", then code the type as "0-No radiation given to primary site" or "7 – Patient or guardian refused", respectively.

2.8 Use code "8-Radiation given, type unknown" when it is known that radiation was given but it is not clear which type.

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

PRIMARY SITE RADIATION THERAPY SEQUENCE WITH SURGERY

ITEM B-8

1. Code:
0 - No/unknown radiation and/or no/unknown cancer-directed surgery
2 - Radiation before surgery
3 - Radiation after surgery
4 - Radiation both before and after surgery
5 - Intraoperative radiation
6 - Intraoperative radiation with other radiation given before or after surgery
9 - Sequence unknown, but both surgery and radiation were given

2. Description:

2.1 This item is used to record information on patients who were treated with BOTH cancer-directed surgery (Item B-6) and radiation therapy to the primary site (Item B-7) during therapy. If only one was given, then this item is sequenced as “0”.

2.2 Code "0 - No/unknown radiation and/or no/unknown cancer-directed surgery" when radiation and/or cancer-directed surgery status is unknown or when the patient did not receive radiation therapy and/or cancer-directed surgery during therapy. (Radiation and Cancer-directed surgery status are unknown or not done when the dates are coded as “00, 77, 97 or 96”).

2.3 Code "2 - Radiation before surgery" when the patient received radiotherapy prior to cancer-directed surgery.

For example: A patient with a polyp biopsied, followed by radiation, followed by a colectomy is coded as "2 - Radiation before surgery".

2.4 Code "3 - Radiation after surgery" when the patient received radiotherapy following surgery.

For example: A patient who had a polyp biopsied, followed by a surgical resection of the colon, then treated with radiation therapy to the colon is coded as "3 -Radiation after surgery".

2.5 Code "4 - Radiation both before and after surgery" when the radiation therapy was given both prior to and following the surgical resection.

RADIATION THERAPY SEQUENCE WITH SURGERY (continued)

ITEM B-8

2.6 Code "5 - Intraoperative radiation" when the patient received radiation therapy directly to the tumor bed during the surgical resection.

2.7 Code "6 - Intraoperative radiation with other radiation given before or after surgery" when the patient received both intraoperative radiation as well as radiation prior to or following the surgical resection.

2.8 Code “9 - Sequence unknown, but both surgery and radiation were given” when it is clear that the patient had both surgery and radiation, but the sequence is unknown and/or the dates are missing (“99”) so the sequence cannot be determined.

RADIATION THERAPY SEQUENCE WITH SYSTEMIC THERAPY

ITEM B-9

1. Code:

0 - No/unknown radiation and/or no/unknown systemic therapy
2 - Radiation before systemic therapy
3 - Radiation after systemic therapy
4 - Radiation both before and after systemic therapy
5 - Concurrent radiation and systemic therapy
6 - Concurrent radiation and systemic therapy with other radiation given before and/or after systemic therapy
7 - Systemic therapy before and after radiation
8 - Concurrent radiation and systemic therapy with other systemic therapy given before and/or after radiation
9 - Sequence unknown, but both systemic therapy and radiation were given

2. Description:

2.1 This item is used to record information on patients who were treated with BOTH radiation therapy (Item B-7) and systemic therapy (Items B-11 to B-27). If only one was given, then this item is sequenced as "0".

2.2 Code "0 - No/unknown radiation and/or no/unknown systemic therapy" when radiation therapy and/or systemic therapy status is unknown or when the patient did not receive radiation therapy and/or systemic therapy. (Radiation and Systemic therapy status are unknown or not done when the dates are coded as "00, 77, 96, or 97").

2.3 Code "2 - Radiation before systemic therapy" when the patient received radiation therapy prior to systemic therapy.

For example: A patient with a biopsy, followed by radiation, followed by systemic therapy is coded as "2 - Radiation before systemic therapy".

RADIATION THERAPY SEQUENCE WITH SYSTEMIC THERAPY (continued)

ITEM B-9

2.4 Code "3 - Radiation after systemic therapy" when the patient received radiotherapy following systemic therapy.

For example: A patient who had a biopsy, followed by systemic therapy, then treated with radiation therapy to the colon is coded as "3 - Radiation after systemic therapy".

