POC 2019 DATA ACQUISITION MANUAL

2017-2018 DIAGNOSIS

NON-SMALL CELL LUNG CANCER
MELANOMA

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 important that the registries involved in this study adopt a uniform policy by which patients are selected for inclusion. This will ensure that the patient populations are comparable across registries and over time. Analyses will include the comparison of data collected for patients diagnosed with NSCLC in 1996, 2005, 2010, and 2015 and melanoma 1995, 1996, and 2001. We recognize that some criteria and coding for these patient populations has changed over time. All NSCLC cases, whether diagnosed in 2017 or 2018, will be coded using 2018 rules.

1. PATIENT SELECTION

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

1.1.1 Men and women diagnosed with Stage IIIB, IIIC (2018 cases only), IV, IVA, or IVB non-small cell lung cancer between January 1, 2017 and December 31, 2018 will be sampled by sex and race/ethnicity.

1.1.2 Men and women diagnosed with Stage IIIA, IIIB, IIIC, IIID, or IV melanoma between January 1, 2018 and December 31, 2018 will be sampled by 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 proportionately 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 For registries using SEER*DMS, algorithms will be implemented within SEER*DMS to identify cases for the POC study. Registry staff will be able to review the cases identified by the POC algorithms in SEER*DMS; and registry staff will use controls in SEER*Abs to pull cases for abstracting.

2.3 For registries not using SEER*DMS to sample cases, assign a random number between 0 and 1 to all eligible cases of melanoma in your registry diagnosed from January 1, 2018 through December 31, 2018 and separately for all eligible cases of NSCLC in your registry diagnosed from January 1, 2017 through December 31, 2018. 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, all NSCLC cases eligible for inclusion in the study would have a random number between 0 and 1 assigned. If the sampling fraction for NSCLC is 0.63 and 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.

2.4 For registries with small numbers of melanoma cases, all melanoma cases rather than a random sample with be included for abstraction.

2.5 At some point during the study, it is likely that cases will be added to the registry's database after sampling has already been completed. To give these additional cases an opportunity to be included in the study, the registries should identify such patients. Registries using SEER*DMS can re-run the sampling extract. Registries not using SEER*DMS can 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 cases into the study will be the sampling fractions (i.e., if the fraction for a cancer site group or subgroup is 0.49, a case will be added to the appropriate SEER Patterns of Care file if the assigned random number is 0.49 or less). **If 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 more than 10 cases found to be ineligible, please discuss with NCI whether additional cases should be sampled.**

2.6 **IMPORTANT:** Non-small cell lung carcinoma is being collected for diagnosis years 2017 and 2018. While all lung cases will be abstracted for the study using 2018 rules and instructions (regardless of diagnosis year), 2017 lung cases will be *sampled* using AJCC 7th edition stage group, while 2018 lung cases will be sampled using AJCC 8th edition stage group. Cases coded as stage IIIB-IV using 7th edition criteria would still be coded stage IIIB-IV using 8th edition criteria, ensuring consistency in sampling across the two diagnosis years.

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 meets the following criteria:

3.2.1 Patient must have a microscopically confirmed NSCLC or melanoma diagnosis.

3.2.2 Patients must be age 20 or older.

3.2.3 Patient with NSCLC must have been initially diagnosed between January 1, 2017 and December 31, 2018. Patient with melanoma must have been initially diagnosed between January 1, 2018 and December 31, 2018.

3.2.4 Malignant neoplasms arising in the ICD-O Topography sites listed below are reportable to SEER POC study. See **SEER Program Coding and Staging Manual 2018** for a list of reportable terms.

3.2.5 This must be the first cancer diagnosed for this patient (except basal cell or squamous cell carcinoma of the skin).

3.2.6 Patients are excluded if there is simultaneously diagnosed cancers of more than one site (e.g., a patient diagnosed with primary colon and primary lung cancer simultaneously).

3.2.7 Site-specific inclusion criteria are listed below.

4. NON-SMALL CELL LUNG CANCER CASES

4.1 Include only cases meeting the following criteria:

- ICD-O-3 C34.0-C34.9
- Histology codes 8012, 8022, 8023, 8031-8033, 8070-8072, 8082, 8083, 8140, 8144, 8200, 8230, 8250, 8252-8257, 8260, 8265, 8333, 8430, 8480, 8551, and 8562
- Behavior code 3 (malignant)
- AJCC Stage IIIB, IIIC (2018 8th edition cases only), IV, IVA, IVB

4.2 Exclude lung cancer cases with the following specifications:

- Histology codes: All other histologies
- Stage: All other stage groups and unknown stage or unstaged cases

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

4.4 Details of Sampling: Eligibility

Site	Race/Ethnicity	Sex
Lung	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN	Male Female

5. MELANOMA CASES

5.1 Include cases meeting the following criteria:

- Primary site skin melanomas only: ICD-O-3 C00.0-C00.2, C00.6,

C44.0-C44.9, C51.0-C51.2, C51.8-C51.9, C60.0-C60.2, C60.8-C60.9, C63.2
- Histology codes ICD-O-3 8720–8780
- Behavior code 3 (malignant)
- AJCC 8th Edition Stage IIIA, IIIB, IIIC, IIID, IV

5.2 Exclude melanoma cases with the following specifications:

- Histology codes: All other histologies
- Stage: All other stage groups and unknown stage or unstaged cases

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

5.4 Details of Sampling: Eligibility

Site	Race/Ethnicity	Sex
Melanoma	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN	Male Female

6. GENERAL NON-REPORTABLE CASES AND MALIGNANCIES

6.1 Cases which are not reportable to the SEER POC study are those with:

- Previous malignancies (except basal cell or squamous cell carcinoma of the skin)
- Simultaneously diagnosed cancers 60 days or less apart, either of the same site or two different sites. For example, a patient simultaneously diagnosed with primary corpus cancer and primary lung cancer a few weeks apart.
- Non-histologically proven diagnosis (clinical diagnosis only)
- Neuroendocrine tumor (NET) histologies
- Lymphoma/hematopoietic histology M-9590/3-9992/3
- Unknown stage or unstaged cases
- Death certificate only diagnosis
- Autopsy only diagnosis
- Cases with age at diagnosis younger the 20 years old

7. REPORTABILITY SUMMARY BY SITE

7.1 Non-small cell lung cancer

- Include primary sites ICD-O-3 C34.0-C34.9
- Include histology codes: 8012, 8022, 8023, 8031-8033, 8070-8072, 8082, 8083, 8140, 8144, 8200, 8230, 8250, 8252-8257, 8260, 8265, 8333, 8430, 8480, 8551, and 8562
- Include behavior code: 3 only
- Include Diagnostic Confirmation codes 1, 2, 4
- Include stages IIIB, IIIC (2018 cases only), IV, IVA, IVB

7.2 Melanoma

- Include primary sites ICD-O-3 C00.0-C00.2, C00.6, C44.0-C44.9, C51.0-C51.2, C51.8-C51.9, C60.0-C60.2, C60.8-C60.9, C63.2
- Include histology codes: 8720–8780
- Include behavior code: 3 only
- Include Diagnostic Confirmation codes 1, 2, 4
- Include AJCC 8th Edition Stage IIIA, IIIB, IIIC, IIID, IV

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 (QC)

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. QC 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 QC case. Code "1" if it **is** a re-abstracted QC case.

2.3 QC 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 QC abstract should be made at the time of completion of the QC form by the QC expert. Any discrepancies should be immediately addressed with the abstractor and it should be determined whether the abstractor or the QC person is correct. Once discrepancies are addressed the appropriate correction should be made to the abstract or to the QC form and a full discussion should take place to be certain that the data is being accurately abstracted and coded. The abstract and the QC form should be reconciled before submission to IMS. The form with the incorrect data, whether it is the study abstract or the QC form, should be corrected so that both forms contain the same data.

2.4 Steps to be taken:

1. Original abstract completed
2. QC abstract completed
3. Immediate comparison of the original and QC forms
4. Identification of differences between the original and QC
5. Determination of correct item or code
6. Discussion of correct abstracting or coding
7. Correction of original or QC abstract
8. Submit ***finalized*** QC and original abstracts

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. It is for registry use only and can be blank if it is 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 the cancers will be first primary cancers.

PRIMARY SITE

ITEM A-6

1. Code: 3-digit code

2. Description:

2.1 The Topography section of the *International Classification of Diseases for Oncology, Third Edition (ICD-O-3)* is used for coding the primary site of all cancers.

2.2 The coding of primary site is to be completed as described in The SEER Program Coding and Staging Manual 2018.

2.3 The 'C' should not be coded and the decimal point should be disregarded.

2.4 **IMPORTANT NOTE:** Non-small cell lung cancer cases diagnosed in 2017 should be abstracted for the study using 2018 rules and instructions. Use 2018 instructions from the SEER Manual, Coding Guidelines, and Solid Tumor Rules 2018 to code the data item Primary Site.

HISTOLOGY AND BEHAVIOR

ITEM A-7

1. Code: 5 digits

Histology	4 digits
Behavior	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 Code histology according to the Solid Tumor Rules and The SEER Program Coding and Staging Manual 2018.

2.3 The BEHAVIOR codes are those used in ICD-O-3 and as described in the 2018 SEER Program Coding and Staging Manual.

2.4 **IMPORTANT NOTE:** Non-small cell lung cancer cases diagnosed in 2017 should be abstracted for the study using 2018 rules and instructions.

DIAGNOSTIC CONFIRMATION

ITEM A-8

1. Code: Microscopically Confirmed
1 = Positive histology
2 = Positive cytology
4 = Positive microscopic confirmation, method not specified

2. Description:

2.1 Eligible codes include only microscopically confirmed diagnosis codes 1, 2, and 4 for non-small cell lung cancer and melanomas. These cases must have their cancers microscopically confirmed.

2.2 Code diagnostic confirmation as described in The SEER Program Coding and Staging Manual 2018.

2.3 Cases diagnosed only at autopsy or by death certificate are not eligible.

2.4 **IMPORTANT NOTE:** Non-small cell lung cancer cases diagnosed in 2017 should be abstracted for the study using 2018 rules and instructions.

HOSPITAL CODE

ITEM A-9

1. Code: 6 digits

2. Description:

2.1 This item will be assigned by the SEER site to the hospital of most definitive surgery or, if no surgery, the most definitive therapy in hierarchical order of radiation then systemic therapy. The codes are used to describe the hospital characteristics. Bed size, residency training program (Teaching Status), hospital classification (Type of Control), TPS Quality Score, Patient Experience Rating (star rating), and average length of stay for oncology patients are provided by the American Hospital Directory at https://www.ahd.com/search.php

2.2 On the American Hospital Directory webpage (https://www.ahd.com/search.php), enter the Hospital Name, State, or Zip Code for the hospital and click Submit. If more than one hospital is listed in the Table of Search Results, select the relevant Hospital Name.

2.3 At the top of the Free Profile for each hospital, the Type of Control (hospital ownership, coded in POC as "Hospital Classification code"), Total Staffed Beds, TPS Quality Score, and Patient Experience Rating are listed under "Identification and Characteristics". Approved Residency Training (yes/no) is listed further down the Free Profile page under "Teaching Status". Average length of stay for oncology patients is listed below "Teaching Status" in the "Inpatient Utilization Statistics by Medical Service" table. Please make sure to select the Oncology row from this table. If Oncology is not listed in this table, code average length of stay for oncology patients as 9 = Unknown.

2.4 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.

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

2.6 The HOSPITAL CODE is comprised of the six components below. All components are listed on the American Hospital Directory entry for a hospital.

HOSPITAL CODE (continued)

ITEM A-9

Digit 1: 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

Digit 2: 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."

Digit 3: 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

Digit 4: TPS (Total Performance Score) Quality Score:

1= 0 - 28.5
2 = >28.5 - 34.2
3 = >34.2 – 39.7
4 = >39.7 – 47.3
5 = >47.3
9 = Unknown

HOSPITAL CODE (continued)

ITEM A-9

Digit 5: Patient Experience Rating:

1 = 1 star
2 = 2 stars
3 = 3 stars
4 = 4 stars
5 = 5 stars
9 = Unknown

Digit 6: Oncology Average Length of Stay:

1 = 0 - 3.16
2= >3.16 - 5.25
3 = >5.25 – 8.48
4 = >8.48
9 = Unknown

2.7 Each hospital will have a six-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 hospital with an approved residency program that is a not-for-profit, State University Hospital and has a TPS Quality Score of 35.0, a 3-star Patient Experience Rating, and an average length of stay for oncology of 4.62 days would be coded as:

5 1 1 3 3 2

2.8 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 100-199 beds hospitals with no residency training program that are non-government/not-for-profit, have TPS Quality Scores between 39.7 and 47.3, have 4-star ratings, and have average length of stay for oncology between 5.25 and 8.48 days. The 6-digit code for all of these hospitals would be:

3 0 2 4 4 3

2.9 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 9 9 9

INSURANCE STATUS

ITEM A-10

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

Code separately for:

- At or within 30 days of diagnosis (≤ 30 days)
- More than 30 days after diagnosis (> 30 days)

- ☐ No insurance/Self pay
- ☐ Medicare fee-for-service (FFS), which may be listed as Part A, Part A/B, or Medicare unspecified
- ☐ Medicare HMO, which may be listed as Medicare Advantage, Medicare managed care, or Medicare Part C
- ☐ Medicare Part D or Medicare prescription drug plan (PDP)
- ☐ Supplemental private insurance with Medicare plan, which may be listed as Medigap insurance (select **only** if patient also has Medicare coverage)
- ☐ Medicaid
- ☐ Medicaid Pending
- ☐ Private Insurance/IPA Plan/HMO or Managed Care Plan *Not Including* Medicare or Medicaid
- ☐ Tricare/Other Military *Not Including Veterans Affairs (VA)*
- ☐ Veterans Affairs (VA)
- ☐ 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 and has two parts; all insurance coverage reported **at or within 30 days** of diagnosis, and separately all insurance coverage reported **more than 30 days after** diagnosis. Cases may have more than one types of insurance. Code all appropriate insurance carriers on the abstract form. Please try to determine insurance status as accurately as possible because insurance status influences selection of therapy for cancer patients**..**

INSURANCE STATUS (continued)

ITEM A-10

2.2 Patients may have codes of "1 – Yes" for multiple types of insurance. For example, a patient with both Medicare and Medicaid insurance would be coded as having "1 – Yes" for both their specific type(s) of Medicare insurance and for Medicaid insurance.

