POC DATA ACQUISITION MANUAL

2015 DIAGNOSIS

BREAST CANCER
NON-SMALL CELL LUNG CANCER
COLON/RECTUM CANCER

POC DATA ACQUISITION MANUAL

SECTION II

PATIENT ELIGIBILITY

SECTION II - PATIENT ELIGIBILITY

CONTENTS

PATIENT ELIGIBILITY

In addition to using a common set of data items and codes, it is also important that the registries involved in this study adopt a uniform policy by which patients are selected for inclusion. This will ensure that the descriptions of the patient populations are comparable. Analyses will include the comparison of data collected for breast and colorectal cancer patients diagnosed in 1987 through 1991, 1995, 2000, 2005, and 2010 and lung cancer patients diagnosed in 1996, 2005, and 2010. It is important that the populations be comparable over time as well.

1. PATIENT SELECTION

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

1.1.1 Sampling will be of pre- and post-menopausal women (defined below) with breast cancer diagnosed between January 1, 2015 and December 31, 2015 by race/ethnicity and stage (defined below). Only women will be included.

1.1.2 Men and women with colon and rectal cancer diagnosed between January 1, 2015 and December 31, 2015 will be sampled by cancer site (colon excluding rectum; and rectum), stage (defined below), sex, and race/ethnicity.

1.1.3 Men and women diagnosed with invasive non-small cell lung cancer between January 1, 2015 and December 31, 2015 will be sampled by stage (defined below), sex and race/ethnicity.

2. SAMPLING

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

2.2. To sample cases, assign a random number between 0 and 1 to all eligible cases of the cancer of interest in your registry for the time period January 1, 2015 through December 31, 2015. The number of cases to be sampled divided by the total number of eligible cases will be your *sampling fraction*. If the case has a number less than or equal to your sampling fraction, X, the case will be included in the study. If the random number assigned is greater than your sampling fraction, the case will not be abstracted for the Patterns of Care study. For example, the sampling fraction for IN SITU breast cancer is 0.63. All IN SITU breast cancer cases eligible for inclusion in the study would have a random number between 0 and 1 assigned. If case 10100001 were given the random number of 0.594, it would be included in the study. Its number is less than the sampling fraction number of 0.63. If case 10100001 were assigned the random number of 0.654, it would not be abstracted for this study because its number is greater than the 0.63 sampling fraction.

2.3 At some point during the study, it is likely that cases will be added to the registry's database for a time period for which sampling has already been completed. In order to give these additional cases an opportunity to be included in the study, the registries should identify such patients, add them to the appropriate Sampling File, and assign them random numbers between 0 and 1. All cases found after the initial sampling **MUST** be sampled in this way. These additional cases will not modify the sampling fractions already obtained for a given time interval. The basis for selection of these patients into the study will be the sampling fractions (i.e., if the fraction for a cancer site group or subgroup is 0.49, a patient will be added to the appropriate SEER Patterns of Care file if his/her assigned random number is 0.49 or less). **In the event that one or more of these additional cases is found to be ineligible after selection into the study, do not replace them with another case. If there are more than 10 cases found to be ineligible, please discuss with NCI whether additional cases should be sampled.**

3. REPORTABLE CASES

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

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

3.2.1 Patient must have a pathologically confirmed diagnosis of carcinoma of one of the following sites: colon, rectum, lung, or female breast.

3.2.2 Patient must have been initially diagnosed between January 1, 2015 and December 31, 2015.

3.2.3 Malignant neoplasms arising in the ICD-O Topography sites listed below and in situ breast cancers are reportable to SEER POC study. See **SEER Program Coding and Staging Manual 2015** for a list of reportable terms.

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

4. BREAST CANCER CASES

4.1 Female Breast (excludes skin of breast), but includes the following

C50.0 Malignant neoplasm of female breast, nipple and areola
C50.1 Central portion of breast
C50.2 Upper-inner quadrant
C50.3 Lower-inner quadrant
C50.4 Upper-outer quadrant
C50.5 Lower-outer quadrant
C50.6 Axillary tail of breast, tail of breast, NOS
C50.8 Other specified sites of breast [1]
Inner breast
Lower breast
Midline of breast
Outer breast
Upper breast
C50.9 Breast, NOS
Mammary gland

4.1.1 Include cases meeting the following criteria:

- Derived AJCC 7 Stage Group 0-II, IIIA (from CS coded fields)
- Women with multiple primaries should be included only if this breast cancer is the first diagnosed cancer.
- Histology codes: 8000-8530, 8550-8576
- Behavior codes: 2, 3

4.1.2 Exclude cases meeting any of the following criteria:

- Males
- Paget's disease with no underlying tumor (CS Extension codes 050, 070 or ICD O-3 code 8540-8543)
- Derived AJCC 7 Stage Group IIIB-IV (from CS coded fields)
- Bilateral breast carcinoma diagnosed simultaneously
- Histology codes: All other histologies
- Unknown stage or unstaged patients

4.2 Pre- and post-menopausal women will be sampled separately by race/ethnicity. Pre-menopausal is defined as ≤ 50 years of age and post-menopausal as > 50 years of age. IN SITU and invasive will also be sampled separately.

[1] NOTE: Tumors that overlap the boundaries of two or more subcategories and whose point of origin cannot be determined should be classified to sub-category "8".