2.5 Code "4 - Radiation both before and after systemic therapy" when radiation therapy was given both prior to and following systemic therapy, but not concurrently.

2.6 Code "5 - Concurrent radiation and systemic therapy" when the patient received radiation during the time that they were receiving systemic therapy.

2.7 Code "6 - Concurrent radiation and systemic therapy with other radiation given before and/or after systemic therapy" when the patient received concurrent radiation and systemic therapy as well as radiation prior to and/or following systemic therapy.

2.8 Code "7 - Systemic therapy before and after radiation" when the patient received systemic therapy prior to and following radiation therapy, but not concurrently.

2.9 Code “8 - Concurrent radiation and systemic therapy with other systemic therapy given before and/or after radiation” when the patient received concurrent radiation and systemic therapy as well as systemic therapy prior to and/or following radiation.

2.10 Code “9 - Sequence unknown, but both systemic therapy and radiation were given” when the patient is known to have received both, but the sequence is unknown and/or the dates are missing (“99”) so the sequence cannot be determined.

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

SYSTEMIC THERAPY SEQUENCE WITH SURGERY

ITEM B-10

1. Code:
0 – No/unknown systemic therapy and/or no/unknown cancer-directed surgery
2 – Systemic therapy before surgery
3 – Systemic therapy after surgery
4 – Systemic therapy both before and after surgery
5 – Systemic therapy given during surgery
6 – Systemic therapy given during surgery with other systemic therapy given before or after surgery
9 – Sequence unknown, but both surgery and systemic therapy were given

2. Description:

2.1 This item is used to record information on patients who were treated with BOTH systemic therapy (Items B-11 to B-27) and cancer-directed surgery (Item B-6). If only one was given, then this item is sequenced as “0”.

2.2 Code "0 – No/unknown systemic therapy and/or no/unknown cancer-directed surgery" when systemic therapy and/or cancer-directed surgery was not received or when the status is unknown. (Surgery and Systemic therapy status are unknown or not done when the dates are coded as “00, 77, 96 or 97”).

2.3 Code "2 - Systemic therapy before surgery" when the patient received systemic therapy prior to the most extensive cancer-directed surgery.

For example: A patient with a biopsy, followed by systemic therapy, followed by a surgical resection is coded as "2 - Systemic therapy before surgery".

2.4 Code "3 - Systemic therapy after surgery" when the patient received systemic therapy following the definitive surgery.

For example: A patient who had a biopsy, followed by a surgical resection; then treated with systemic therapy is coded as "3 - Systemic therapy after surgery".

2.5 Code "4 - Systemic therapy both before and after surgery" is used when systemic therapy was given both prior to and following the most extensive cancer-directed surgery.

2.6 Use codes 5 or 6 if systemic therapy was given during surgery.

2.7 Code “9 - Sequence unknown” when both systemic therapy and surgery were received by the patient but it cannot be determined whether systemic therapy was given before or after surgery.

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

SYSTEMIC THERAPY AGENTS

ITEMS B-11 through B-27

1. Code: MM-DD-YYYY
00-00-0000 - No Systemic therapy given

Month	Day	Year
01 - January	01	Use 4-digit year
02 - February	02	
.	.	
.	.	
.	.	
77	77	7777 - Patient/guardian refused
96	96	9696 - Recommended, unknown if given
97	97	9797 - Unknown if given
99 - Month Unknown	99 - Day Unknown	9999 - Year Unknown

Start Date _ _ / _ _ / _ _ _ _

B-11 CapeOx

B-12 FLOX

B-13 FOLFOX

B-14 FOLFIRI

B-15 5-Fluorouracil (5-FU)

B-16 Bevacizumab (Avastin)

B-17 Capecitabine (Xeloda)

B-18 Cetuximab (Erbitux)

B-19 Folinic acid (Leucovorin) (Ancillary drug)

B-20 Irinotecan (CPT-11, Camptosar)

SYSTEMIC THERAPY AGENTS (continued)

ITEMS B-11 through B-27

B-21 Levamisole (Ergamisol)

B-22 Oxaliplatin (Eloxatin)

B-23 Panitumumab (Vectibix)

B-24 Ramucirumab (Cyramza)

B-25 Regorafenib (Stivarga)

B-26 Ziv-aflibercept (Zaltrap)

B-27 Other, specify:_____

Examples of other systemic therapeutic agents that might have been given are:

Mitomycin C (Mutamycin)
Cisplatinum (CDDP, Platinol)
Streptozotocin (Zanosar)

This list is by no means complete and if other systemic therapeutic agents are found, please list them as well. Please be sure to limit to systemic agents.