2.3 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. If the medical record states that a patient subsequently has insurance during the same time period (30 days or less after diagnosis vs. more than 30 days after diagnosis), the type(s) of insurance specified should also be indicated by "1 – Yes". If a patient has insurance at diagnosis and subsequently loses **all** insurance, code "1 – Yes" for No Insurance in addition to coding "1 – Yes" for other insurance that the patient previously had during the time period.

2.4 For patients with Medicare insurance, code "1 – Yes" for Medicare HMO if they are listed as having Medicare Advantage insurance (which is also called Medicare managed care or Medicare Part C). If patients are listed as having Medicare insurance **or** the type of Medicare plan is not specified, code "1 – Yes" for Medicare fee-for-service (FFS).

2.5 Medicare patients may also have a separate Medicare prescription drug plan, which is also known as Medicare Part D. For these patients, both their main Medicare insurance and Medicare Part D should be coded "1 – Yes".

2.6 For patients with Medicare insurance and private insurance (sometimes called Medigap insurance), both their main Medicare insurance the "Supplemental private insurance with Medicare plan" should be coded "1 – Yes". "Supplemental private insurance with Medicare plan" should be coded "1 – Yes" only for patients who also have another type of Medicare insurance.

2.7 Code "1 – Yes" for Medicaid if the patients is listed as having Medicaid (not otherwise specified) or any type of Medicaid coverage (e.g., Medicaid HMO or Medicaid managed care). Code "1 – Yes" for Medicaid Pending if the patient is listed as having applied for Medicaid or that Medicaid coverage is pending. Do not code "1 – Yes" for Medicaid Pending if the patient is uninsured and there is no mention of applying for Medicaid coverage or Medicaid coverage being pending.

INSURANCE STATUS (continued)

ITEM A-10

2.8 Code “1 – Yes” for private insurance when the patient is reported to have a private insurance carrier such as Blue Cross, Travelers, Aetna, whether or not this is an HMO or managed care program, including an IPA. As stated in (2.6), individuals with Medicare and private insurance should have codes of “1 – Yes” for both their main type of Medicare insurance and Supplemental private insurance with Medicare plan”. Individuals with “Supplemental private insurance with Medicare plan” should not also have private insurance coded as “1 – Yes” unless their insurance changed from private insurance to Medicare coverage.

2.9 A small number of patients may have Indian Health Service (IHS) Insurance. Code “1 – Yes” when the patient has IHS insurance.

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

Specifics:

2.11 Medicaid is insurance provided by the state and supplemented by the federal government for those who are low-income, 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 except for some patients on Medicare. If Medicaid is coded “1 – Yes,” then all other insurance variables will most likely be coded “0 – No.”

2.12 Blue Cross/Blue Shield is one of the most common non-governmental insurance carriers. There are many other similar companies, such as Aetna, Prudential, Travelers, UnitedHealthcare, Cigna, Humana, etc. These companies offer a variety of insurance plans including HMOs (Health Maintenance Organizations, also referred to as managed care), IPAs (Independent Practice Associations), and other plans types. These companies may also provide Medicare or Medicaid coverage. Therefore, having Blue Cross/Blue Shield or a similar company listed does not necessarily mean private insurance. Determine the type of insurance (private, Medicare, or Medicaid) provided for the patient and code appropriately.

2.13 Tricare/Other Military vs. VA: Tricare is a comprehensive insurance plan provided by the federal government for retired military and diplomatic personnel and their dependents. This form ofhealth insurance was previously known as CHAMPUS. VA (Veterans Affairs) is different from Tricare; this coverage entitles patients to treatment at no cost at VA hospitals. Code Tricare/Other

INSURANCE STATUS (continued)

ITEM A-10

Military as "1 – Yes" if the patient has this type of insurance; code VA as "1 – Yes" if the patient received care at a VA facility.

Examples:

2.14 Patient with Medicare and supplemental Blue Cross/Blue Shield private insurance: Code "1 – Yes" to both Medicare and Supplemental private insurance. Patients who have only Medicare managed care/HMO insurance that is administered by Blue Cross/Blue Shield should have "1- Yes" coded ONLY for "Medicare HMO".

2.15 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."

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

2.17 If Medicaid pending is coded as "1 – Yes". It is unlikely that the patient has any other type of insurance, although they may be pending for enrollment in a Medicaid managed care program.

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. This includes registration in protocols to treat cancer or to treat cancer-related symptoms (e.g. fatigue).

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.

2.8 **For this item record the protocol sponsor and number not the clinical trial registration number.**

TREATMENT PROTOCOL SPONSOR AND NUMBER (continued)

ITEM A-12

Examples:

2.9 SWOG 8711 is coded:

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

Sponsor: SWOG

Number: 8711

2.10 Local protocol is coded:

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

2.11 Drug company protocol is coded:

A-12 ASTRAZENECA _

Sponsor: AstraZeneca

CASE INFORMATION VERIFIED WITH PHYSICIAN OR OFFICE STAFF

ITEM A-13

1. Code: 0 = No outpatient verification and unified record not available
1 = Yes, physician or office staff
2 = Unified record review
3 = Death prior to discharge from hospitalization for initial cancer treatment
4 = Discharge from hospitalization for initial cancer treatment to hospice

2. Description:

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

2.2 Unified medical record refers to a medical record **that has all inpatient plus outpatient medical records.** If you have reviewed the unified medical record, there is no need to send a physician verification form.

2.3 If the medical record indicates the patient was hospitalized prior to initiation of cancer therapy and died during this hospitalization, code this Item as "3". If the medical record indicates that the patient was hospitalized prior to initiation of cancer therapy and was then discharged to hospice, code this item as "4". For either of these scenarios, physician verification is not required and the abstraction is in the same category as if a unified medical record was used.

2.4 If the case information was not verified by the physician or office staff, there was no review of the patient's unified record, and the patient neither died during a hospitalization prior to initial treatment nor was discharged to hospice after a hospitalization prior to initial treatment, then code this item as "0 – No outpatient verification and unified record not available." 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. (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 to medical records.

2.5 If the case information was verified through contact with the physician or office staff, code "1 – Yes, physician or office staff." **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 by a POC abstractor.**

2.6 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."

HEIGHT / WEIGHT

ITEM A-14

1. Code: Height

030-998 = Actual height
999 = Unknown/not recorded

Units

1 = Inches (in)
2 = Centimeters (cm)
3 = Other specify _____
9 = Unknown/not stated

Weight

010-998 = Actual body weight
999 = Unknown/not recorded

Units

1 = Pounds (lbs)
2 = Kilograms (kg)
3 = Other specify _____
9 = Unknown/not stated

PLEASE BE CERTAIN TO RECORD THE UNITS OF ALL OF THESE MEASURES.

2. Description:

2.1 Body mass, overweight and obesity have been associated with certain types of cancer. Of particular concern is whether those who are overweight or obese are receiving appropriate therapy which will decrease the disparity in survival rates. ASCO reports that as many as 40% of obese patients do not receive systemic therapy based on their weight. The ASCO has established guidelines for physicians to consider actual weight rather than ideal weight to determine dose.

2.2 Record the height of the patient. Round height to the nearest whole number if a decimal point has been recorded. Record the unit of measure, inches or cm. If it is unknown or not stated which unit of measure is used, then record "9 = unknown."

HEIGHT / WEIGHT (continued)

ITEM A-14

2.3 Record the patient weight from the medical record. This is a difficult variable to find in the record. Please record weight closest to the time of treatment, if possible, since the concern is the appropriate dose of chemotherapy. If weight at diagnosis is not available, then record "usual" weight if stated. Round weight to the nearest whole number if a decimal point has been recorded.

2.4 Record the units of measure for each item. They are extremely important in calculating body mass or obesity. Do not convert from one unit of measure to another, i.e. kilograms to pounds.

PAIN, DEPRESSION, AND PSYCHOSOCIAL DISTRESS ASSESSMENT AND TREATMENT

ITEM A-15

1. **Code separately for:**
   - **Pain**
   - **Depression**
   - **Psychosocial distress**

   Note: Each section (i-vi) must be completed for each of the above symptoms

   i) Symptom assessed/mentioned AFTER DIAGNOSIS?

   0 = Symptom not listed in medical record
   1 = Symptom listed in medical record

   ii) Date symptom **FIRST** appears in record after diagnosis:

   MM-DD-YYYY
   00-00-0000 - Symptom not listed in medical record.
   99-99-9999 – Date not available for first listing of symptom in medical record

Month	Day	Year
01- January	01	Use 4-digit Year
02-February	02	
.	.	
12- December	31	

   iii) Term/phrase **FIRST** used:

   Exact term or phrase **first** used in the medical record to describe the symptom. **Mark all that apply** if multiple terms were used on the same date. Code as not applicable (N/A) if symptom is not listed in the medical record.

   Pain Symptoms

   ☐ Pain
   ☐ Painful
   ☐ Ache
   ☐ Hurt
   ☐ Other _____
   ☐ N/A

PAIN, DEPRESSION, AND PSYCHOSOCIAL DISTRESS ASSESSMENT AND TREATMENT (continued)

ITEM A-15

Depression

- ☐ Depressed
- ☐ Depression
- ☐ Other _____
- ☐ N/A

Psychosocial distress

- ☐ Anxiety
- ☐ Fear
- ☐ Worry
- ☐ Emotional distress
- ☐ Psychological distress
- ☐ Psychosocial distress
- ☐ Other _____
- ☐ N/A

iv) Medical record section:

Section of the medical record/EHR where the symptom was **first** mentioned. **Mark all that apply** if the term(s) was mentioned in multiple sections on the same date. Code as not applicable (N/A) if the symptom is not listed in the medical record.

- ☐ Physician progress notes
- ☐ Nursing progress notes
- ☐ Review of symptoms / Review of systems
- ☐ Assessment / Plan
- ☐ Other _____
- ☐ N/A

PAIN, DEPRESSION, AND PSYCHOSOCIAL DISTRESS ASSESSMENT AND TREATMENT (continued)

ITEM A-15

v) Treatment/referral for symptom listed:

Complete for each symptom (pain, depression, psychosocial distress)
0 = No
1 = Yes
9 = Symptom not mentioned.

vi) Same symptom mentioned again in medical record on a different date (even if using a different term for the symptom):
0 = No
1 = Yes
9 = Symptom not mentioned.

2. Description:

2.1 Items A-15 and A-16 are pilot tests to assess whether information on assessment and/or treatment of symptoms can be collected from the medical record **after diagnosis.** Item A-15 includes the three most frequent symptoms in the study population: pain, depression, and psychosocial distress.

2.2 If the medical record indicates the long-term presence of a symptom (e.g., chronic pain or history of depression), all information on the symptom should still be completed and the date after diagnosis that the symptom was first mentioned should be entered in (ii). In addition, chronic or long-term present symptoms should also be entered as co-morbidities in Item C.

2.3 Indicate separately whether each of the three symptoms is mentioned in the medical record. "Pain" may be indicated by the words "pain", "painful", and other words listed above. Depression may be indicated by the words "depressed", "depression" and other words listed above. Psychosocial distress may include a broad set of terms, including anxiety, fear, worry, emotional distress, and mental distress.

2.4 Specify the date that each symptom was **first** mentioned in the medical record in item (ii). If the symptom was not mentioned, code as 00-00-0000.

PAIN, DEPRESSION, AND PSYCHOSOCIAL DISTRESS ASSESSMENT AND TREATMENT (continued)

ITEM A-15

2.5 In item (iii), for each symptom (pain, depression, psychosocial distress), choose the exact term **first** used in the medical record to describe the symptom. If the term used to describe the symptom is not present in the code list, then choose "Other" and enter the term in the text field. If the symptom is not present in the medical record, code as not applicable (N/A).

2.6 In item (iv), for each symptom (pain, depression, psychosocial distress), choose the section of the medical record where the symptom was **first** listed. If the medical record section is not present in the code list, then choose "Other" and enter the section name in the text field. If the symptom is not present in the medical record, code as not applicable (N/A).

2.7 In item (v), for each symptom (pain, depression, psychosocial distress), record whether the medical record indicates any treatment for the symptom or referral to another health care provider for the symptom. This item does not record the specific treatment or referral, just whether any treatment or referral for the symptom is listed in the medical record. Treatment/referral does not need to be listed on the same date the symptom was first mentioned (item ii) but could be listed at a later date. Code item (v) as "0 = No" if the symptom is listed (item i coded as "1 = Yes") but no treatment/referral for the symptom is specified in the medical record. Code item (v) as "1 = Yes" if the symptom is listed (item i coded as "1 = Yes") and any treatment/referral for the symptom is specified in the medical record. If the symptom is not present, code item (v) as "9 = Symptom not mentioned".