4.3 Details of Sampling; Eligibility

Note: Derived AJCC 7 Stage Group categories (from CS coded fields)

Site	Derived AJCC 7 Stage Group	CS codes	Age	Race/Ethnicity
Breast	0	000	≤ 50 >50	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN
	I A-B, NOS	100-120, 150	≤ 50 > 50	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN
	II A-B, NOS	300-320, 330	≤ 50 > 50	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN
	IIIA	520	≤ 50 > 50	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN

5.0 Colon and Rectal Cancer Cases

5.1 Colon/Rectum includes the following:

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

5.2 Colon Cancer

5.2.1 Include only cases of:

- Derived AJCC 7 Stage Group II (from CS coded fields):
  Tumor invades bowel wall with extension into pericolic adipose tissue and/or immediately adjacent structures; negative regional lymph nodes; no distant metastases.
- Derived AJCC 7 Stage Group III (from CS coded fields):
  Tumor invades bowel wall to any depth; positive regional nodes; no distant metastases.
- Histology codes: M-8000-8152, 8154-8231, 8243-8245, 8247, 8248, 8250-8576
- Behavior code: 3 only

5.2.2 Exclude cases of:

- C18.1 (appendix)
- Derived AJCC 7 Stage Group I (from CS coded fields):
  Tumor confined to mucosa and submucosa of the bowel; regional nodes negative; no distant metastases.
- Derived AJCC 7 Stage Group IV (from CS coded fields):
  Tumor has spread to distant sites and/or lymph nodes.
- Histology Codes: All other histologies
- Unknown stage or unstaged patients

5.2.3 Details of sampling; Eligibility

Site	Derived AJCC Stage Group	CS Code	Race/Ethnicity	SEX
Colon	II	300-320, 330, 340	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN	Male Female
	III	500-540	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN	Male Female

5.3 RECTAL CANCER

5.3.1 Include only cases of:

- C19.9, C20.9
- Derived AJCC 7 Stage Group II (from CS coded fields):
  Tumor invades bowel wall with extension into pericolic adipose tissue and/or immediately adjacent structures; negative regional lymph nodes; no distant metastases.
- Derived AJCC 7 Stage Group III (from CS coded fields):
  Tumor invades bowel wall to any depth; positive regional nodes; no distant metastases.
- Histology codes: 8000-8152, 8154-8231, 8243-8245, 8247, 8248, 8250-8576
- Behavior code: 3 only

5.3.2 Exclude cases of:

- Histology codes: All other histologies
- Derived AJCC 7 Stage Group I (from CS coded fields)
  Tumor confined to mucosa and submucosa of the bowel; regional nodes negative; no distant metastases.
- Derived AJCC 7 Stage Group IV (from CS coded fields):
  Tumor has spread to distant sites and/or lymph nodes.
- Unknown stage or unstaged patients

5.3.3 Details of sampling:

Site	Derived AJCC Stage Group	CS Codes	Race/Ethnicity	SEX
Rectum	II	300-320, 330, 340	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN	Male Female
	III	500-540	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN	Male Female

6. NON-SMALL CELL LUNG CANCER

6.1 Lung Cancer Cases

6.1.1 Include only cases of:

- ICD-0-3 C34.0-34.3,34.8-34.9
- Histologies/; 8000-8035, 8046-8576
- Include cases of malignant (behavior code 3)
- Include all stages EXCEPT Derived AJCC 7 Stage Group 0 (from CS coded fields) (in situ) and unknown stage

6.1.2 Exclude cases of lung cancer with:

- Histology codes: All other histologies
- AJCC7 Stage Group 0 and Unknown stage or unstaged patients

6.1.3 Details of sampling:

Site	Derived AJCC Stage Group	CS codes	Race/Ethnicity	Sex
Lung	Stages I/II	100-120, 150 300-320,330	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN	Male Female
	Stage IIIA	520	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN	Male Female
	Stages IIIB/IV	530 700	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN	Male Female

7. GENERAL NON-REPORTABLE CASES AND MALIGNANCIES

Cases which are not reportable to 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 breast cancer and primary lung cancer a few weeks apart. Or, a patient simultaneously diagnosed with bilateral lung cancer within 60 days.
- Non-histologically proven carcinoma (clinical diagnosis)
- Lymphomas of the breast, colon, rectum or lung
- NET histologies of the colon or rectum
- Unknown stage or unstaged cases
- Death certificate only diagnosis
- Autopsy only diagnosis
- Patient younger than adult (adult is 20+ years old)

8. REPORTABLE HISTOLOGIES AND BEHAVIORS BY SITE

8.1 Breast

Include histology codes: 8000-8530, 8550-8576
Include behavior codes: 2, 3
Exclude histology codes: 8540-8543, 8580-9989

8.2 Colon

Include histology codes: M-8000-8152, 8154-8231,8243-8245,8247,8248,8250-8576
Includes behavior code: 3 only
Exclude histology codes: 8153, 8240-8242, 8246, 8249, 8880-9975

8.3 Rectum

Include histology codes: 8000-8152, 8154-8231, 8243-8245, 8247, 8248, 8250-8576
Includes behavior code: 3 only
Exclude histology codes: 8153, 8240-8242, 8246, 8249, 8720-9975

8.3 Lung

Include histology codes: 8000-8035, 8046-8671
Include behavior codes: 3 only
Exclude histology codes: 8041-8045, 8680-9989

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:
Original abstract completed
QC abstract completed
Immediate comparison of the original and QC forms
Identification of differences between the original and QC
Determination of correct item or code
Discussion of correct abstracting or coding
Correction of original or QC abstract
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 Disease for Oncology*, Third edition (ICD-O-3, 2001) is used for coding the primary site of all solid tumors.

2.2 The coding of primary site is to be completed as described in *The SEER Program Coding and Staging Manual 2015* Section IV, Primary Site.

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

MORPHOLOGY

ITEM A-7

1. Code: 6 digits

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

2. Description:

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

2.2 Use the SEER Program Coding and Staging Manual 2015 for morphology coding instructions.

2.3 The BEHAVIOR codes are those used in ICD-O-3 and as described in The SEER Program and Coding and Staging Manual 2015.