2. Description:

2.1 Code information on all systemic therapeutic agents received. Code the first date the systemic therapy was given.

2.2 Code "00-00-0000 - Not given" when the patient did not receive a systemic therapy agent, even if it was recommended. If no systemic therapy agent was given, then all agents must be coded as "00-00-0000", unless the patient or the patient's guardian refused the systemic therapy. (See also code "77 - Patient/guardian refused").

2.3 Code "77-77-7777 - Patient/guardian refused" when a systemic therapy agent was recommended, but not administered due to patient/guardian refusal. If the patient refused systemic therapy, but it is not known which specific drug was refused, all agents known to have not been given should be coded as "77-77-7777".

SYSTEMIC THERAPY AGENTS (continued)

ITEMS B-15 through B-31

2.4 Code “96-96-9696 - Recommended, unknown if given” when a patient was recommended to receive a systemic therapy agent, but it is unknown if it was actually given. When systemic therapy was recommended but the treatment agents to be used were not documented, all agents must be coded as "96-96-9696".

2.5 Code “97-97-9797 – Unknown if given” when it is unknown if systemic therapy was offered or given to the patient from the medical records or from the treating physician.

2.6 Code “99-99-9999” if it is known that the patient had the agent, but the date given cannot be determined. If the exact date of the first administration is unknown, then code an estimate. For example, if in history and physical, the physician states the patient received Cetuximab beginning two weeks ago, then code date of first Cetuximab as 14 days prior to that date. If the record states that the Cetuximab was given recently, then code the month and year, and code the day as “99”. Coding the closest approximation is preferable to coding “Unknown”.

2.7 It is unlikely that folinic acid (leucovorin) or levamisole (Ergamisole) will be given without 5-FU. Please check carefully whether either of these was given without 5-FU.

POC DATA ACQUISITION MANUAL

SECTION VI

CHRONIC LYMPHOCYTIC LEUKEMIA/ SMALL LYMPHOCYTIC LYMPHOMA DATA SET

SECTION VI – CLL/SLL DATA SET
CONTENTS

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

BONE MARROW EXAM

ITEM B-1

1. Code: 0 – No
1 – Yes
9 – Unknown

2. Description:

2.1 Investigators want to determine whether a bone marrow aspiration and/or biopsy was performed to confirm the diagnosis of CLL/SLL. Unless the patient is hospitalized for some other reason, this will probably be performed in the physician's office. Please record this information NO MATTER HOW LONG AFTER THE DIAGNOSIS of CLL/SLL the bone marrow biopsy occurs.

2.2 Code "0 – No" if no bone marrow aspiration and/or biopsy was performed on the patient.

2.3 Code "1 – Yes" if a bone marrow aspiration and/or biopsy was performed.

2.4 Code "9 – Unknown" if it is not known whether the patient had a bone marrow aspiration and/or biopsy.

LYMPH NODE BIOPSY

ITEM B-2

1. Code: 0 – No
1 – Yes
9 – Unknown

2. Description:

2.1 This procedure will usually be performed in a day-surgery setting. The patient is not technically hospitalized, but comes to the hospital in the morning, has the nodal biopsy and returns home later that day. Please record the lymph node biopsy NO MATTER HOW LONG AFTER THE DIAGNOSIS of CLL/SLL it occurs.

2.2 Code "0 – No" if no lymph node biopsy was performed on the patient.

2.3 Code "1 – Yes" if the physician performed a lymph node biopsy.

2.4 Code "9 – Unknown" if it is not known whether the patient had a lymph node biopsy.

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

INDICATION FOR THERAPY

ITEM B-3

1. Code: 0 = No
1 = Yes
9 = Unknown

Indications
Lymphadenopathy
Splenomegaly
Recurrent infections
Cytopenia
Elevated lymphocyte count only
Disease-related symptoms

2. Description:

2.1 This item is an attempt to determine the primary indication for treatment of the patient's chronic lymphocytic leukemia/small cell leukemia. Code ALL indications for therapy that apply.