2.8 In item (vi), for each symptom (pain, depression, psychosocial distress), code whether the medical record lists the symptom, assessment of the symptom, or treatment/referral for the symptom on any date after the date recorded in item (ii). Code item (vi) as "0 = No" if the symptom is listed on one date in the medical record (item i coded as "1 = Yes") and is not listed on any other date (in other words, it is mentioned only once). Code item (vi) as "1 = Yes" if the symptom is listed (item i coded as "1 = Yes") on the date specified in item (ii) **and** is also listed on at least one date after this. Code item (vi) as "1 = Yes" even if the symptom is listed on the date specified in item (ii) even if a different term is used for the symptom (e.g., "pain" on one date and "hurt" on another date). If the symptom is not present, code item (vii) as "9 = Symptom not mentioned".

PAIN, DEPRESSION, AND PSYCHOSOCIAL DISTRESS ASSESSMENT AND TREATMENT (continued)

ITEM A-15

2.9 Examples of terms that should be coded in the "Other" category include:

Pain

- Chronic pain
- Visceral pain
- Musculoskeletal pain
- Words ending in –algia

Depression

- Sad, sadness, chronic sadness
- Major depression

Psychosocial distress

- Distress, NOS
- Stress

OTHER SYMPTOMS

ITEM A-16

1. **Code separately for**
   - **Nausea/Vomiting/Emesis**
   - **Fatigue/Tiredness/Lack of Energy**
   - **Nutrition/Weight Loss/Cachexia**

   Note: Each section (i and ii) must be completed for each of the above symptoms

   i) Symptom assessed/mentioned AFTER DIAGNOSIS?

   0 = Symptom not listed in medical record
   1 = Symptom listed in medical record

   ii) Treatment/referral for symptom listed:

   0 = No
   1 = Yes
   9 = Symptom not mentioned.

2. **Description**:

   2.1 Items A-15 and A-16 are pilot tests to assess whether information on assessment and/or treatment of symptoms can be collected from the medical record after diagnosis. Item A-16 includes three symptoms often seen in the study population: nausea/vomiting/emesis; fatigue/tiredness/lack of energy; and nutrition/weight loss/cachexia.

   2.2 If the medical record indicates the long-term presence of a symptom (e.g., chronic fatigue or history of weight loss), all information on the symptom should still be completed. In addition, chronic or long-term present symptoms should also be entered as co-morbidities in Item C.

   2.3 In item (i), code separately whether each of the three symptoms is listed in the medical record. Use the terms listed above (1) to determine if the symptom is listed. If item (i) is coded "0" for a particular symptom, then (ii) must be coded 9 for that symptom.

OTHER SYMPTOMS (continued)

ITEM A-16

2.4 In item (ii), record whether the medical record indicates any treatment for the symptom or referral to another health care provider for the symptom. This item does not record the specific treatment or referral, just whether any treatment or referral for the symptom is listed in the medical record. Code item (ii) as "0 = No" if the symptom is listed (item i coded as "1 = Yes") but no treatment/referral for the symptom is specified in the medical record. Code item (ii) as "1 = Yes" if the symptom is listed (item i coded as "1 = Yes") and any treatment/referral for the symptom is specified in the medical record. If the symptom is not present, code item (ii) as "9 = Symptom not mentioned".

FINANCIAL / COST DISCUSSION WITH PATIENT

ITEM A-17

1. Code:

i) Financial/cost discussion with patient listed?

0 = No discussion with the patient of financial or cost issues listed in medical record
1 = Discussion with the patient of financial or cost issues listed in medical record

ii) Date financial/cost discussion **FIRST** appears in record:

MM-DD-YYYY
00-00-0000 - Symptom not listed in medical record.
99-99-9999 – Date not available for first listing of symptom in medical record

Month	Day	Year
01- January	01	Use 4-digit Year
02-February	02	
.	.	
12- December	31	

iii) Term/phrase **FIRST** used:

Exact term or phrase **first** used in the medical record describing the financial/cost discussion. **Mark all that apply** if multiple terms were used on the same date. Code as not applicable (N/A) if financial/cost discussion is not listed in the medical record.

Financial/Cost Discussion Terms

- ☐ Financial burden
- ☐ Financial hardship
- ☐ Financial toxicity
- ☐ Inability to pay / Unable to pay
- ☐ Patient assistance plan
- ☐ Out-of-pocket cost
- ☐ Other _____
- ☐ N/A

FINANCIAL / COST DISCUSSION WITH PATIENT (continued)

ITEM A-17

iv) Medical record section:

Section of the medical record/EHR where the financial/cost discussion was **first** mentioned. **Mark all that apply** if the term(s) was mentioned in multiple sections on the same date. Code as not applicable (N/A) if symptom is not listed in the medical record.

- ☐ Physician progress notes
- ☐ Nursing progress notes
- ☐ Assessment / Plan
- ☐ Other _____
- ☐ N/A

v) Interventions for patient financial/cost issues in medical record:

	No	Yes	Financial/cost discussion not in medical record
Referral to financial counselor/other professional for financial/cost issues	0	1	9
Patient assistance program	0	1	9
Other support/assistance for patient financial/cost issues (specify) _____	0	1	9

vi) Financial/cost discussion, referral, patient assistance program, or other patient financial/cost support or assistance listed in medical record on a different date:

0 = No
1 = Yes
9 = Financial/cost discussion not listed in medical record.

2. Description:

2.1 Item A-17 is a pilot test to assess whether information on financial/cost discussions with patients and referrals or support to address patient financial/cost can be collected from the medical record.

FINANCIAL / COST DISCUSSION WITH PATIENT (continued)

ITEM A-17

2.2 Indicate whether a discussion with the patient regarding financial or cost issues is listed in the medical record. This may involve key words including key words cost, out of pocket, cost-sharing, copay, copayment, coinsurance, deductible, afford, affordability, patient assistance plans, coupons, expense, money, paying for treatment, expensive, cheap, finances, financial burden, financial hardship, financial toxicity, or referral to financial counselor. Note that any listing in the medical record of a referral (e.g., to a social worker or counselor) for financial/cost issues or support for financial/cost issues (e.g., mention of a patient assistance program) indicates that a financial/cost discussion occurred with the patient and item (i) should be coded as "1 = Discussion with the patient of financial or cost issues listed in medical record".

2.3 Specify the date that the financial/cost discussion was **first** mentioned in the medical record in item (ii). If the discussion was not mentioned (item i is coded 0), code as 00-00-0000.

2.4 In item (iii), record the exact term **first** used in the medical record for the financial/cost discussion. If the discussion is not present in the medical record, code as not applicable (N/A).

2.5 In item (iv), code the section of the medical record where the financial/cost discussion was **first** listed. This could include physician progress notes, nurse progress notes, etc. If a financial/cost discussion is not present in the medical record, code as not applicable (N/A).

2.6 Item (v): **Interventions for patient financial/cost issues in medical record.** Record whether each of the following interventions was mentioned in the medical record. If any of the following data items are coded "1-Yes", then item (i) should also be coded 1. If no patient financial/cost discussion is listed, code the items below as "9 = Financial/cost discussion not listed in medical record". If financial/cost discussions were mentioned in the medical record but no interventions were mentioned, then code "0-No".

- **Referral to financial counselor/other professional for financial/cost issues:** Record whether the medical record indicates any referral to a counselor or professional (e.g., to a social worker or financial counselor) for financial/cost issues. This item does not record the specific referral, just whether any referral for the symptom is listed in the medical record. The referral does not need to be listed on the same date the financial/cost discussion was first mentioned (item ii) but could be listed at a later date.

FINANCIAL / COST DISCUSSION WITH PATIENT (continued)

ITEM A-17

- **Patient assistance program:** Record whether the medical record lists any patient assistance program for financial/cost issues. This item does not record the specific assistance program, just whether any assistance program for financial/cost issues is listed in the medical record. Listing of the patient assistance program does not need to be on the same date the financial/cost discussion was first mentioned (item ii) but could be listed at a later date.

- **Other support/assistance for patient financial/cost issues**: Record whether the medical record lists any other support or assistance provided to the patient for financial/cost issues, not including referrals to professionals or patient assistance programs. The financial cost support or assistance does not need to be on the same date the financial/cost discussion was first mentioned (item ii) but could be listed at a later date.

2.7 In item (vi), code whether the medical record lists a financial/cost discussion, referral for financial/cost issues, patient assistance programs, or any other support or assistance for patient financial/cost issues on any date after the date recorded in item (ii). Code item (vi) as "0 = No" if a financial/cost discussion, referral, assistance program, or other patient financial/cost support/assistance is listed on one date in the medical record (item i coded as "1 = Yes") and is not listed on any other date. Code item (vi) as "1 = Yes" if a financial/cost discussion, referral, assistance program, or other financial/cost support/assistance is listed (item i coded as "1 = Yes") on the date specified in item (ii) **and** are also listed on at least one date after this, even if a different term for the financial/cost discussion is used. If a financial/cost discussion is not present (item i coded as "0 = No discussion with the patient of financial or cost issues listed in medical record", code item (viii) as "9 = Financial/cost discussion not listed in medical record".

PALLIATIVE CARE

ITEM A-18

1. Code:

0 No palliative care provided (Code date as 00-00-0000)
1 Surgery (which may involve a bypass procedure) to alleviate symptoms, but no attempt to diagnose, stage, or treat the primary tumor is made.
2 Radiation therapy to alleviate symptoms, but no attempt to diagnose, stage, or treat the primary tumor is made.
3 Chemotherapy, hormone therapy, or other systemic drugs to alleviate symptoms, but no attempt to diagnose, stage, or treat the primary tumor is made.
4 Patient received or was referred for pain management therapy with no other palliative care.
5 Any combination of codes 1, 2, and/or 3 without code 4.
6 Any combination of codes 1, 2, and/or 3 with code 4.
7 Palliative care was performed or referred, but no information on the type of procedure is available in the patient record.
8 Palliative care was provided that does not fit the descriptions for codes 1–6.
9 It is unknown if palliative care was performed or referred; not stated in patient record (Code date as 00-00-0000).

Date palliative care FIRST appears in record

MM-DD-YYYY
00-00-0000 – Palliative care not listed in medical record or not given.
99-99-9999 – Date not available for first listing of palliative care in medical record

2. Description:

2.1 Record the type of palliative care provided. This item is based on NAACCR Item #3280.

2.2 Surgical procedures, radiation therapy, or systemic therapy provided to prolong the patient's life by controlling symptoms, to alleviate pain, or to make the patient comfortable should be coded palliative care and as first course therapy if that procedure removes or modifies either primary or metastatic malignant tissue.

2.3 Palliative care is not used to diagnose or stage the primary tumor or for potentially curative treatment.

2.4 Do not code routine pain management following surgery or other treatment; do code first course pain management for persistent pain.

2.5 Specify the date that palliative care was first mentioned in the medical record. If palliative care was not mentioned or not done, (i.e., coded 9 or 0), then code as 00-00-0000.

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.** Symptoms due to cancer or side-effects from cancer treatment are not considered co-morbid conditions. Comorbidities are conditions that were present **prior to the diagnosis** of cancer or are not related to cancer or cancer therapy.

Certain symptoms/conditions related to cancer or cancer therapy are collected in items A-15 and A-16. For example, depression that is present **after cancer diagnosis** should be coded in item A-15, not as a comorbidity. However, a "history of depression" occurring **prior to cancer diagnosis** should be coded as a comorbidity.

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 **This item is to record co-morbidities, <u>not side effects of treatment</u>**. A medical condition that is related to the cancer or cancer therapy should not be included. Certain symptoms related to cancer or cancer therapy are collected in items A-15 and A-16.

2.5 If there are no comorbidities, enter "None" in the first field only and **leave the remaining fields blank**. Do not enter "None" in any of the fields except the first comorbidity.

ABSTRACTOR ID

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

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 the physician verification form was completed or the office visited.**

POC DATA ACQUISITION MANUAL

SECTION IV

NON-SMALL CELL LUNG CANCER DATA SET

SECTION IV – NON-SMALL CELL LUNG CANCER DATA SET

CONTENTS

DATE OF FIRST POSITIVE BIOPSY

ITEM B-1

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

Month	Day	Year
01 - January	01	Use 4-digit Year
02 - February	02	
.	.	
12 - December	31	
77	77	7777-Patient or guardian refused
95	95	9595-Recommended, not performed
96	96	9696-Recomm., unknown if performed
97	97	9797-Unknown if performed
99 - Month Unk	99 - Day Unk	9999-Year Unknown

2. Description:

2.1 This item refers to the date of the first diagnosis of this tumor confirmed by biopsy for this current diagnosis. This may be a biopsy of the primary site, lymph node or metastatic site that confirmed the diagnosis of NSCLC. Code the date the specimen was obtained (NOT the date of the pathology/cytology report).

2.2 If the biopsy was performed on the same day as definitive surgery, the biopsy date and the Date of Cancer Directed Surgery to Primary Site will be the same. The first positive biopsy may have been done as an outpatient procedure, but must be no later than the Date of Fist Cancer-Directed Surgery to Primary Site.

2.3 If there was no biopsy done prior to, or at the time of surgical resection, code "00-00-0000".

2.4 Code “99-99-9999” if it is **KNOWN** that the patient had biopsy/aspiration, but the day, month and/or year given cannot be determined. If the exact date of the first positive biopsy is unknown, code an estimate (e.g., if in history and physical, the physician states the patient had a biopsy two weeks ago, code date of biopsy as 14 days prior to date of admission). Coding closest approximation is preferable to coding unknown.

DATE OF FIRST POSITIVE BIOPSY (continued)

ITEM B-1

2.5 Code “77-77-7777” if patient or the patient’s guardian refused biopsy.

2.6 Code “95-95-9595 – Recommended, not performed” when the records indicate that biopsy was recommended, but was not performed for a reason other than refusal.

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

2.8 If it is unknown whether or not a biopsy was performed, code “97-97-9797”.

2.9 Histologic diagnoses are based upon microscopic examination of tissue specimens from biopsy, frozen section, and surgical specimens. Cytologic diagnoses are based upon microscopic examination of cells instead of tissues.