2.4 For a complete description of coding of GRADE/differentiation, see Section IV, Grade, Differentiation or Cell Indicator of *The SEER Program Coding and Staging Manual 2015*. This is histologic grade.

DIAGNOSTIC CONFIRMATION

ITEM A-8

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

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

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

2. Description:

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

2.2 Code diagnostic confirmation as described in the SEER Program Coding and Staging Manual 2015, Section IV.

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

HOSPITAL CODE

ITEM A-9

1. Code: 3 digits

2. Description:

2.1 This item number will be assigned by the SEER site to the hospital of most definitive surgery or, if no surgery, the most definitive therapy in hierarchical order of radiation then systemic therapy. The codes are used to describe the hospital characteristics. Bed size, residency training program and hospital classification are provided by the American Hospital Association Guidebook[1]. You may also access hospital data at https://www.ahadataviewer.com/.

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

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

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

Bed size code:

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

Approved Residency training

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

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

[1]American Hospital Association. American Hospital Association Guide to the Health Care Field. Chicago, IL. https://www.ahadataviewer.com/

HOSPITAL CODE (continued)

ITEM A-9

Hospital Classification code:

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

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

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

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

9 = Unknown

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

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

5 1 1

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

3 0 2

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

8 0 3

INSURANCE STATUS

ITEM A-10

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

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

2. Description:

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

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

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

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

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

INSURANCE STATUS (continued)

ITEM A-10

3. Specifics:

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

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

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

3.4 Medicare patients may join an HMO as part of “Medicare Advantage.” If you determine that the patient has “Medicare Advantage” code HMO as “1 – Yes” and Medicare as “1 – Yes.” The patient has **BOTH** Medicare and is in an HMO.

3.5 If a Medicaid patient is in a Medicaid managed care (HMO) program, code HMO as “1 – Yes” and Medicaid as “1 – Yes.” The patient has **BOTH** Medicaid and is in an HMO.

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

INSURANCE STATUS (continued)

ITEM A-10

4. Examples:

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

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

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

4.4 If Medicaid pending is coded as "1 – Yes", it is unlikely that the patient has insurance other than, perhaps, Medicare; although they may be in a Medicaid managed care program.

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

TREATMENT PROTOCOL REGISTRATION

ITEM A-11

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

2. Description:

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

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

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

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

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

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

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

TREATMENT PROTOCOL SPONSOR AND NUMBER

ITEM A-12

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

2. Description:

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

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

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

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

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

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

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

TREATMENT PROTOCOL SPONSOR AND NUMBER (continued)

ITEM A-12

3. Examples:

3.1 SWOG 8711 is coded:

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

Sponsor: SWOG

Number: 8711

3.2 Local protocol is coded:

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

3.3 Drug company protocol is coded:

A-12

AstraZeneca

Sponsor:

AstraZeneca

THERAPY VERIFIED WITH PHYSICIAN OR OFFICE STAFF

ITEM A-13

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

2. Description:

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

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

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

2.4 If the therapy was verified through contact with the physician 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.**

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

CO-MORBID CONDITIONS

Item C

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

2. Description:

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

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

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

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

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

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

BREAST DATA SET

Partially adapted from previous manuals

SECTION IV - BREAST DATA SET

CONTENTS

HEIGHT / WEIGHT

ITEM B-1

1. Code:

Height

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

Units

1 = Inches
2 = Cm
3 = Other specify _____
9 = Unknown/not stated

Weight

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

Units

1 = Pounds
2 = Kilograms
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."

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.

DATE OF FIRST POSITIVE BIOPSY/ASPIRATION PROCEDURE

ITEM B-2

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

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

2. Description:

2.1 This item refers to the date of the first positive biopsy or aspiration procedure. This will be of interest for researchers interested in time from presentation to first diagnostic procedure. Code the date the specimen was obtained (NOT the date of the pathology/cytology report).

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

2.3 If the positive biopsy/aspiration was performed on the same day as definitive surgery, then the biopsy date (Item B-2) will be the same as the Date of First Cancer-Directed Surgery to Primary Site (Item B-9). The first positive biopsy/aspiration may have been done as an outpatient, but must be no later than the Date of First Cancer-Directed Surgery to Primary Site.

2.4 If the exact date of the first positive biopsy/aspiration is unknown, then estimate. For example, if in history and physical, the physician states the patient had a biopsy two weeks ago, then code the date of biopsy as 14 days prior to date of admission. Coding closest approximation is preferable to coding unknown. If an estimate cannot be made, then code “99-99-9999”.

DATE OF FIRST POSITIVE BIOPSY/ASPIRATION PROCEDURE (continued)

ITEM B-2

3. Specifics:

3.1 Code the date of the PROCEDURE performed to obtain the specimen, NOT the date of the pathology/cytology report.

3.2 Histologic diagnoses are based upon microscopic examination of tissue specimens from biopsy, frozen section, aspiration (including aspiration biopsy) and surgical specimens.

3.3 Cytologic diagnoses are based upon microscopic examination of cells, as contrasted with tissues. Examples are breast aspiration cytology and cytologic examination of breast secretions.

DATE OF PATHOLOGIC CONFIRMATION REPORT

ITEM B-3

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

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

2. Description:

2.1 This item refers to the date of the REPORT of the pathologic confirmation of breast cancer by the biopsy or aspiration coded in Item B-2. This is NOT the date the specimen was obtained. This is NOT the date the breast cancer was suspected. Researchers are interested in the time from confirmation of breast cancer to treatment. If the pathology department has "real-time" reporting (the reports are sent electronically as they are completed to the physicians' offices), then the date of the report may be the same as the date of pathologic confirmation.