2.2 Code "0-No," "1-Yes" or "9-Unknown" for each of the six indication for therapy items.

2.3 This will require verification. If the physician does not return the verification form and there is some indication in the chart the reason therapy was initiated, please record that information.

2.4 If it cannot be determined why the therapy was initiated, code "9-unknown" in all six indication for therapy items. Leave no items blank.

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

FLOW CYTOMETRY FOR MINIMAL RESIDUAL DISEASE

ITEM B-4

1. Code: 0 – No, not performed
1 – Yes
9 – Unknown if performed

2. Description:

2.1 This item is an attempt to determine whether the patient had flow cytometry for minimal residual disease following a clinical response. This may be found in the hospital record, but it will more often be ordered by the physician following a clinical response to treatment.

2.2 This will require verification. If the physician does not return the verification form and there is some indication in the chart the test was or was not performed, please record that information.

2.3 Code "0—No, not performed" if the patient has not had flow cytometry.

2.4 If the physician indicates that the patient had the test, then code "1 – Yes".

2.5 If it cannot be determined whether the patient had the test, then code "9-Unknown if performed."

BETA-2 MICROGLOBULIN

ITEM B-5

1. Code:
0 – Not performed
1 – Within normal limits
2 – Elevated
8 – Test performed, results unknown
9 – Unknown if performed

2. Description

2.1 Record whether a Beta-2 microglobulin test was performed within 2 months of diagnosis. If no test was performed, then code "0 – Not performed".

2.2 If the test was performed and was within normal limits, then code "1 – Within normal limits".

2.3 If the test was performed and the result was an elevated level, then code "2 – Elevated".

2.4 It may be apparent that the test was performed, but you cannot find the results in the record. In this case, code "8 – Test, performed, results unknown".

2.5 If you cannot determine whether the test was performed, then code "9 – Unknown if performed".

MUTATED VARIABLE IMMUNOGLOBULIN HEAVY CHAIN

ITEM B-6

1. Code:
0 – Not performed
1 – Within normal limits
2 – Elevated
8 – Test performed, results unknown
9 – Unknown if performed

2. Description

2.1 The immunoglobulin heavy chain (IgH) is a large polypeptide subunit of an antibody. Record whether the heavy chain variable region is mutated. If no test was performed within 2 months of diagnosis, then code "0 – Not performed".

2.2 If the test was performed and was within normal limits, then code "1 – Within normal limits".

2.3 If the test was performed and the result was an elevated level, then code "2 – Elevated".

2.4 It may be apparent that the test was performed, but you cannot find the results in the record. In this case, code "8 – Test performed, results unknown".

2.5 If you cannot determine whether the test was performed, then code "9 – Unknown if performed".

MORE THAN 3 NODAL SITES INVOLVED

ITEM B-7

1. Code: 0 – Three or fewer nodal sites involved
1 – More than 3 nodal sites involved
9 – Unknown number of nodal sites involved.

2. Description

2.1 Nodal sites refer to such areas as the axillary, cervical, inguinal, mediastinal, supraclavicular, etc. This does not refer to the number of positive nodes in a single area. Four positive nodes in single area (e.g. cervical) have a different prognosis than does having 4 different areas with nodal involvement.

2.2 Record whether there were more than 3 nodal sites involved. If there are 3 or fewer nodal sites involved, then code "0 – Three or fewer nodal sites involved". No nodal involvement would be coded "0 – Three or fewer nodal sites involved."

2.2 If there were more than 3 nodal sites involved, then code "1 – More than 3 nodal sites involved."

2.3 If you cannot determine the number of nodal sites involved, then code "9 – Unknown number of nodal sites involved."

LDH

ITEM B-8

1. Code: 0 – Not performed
1 – Within normal limits
2 – Elevated
8 – Test performed, results unknown
9 – Unknown if performed

2. Description

2.1 A lactate dehydrogenase (LDH) test is a non-specific test that may be used in the evaluation of a number of diseases and conditions. LDH is an enzyme that is found in almost all of the body's cells and is released from cells into the fluid portion of blood (serum or plasma) when cells are damaged or destroyed. Thus, the blood level of LDH is a general indicator of tissue and cellular damage.