SIZE OF PRIMARY TUMOR

ITEM B-2

1. Code: 000 - No mass/tumor found
001 - 1 mm or described as less than 1 mm
002-988 - Exact size in millimeters (2 mm to 988 mm) 989 - 989 millimeters or larger
990 - Microscopic focus or foci only and no size of focus is given
999 - Unknown; size not stated/not documented in patient record; Size of tumor cannot be assessed; Not applicable

Type of Staging (see notes below for further guidance)

Clinical – size of primary tumor **before** any treatment
Pathologic – size of primary tumor that has been resected

2. Description:

2.1 Refer to the 2018 SEER Program Coding and Staging Manual for complete details. **Code information about both clinical and pathologic tumor size for each patient.**

2.2 For clinical tumor size, record size in the following specified order:

1. The largest measurement of the primary tumor from imaging or other diagnostic procedures **before any form of treatment.**
2. The largest size from all information available within four months of the date of diagnosis, in the absence of disease progression when no treatment is administered.

Note 1: Tumor size noted in a resection operative report is a clinical tumor size, and not a pathologic tumor size.

Note 2: Check the Clinical History/Clinical Impression/Clinical Information section of the pathology report for information on the clinical size of the tumor.

2.3 For pathologic tumor size, code the size as recorded from the surgical resection specimen as noted in the pathology report or the synoptic/CAP protocol. Code the largest size of the primary tumor *(invasive portion)* measured on the surgical resection specimen when **surgery is administered as part of the first course treatment.**

SIZE OF PRIMARY TUMOR (continued)

ITEM B-2

a. Code the size from the synoptic report (also known as CAP protocol or pathology report checklist) when there is a discrepancy among tumor size measurements in the various sections of the pathology report.
b. Use final diagnosis, microscopic, or gross examination, in that order, when only a pathology report is available.

Example 1: Chest x-ray shows 3.5 cm mass; the pathology report from the surgery states that the same mass is malignant and measures 2.8 cm. Record tumor size as 028 (28 mm).

Example 2: Pathology report states lung carcinoma is 2.1 cm x 3.2 cm x 1.4 cm. Record tumor size as 032 (32 mm).

Note: The pathologic tumor size is recorded from the surgical resection specimen when surgery (including after neoadjuvant therapy) is administered as part of the first course treatment.

2.4 When the tumor is multi-focal or when multiple tumors are reported as a single primary, code the size of the largest invasive tumor, or the largest in situ tumor if all tumors are in situ. Code the exact value in millimeters from 001 (00.1 cm) through 988 (98.8 cm).

2.5 Code only the size of the primary tumor. Do not code the size of other structures like cysts.

2.6 If there is no tumor or mass found after neoadjuvant therapy code pathologic tumor size "000 - No mass/tumor found."

2.7 When there was an excisional biopsy followed by a more extensive resection with residual tumor removed, code the largest tumor size recorded among the specimens. Do not add the dimensions of the individually excised tumor tissues together.

2.8 Refer to the 2018 SEER Program Coding and Staging Manual for rules on rounding measurements, less than/greater than statements, priority order of reports and discrepancies between reports.

3. Examples:

A tumor of 0.9 cm (9 mm) in size is coded "009".
A tumor of 5.5 cm (55 mm) in size is coded "055".
A tumor of 8.3 cm (83 mm) in size is coded "083".
A tumor of 10.0 cm (100 mm) in size is coded "100".

NUMBER OF REGIONAL LYMPH NODES POSITIVE and EXAMINED

ITEM B-3 & B-4

1. Code: B-3 – Number of positive regional lymph nodes

00 – All examined nodes negative
01 – One positive node
02 – Two positive nodes
...
...
90 – 90 or more positive nodes
95 – Positive aspiration or core biopsy of lymph node(s) performed
97 – Positive nodes documented – number unspecified
98 – No nodes examined
99 – Unknown, not stated

B-4 – Number of regional lymph nodes examined

00 – No nodes examined (no nodal dissection performed)
01 – One node examined
02 – Two nodes examined
...
...
90 – 90 or more examined
95 – No regional nodes removed, but aspiration or core biopsy of regional nodes performed
96 – Regional lymph node removal documented as sampling and number of nodes unknown/not stated
97 – Regional lymph node removal documented as dissection and number of nodes unknown/not stated
98 – Regional lymph nodes surgically removed but number of nodes unknown/not stated and not documented as sampling or dissection; nodes examined but number unknown
99 – Unknown/not stated whether nodes examined

2. Description:

2.1 For information on which nodes are considered regional, refer to the AJCC Staging Manual 8th Edition.

2.2 Record the number of regional nodes examined by a pathologist and found to contain metastasis.

NUMBER OF REGIONAL LYMPH NODES POSITIVE & EXAMINED (continued)

ITEMS B-3 & B-4

2.3 Code the number of regional lymph nodes positive in Item B-3 and the number of regional lymph nodes examined in Item B-4. Include all node dissections done during the first course of therapy.

2.4 If more than one dissection was done during the first course of treatment, code the total number of lymph nodes positive and examined.

2.5 If the number of nodes positive was 90 or greater, code Item B-3 as “90”. If the number of nodes examined was 90 or greater, code Item B-4 as “90”.

2.6 If lymph nodes were known to be positive, but the exact number positive is unknown, code Item B-3 as “97”.

2.7 If lymph nodes were known to be positive, but the exact number positive is unknown and the exact number examined is unknown, code Item B-3 as “97” and Item B-4 as “96”, “97”, or “98”.

2.8 If no regional lymph nodes were positive, and the number examined is at least one, but the total is unknown, code Item B-3 “00” and B-4 “96”, “97” or “98”.

2.9 If no regional node dissection was done or no regional lymph nodes were removed/examined, code Item B-3 “98” and B-4 “00”.

2.10 If it is unknown or not stated whether any nodes were either positive or examined, then code “99” in Items B-3 and B-4.

2.11 If regional lymph nodes were aspirated, code Item B-3 either “00” for negative or “95” if positive and code Item B-4 as “95”.

2.12 When there is a difference in the number of nodes positive and/or examined between the body of the pathology report and the final diagnosis, code the information from the final diagnosis.

METASTASIS AT DIAGNOSIS

ITEM B-5

1. Code:

0 – No evidence of metastasis at the site
1 – Yes, only pathologic confirmation of metastasis at the site
2 –Yes, only clinical confirmation of metastasis at the site
3 – Yes, both clinical and pathologic confirmation of metastasis at the site
9 – Unknown if metastasis at the site

Sites

Bone
Brain
Liver
Distant lymph node(s)
Other (Specify) _____

2. Description:

2.1 Refer to the 2018 SEER Program Coding and Staging Manual for complete details. Code information about metastasis identified at the time of diagnosis. Information about metastatic involvement may be clinical or pathologic. These codes are NOT the codes from the SEER Manual—the POC codes are expanded to capture clinical and pathologic information.

2.2 Code "0 – No" if there is no evidence of distant metastasis in the medical record or imaging reports.

2.3 Code "1 – Yes, only pathologic confirmation of metastasis at the site" when there is pathologic but no clinical evidence of distant metastasis. Pathologic confirmation requires a biopsy positive for cancer at the metastatic site and may be reported in a pathology report or surgical records.

2.4 Code "2 – Yes, only clinical confirmation of metastasis at the site" when there is clinical but no pathologic evidence of distant metastasis. Clinical confirmation can be derived from documentation in patient history or physical examination and imaging reports. However, imaging of distant organs is not required.

2.5 Code "3 – Yes, both clinical and pathologic confirmation of metastasis at the site" when there is clinical and pathologic confirmation of distant metastasis.

2.6 Code "9 - Unknown" if it is unknown whether there is metastasis at the site. If there is no information about whether the patient had any metastatic disease, all sites should be coded "9 – Unknown."

METASTASIS AT DIAGNOSIS (continued)

ITEM B-5

2.7 If the record indicates that there is "metastatic disease" but does not provide any information on the site of metastasis, code bone, brain, distant lymph node and liver as "9 – unknown" and code other (Specify) as "1 – Yes." Enter "other site" in the text field.

2.8 If there is no evidence of metastases at any site, all should be coded as "0 – No."

2.9 Refer to the 2018 SEER Program Coding and Staging Manual for interpretation of ambiguous terminology.

3. Specifics

3.1 Metastasis to all sites may be a single metastatic lesion or multiple in the same site.

3.2 Bone involvement does **NOT** include bone marrow involvement.

3.3 Brain involvement does **NOT** include spinal cord or other parts of the central nervous system.

3.4 Distant lymph node involvement does **NOT** include regional lymph nodes.

3.5 Other sites include distant involvement in sites not including bone, brain, distant lymph nodes, and liver. It includes involvement of other more specific sites and more generalized metastasis (ex. adrenal gland, bone marrow, pleura, peritoneum, malignant pleural effusion).

DATE OF CANCER-DIRECTED SURGERY TO PRIMARY SITE

ITEM B-6

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

Month	Day	Year
01 - January	01	Use 4-digit Year
02 - February	02	
.	.	
12 - December	31	
77	77	7777-Patient or guardian refused
95	95	9595-Recommended, not performed
96	96	9696-Recomm., unknown if performed
97	97	9797-Unknown if performed
99 - Month Unk	99 - Day Unk	9999-Year Unknown

2. Description:

2.1 Enter the date of the most definitive cancer-directed surgery to the primary site. Refer to the 2018 SEER Program Coding and Staging Manual Section VII for definition of first course of therapy. This does not include biopsy. If the biopsy/aspiration was performed on the same day as definitive surgery, the biopsy date and the Date of Cancer-Directed Surgery to Primary Site will be the same

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 patient’s guardian refused.

2.4 Code “95-95-9595 – Recommended, not performed” when the records indicate that surgery was recommended, but was not performed for a reason other than refusal.

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

2.6 Code “97-97-9797-Unknown” if it is unknown whether surgery was recommended AND unknown if surgery was performed.

2.7 Code “99-99-9999” if it is KNOWN that the patient had surgery to the primary site, but the day, month and/or year given cannot be determined. If the exact date of the surgery is unknown, then code an estimate. Coding the closest approximation is preferable to coding unknown.

MUTATIONS

ITEM B-7

1. Code: 0 – Test not performed/no mention
1 – Test positive
2 – Test negative
8 – Test performed, result unknown
9 – Unknown if test performed

Tests
- EGFR
- ALK
- ROS1
- KRAS
- RET
- MET
- PD-1 or PD-L1
- BRAF
- MEK
- NTRK

2. Description:

2.1 Epidermal growth factor receptor (EGFR) exists on the cell surface. Mutations that lead to EGFR overexpression (known as upregulation) or overactivity have been associated with a number of cancers, including lung cancer, anal cancers and glioblastoma multiforme. Patients with EGFR overexpression have been shown to have a higher likelihood of response to certain therapeutic agents. There are multiple methods for testing for the mutation including: direct sequencing, loop-hybrid mobility shift assay, PCR-RFLP and length analysis, MALDI-TOF MS–based genotyping, and single-molecule sequencing.

2.2 Anaplastic lymphoma kinase (ALK) fuses with another gene EML4 to form a fusion oncogene (EML4-ALK). This fusion oncogene rearrangement defines a distinct clinicopathologic subset of NSCLC. Tumors that contain the EML4-ALK fusion oncogene or its variants are associated with specific clinical features, including never or light smoking history, younger age, and adenocarcinoma with signet ring or acinar histology. ALK gene arrangements are largely mutually exclusive with epidermal growth factor receptor (EGFR) or KRAS mutations. Screening for this fusion gene in NSCLC is important, as "ALK-positive" tumors (tumors harboring a rearranged ALK gene/fusion protein) are highly sensitive to therapy with ALK-targeted inhibitors.

MUTATIONS (continued)

ITEM B-7

2.3 ROS1 is a receptor tyrosine kinase of the insulin receptor family that acts as a driver oncogene in 1 to 2 percent of NSCLC via a genetic translocation between ROS1 and other genes. Histologic and clinical features that are associated with ROS1 translocations include adenocarcinoma histology, younger patients, and never- smokers. ROS1 translocations are identified by a FISH break-apart assay similar to that used for ALK translocations.

2.4 KRAS is a member of the RAS family of oncogenes which are involved help control cell proliferation and apoptosis. KRAS is associated with smoking-associated adenocarcinoma of the lung. The presence of a KRAS mutation appears to have at most a limited effect on overall survival in patients with early stage NSCLC, although some of older data had suggested that it was associated with a worse prognosis.

2.5 The RET gene encodes a cell surface tyrosine kinase receptor. Recurrent translocations between RET and various fusion partners have been identified in 1 to 2 percent of patients with adenocarcinoma or adenosquamous carcinoma of the lung. Those with a RET translocation tend to be younger and never smokers.

2.6 MET is a tyrosine kinase receptor for hepatocyte growth factor (HGF). Increased MET expression may predict response to MET targeted drugs. Standard testing methods for MET expression testing include immunohistochemistry (IHC), which is positive in 25 to 50 percent of NSCLC specimens, and FISH for MET gene amplification, which occurs at an intermediate or high level in approximately 6 percent of patients with NSCLC and appears to be smoking related. MET expression also appears to be associated with a worse prognosis.

2.7 PD-L1/PD-1 interaction plays an important role in the reduction of specific T cell apoptosis, inhibition of immune response to tumors, and immune evasion of tumors. The inhibition of PD-1/PD-L1 pathway may hamper the proliferation of activated effector T cell, causing the tumor evasion from the killing of cytotoxic T lymphocytes, resulting in the weakening of anti-tumor immune response.

2.8 BRAF is a gene that encodes a protein formally known as serine/threonine-protein kinase B-Raf. It is important in cell signaling and directing cell growth.