2.2 If the patient or guardian refused the biopsy, code "77-77-7777- Patient/guardian refused." This is unlikely for these patients because the diagnosis must be pathologically confirmed.

2.3 If the biopsy/aspiration was recommended but it is unknown if it was performed, code "96-96-9696 – Recommended, unknown if performed." This is unlikely for these patients because the diagnosis must be pathologically confirmed.

2.4 If it is unknown if biopsy/aspiration was offered or performed, code "97-97-9797 – Unknown if offered or performed." This is unlikely for these patients because the diagnosis must be pathologically confirmed.

2.5 If the exact date of the first positive biopsy/aspiration is unknown, then estimate. For example, if in history and physical, the physician states the patient had a biopsy two weeks ago, then code the date of biopsy as 14 days prior to date of admission. Coding closest approximation is preferable to coding unknown. If an estimate cannot be made, then code "99-99-9999". If the pathology department has real-time reporting, record the date the report was received.

SIZE OF PRIMARY TUMOR

ITEM B-4

1. Code:

000 -	No mass; no tumor found
001-988-	001-988 millimeters (exact tumor size)
989 -	989 millimeters or larger
990 -	Microinvasion; microscopic focus or foci only; no size given; described as less than 1 mm.
991 -	Described as less than 1 cm
992 -	Described as less than 2 cm
993 -	Described as less than 3 cm
994 -	Described as less than 4 cm
995 -	Described as less than 5 cm
996 -	Mammographic/xerographic diagnosis only, no size given; clinically not palpable
998 -	Diffuse
999 -	Not stated; unknown; not documented in medical record (palpable tumors only)

2. Description:

2.1 Code the size of the primary tumor as recorded in the pathology report, imaging report or physical examination **in priority order**. When multiple masses are present, code the longest diameter. Code the exact value from 001 (00.1 cm) through 989 (98.9 cm). Be certain that the units are correctly recorded. Do not confuse mm and cm. 5 mm and 5 cm are markedly different and have different therapies.

2.2 Code the tumor size recorded prior to initiation of therapy.

2.3 If the tumor was palpable, but no size is documented, then code "999 - Not stated".

2.4 When there was a biopsy followed by a more extensive resection with residual tumor removed, code the largest tumor size recorded, but do not add the dimensions of the excised tumor tissue together.

2.5 If the tumor was only diagnosed by mammography/xerography with no size given and is not clinically palpable, code “996-Mammography/xerography diagnosis only with no size given (clinically not palpable)”.

3. Examples: A tumor of 0.9 cm (9 mm) in size is coded as "009".
A tumor of 5.5 cm (55 mm) in size is coded as "055".
A tumor of 8.3 cm (83 mm) in size is coded as "083".

METHOD OF MEASUREMENT

ITEM B-5

1. Code:
0 - No mass; no tumor found
1 - Microscopic focus or foci only
2 - Mammography/xerography measurement
3 - Ultrasound
4 - Pathological specimen
5 - Other (specify _____)
9 - Size unknown/not stated

2. Description:

2.1 Code the method used to determine the tumor size coded in Item B-4. This will most often be the pathological specimen. However, if this is unavailable, other methods of measurement may be available. Use the CS Tumor Size coding hierarchy in the SEER Program Coding and Staging Manual 2015, Appendix C.

2.2 Code "0" when no mass or tumor is found. Item B-4 (Tumor Size) should be coded as "000".

2.3 Code "1" when only microscopic foci are found. Item B-4 (Tumor Size) should be coded as "990".

2.4 Code "2" when the measurement is from a mammogram or xerographic measurement. Item B-4 (Tumor Size) should be coded as the exact tumor size when a size is given, or as "996" when the tumor size is not given.

2.5 Code "3" when the measurement is taken at the time of an ultrasound.

2.6 The preferred measurement is one taken from the specimen obtained when the tumor is removed. This can usually be found in the path report. This measurement is preferred over others. Use the SEER coding hierarchy.

2.7 Code "9" when the size is unknown or not stated for palpable tumors. Item B-4 (Tumor Size) should be coded as "999".

METHOD OF DETECTION

ITEM B-6

1. Code:
1 – Signs/symptoms
2 – Physician's physical exam
3 – Self-discovered
4 – Screening Mammography
5 – Spouse or partner
6 – Other, specify_____
9 – Unknown/Not specified

2. Description:

2.1 Code the method by which the tumor was initially detected. This refers to the first notice of a breast tumor, NOT the diagnostic procedures that followed.

2.2 Code "1 – Signs/symptoms" when the patient had signs/symptoms such as changes in appearance (color, shape, or size) of the breast or nipple, nipple discharge other than breast milk, breast pain/discomfort.

2.3 Code "2 – Physician's physical exam" when the patient's breast abnormality was initially detected by a routine breast exam performed by her physician.

2.4 Code "3 – Self-discovered" when the patient found a breast abnormality herself while doing a breast self-exam or while in the shower.