2.2 Record whether an LDH test was performed **before therapy; before or as close to diagnosis as possible**. If no test was performed, then code "0 – Not performed".

2.3 If the test was performed and was within normal limits, then code "1 – Within normal limits". Use the laboratory normal limits to determine whether the LDH was "normal."

2.4 If the test was performed and the result was an elevated level, then code "2 – Elevated".

2.5 If it is apparent that the test was performed but you cannot find the results in the record, then code "8 – Test, performed, results unknown".

2.6 If it cannot be determined whether the test was performed, then code "9 – Unknown if performed".

CYTOGENETICS PERFORMED

ITEM B-9

1. Code: 0 – Not performed
1 – Performed
9 – Unknown if performed or no mention

2. Description

2.1 Cytogenetics is the study of normal and abnormal chromosomes. This includes examination of chromosome structure, the relationships between chromosome structure and phenotype, and the causes of chromosomal abnormalities.

2.2 Record whether cytogenetics was performed. If no test was performed, then code "0 – Not performed".

2.3 If cytogenetics were performed, then code "1 – Performed".

2.4 If it cannot be determined whether the test was performed or it was not mentioned, then code "9 – Unknown if performed or no mention".

NORMAL KARYOTYPE

ITEM B-10

1. Code:
0 – No karyotype performed
1 – Abnormal karyotype
2 – Normal karyotype
8 – Performed, results unknown
9 – Unknown if performed or no mention

2. Description

2.1 A karyotype is a description of the number and structure of the chromosomes. Record whether a karyotype was performed. If no karyotype was performed, then code "0 – Not performed".

2.2 If there was an abnormal karyotype, then code "1 – Abnormal karyotype".

2.3 If the patient's karyotype was normal, then code "2 – Normal karyotype". If any of items B-11 through B-14 are coded 1, then the patient's karyotype cannot be coded as normal.

2.4 If the test was performed, but the test results are unknown, code "8 – Test performed, results unknown."

2.5 If you cannot determine whether there was a karyotype performed, then code "9 – Unknown if performed or no mention".

17p DELETION

ITEM B-11

1. Code:
0 – No 17p deletion
1 – 17p deletion
2 – Results unknown
8 – Not performed
9 – Unknown if performed or no mention

2. Description

2.1 The presence of 17p deletion, assessed either by conventional cytogenetics or, more commonly, by interphase fluorescent in situ hybridization (FISH), is associated with the worst clinical outcomes in patients with CLL/SLL.

2.2 Record whether a 17p deletion was present. If no deletion was present, then code "0 – No 17p deletion".

2.3 If there was a 17p deletion, then code "1 – 17p deletion".

2.4 If the test was performed but the results are unknown, then code, "2-Results unknown."

2.5 If the test was not performed, then code "8 - Not performed".

2.6 If you cannot determine whether the test was performed or was not mentioned, then code "9 – Unknown if performed or no mention".

11q DELETION

ITEM B-12

1. Code: 0 – No 11q deletion
1 – 11q deletion
2 – Results unknown
8 – Not performed
9 – Unknown if performed or no mention

2. Description

2.1 CLL patients with 11q deletion are characterized by large and multiple lymphadenopathies and have been associated with poor prognostic factors.

2.2 Record whether an 11q deletion was present. If no deletion was present, then code "0 – No 11q deletion".

2.3 If there was an 11q deletion, code "1 –11q deletion".

2.4 If the test was performed but the results are unknown, then code, "2-Results unknown."

2.5 If the test was not performed, then code "8 - Not performed".

2.6 If you cannot determine whether the test was performed or was not mentioned, then code "9 – Unknown if performed or no mention".