2.9 MEK is two genes (MEK1 and MEK2) that code mitogen-activated protein kinase enzymes. This enzyme pathway may be activated in certain cancers.

2.10 NTRK is the neurotrophic tropomyosin receptor kinase gene. In certain cancers, this gene may break, join with a gene on another chromosome, and produce abnormal fusion proteins that may cause cancer cells to grow.

MUTATIONS (continued)

ITEM B-7

2.11 Record whether the test results were positive or negative. If the test was not performed or there is no mention in any of the records, then code “0 – Test not performed/no mention”.

2.12 If there is mention of the test being performed in the record but no results, then code “8 – Test performed, results unknown”.

2.13 If there is mention of the test in the records but no indication that the test was performed, then code “9 – Unknown if test performed”.

EOD OF PRIMARY TUMOR

ITEM B-8

1. Code: Lung

Code	Description	SS2018 T
000	In situ, Noninvasive, intraepithelial Squamous cell carcinoma in situ (SCIS) Adenocarcinoma in situ (AIS): adenocarcinoma with pure lepidic pattern, less than or equal to 3 cm in greatest dimension	IS
100	Minimally invasive adenocarcinoma • Adenocarcinoma tumor ▪ WITH predominantly lepidic pattern measuring less than or equal to 3 cm in greatest dimension ▪ WITH invasive component measuring less than or equal to 5 mm in greatest dimension	L
200	Superficial spreading tumor, any size • WITH invasive component limited to bronchial wall • WITH or WITHOUT proximal extension to main stem bronchus (these types of tumors are uncommon)	L
300	Any size tumor • Confined to lung, NOS • Localized, NOS	L
400	Any size tumor • Adjacent ipsilateral lobe (direct tumor invasion) • Confined to hilus • Main stem bronchus, NOS (without involvement of the carina) ▪ Including extension from other part of lung	L

Code	Description	SS2018 T
450	Any size tumor • Atelectasis/obstructive pneumonitis ▪ Extends to hilar region, involving part or all of lung • Pleura, NOS • Pulmonary ligament • Visceral pleura (PL1 or PL2)	RE
500	Any size tumor • Brachial plexus, inferior branches or NOS • Chest wall (thoracic wall) (separate lesion-see EOD Mets) • Pancoast tumor (superior sulcus syndrome), NOS • Parietal pericardium • Parietal pleura (PL3) • Pericardium, NOS • Phrenic nerve Separate tumor nodule(s) in the same lobe as the primary	RE
600	Tumor limited to the carina	L
650	Blood vessel(s) (major) • Aorta • Azygos vein • Pulmonary artery or vein • Superior vena cava (SVC syndrome) Carina from lung Compression of esophagus or trachea not specified as direct extension Esophagus Mediastinum, extrapulmonary or NOS Nerve(s) • Cervical sympathetic (Horner's syndrome) • Recurrent laryngeal (vocal cord paralysis) • Vagus Trachea	RE

Code	Description	SS2018 T
675	Any size tumor • Adjacent rib • Rib • Skeletal muscle • Sternum	D
700	Heart Inferior vena cava Neural foramina Vertebra(e) (vertebral body) Visceral pericardium Separate tumor nodule(s) in a different ipsilateral lobe Further contiguous extension	D
800	No evidence of primary tumor	U
980	Tumor proven by presence of malignant cells in sputum or bronchial washings but not visualized by imaging or bronchoscopy; "occult" carcinoma	U
999	Unknown; extension not stated Primary tumor cannot be assessed Not documented in patient record Death Certificate Only	U

Note 1: Bronchopneumonia is not the same thing as obstructive pneumonitis and should not be coded as such.

- Bronchopneumonia is an acute inflammation of the walls of the bronchioles, usually a result of spread of infection from the upper to the lower respiratory tract
- Obstructive pneumonitis is a combination of atelectasis, bronchiectasis with mucous plugging, and parenchymal inflammation that develops distal to an obstructing endobronchial lesion

Note 2: Code 100 is to be used only when the following criteria are met

- Minimally invasive adenocarcinoma (less than or equal to 3 cm)

- **WITH** predominantly **lepidic pattern AND**
- less than or equal to 5 mm invasion in greatest dimension
- If predominantly **lepidic pattern** is present and the size of the invasive component is unknown, see code 300

Note 3: Code 200 is to be used for **superficial spreading tumors** only. The pathology report must state that it is superficially spreading.

- These types of tumor are uncommon, and this code should be used very sparingly. If in doubt, do not use this code

Note 4: Code 300 is to be used for a localized cancer where size defines the extent of the primary tumor. It is not a predominantly lepidic pattern (code 100), or a superficial spreading tumor (code 200), and there is no involvement of adjacent structures or invasion of the pleural (codes 400 and above).

Note 5: Atelectasis is the failure of the lung to expand (inflate) completely. This may be caused by a blocked airway, a tumor, general anesthesia, pneumonia or other lung infections, lung disease, or long-term bed rest with shallow breathing. Sometimes called a collapsed lung.

- For staging purposes, atelectasis must present with an obstructing tumor

Note 6: Specific information about visceral pleura invasion is captured in codes 450 (PL1, PL2, or NOS) and 500 (PL3). Elastic layer involvement has prognostic significance for lung cancer.

Note 7: Penetration of the visceral pleura indicates a progression of invasion, even in small (≤ 3cm) tumors, and indicates a less favorable prognosis. Visceral pleural invasion is considered present both in tumors that extend to the visceral pleural surface (type PL2 invasion), and in tumors that penetrate beyond the elastic layer of the visceral pleura (type PL1 invasion). Further invasion, which extends to the parietal pleura, is also described as type PL3 invasion.

Note 8: Separate ipsilateral tumor nodules of the same histopathological type (intrapulmonary metastases) are coded either 500 (same lobe) or 700 (different ipsilateral lobe). Separate tumor nodules in the contralateral lung are assigned in EOD Mets.

Note 9: Occult carcinoma occurs when tumor is proven by the presence of malignant cells or bronchial washings, but there is no other evidence of the tumor. In these cases, assign EOD Primary Tumor 980, EOD Regional Nodes 000, and EOD Mets 00.

2. Description:

2.1 USE 2018 SEER CODING RULES – see EOD Lung Data on SEER*RSA.

PATHOLOGICAL MARGINS

ITEM B-9

1. Code:

0 – No resection/surgery performed; biopsy only
1 – Margins of resection pathologically free of tumor
2 – Tumor at margins of resection, or residual tumor in area of primary
3 – Margins not stated in pathology report--surgeon indicates no residual tumor
8 – Resection recommended unknown if performed
9 – Unknown, not stated

2. Description:

2.1 This item records the pathological margin status following the most definitive surgery performed after diagnosis (Item B-6).

2.2 Code "0 – No resection/surgery performed" when no cancer-directed surgery or only a biopsy was performed.

2.3 Code "1 – Margins of resection pathologically free of tumor" when the pathologist reported no residual tumor in the area of the primary site.

2.4 Code "2 – Tumor at margins of resection, or residual tumor in area of primary" when the pathologist reported involvement of the surgical resection margins.

2.5 Code "3 – Margins not stated in pathology report--surgeon indicates no residual tumor" when the pathology report does not document the pathologic margin status, but the surgeon states in the operative report that no tumor was left in the area of the primary site.

2.6 Code “8 – Resection recommended unknown if performed” if the physician recommended surgery, but it is unknown whether it was performed.

2.7 Code "9 – Unknown, not stated" when there is no information in the pathology report regarding pathologic margins and the surgeon does not document margin status in the operative report.

GRADE

ITEM B-10

1. Code: 3 digits

Clinical Grade	1 digit
Pathological Grade	1 digit
Post Therapy Grade	1 digit

2. Description:

2.1 All pathology reports related to this cancer for the case should be examined.

2.2 IMPORTANT NOTE: Grade for NSCLC cases diagnosed in 2017 should be abstracted and coded for the study using 2018 rules and instructions. For complete coding instructions for the three grade fields, use the 2018 Grade Coding Instructions and Tables. Valid codes for Clinical, Pathological, and Post Therapy Grade for NSCLC are 1-4 or 9.

2.3 Clinical Grade records the grade of a tumor before any treatment (surgical resection or initiation of any treatment including neoadjuvant). Clinical Grade must not be blank. Assign the highest grade from the primary tumor assessed during the clinical time frame.

2.4 Code Clinical Grade as 9 when the grade from the primary site is not documented; clinical workup is not done (for example, cancer is an incidental finding during surgery for another condition); or grade checked "not applicable" on CAP Protocol (if available) and no other grade information is available. If there is only one grade available and it cannot be determined if it is clinical or pathological, assume it is a clinical grade and code appropriately. Then code unknown (9) for pathological grade and blank for post therapy grade.

2.5 Pathological Grade records the grade of a solid primary tumor that has been resected and for which no neoadjuvant therapy was administered. If AJCC staging is being assigned, the tumor must have met the surgical resection requirements in the AJCC manual. This may include the grade from the clinical workup. Record the highest grade documented from any microscopic specimen of the primary site whether from the clinical workup or the surgical resection. Pathological grade must not be blank. If the clinical grade is the highest grade identified, use the grade that was identified during the clinical time frame for both the clinical grade and the pathological grade. If a resection is done of a primary tumor and there is no grade documented from the surgical resection, use the grade from the clinical workup. If a resection is done of a primary tumor and there is no residual cancer, use the grade from the clinical workup. Pathological Grade code 4 includes anaplastic.

GRADE (continued)

ITEM B-10

2.6 Code Pathological Grade as 9 when grade from primary site is not documented; there was no resection of the primary site; neo-adjuvant therapy is followed by a resection (see Post Therapy Grade); this is a clinical case only (see clinical grade); there is only one grade available and it cannot be determined if it is clinical, pathological, or after neo-adjuvant therapy; or grade checked "not applicable" on CAP Protocol (if available) and no other grade information is available.

2.7 Post Therapy Grade records the grade of a solid primary tumor that has been resected following neoadjuvant therapy. If AJCC staging is being assigned, the tumor must have met the surgical resection requirements in the AJCC manual. Record the highest grade documented from the surgical treatment resection specimen of the primary site following neoadjuvant therapy. Leave Post Therapy Grade blank when there is no neoadjuvant therapy; this is a clinical or pathological case only; or there is only one grade available and it cannot be determined if it is clinical, pathological or post therapy. Assign the highest grade from the resected primary tumor assessed after the completion of neoadjuvant therapy. Post Therapy Grade 4 includes anaplastic. Code Post Therapy Grade as 9 when surgical resection is done after neoadjuvant therapy and grade from the primary site is not documented; surgical resection is done after neoadjuvant therapy and there is no residual cancer; or grade is checked "not applicable" on CAP Protocol (if available) and no other grade information is available.

DATE RADIATION TO PRIMARY SITE BEGAN

ITEM B-11

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

Month	Day	Year
01 - January	01	Use 4-digit Year
02 - February	02	
.	.	
12 - December	31	
77	77	7777-Patient or guardian refused
95	95	9595-Recommended, not given
96	96	9696-Recomm., unknown if given
97	97	9797-Unknown if given
99 - Month Unk	99 - Day Unk	9999-Year Unknown

2. Description:

2.1 Enter the date the patient first received radiation TO THE PRIMARY SITE at any time after diagnosis. Bronchus is included in primary site.

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

2.3 Code “77-77-7777 – Patient/guardian refused radiation” if the patient or the guardian refused radiation.

2.4 Code “95-95-9595 – Recommended, not given” when the records indicate that radiation was recommended, but was not given for a reason other than refusal.

2.5 Code “96-96-9696 – Recommended, unknown if given" if it is unknown whether the recommended radiation was performed.

2.6 If it is unknown whether the patient had radiation therapy, code “97-97-9797 – Unknown if radiation given”.

2.7 Code “99-99-9999” if it is **KNOWN** that the patient had radiation therapy, but the day, month and/or year given cannot be determined. If the exact date of the first therapy is unknown, code an estimate. For example, if in history and physical, the physician states the patient had radiation therapy beginning two weeks ago, code date of radiation as 14 days prior to that date. If the record states that radiation was given recently, code the month and year, but not the day. Code the day as “99.” Coding the closest approximation is preferable to coding unknown.

RADIATION THERAPY (PRIMARY SITE) SEQUENCE WITH SURGERY

ITEM B-12

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

2. Description:

2.1 This item is used to record information on patients who were treated with BOTH radiation therapy to primary site and cancer-directed surgery at any time after diagnosis. If only one (radiation **or** surgery) was given, then this item is coded as "0".

2.2 Code "0 - No/unknown radiation to primary site and/or no/unknown cancer-directed surgery" when radiation (Item B-11) and/or cancer-directed surgery status (Item B-6) is unknown or when the patient did not receive radiation therapy and/or cancer- directed surgery. (Radiation and Cancer-directed surgery status are unknown or not done when they are coded as "00, 97, 77 or 96").

2.3 Code "2 - Radiation to primary site before surgery" when the patient received radiation therapy prior to the most definitive cancer-directed surgery.

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

2.4 Code "3 - Radiation to primary site after surgery" when the patient received radiation therapy following the most definitive cancer-directed surgery.

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

2.5 Code "4 - Radiation to primary site both before and after surgery" when the radiation therapy was given both prior to and following the most definitive cancer-directed surgery.

RADIATION THERAPY SEQUENCE WITH SURGERY (continued)

ITEM B-12

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

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

2.8 Code “9 - Sequence unknown, but both surgery and radiation to primary site 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-13

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

***Note*:** Radiation and systemic therapy are concurrent if:

1. The medical record states the therapy was "concurrent"
2. There is **any** overlap in the timing of radiation and systemic therapy. There is overlap if:
   a. the start and end dates for radiation are known AND
   b. the start and end dates for systemic therapy are known AND these dates overlap

If there is no mention of concurrence in the medical record and there are no therapy end dates to determine overlap, DO NOT code as concurrent therapy.