2.5 Code "4 – Screening Mammography" when the tumor was first seen on a routine screening mammogram.

2.6 Code "5 – Spouse or Partner" if the woman's spouse or partner discovered a mass.

2.7 Code "6 – Other, specify" when the tumor was discovered by some other means. Specify the method of discovery.

2.8 Code "9 – Unknown/Not specified" when it cannot be determined from the records how the tumor was initially detected.

GRADE/TYPE

ITEM B-7

1. Code: GRADE

Breast Grading Conversion Table

BR Scores	BR Grade	Nuclear Grade	Terminology	Histologic Grade	SEER Code
3-5	Low	1/3; 1/2	Well differentiated	I/III; 1/3	**1**
6, 7	Intermediate	2/3	Moderately differentiated	II/III; 2/3	**2**
8, 9	High	2/2; 3/3	Poorly differentiated	III/III; 3/3	**3**

TYPE

1 = Bloom Richardson (BR) Score
2 = Bloom Richardson Grade
3 = Nuclear
4 = Terminology (well-diff, mod-diff, etc.)
5 = Histologic Grade
9 = Type not stated

2. Description:

GRADE

2.1 Use the Breast Grading Conversion Table to convert the score, grade or term into the SEER code.

2.2 Code grade, converted to SEER Code, in the following priority order:

1. Bloom-Richardson scores 3-9
2. Bloom Richardson grade (low, intermediate, high)
3. Nuclear grade only
4. Terminology
    a. Differentiation (well differentiated, moderately differentiated, etc).
5. Histologic grade
    a. Grade 1/I/i, grade 2/II/ii, grade 3/III/iii, grade 4/IV/iv

2.3 Bloom Richardson may also be called: modified Bloom-Richardson, Scarff-Bloom-Richardson, SBR grading, BR grading, Elston-Ellis modification of Bloom Richardson score, the Nottingham modification of Bloom Richardson score, Nottingham-Tenovus, or Nottingham grade.

GRADE/TYPE (continued)

ITEM B-7

2.4 BR may be expressed in **scores** (range 3-9).

2.5 The score is based on three morphologic features of "invasive no-special-type" breast cancers (degree of tubule formation/histologic grade, mitotic activity, nuclear pleomorphism of tumor cells).

2.6 BR may be expressed as a **grade** (low, intermediate, high).

2.7 BR grade is derived from the BR score. Note that the conversion of low, intermediate, and high for breast is different from the conversion used for all other tumors.

TYPE

2.8 Code which type of grade was used to convert to SEER grade.

REGIONAL NODE DISSECTION

ITEM B-8

1. Code:
0 – No nodal dissection
1 – Axillary nodal dissection only
2 – Sentinel node biopsy only
3 – Sentinel node biopsy followed by axillary node biopsy and/or dissection
4 – Internal mammary node biopsy or excision only
5 – Both axillary and internal mammary node biopsy or excision
6 – Other, specify_____
8 – Node dissection performed, type unknown
9 – Unknown/Not stated

NOTE: THESE ARE NOT THE SEER CODES.

2. Description:

2.1 Code "0 – No nodal dissection" when the woman did not have her nodes dissected/biopsied. If this item is coded as "0", then Item B-10 (Number of Regional Nodes Positive) should be coded as "98" and Item B-11 (Nodes Examined) should be coded "00".

2.2 Code "1 – Axillary nodal dissection only" when the surgeon performed the traditional axillary lymph node dissection.

2.3 Code "2 – Sentinel node biopsy only" when the surgeon injected dye or radioactive material into the tumor and removed the node(s) that took up the dye or radioactive material.

2.4 Code "3 – Sentinel node biopsy followed by axillary node biopsy" when the surgeon performed a sentinel node biopsy, but followed it with an axillary node biopsy. If the nodes were positive on frozen section, additional nodes might be removed through an axillary node dissection.

2.5 Code "6 – Other, specify" when a different type of nodal dissection is performed. Specify the type of nodal dissection.

2.6 Code "9 – Unknown/Not stated" if it cannot be determined whether a nodal dissection/biopsy was performed. If this item is coded as unknown, then B-10 (Number of Regional Nodes Positive) & Item B-11 (Nodes Examined) would also be unknown.

DATE OF CANCER-DIRECTED SURGERY TO PRIMARY SITE

ITEM B-9

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	
.	.	
.	.	
.	.	
77	77	7777 - Patient/guardian refused surgery
96	96	9696 – Recomm., unknown if performed
97	97	9797 - Unknown if recomm or performed
99 - Month Unknown	99 - Day Unknown	9999 - Year Unknown

2. Description:

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

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

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

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

2.5 Code "97-97-9797 – Unknown if surgery performed" if it is unknown whether surgery was recommended and performed.

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

NUMBER OF REGIONAL LYMPH NODES POSITIVE and EXAMINED

ITEM B-10 & B-11

1. Code: B-10 - Number of positive regional lymph nodes

00 - All nodes examined negative
01-89 1-89 positive nodes (exact number of positive nodes)
90 - 90 or more nodes positive
95 - Positive aspiration of lymph node(s)
97 - Positive nodes, number unspecified
98 - No nodes examined
99 - Unknown, if nodes are positive; not documented in patient record

B-11 - Number of regional lymph nodes examined

00 - No nodes examined
01-89 1-89 nodes examined (exact number of examined nodes)
90 - 90 or more regional lymph nodes examined
95 - No regional lymph node(s) removed, but aspiration or core biopsy of regional lymph node(s) was performed
96 - Regional lymph node removal documented as a sampling and number of lymph nodes unknown/not stated
97 - Regional lymph node removal documented as dissection and number of lymph 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 if nodes were examined; documented in patient record

2. Description:

2.1 For information on which nodes are considered regional, see SEER Program Coding and Staging Manual 2015.

2.2 Code the number of regional lymph nodes positive in Item B-10 and the number of regional lymph nodes examined in Item B-11. Include all axillary and/or other regional node dissection/biopsy procedure(s) done during the first course of therapy.

2.3 If more than one dissection/biopsy was done during the first course of therapy, code the total number of regional lymph nodes positive and examined.