12 TRISOMY

ITEM B-13

1. Code:
0 – No 12 trisomy
1 – 12 trisomy
2 – Results unknown
8 – Not performed
9 – Unknown if performed or no mention

2. Description

2.1 Trisomy 12 is the third most frequent chromosomal aberration in CLL (10–20% of cases).

2.2 Record whether a 12 trisomy was present. If no 12 trisomy was present, then code "0 – No 12 trisomy."

2.3 If there was a 12 trisomy, then code "1 – 12 trisomy".

2.4 If the test was performed but the results are unknown, then code, "2-Results unknown."

2.5 If the test was not performed, then code "8 - Not performed".

2.6 If you cannot determine whether the test was performed or was not mentioned, then code "9 – Unknown if performed or no mention".

13q DELETION

ITEM B-14

1. Code: 0 – No 13q deletion
1 – 13q deletion
2 – Results unknown
8 – Not performed
9 – Unknown if performed or no mention

2. Description

2.1 Deletion of 13q, found in more than 50% of CLL patients, is the most common cytogenetic abnormality detected by fluorescence in situ hybridization (FISH) and has historically been associated with good prognosis.

2.2 Record whether a 13q deletion was present. If no deletion was present, then code "0 – No 13q deletion".

2.3 If there was a 13q deletion, then code "1 – 13q deletion".

2.4 If the test was performed but the results are unknown, then code, "2-Results unknown."

2.5 If the test was not performed, then code "8 - Not performed".

2.6 If you cannot determine whether the test was performed or was not mentioned, then code "9 – Unknown if performed or no mention".

DATE OF SPLENECTOMY

ITEM B-15

1. Code: MM-DD-YYYY
00-00-0000 - No Splenectomy done.

Month	Day	Year
01 - January	01	Use 4-digit Year
02 - February	02	
.	.	
.	.	
12 - December	31	
77	77	7777 – Patient/guardian refused
96	96	9696 – recommended, unknown if perf.
97	97	9797 – Unknown if performed
99 - Month Unknown	99 - Day Unknown	9999 – Year Unknown

2. Description:

2.1 This item refers to the date of splenectomy. A surgical report will be generated from this procedure. **Code the date of the procedure, not the date of the surgical report.**

2.2 If there was no splenectomy done, then code "00-00-0000".

2.3 Please record the date of the splenectomy, NO MATTER HOW LONG AFTER THE DIAGNOSIS of CLL/SLL.

2.4 If the patient or guardian refused splenectomy, then code “77-77-7777 – Patient/guardian refused”.

2.5 If it is known that splenectomy was recommended but it is unknown if it was performed, then code “96-96-9696 – Recommended, unknown if performed”.

2.6 If it is unknown whether the patient had a splenectomy, then code “97-97-9797 - Unknown.”

2.7 If the exact date of the splenectomy is unknown, code an estimate (e.g., if in history and physical, the physician states the patient had a splenectomy two weeks ago, code date of splenectomy as 14 days prior to date of admission). Coding closest approximation is preferable to coding unknown. If it states the definitive surgery was performed “recently”, then code the month and year, but code the day as “99”.

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

TYPE/DATE OF ALLOGENEIC BONE MARROW/STEM CELLTRANSPLANT

ITEM B-16

1. Code: 0 – No transplant
1 – Matched related donor
2 – Matched unrelated donor
8 – Transplant donor unknown
9 – Unknown whether patient had transplant

MM-DD-YYYY
00-00-0000 - No transplant performed

Month	Day	Year
01 - January	01	Use 4-digit Year
02 - February	02	
.	.	
.	.	
12 - December	31	
77	77	7777 – Patient/guardian refused
96	96	9696 – Recommended, unk. if given
97	97	9797 – Unknown if given
99 - Month Unknown	99 - Day Unknown	9999 – Year Unknown

2. Description:

2.1 This item refers to the first date allogeneic transplant was performed. Record whether the allogeneic transplant donor was a related donor or whether the donor was unrelated.

2.2 Code the date of the transplant, NO MATTER HOW LONG AFTER THE DIAGNOSIS of CLL/SLL.

2.3 If no transplant was performed, code "00-00-0000".

2.4 If the patient or guardian refused transplant, code “77-77-7777 – Patient/guardian refused”.

2.5 If it known that a transplant was recommended, but it is unknown if it was performed, then code “96-96-9696 – Recommended, unknown if performed”.