2. Description:

2.1 This item is used to record information on patients who were treated with BOTH radiation therapy and systemic therapy at any time after diagnosis. If only one (radiation or systemic therapy) was given, then this item is coded as "0".

2.2 Code "0 - No/unknown radiation and/or no/unknown systemic therapy" when radiation therapy (Item B-11) and/or systemic therapy (Items B-16 to B-35) 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 they 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-13

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

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

2.5 Code "4 - Radiation both before and after systemic therapy" when the 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 also receiving systemic therapy.

2.7 Code "6 - Concurrent radiation and systemic therapy with other radiation given before and/or after chemotherapy" 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.

SYSTEMIC THERAPY SEQUENCE WITH SURGERY

ITEM B-14

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 - Intraoperative systemic therapy
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 and cancer-directed surgery at any time after diagnosis. If only one (systemic therapy **or** surgery) was given, then this item is coded as “0”.

2.2 Code "0 – No/unknown systemic therapy and/or no/unknown cancer-directed surgery" when systemic therapy (Items B-16 to B-35) and/or Cancer-Directed surgery status (Item B-6) is unknown or when the patient did not receive systemic therapy and/or cancer-directed surgery. (Surgery and Systemic therapy status are unknown or not done when they 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 definitive cancer-directed surgery.

For example: A patient with an excisional biopsy, followed by systemic therapy, followed by pneumonectomy is coded as "2 - Systemic therapy before surgery".

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

For example: A patient who had a biopsy, followed by a lobectomy, then treated with systemic therapy would be coded as "3 – Systemic therapy after surgery".

2.5 Code "4 - Systemic therapy both before and after surgery" is used when chemotherapy was given both prior to and following the definitive surgery.

2.6 Code "5 - Intraoperative systemic therapy" when the patient received systemic therapy during the most definitive cancer-directed surgery.

2.7 Code “9 - Sequence unknown” when both systemic therapy and surgery were received by the patient but the sequence is unknown and/or the dates are missing (99) so the sequence cannot be determined.

DATE RADIATION TO OTHER SITE BEGAN

ITEM B-15

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

Month	Day	Year
01 - January	01	Use 4-digit Year
02 - February	02	
.	.	
12 - December	31	
77	77	7777-Patient or guardian refused
95	95	9595-Recommended, not given
96	96	9696-Recomm., unknown if given
97	97	9797-Unknown if performed
99 - Month Unk	99 - Day Unk	9999-Year Unknown

2. Description:

2.1 Enter the date the patient first received radiation to ANOTHER site, not to the primary lung cancer site, at any time after diagnosis. This may be radiation to the brain or perhaps radiation to the bone. These treatments are not intended to cure the lung cancer, but are generally considered prophylactic to the brain or palliative to the bone. Radiation to the bronchus is not coded in this item; rather it is coded in Radiation to Primary Site (Item B-11).

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

2.3 Code “77-77-7777 – Patient/guardian refused radiation” when the records indicate that radiation to other site was recommended, but the patient or patient’s guardian refused.

2.4 Code “95-95-9595 – Recommended, not given” when the records indicate that radiation to other site was recommended, but was not given for a reason other than refusal.

2.5 Code “96-96-9696 – Unknown” if it is unknown whether the recommended prophylactic or palliative radiation was performed.

2.6 If the exact date of radiation is unknown, then an estimate should be made. If it is not possible to estimate, then code “99-99-9999-Date Unknown”.

2.7 If it cannot be determined whether prophylactic or palliative radiation was recommended and given, code “97-97-9797-Unknown if offered/given”.

SYSTEMIC THERAPY AGENTS

ITEMS B-16 through B-40

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	
.	.	
12 - December	31	
77	77	7777-Patient or guardian refused
95	95	9595-Recommended, not given
96	96	9696-Recomm., unknown if given
97	97	9797-Unknown if given
99 - Month Unk	99 - Day Unk	9999-Year Unknown

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

B-16 Afatinib (Gilotrif)

B-17 Alectinib (Alecensa)

B-18 Bevacizumab (Avastin)

B-19 Carboplatin

B-20 Ceritinib (Zykadia)

B-21 Cisplatin (CDDP, Platinol)

B-22 Crizotinib (Xalkori)

B-23 Docetaxel (Taxotere)

B-24 Durvalumab (Imfinzi)

B-25 Erlotinib (Tarceva)

B-26 Etoposide (Vepesid)

SYSTEMIC THERAPY (continued)

ITEMS B-16 through B-40

B-27 Gefitinib (Iressa)

B-28 Gemcitabine (Gemzar)

B-29 Lorlatinib (Lorbrena)

B-30 Necitumumab (Portrazza)

B-31 Nivolumab (Opdivo)

B-32 Osimertinib (Tagrisso)

B-33 Paclitaxel (Taxol)

B-34 Paclitaxel Albumin-stabilized Nanoparticle Formulation (Abraxane)

B-35 Panitumumab (Vectibix)

B-36 Pembrolizumab (Keytruda)

B-37 Pemetrexed (Alimta)

B-38 Ramucirumab (Cyramza)

B-39 Vinorelbine (Navelbine)

B-40 Other, specify: _____

Examples of other therapeutic agents which might have been given are:

Cyclophosphamide
Methotrexate

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

2. Description:

2.1 Code the date therapy started for each systemic therapy agent given at any time after diagnosis.

SYSTEMIC THERAPY (continued)

ITEMS B-16 through B-40

2.2 Code "00-00-0000-Not given" when the patient did not receive systemic therapy, even when it was recommended. Also, use this code when the agent was considered or recommended, and it is known that the patient did not receive it. (See also “77-77-7777-Refused”.) If no chemotherapy agent was given, then all agents should be coded as "00-00-0000", unless the patient or the patient's guardianrefused the systemic therapy. (See also code “7777-Patient/guardian refused").

2.3 Code "77-77-7777-Patient/guardian refused" when systemic therapy 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 been not given should be coded as "77-77-7777".

2.4 Code “95-95-9595 – Recommended, not given” when the records indicate that systemic therapy was recommended, but was not given for a reason other than refusal.

2.5 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 agents to be used were not documented, all agents must be coded "96-96-9696".

2.6 Code “97-97-9797-Unknown if given” when it is unknown if systemic therapy was offered or given to the patient.

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

MAINTENANCE THERAPY

ITEM B-41

1. Code: 0 – No maintenance therapy given
1 – Maintenance therapy given
9 – Unknown

2. Description:

2.1 Item B-41 collects information on whether the patient received systemic treatment described as "maintenance therapy" in the medical record. The FDA has approved pemetrexed (Alimta) for maintenance therapy for advanced stage lung cancer. However, other agents might be used and we are not asking for the agent given.

2.2 In order to code this data item a "1 – Maintenance therapy given", the record must specifically state that the agent was given for maintenance therapy.

2.3 If there is no indication in the medical record whether or not maintenance therapy was given, code "9 – Unknown."

SMOKING

ITEM B-42

1. Code: **Number of packs per day**

00.0 – Never smoked
00.5 – Half a pack or less per day (≤0.5 ppd)
00.9 – More than half a pack to less than 1 pack per day (>0.5 to <1 ppd)
01.0 – 1 pack per day
02.0 – 2 packs per day
03.0 – 3 packs per day
...
...
55.5 – Light or occasional smoker
66.6 – Moderate smoker
77.7 – Heavy smoker
88.8 – Smoked, number of packs unknown
99.9 – Unknown, not stated whether patient smoked

Number of years

00 – Never smoked
01 – Smoked for one year
02 – Smoked for two years
...
...
88 – Smoked, number of years unknown
99 – Unknown, not stated whether patient smoked

Pack years

00 – Never smoked
01 – Smoked for one year
02 – Smoked for two years
...
...
88 – Smoked, pack years unknown
89 - ≥88 pack years
99 – Unknown, not stated whether patient smoked

Smoking Status at Diagnosis

0 – Never smoked
1 – Current smoker
2 – Former smoker
9 – Unknown

SMOKING (continued)

ITEM B-42

2. Description:

2.1 This item is to be coded for **any information** known about the patient's smoking status. Code the number of packs per day, the number of years smoked and/or the pack years smoked, as well as smoking status at diagnosis. If the patient never smoked, code "00.0" in Packs Per Day, the Number of Years Smoked and the Pack Years, and code Smoking Status at Diagnosis as "0".

2.2 If the patient smoked "half a pack per day," then code "00.5" in packs per day. If the record notes the patient smoked "less than a pack per day," then code "00.9" in packs per day. Code the appropriate amount for less than one pack per day.

2.3 There are 20 cigarettes per pack. If the record states that the individual smoked 40 cigarettes per day for 10 years, then code *02.0* packs in the packs per day and 10 in number of years smoked; not *40.0* in the packs per day and 10 in the number of years smoked. Do not calculate pack years; code "88 – smoked pack years unknown" if not provided in the medical record. Record pack years *only* if it is given in the medical record.

2.4 If the patient is known to have smoked, but the number of packs is unknown, code "88.8- Smoked, number of packs unknown."

2.5 If the record does not give the number of cigarettes smoked, but instead states that the person was a heavy smoker, code "77.7 – Heavy smoker". A moderate smoker would be coded as "66.6" and a light smoker would be coded as "55.5".

2.6 If it is unclear or if it is not mentioned in the record whether the patient smoked, then code "99.9 - Unknown, not stated whether patient smoked" in packs, "99" in years and pack years, and "9" in Smoking Status at Diagnosis.

2.7 If the patient is known to have smoked but the number of years he/she smoked is unknown, then code "88.8 - Smoked, number of years unknown" in packs, and "88" in years and pack years.

2.8 If the record states, "The patient has been a heavy smoker for many years," then code "77.7 – Heavy smoker" in packs, and "88 – Smoked, number of years unknown" in years.

2.9 If the record states only pack years, code the number of pack years in the last two boxes and code, "88.8 - Smoked, number of packs unknown" for packs per day and "88 – Smoked, number of years unknown" for years smoked. If the pack years smoked is 88 or more pack years, code "≥88 pack years."

PASSIVE SMOKING EXPOSURE

ITEM B-43

1. Code: 0 – Not exposed to passive smoke
1 – Exposed to passive smoke
9 – Unknown/not mentioned whether exposed to passive smoke

2. Description:

2.1 Passive smoking is thought to be a risk for developing lung cancer. Passive smoking occurs when an individual in the patient's environment smokes. Whether or not the patient smokes, (s)he is forced to inhale the smoky air when (s)he breathes. Smoking is usually done by parents or a spouse but can occur when an individual works in a smoky atmosphere, such as a bar or cocktail lounge.

2.2 Code "0 – Not exposed to passive smoke" if the record indicates that the individual was not exposed to passive smoking. A statement such as, "Mother and father were non-smokers and husband is a non-smoker" would be accepted as not exposed to passive smoking. However, the person would be considered "exposed" if (s)he worked in a smoking environment, such as in a bar.

2.3 A statement such as, "Husband/wife is a smoker" would indicate that the patient was exposed to passive smoking and should be coded as "1 – Exposed to passive smoke".

2.4 If it is unclear or not mentioned whether the patient was exposed to passive smoking, then code "9– Unknown, not mentioned whether exposed to passive smoke".

ASBESTOS EXPOSURE

ITEM B-44

1. Code: 0 – Not exposed to asbestos
1 – Exposed to asbestos
9 – Unknown/not mentioned whether exposed to asbestos

2. Description:

2.1 Asbestos is a substance that was frequently used as a fire barrier because it does not burn well. It is a chalky, fibrous substance and was even used to make ceiling tiles. The most likely way for people to be exposed is by working with it occupationally. However, a person can be exposed to asbestos merely by being in the vicinity of crumbling ceiling tiles. Asbestos has not been used for a number of years and currently must be removed from buildings by a specially licensed contractor.

2.2 Code "0– Not exposed to asbestos" if the record indicates that the patient was not exposed to asbestos.

2.3 Code "1 – Exposed to asbestos" if the record indicates that the patient was exposed to asbestos.

2.4 If it is unclear or is not mentioned in the record whether the patient was exposed to asbestos, then code "9 – Unknown".

POC DATA ACQUISITION MANUAL

SECTION V

MELANOMA DATA SET

SECTION V- MELANOMA DATA SET

CONTENTS

DATE OF FIRST POSITIVE BIOPSY

ITEM B-1

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

Month	Day	Year
01 - January	01	Use 4-digit Year
02 - February	02	
.	.	
12 - December	31	
77	77	7777-Patient or guardian refused
94	94	9494-Biopsy became definitive surgery
95	95	9595-Recommended, not performed
96	96	9696-Recomm., unknown if performed
97	97	9797-Unknown if performed
99 - Month Unk	99 - Day Unk	9999-Year Unknown

2. Description:

2.1 This item refers to the date of the first diagnosis of this tumor confirmed by biopsy for this current diagnosis. This may be a biopsy of the primary site, lymph node or metastatic site that confirmed the diagnosis of melanoma. Code the date the specimen was obtained (NOT the date of the pathology/cytology report).

2.2 If the biopsy was performed on the same day as definitive surgery, the biopsy date and the Date of Cancer Directed Surgery to Primary Site will be the same. The first positive biopsy may have been done as an outpatient procedure, but must be no later than the Date of Cancer-Directed Surgery to Primary Site.

2.3 If there was no biopsy done prior to, or at the time of surgical resection, code "00-00-0000".

2.4 Code “99-99-99” if it is **KNOWN** that the patient had biopsy/aspiration, but the day, month and/or year given cannot be determined. If the exact date of the first positive biopsy is unknown, code an estimate (e.g., if in history and physical, the physician states the patient had a biopsy two weeks ago, code date of biopsy as 14 days prior to date of admission). Coding closest approximation is preferable to coding unknown.