NUMBER OF REGIONAL LYMPH NODES POSITIVE and EXAMINED (continued)

ITEM B-10 & B-11

2.4 If the number of nodes positive was 90 or greater, then code Item B-10 as "90". If the number of nodes examined was 90 or greater, then code Item B-11 as “90”.

2.5 If regional lymph nodes were known to be positive, but the exact number is unknown, then code Item B-10 as "97" and Item B-11 as “96”, “97” or “98”.

2.6 If no regional nodes were examined, then code Item B-10 as "98" and Item B-11 as “00”.

2.7 If it is unknown or not stated whether any nodes were positive or examined, then code "99" in Item B-10 and/or Item B-11.

3. Specifics:

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

EXTENSION OF PRIMARY TUMOR

ITEM B-12

1. Code: Breast
CS Extension

Code	Description
000	In situ: noninfiltrating; intraepithelial Intraductal WITHOUT infiltration Lobular neoplasia
050	Paget disease of nipple WITHOUT underlying tumor
070	Paget Disease disease of nipple WITHOUT underlying invasive carcinoma pathologically
100	Confined to breast tissue and fat including nipple and/or areola Localized, NOS
110	Stated as T1mi with no other information on extension
120	Stated as T1a with no other information on extension
130	Stated as T1b with no other information on extension
140	Stated as T1c with no other information on extension
170	Stated as T1 [NOS] with no other information on extension or size
180	Stated as T2 with no other information on extension or size
190	Stated as T3 with no other information on extension or size
200	Invasion of subcutaneous tissue Local infiltration of dermal lymphatics adjacent to primary tumor involving skin by direct extension Skin infiltration of primary breast including skin of nipple and/or areola
300	Attachment or fixation to pectoral muscle(s) or underlying tissue Deep fixation Invasion of (or fixation to) pectoral fascia or muscle
400	Invasion of (or fixation to): Chest wall Intercostal or serratus anterior muscle(s) Rib(s) See codes 610 (obsolete), 612-615, and 620 (obsolete) for combinations with this code
410	Stated as T4a with no other information on extension

Code	Description
510	OBSOLETE DATA RETAINED V0200 Extensive skin involvement, including: Satellite nodule(s) in skin of primary breast Ulceration of skin of breast Any of the following conditions described as involving not more than 50% of the breast, or amount or percent of involvement not stated: Edema of skin En cuirasse Erythema Inflammation of skin Peau d'orange ("pigskin")
512	Extensive skin involvement, including: Satellite nodule(s) in skin of primary breast Ulceration of skin of breast
514	Any of the following conditions described as involving less than one-third (33%) of the breast WITHOUT a stated diagnosis of inflammatory carcinoma WITH or WITHOUT dermal lymphatic infiltration: Edema of skin En cuirasse Erythema Inflammation of skin Peau d'orange ("pigskin")
516	514 + 512
518	Any of the following conditions described as involving one third (33%) or more but less than or equal to half (50%) of the breast WITHOUT a stated diagnosis of inflammatory carcinoma WITH or WITHOUT dermal lymphatic infiltration: Edema of skin En cuirasse Erythema Inflammation of skin Peau d'orange ("pigskin")
519	518 + 512
520	Any of the following conditions described as involving more than 50% of the breast WITHOUT a stated diagnosis of inflammatory carcinoma WITH or WITHOUT dermal lymphatic infiltration: Edema of skin En cuirasse Erythema Inflammation of skin Peau d'orange ("pigskin")
575	520 + 512

Code	Description
580	Any of the following conditions with amount or percent of breast involvement not stated and WITHOUT a stated diagnosis of inflammatory carcinoma WITH or WITHOUT dermal lymphatic infiltration: Edema of skin En cuirasse Erythema Inflammation of skin Peau d'orange ("pigskin")
585	580 + 512
600	Diagnosis of inflammatory carcinoma WITH a clinical description of inflammation, erythema, edema, peau d'orange, etc., involving less than one-third (33%) of the skin of the breast, WITH or WITHOUT dermal lymphatic infiltration
605	Stated as T4b with no other information on extension
610	OBSOLETE DATA RETAINED V0200 (400) + (510)
612	Any of (512-516) + 400
613	Any of (518-519) + 400
615	Any of (520-585) + 400
620	OBSOLETE DATA RETAINED V0200 (400) + (520)
680	Stated as T4c with no other information on extension
710	OBSOLETE DATA RETAINED V0200 Diagnosis of inflammatory carcinoma WITH a clinical description of inflammation, erythema, edema, peau d'orange, etc., involving not more than 50% of the skin of the breast, WITH or WITHOUT dermal lymphatic infiltration Inflammatory carcinoma, NOS Previous wording (V0100): Diagnosis of inflammatory carcinoma WITHOUT a clinical description of inflammation, erythema, edema, peau d'orange, etc., of more than 50% of the breast, WITH or WITHOUT dermal lymphatic infiltration Inflammatory carcinoma, NOS
715	OBSOLETE DATA RETAINED V0202 Diagnosis of inflammatory carcinoma WITH a clinical description of inflammation, erythema, edema, peau d'orange, etc., involving not more than one-third (33%) of the skin of the breast, WITH or WITHOUT dermal lymphatic infiltration