TYPE/DATE OF TRANSPLANT (continued)

ITEM B-16

2.6 If it is unknown whether the patient had a transplant, code "97-97-9797 - Unknown."

2.7 If the exact date of the transplant was performed is unknown, code an estimate (e.g., if in history and physical, the physician states the patient had a transplant two weeks ago, code date of the transplant as 14 days prior to date of the note). If the record state that the transplant was recent, code the month and year, but code the day as "99". Coding closest approximation is preferable to coding unknown.

----------THIS ITEM REQUIRES OUTPATIENT VERIFICATION----------

SYSTEMIC THERAPY

ITEMS B-17 through B-35

1. Code: MM-DD-YYYY
00-00-0000 - No Systemic therapy

Month	Day	Year
00	00	00 – Not given
01 - January	01	Use 4-digit year
02 - February	02	
.	.	.
.	.	.
12 - December		
77	77	7777 – Patient/guardian refused
96	96	9696 - Recommended, unk. if given
97	97	9797- Unknown if given
99 - Month Unknown	99 - Day Unknown	9999 - Year unknown

B-17 Alemtuzumab (campath-1H)

B-18 Bendamustine (Treanda, Ribomustin)

B-19 Chlorambucil

B-20 Cladribine (2-Chlorodeoxyadenosine (2CDA), Leustatin,Litak, Movectro)

B-21 Cyclophosphamide (Cytoxan)

B-22 Fludarabine (Fludara)

B-23 Flavopiridol (Alvocidib)

B-24 Ibrutinib (Imbruvica)

B-25 Idelalisib (Zydelig)

B-26 Interferon

B-27 Lenalidomide (Revlimid)

SYSTEMIC THERAPY (continued)

ITEM B-17-B-35

B-28 Obatoclax (GeminX, GX15-070MS)

B-29 Obinutuzumab (Gazyva)

B-30 Ofatumumab (Arzerra)

B-31 Pentostatin (DCF – deoxycoformycin, Nipent)

B-32 Prednisone

B-33 Rituximab (Rituxan)

B-34 Vincristine

B-35 Other, specify: _____

Examples of other chemotherapeutic agents which might have been given are:
Thiotepa
Vinblastine (Velban)
Doxorubicin (Adriamycin)
Mitoxantrone (Novantrone)

This list is by no means complete and if other agents are found, please list them as well.

2. Description:

2.1 Enter the date each systemic therapy was first given NO MATTER HOW LONG AFTER THE DIAGNOSIS of CLL/SLL. Code information on all systemic therapeutic agents received at any time after the diagnosis of CLL/SLL.

2.2 Code "00-00-0000 - Not given" when the patient did not receive the systemic therapy following the diagnosis of CLL/SLL.

2.3 If no systemic therapy was given, all agents must be coded "00-00-0000", unless the patient or patient's guardian refused (see also code "7 - Patient or patient's guardian refused").

2.4 Code "the month, day and year" when each systemic therapy agent was first given following the diagnosis of CLL/SLL.

SYSTEMIC THERAPY (continued)

ITEMS B-17 through B-35

2.5 Code "77-77-7777 - Patient or patient's guardian refused systemic therapy" when systemic therapy was recommended, but not administered because of patient or guardian refusal. If the patient refuses systemic therapy, but it is not known which specific drug was refused, all agents not known to have been given should be coded "77-77-7777".

2.6 Code "96-96-9696 - Recommended, unknown if given" when a patient was recommended to receive a systemic therapy agent, but it is unknown if it was actually received. When systemic therapy was recommended, but the treatment agents used were not documented, all agents must be coded "96-96-9696- unknown if given".

2. 7 Code "97-97-9797 - Unknown" when there is no documentation regarding systemic therapy in the medical records reviewed and there is no information about the systemic therapy from the treating physician.

2.8 Code “99-99-9999” if it is known that the patient had the agent, but the date given cannot be determined. If the exact date of the first administration is unknown, then code an estimate (e.g., if in history and physical, the physician states the patient had Cytoxan beginning two weeks ago, code date of first Cytoxan as 14 days prior to that date). If the records state that the Cytoxan was given recently, then code the month and year, but code the day as “99.” Coding closest approximation is preferable to coding unknown.