2.5 Code “77-77-7777” if patient or the patient’s guardian refused biopsy.

2.6 Code “94-94-9494” when a biopsy is performed and results in a sample with negative margins, and is therefore considered to be definitive surgery.

DATE OF FIRST POSITIVE BIOPSY (continued)

ITEM B-1

2.7 Code “95-95-9595 – Recommended, not performed” when the records indicate that biopsy was recommended, but was not performed for a reason other than refusal.

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

2.9 If it is unknown whether or not a biopsy was performed, code “97-97-9797”.

2.10 Code the date of the procedure used to obtain the specimen, not the date of the pathology report.

2.11 Histologic diagnoses are based upon microscopic examination of tissue specimens from biopsy, frozen section, and surgical specimens. Cytologic diagnoses are based upon microscopic examination of cells instead of tissues.

PRIMARY TUMOR THICKNESS (BRESLOW'S THICKNESS)

ITEM B-2

1. Code:
000 – No mass: no tumor found
001 – 0.1 mm
002 – 0.2 mm
003 – 0.3 mm
074 – 07.4 mm
103 – 10.3 mm
...
...
...
980 - 98.0+ mm
999 – Unknown/not stated

2. Description:

2.1 The Breslow's classification is the vertical thickness in millimeters of the malignant melanoma. This helps to predict the prognosis for the patient. The greater the depth of invasion, the poorer the prognosis.

2.2 Breslow's thickness is collected in tenths of millimeters. If the measurement is given in the record in hundredths of a millimeter, then use standard rounding rules to round up. The decimal point is not coded.

2.3 Code any measurement of tumor thickness 0.1 mm to 98.0+ mm as "001 to 980".

2.4 If there is no Breslow depth or tumor thickness given, then code "999—Unknown/ not stated".

2.5 For measurements described as "at least" or "greater than", see the examples below.

Examples:

If the measurement in the record is stated as:

- **0.05 mm –** code 001 (0.1 mm)
- **1.14 mm –** code 011 (1.1 mm)
- **"At least 2 mm" –** code as 020 (2.0 mm)
- **"Greater than 2 mm" –** code as 021 (2.1 mm)

BE CERTAIN THAT THE THICKNESS IS RECORDED IN MM.

CLARK'S LEVEL

ITEM B-3

1. Code: 1 – Level I
2 – Level II
3 – Level III
4 – Level IV
5 – Level V
9 – Unknown / Not reported

2. Description:

2.1 The Clark's level is the anatomic level of local invasion, also called the Clark's classification. Clark's level is used in the staging system for tumors less than 1 mm. Record Clark's level for all melanoma patients when it is present in the pathology report.

Level I: lesions involving only the epidermis (in situ melanoma); not an invasive lesion;
Level II: invasion of the papillary dermis, but does not reach the papillary-reticular dermal interface;
Level III: invasion fills and expands the papillary dermis, but does not penetrate the reticular dermis;
Level IV: invasion into the reticular dermis but not into the subcutaneous tissue; Level V: invasion through the reticular dermis into the subcutaneous tissue.

2.2 This information is found in the **PATHOLOGY REPORT**. The pathologist reports the Clark's level. It is not possible to deduce from other information what the Clark's level is. Record the Clark's level as reported in the pathology report. Code 1, 2, 3, 4, 5 for I, II, III, VI, or V, respectively. Because these patients have metastatic melanoma, their Clark's level may be in the higher range.

2.3 If it cannot be determined or there is no mention of Clark's level in the pathology report, then code "9 – Unknown/Not reported."

IN-TRANSIT METASTASES

ITEM B-4

1. Code: 0 –No in-transit metastases/Not Mentioned
1 –Yes in-transit metastases present
9 – Unknown

2. Description:

2.1 In-transit metastases are satellite lesions that occur between the primary melanoma and the first major regional nodal group. They are associated with a poorer outcome.

2.2 Record “0–No in-transit metastases/Not mentioned” if there is no evidence of in-transit metastases noted in the medical record.

2.3 Record “1–Yes in-transit metastases present” if there are in-transit metastases.

2.4 Record “9–Unknown” when it is unknown whether or not in-transit metastases are present. This might be the case if there is no medical record available for review.

ULCERATION OF THE PRIMARY LESION

ITEM B-5

1. Code: 0 - No ulceration/Not Mentioned
1 - Yes, ulceration present
9 - Unknown

2. Description:

2.1 Ulceration, or a wound that will not heal, is one of the seven warning signs of cancer, especially for melanoma. This may have been the reason for the person seeking medical attention. Ulceration of the primary lesion is associated with a poorer outcome.

2.2 Record "0—No ulceration/Not mentioned" if there is no evidence of ulceration noted in the medical record.

2.3 Record "1—Yes" if there is ulceration of the primary lesion.

2.4 Code "9 – Unknown," when it is unknown whether or not ulceration was present. This might be the case if there is no medical record available for review.

2.5 This item refers to ulceration of the melanoma prior to treatment. It does not refer to post-operative ulceration which develops at the melanoma excision site as part of the healing process.

NUMBER OF REGIONAL LYMPH NODES POSITIVE and EXAMINED

ITEM B-6 & B-7

1. Code: B-6 – Number of positive regional lymph nodes

00 – All examined nodes negative
01 – One positive node
02 – Two positive nodes
...
90 – 90 or more positive nodes
95 – Positive aspiration or core biopsy of lymph node(s) performed
97 – Positive nodes documented – number unspecified
98 – No nodes examined
99 – Unknown, not stated

B-7 – Number of regional lymph nodes examined

00 – No nodes examined (no nodal dissection performed)
01 – One node examined
02 – Two nodes examined
...
90 – 90 or more examined
95 – No regional nodes removed, but aspiration or core biopsy of regional nodes performed
96 – Regional lymph node removal documented as sampling and number of nodes unknown/not stated
97 – Regional lymph node removal documented as dissection and number of nodes unknown/not stated
98 – Regional lymph nodes surgically removed but number of lymph nodes unknown/not stated and not documented as sampling or dissection; nodes examined, but number unknown
99 - Unknown/not stated if nodes were examined

2. Description:

2.1 For information on which nodes are considered regional, refer to the AJCC Staging Manual 8th Edition.

2.2 Record the number of regional nodes **examined by a pathologist** and found to contain metastasis.

NUMBER OF REGIONAL LYMPH NODES POSITIVE & EXAMINED (continued)

ITEMS B-6 & B-7

2.3 Code the number of regional lymph nodes positive in Item B-6 and the number of regional lymph nodes examined in Item B-7. Include all node dissections done during the first course of therapy.

2.4 If more than one dissection was done during the first course of treatment, code the total number of lymph nodes positive and examined.

2.5 If the number of nodes positive was 90 or greater, code Item B-6 as "90". If the number of nodes examined was 90 or greater, code Item B-7 as "90".

2.6 If lymph nodes were known to be positive, but the exact number positive is unknown, code Item B-6 as "97".

2.7 If lymph nodes were known to be positive, but the exact number positive is unknown **and** the exact number examined is unknown, code Item B-6 as "97" and Item B-7 as "96", "97", or "98".

2.8 If no regional lymph nodes were positive, and the number examined is at least one, but the total is unknown, code B-6 "00" and B-7 "96", "97" or "98".

2.9 If no regional node dissection was done or no regional lymph nodes were removed/examined, code Item B-6 "98" and B-7 "00".

2.10 If it is unknown or not stated whether any nodes were either positive or examined, then code "99" in Items B-6 and B-7.

2.11 If regional lymph nodes were aspirated, code Item B-6 either "00" for negative or "95" if positive and code Item B-7 as "95".

2.12 When there is a difference in the number of nodes positive and/or examined between the body of the pathology report and the final diagnosis, code the information from the final diagnosis.

TECHNIQUE OF LYMPH NODE DISSECTION

ITEM B-8

1. Code: 0 – No lymph node dissection
1 – Traditional surgical nodal dissection only
3 – Sentinel lymph node biopsy with no additional dissection
4 – Sentinel lymph node biopsy with additional lymph node dissection (on same date or later date)
8 – Technique unknown
9 – Unknown if lymph node dissection performed.

THIS IS NOT THE SEER CODING OF SENTINEL NODE BIOPSY

2. Description:

2.1 Lymph node dissection can be done by a traditional open surgical technique whereby the nodes in the region draining the primary site are resected as completely as possible.

2.2 Sentinel lymph node biopsy is a technique whereby a tracer material is inserted into the primary tumor and is then followed into the draining lymph node where it concentrates in the "sentinel" node. This node is then resected. If it is negative for tumor, the open dissection is not needed. If it is positive, an open dissection as in 2.1 above may be carried out.

2.3 Code "0 - No lymph node dissection" if there were no lymph nodes sampled.

2.4 Code "1—Traditional surgical nodal dissection only" if only a traditional surgical nodal dissection is performed.

2.5 Code "3—Sentinel lymph node biopsy with no additional dissection" if a sentinel node biopsy is performed, and there is no subsequent traditional dissection following. This would typically be the case when the sentinel node is found to be negative for tumor, though this is not always true.

2.6 Code "4 – Sentinel lymph node biopsy with additional lymph node dissection" if a lymph node dissection follows the sentinel node biopsy. This is usually done if the sentinel node is found to be positive. Whether the sentinel node is negative or positive, if there is a lymph node dissection following a sentinel node biopsy either on the same date or a later date, code "4."

2.7 Code "8 – Technique unknown" if it is unclear whether or not a traditional or sentinel dissection was performed.

2.8 Code "9 – Unknown if lymph node dissection performed" if there is no information regarding nodal dissection.

EOD OF PRIMARY TUMOR

ITEM B-9

1. Code: Melanoma Skin

Code	Description	SS2018 T
000	In situ, intraepidermal, intraepithelial, noninvasive (Basement membrane of the epidermis is intact) Clark level I	IS
100	Papillary dermis invaded Clark level II	L
200	Papillary-reticular dermal interface invaded Clark level III	L
300	Reticular dermis invaded Clark level IV	L
400	Skin/dermis, NOS Localized, NOS	L
500	Subcutaneous tissue (through entire dermis) Clark level V	RE
700	Bone Skeletal muscle Underlying cartilage Further contiguous extension	D
800	No evidence of primary tumor Regressed melanoma (complete)	U
999	Unknown; extension not stated Primary tumor cannot be assessed Not documented in patient record Death Certificate Only	U

EOD OF PRIMARY TUMOR (continued)

ITEM B-9

Note 1: If there is a discrepancy between the Clark level and the pathological description of extent (invasion into the layers of the dermis), use the higher (more extensive) code.

Note 2: Code the greatest extent of invasion from any procedure performed on the lesion, whether it is described as a biopsy or an excision. For example, if a punch biopsy with involvement of Clark level IV is followed by a re-excision with residual tumor involving Clark level II, code 300 (Clark level IV).

Note 3: Satellite lesions/nodules or in-transit metastases are coded in EOD Regional Nodes.

Note 4: If a Breslow's depth is given in the pathology report and there is no other indication of involvement, the following guidelines may be used (Note: If a physician documents a different Clark's Level then provided by these guidelines, go with the physician's Clark Level)

- Code 000: In situ
- Code 100: Level I (< 0.75 mm Breslow's Depth)
- Code 200: Level II (0.76 mm to 1.50 mm Breslow's Depth)
- Code 300: Level III (> 1.50 mm Breslow's Depth)

2. Description:

2.1 USE SEER CODING RULES – see SEER*RSA

METASTASIS AT DIAGNOSIS

ITEM B-10

1. Code:

0 – No evidence of metastasis at the site
1 – Yes, only pathologic confirmation of metastasis at the site
2 –Yes, only clinical confirmation of metastasis at the site
3 – Yes, both clinical and pathologic confirmation of metastasis at the site
9 – Unknown if metastasis at the site

Sites

Bone
Brain
Liver
Lung
Distant lymph node(s)
Other (Specify) _____

2. Description:

2.1 Refer to the 2018 SEER Program Coding and Staging Manual for complete details. Code information about metastasis identified at the time of diagnosis. Information about metastatic involvement may be **clinical or pathologic.** These codes are NOT the codes from the SEER Manual—the POC codes are expanded to capture clinical and pathologic information.

2.2 Code "0 – No" if there is no evidence of distant metastasis in the medical record or imaging reports.

2.3 Code "1 – Yes, only pathologic confirmation of metastasis at the site" when there is pathologic but no clinical evidence of distant metastasis. Pathologic confirmation requires a biopsy positive for cancer at the metastatic site and may be reported in a pathology report or surgical records.

2.4 Code "2 – Yes, only clinical confirmation of metastasis at the site" when there is clinical but no pathologic evidence of distant metastasis. Clinical confirmation can be derived from documentation in patient history or physical examination and imaging reports. However, imaging of distant organs is not required.

2.5 Code "3 – Yes, both clinical and pathologic confirmation of metastasis at the site" when there is clinical and pathologic confirmation of distant metastasis.

2.6 Code "9 - Unknown" if it is unknown whether there is metastasis at the site. If there is no information about whether the patient had any metastatic disease, all sites should be coded "9 – Unknown."

METASTASIS AT DIAGNOSIS (continued)

ITEM B-10

2.7 If the record indicates that there is "metastatic disease" but does not provide any information on the site of metastasis, code bone, brain, liver, lung, and distant lymph node as "9 – unknown" and code other (Specify) as "1 – Yes." Enter "other site" in the text field.