Code	Description
725	Diagnosis of inflammatory carcinoma WITH a clinical description of inflammation, erythema, edema, peau d'orange, etc., involving one-third (33%) or more but less than or equal to one-half (50%) of the skin of the breast, WITH or WITHOUT dermal lymphatic infiltration
730	Diagnosis of inflammatory carcinoma WITH a clinical description of inflammation, erythema, edema, peau d'orange, etc., involving more than one-half (50%) of the skin of the breast, WITH or WITHOUT dermal lymphatic infiltration
750	Diagnosis of inflammatory carcinoma WITH a clinical description of inflammation, erythema, edema, peau d'orange, etc., but percent of involvement not stated, WITH or WITHOUT dermal lymphatic infiltration. Note: If percentage is known, code to 600, 725, or 730. Diagnosis of inflammatory carcinoma WITHOUT a clinical description of inflammation, erythema, edema, peau d'orange, etc., WITH or WITHOUT dermal lymphatic infiltration Inflammatory carcinoma, NOS
780	Stated as T4d with no other information on extension
790	Stated as T4 [NOS] with no other information on extension
950	No evidence of primary tumor
999	Unknown; extension not stated Primary tumor cannot be assessed Not documented in patient record

- Note 1: Changes such as dimpling of the skin, tethering, and nipple retraction are caused by tension on Cooper's ligament(s), not by actual skin involvement. They do not alter the classification.
- Note 2: Consider adherence, attachment, fixation, induration, and thickening as clinical evidence of extension to skin or subcutaneous tissue, code 200.
- Note 3: Consider fixation, NOS as involvement of pectoralis muscle, code 300.
- Note 4: If CS Extension code is 000, then Behavior code must be 2; if CS Extension code is 050 or 070, then Behavior code may be 2 or 3; and if CS Extension code is 100, then Behavior code must be 3.

EXTENSION OF PRIMARY TUMOR (continued)

ITEM B-12

- Note 5: Inflammatory Carcinoma: AJCC includes the following text in the Cancer Staging Manual 7th Edition: "Inflammatory carcinoma is a clinicopathologic entity characterized by diffuse erythema and edema (peau d'orange) of the breast, often without an underlying palpable mass. These clinical findings should involve the majority of the skin of the breast. Classically, the skin changes arise quickly in the affected breast. Thus the term of inflammatory carcinoma should not be applied to a patient with neglected locally advanced cancer of the breast presenting late in the course of her disease. On imaging, there may be a detectable mass and characteristic thickening of the skin over the breast. This clinical presentation is due to tumor emboli within dermal lymphatics, which may or may not be apparent on skin biopsy. The tumor of inflammatory carcinoma is classified T4d. It is important to remember that inflammatory carcinoma is primarily a clinical diagnosis. Involvement of the dermal lymphatics alone does not indicate inflammatory carcinoma in the absence of clinical findings. In addition to the clinical picture, however, a biopsy is still necessary to demonstrate cancer either within the dermal lymphatics or in the breast parenchyma itself."

- Note 6: For CS coding, the abstractor should record a stated diagnosis of inflammatory carcinoma, and also record any clinical statement of the character and extent of skin involvement in the text area. Code 600 should be used if there is a stated diagnosis of inflammatory carcinoma and a clinical description of the skin involvement is less than one-third (33%) of the skin of the breast. Code 725 should be used if there is a stated diagnosis of inflammatory carcinoma and a clinical description of the skin involvement is greater than or equal to one-third (33%) and less than or equal to one-half (50%) of the skin of the breast. Code 730 should be used if there is a stated diagnosis of inflammatory carcinoma and a clinical description of the skin involvement in more than one-half (50%) (majority or diffuse) of the skin of the breast. Cases with a stated diagnosis of inflammatory carcinoma but no such clinical description should be coded 750. A clinical description of inflammation, erythema, edema, peau d'orange, or other terms describing skin changes without a stated diagnosis of inflammatory carcinoma should be coded 512-585 depending on described extent of the condition.

PATHOLOGICAL MARGINS

ITEM B-13

1. Code:
0 – No definitive surgery performed
1 – Margins of resection pathologically free of tumor
2 – Tumor at margins of surgical specimen, or residual tumor in area of primary
3 – Margins not stated in pathology report--surgeon reports no residual tumor
8 – Resection recommended, unknown if performed.
9 – Unknown, not stated

2. Description:

2.1 This item records the pathological margin status for a patient's most definitive surgical treatment.

2.2 Code "0 – No definitive surgery" when a patient did not have definitive surgery performed.

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

2.4 Code "3 – Margins not stated in path 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.

2.5 Code "8 – Resection recommended unknown if performed" if the physician recommended but it is unknown whether or not the patient had a resection.

2.6 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.

PROPHYLACTIC CONTRALATERAL MASTECTOMY

ITEM B-14

1. Code: 0 – No prophylactic contralateral mastectomy
1 – Prophylactic contralateral mastectomy
2 – Contralateral mastectomy, unclear whether prophylactic
9 – Unknown whether prophylactic contralateral mastectomy

2. Description:

2.1 A prophylactic contralateral mastectomy is a mastectomy on the contralateral (opposite) breast although there is no indication that there is cancer in that breast. If a patient had a mastectomy on the contralateral (opposite) breast because the contralateral (opposite) breast had cancer, this would not be prophylactic and the patient would be ineligible due to simultaneous diagnosis.

2.2 Code "0 – No prophylactic contralateral mastectomy" when there was no prophylactic contralateral mastectomy performed.

2.2 Code "1 - Prophylactic contralateral mastectomy" when the patient received a prophylactic contralateral mastectomy.

2.3 Code "2 - Contralateral mastectomy, unclear whether prophylactic" when the woman received a contralateral mastectomy, but it is not clear if there was cancer in the removed breast.

2.4 Code "9- Unknown whether prophylactic contralateral mastectomy" if it is unknown whether prophylactic contralateral mastectomy was performed.

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

DATE RADIATION TO PRIMARY SITE BEGAN - COMPLETED

ITEM B-15

1. Code: MM-DD-YYYY
00-00-0000 - No radiation
0, 1, 2, 9 – Radiation completion

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

Radiation course completion status

0 – No, not completed
1 – Yes, completed
2 – No radiation given to primary site
9 – Unknown whether radiation was given or completed

2. Description:

2.1 Enter the date the patient was first given radiation to the primary site (breast/chest wall) at any time after diagnosis.