2.8 If there is no evidence of metastases at any site, all should be coded as "0 – No."

2.9 Refer to the 2018 SEER Program Coding and Staging Manual for interpretation of ambiguous terminology.

3. Specifics

3.1 Metastasis to all sites may be a single metastatic lesion or multiple in the same site.

3.2 Bone involvement does **NOT** include bone marrow involvement.

3.3 Brain involvement does **NOT** include spinal cord or other parts of the central nervous system.

3.4 Distant lymph node involvement does **NOT** include regional lymph nodes.

3.5 Lung involvement does **NOT** include pleura or pleural fluid.

3.6 Other sites include distant involvement in sites not including bone, brain, distant lymph nodes, liver, and lung. It includes involvement of other more specific sites and more generalized metastasis (ex. adrenal gland, bone marrow, pleura, peritoneum, malignant pleural effusion).

MUTATIONS

ITEM B-11

1. Code: 0 – Test not performed/no mention
1 – Test positive
2 – Test negative
8 – Test performed, result unknown
9 – Unknown if test performed

Tests
- BRAF
- RAS/NRAS
- NF1
- MEK
- C-KIT

2. Description:

2.1 NRAS is a gene that encodes a protein with the official name of "neuroblastoma RAS viral (v-ras) oncogene homolog. These proteins instruct the cell to grow and divide or to mature and take on specialized functions. Studies suggest that *NRAS* gene mutations are common in an aggressive form of melanoma. Mutations in the *NRAS* gene have also been found in other types of cancer.

2.2 BRAF is a gene that encodes a protein formally known as serine/threonine-protein kinase B-Raf. It is important in cell signaling and directing cell growth. Drugs that treat the cancers that are involved with a mutation in BRAF have been developed. Vemurafenib has been approved for late-stage melanoma associated with BRAF positive tumors.

2.3 NF1 codes for neurofibromin, a protein that negatively regulates RAS proteins through GTPase activity. Melanomas with NF1 mutations typically occur on chronically sun-exposed skin or in older individuals, and are more common among desmoplastic melanoma.

2.4 MEK is two genes (MEK1 and MEK2) that code mitogen-activated protein kinase enzymes. This enzyme pathway may be activated in certain cancers.

2.5 Mutations in the CD117 gene, commonly called *KIT* or C-KIT, are relevant for melanoma and are most often found in melanomas related to sun exposure, although overall it is positive in only about 2% of patients. This test may or may not be performed. If there is no mention in the medical record, then code "0 – Not performed/no mention."

MUTATIONS (continued)

ITEM B-11

2.6 Information on the presence of a **normal or mutated genes should come from the medical record.** Examine the record carefully for statements about mutations or abnormalities.

2.7 Record whether the test results were positive or negative. If the test was not performed or there is no mention in any of the records, then code "0 – Test not performed/no mention".

2.8 If there is mention of the test being performed in the record but no results, then code "8 – Test performed, results unknown".

2.9 If there is mention of the test in the records but no indication that the test was performed, then code "9 – Unknown if test performed".

FAMILY HISTORY OF MELANOMA/NUMBER OF MEMBERS

ITEM B-12

1. Code: **Family History**

0 – No family history of melanoma
1 – Family history of melanoma
9 – Unknown/no mention whether there is a family history of melanoma

Number of Family Members with History of Melanoma

0 – No family history of melanoma
1 – One family member
2 – Two family members
.
.
7 – Seven family members
8 – 8 or more family members
9 – Family members had melanoma, but number unknown

2. Description:

2.1 Code "0 – No family history" if the record states that there is no family history of melanoma.

2.2 Code "1 – Family history of melanoma" if the record indicates that the patient has a family history of melanoma.

2.3 If the record indicates that the patient does not know whether there is a family history of melanoma, or if the record does not mention family history, then code "9 – Unknown".

2.4 Code the number of family members that are noted to have had melanoma in the second box. If the family history is unknown, then leave the second box blank.

DATE OF CANCER-DIRECTED SURGERY TO PRIMARY SITE

ITEM B-13

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

Month	Day	Year
01 - January	01	Use 4-digit Year
02 - February	02	
.	.	
12 - December	31	
77	77	7777-Patient or guardian refused
95	95	9595-Recommended, not performed
96	96	9696-Recomm., unknown if performed
97	97	9797-Unknown if performed
99 - Month Unk	99 - Day Unk	9999-Year Unknown

2. Description:

2.1 Enter the date of the ***most definitive*** cancer-directed surgery to the primary site. Refer to the 2018 SEER Program Coding and Staging Manual Section VII for definition of first course of therapy.

2.2 This does not include biopsy unless the biopsy became definitive surgery and the date for Item B-1 is coded as “94-94-9494”.

2.3 If the biopsy/aspiration was performed on the same day as definitive surgery and they were separate procedures, the biopsy date and the Date of Cancer-Directed Surgery to Primary Site will be the same.

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

2.5 Code“77-77-7777 – Patient/guardian refused surgery” if the records indicate that surgery was recommended, but the patient or patient’s guardian refused.

2.6 Code “95-95-9595 – Recommended, not performed” if the records indicate that surgery was recommended, but was not performed for a reason other than refusal.

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

2.8 Code “97-97-9797 – Unknown” if it is unknown whether surgery was recommended AND unknown if surgery was performed.

DATE OF CANCER-DIRECTED SURGERY TO PRIMARY SITE (continued)

ITEM B-13

2.9 Code "99-99-9999" if it is **KNOWN** that the patient had surgery to the primary site, but the day, month and/or year given cannot be determined. If the exact date of the surgery is unknown, then code an estimate. Coding the closest approximation is preferable to coding unknown.

PATHOLOGICAL MARGINS

ITEM B-14

1. Code:

0 – No resection/surgery performed; biopsy only
1 – Margins of resection pathologically free of tumor
2 – Tumor at margins of resection, or residual tumor in area of primary
3 – Margins not stated in pathology report--surgeon indicates no residual tumor
8 – Resection recommended unknown if performed
9 – Unknown, not stated

2. Description:

2.1 This item records the pathological margin status following the ***most definitive surgery*** performed after diagnosis.

2.2 Code "0 – No resection/surgery performed" when no cancer-directed surgery or only a biopsy was performed.

2.3 Code "1 – Margins of resection pathologically free of tumor" when the pathologist reported no residual tumor in the area of the primary site.

2.4 Code "2 – Tumor at margins of resection, or residual tumor in area of primary" when the pathologist reported involvement of the surgical resection margins.

2.5 Code "3 – Margins not stated in pathology report--surgeon indicates no residual tumor" when the pathology report does not document the pathologic margin status, but the surgeon states in the operative report that no tumor was left in the area of the primary site.

2.6 Code “8 – Resection recommended unknown if performed” if the physician recommended surgery, but it is unknown whether it was performed.

2.7 Code "9 – Unknown, not stated" when there is no information in the pathology report regarding pathologic margins and the surgeon does not document margin status in the operative report

GRADE

ITEM B-15

1. Code: 3 digits

Clinical Grade	1 digit
Pathological Grade	1 digit
Post Therapy 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 For complete coding instructions for the three grade fields, use the 2018 Grade Coding Instructions and Tables. Clinical, Pathological, and Post Therapy Grade for melanoma of the skin are each coded as A-D or 9.

2.3 Clinical Grade records the grade of a tumor before any treatment (surgical resection or initiation of any treatment including neoadjuvant). Clinical Grade must not be blank. Assign the highest grade from the primary tumor assessed during the clinical time frame. Code Clinical Grade as 9 when the grade from the primary site is not documented or clinical workup is not done (for example, cancer is an incidental finding during surgery for another condition), or grade checked "not applicable" on CAP Protocol (if available) and no other grade information is available. If there is only one grade available and it cannot be determined if it is clinical or pathological, assume it is a clinical grade and code appropriately. Then code unknown (9) for pathological grade and blank for post therapy grade.

2.4 Pathological Grade records the grade of a solid primary tumor that has been resected and for which no neoadjuvant therapy was administered. If AJCC staging is being assigned, the tumor must have met the surgical resection requirements in the AJCC manual. This may include the grade from the clinical workup. Record the highest grade documented from any microscopic specimen of the primary site whether from the clinical workup or the surgical resection. Pathological grade must not be blank. If the clinical grade is the highest grade identified, use the grade that was identified during the clinical time frame for both the clinical grade and the pathological grade. If a resection is done of a primary tumor and there is no grade documented from the surgical resection, use the grade from the clinical workup. If a resection is done of a primary tumor and there is no residual cancer, use the grade from the clinical workup. Code Pathological Grade as 9 when grade from primary site is not documented; there was no resection of the primary site; neo-adjuvant therapy is followed by a resection (see Post Therapy Grade); this is a clinical case only (see clinical grade); or there is only one grade available and it cannot be determined if it is clinical, pathological, or after neo-adjuvant therapy.

GRADE (continued)

ITEM B-15

2.5 Post Therapy Grade records the grade of a solid primary tumor that has been resected following neoadjuvant therapy. If AJCC staging is being assigned, the tumor must have met the surgical resection requirements in the AJCC manual. Record the highest grade documented from the surgical treatment resection specimen of the primary site following neoadjuvant therapy. Leave Post Therapy Grade blank when there is no neoadjuvant therapy; this is a clinical or pathological case only; or there is only one grade available and it cannot be determined if it is clinical, pathological or post therapy. Assign the highest grade from the resected primary tumor assessed after the completion of neoadjuvant therapy. Code Post Therapy Grade as 9 when surgical resection is done after neoadjuvant therapy and grade from the primary site is not documented; surgical resection is done after neoadjuvant therapy and there is no residual cancer; or grade is checked "not applicable" on CAP Protocol (if available) and no other grade information is available.

SYSTEMIC THERAPY SEQUENCE WITH SURGERY

ITEM B-16

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 – Intraoperative systemic therapy
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 and cancer-directed surgery at any time after diagnosis. If only one (systemic therapy or surgery) was given, then this item is coded as “0”.

2.2 Code "0 – No/unknown systemic therapy and/or no/unknown cancer-directed surgery" when systemic therapy (Items B-17 to B-33) and/or Cancer-Directed surgery status (Item B-6) is unknown or when the patient did not receive systemic therapy and/or cancer-directed surgery. (Surgery and Systemic therapy status are unknown or not done when they 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 definitive cancer-directed surgery.

For example: A patient with an excisional biopsy, followed by systemic therapy, followed by excision is coded as "2 - Systemic therapy before surgery".

2.4 Code "3 – Systemic therapy after surgery" when the patientreceived systemic therapy following the most definitive cancer-directed surgery.

For example: A patient who had a biopsy, followed by an excision, then treated with systemic therapy would be coded as "3 – Systemic therapy after surgery".

2.5 Code "4 – Systemic therapy both before and after surgery" is used when chemotherapy was given both prior to and following the definitive surgery.

2.6 Code "5 – Intraoperative systemic therapy" when the patient received systemic therapy during the most definitive cancer-directed surgery.

2.7 Code “9 – Sequence unknown” when both systemic therapy and surgery were received by the patient but the sequence is unknown and/or the dates are missing (99) so the sequence cannot be determined.

SYSTEMIC THERAPY AGENTS

ITEMS B-17 through B-39

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	
.	.	
12 - December	31	
77	77	7777-Patient or guardian refused
95	95	9595-Recommended, not given
96	96	9696-Recomm., unknown if given
97	97	9797-Unknown if given
99 - Month Unk	99 - Day Unk	9999-Year Unknown

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

B-17 Binimetinib (Mektovi)

B-18 Carboplatin

B-19 Cisplatin

B-20 Cobimetinib (Cotellic)

B-21 Dabrafenib (Tafinlar)

B-22 Dacarbazine (DTIC)

B-23 Encorafenib (Braftovi)

B-24 High dose IL-2

B-25 IL-2

B-26 Imatinib (Gleevec)

B-27 Interferon alpha

B-28 Ipilimumab (Yervoy)

SYSTEMIC THERAPY (continued)

ITEMS B-17 through B-39

B-29 Nivolumab (Opdivo)

B-30 Paclitaxel

B-31 Peginterferon Alfa-2b (Sylatron)

B-32 Pembrolizumab (Keytruda)

B-33 Sorafenib (Nexavar)

B-34 Sunitinib (Sutent)

B-35 Talimogene Laherparepvec (T-VEC, Imlygic)

B-36 Temozolomide (Temodar)

B-37 Trametinib (Mekinist)

B-38 Vemurafenib (Zelboraf)

B-39 Other, specify: _____

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

Please be sure to record all systemic therapy agents. SEER*Rx is useful for looking up chemotherapy, hormonal therapy, immunotherapy, and other agents used to treat cancer. It can be accessed via the web or loaded onto your laptop for easy reference.

2. Description:

2.1 Code the date therapy started for each systemic therapy agent given at any time following diagnosis.

2.2 Code "00-00-0000-Not given" when the patient did not receive systemic therapy, even when it was recommended. Also, use this code when the agent was considered or recommended, and it is known that the patient did not receive it. (See also “77-77-7777-Refused”.) If no chemotherapy agent was given, then all agents should be coded as "00-00-0000", unless the patient or the patient's guardianrefused the systemic therapy. (See also code “7777-Patient/guardian refused").

SYSTEMIC THERAPY (continued)

ITEMS B-17 through B-39

2.3 Code “77-77-7777” if an agent was recommended, but was not administered because of patient or guardian refusal. If the patient refuses therapy, but it is not known which specific drug was refused, all agents known to have been recommended should be coded "77-77-7777”.

2.4 Code “95-95-9595 – Recommended, not given” when the records indicate that systemic therapy was recommended, but was not given for a reason other than refusal.

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

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

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

2.8 High dose Interleukin is given in the hospital. Low dose Interleukin may be given in an outpatient setting. If the physician does not provide information about whether the Interleukin was low dose or high dose, but the patient is hospitalized for administration of the Interleukin, code as high dose.