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

2.3 Code “96-96-9696 - Unknown" if radiation was recommended but it is unknown whether the recommended radiation was performed.

2.4 If a patient or guardian refuses radiation code “77-77-7777 - Patient/guardian refused.”

2.5 If it cannot be determined whether radiation was recommended and given, then code “97-97-9797 – Unknown if offered/given”.

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

DATE RADIATION TO PRIMARY SITE BEGAN – COMPLETED (continued)

ITEM B-15

2.6 If the exact date of radiation is unknown, then an estimate should be made. Otherwise, code "99-99-9999 - Date Unknown".

2.7 Code whether the full course of radiation was completed (Code 1– Yes, completed) or if the patient received less than a full course of radiation (Code 0 – No, not completed).

2.8 If the patient did not receive radiation to the primary site (breast/chest wall), code date as "00-00-0000" and completion as "2 – No radiation given to primary site."

2.9 If it is unknown whether radiation to the primary site (breast/chest wall) was given or completed, then code completion as "9 - unknown."

RADIATION THERAPY RECEIVED

ITEM B-16

1. Code:
0 – No radiation received
1 – Received whole breast radiation
2 – Received chest wall radiation
3 – Received accelerated partial breast irradiation (Brachytherapy)
4 – Received breast and regional nodal radiation
5 – Received chest wall and regional nodal radiation
6 – Other, Specify _____
8 – Received radiation, type unknown
9 – Unknown whether radiation received

2. Description:

2.1 Code "0 – No radiation received" if the patient did not receive radiation in Item B-15.

2.2 Code "1 – Whole breast radiation" when the patient received traditional external beam radiation to the entire breast region.

2.3 Code "2 – Chest wall radiation" when the patient received radiation to the chest wall, the mastectomy scar and the drain sites (when present).

2.4 Code "3 – Accelerated partial breast irradiation" when the patient received radiation therapy targeted just to the tumor site. This is often referred to as conformal, 3-D radiation, or brachytherapy

2.5 Code "4 – Breast and regional nodal radiation" When the patient received external beam radiation to the breast AND to lymph nodes including the paraclavicular, axillary, and internal mammary nodes.

2.6 Code "5 – Chest wall and regional nodal radiation" when the patient received radiation to the chest wall, the mastectomy scar and the drain sites (when present) to lymph nodes including the paraclavicular, axillary, and internal mammary nodes.

2.7 Code "6 – Other, specify" when the patient received a different kind of radiation or radiation to a different site. Specify the type of radiation and site.

2.8 Code "8 – Received radiation, type unknown" when the woman received radiation but the type of radiation is not specified.

RADIATION THERAPY SEQUENCE WITH SURGERY

ITEM B-17

1. Code:

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

2. Description:

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

2.2 Code "0 - No/unknown radiation and/or no/unknown cancer-directed surgery" when radiation (Item B-15) and/or cancer-directed surgery status (Item B-9) 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 before surgery" when the patient received radiation therapy (Item B-15) prior to cancer-directed surgery (Item B-9).

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

2.4 Code "3 - Radiation after surgery" when the patient received radiotherapy (Item B-15) following surgery (Item B-9).

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

2.5 Code "4 - Radiation both before and after surgery" when the radiation therapy (Item B-15) was given both prior to and following the surgical resection (Item B-9).

RADIATION THERAPY SEQUENCE WITH SURGERY (continued)

ITEM B-17

2.6 Code "5 - Intraoperative radiation" when the patient received radiation therapy (Item B-15) directly to the tumor bed during the surgical resection (Item B-9).

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

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

RADIATION THERAPY SEQUENCE WITH SYSTEMIC THERAPY

ITEM B-18

1. Code:

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

2. Description:

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

2.2 Code "0 - No/unknown radiation and/or no/unknown systemic therapy" when radiation therapy (Item B-15) and/or systemic therapy status (Items B-23 to B-41) 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 (Item B-15) prior to systemic therapy (Items B-23 to B-41).

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-18

2.4 Code "3 - Radiation after systemic therapy" when the patient received radiation therapy (Item B-15) following systemic therapy (Items B-23 to B-41).

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

2.5 Code "4 - Radiation both before and after systemic therapy" when radiation therapy (Item B-16) was given both prior to and following systemic therapy (Items B-23 to B-41), but not concurrently.

2.6 Code "5 - Concurrent radiation and systemic therapy" when the patient received radiation (Item B-15) during the time that she was receiving systemic therapy (Items B-23 to B-41).

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

2.8 Code "7 - Systemic therapy before and after radiation" when the patient received systemic therapy (Items B-23 to B-41) prior to and following radiation therapy (Item B-16), 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 radiation and systemic therapy, but it is unclear in which order they were given.

SYSTEMIC THERAPY SEQUENCE WITH SURGERY

ITEM B-19

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
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 was given, then this item is sequenced as “0”.

2.2 Code "0 – No/unknown systemic therapy and/or no/unknown cancer-directed surgery" when systemic therapy (Items B-23 to B-41) and/or Cancer-Directed surgery status (Item B-19) 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 (Items B-23 to B-41) prior to the most extensive cancer-directed surgery (Item B-9).

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

2.4 Code "3 - Systemic therapy after surgery" when the patient received systemic therapy (Items B-23 to B-41) following the definitive surgery (Item B-9).

For example: A patient who had a biopsy, followed by a modified radical mastectomy, 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 systemic therapy (Items B-23 to B-41) was given both prior to and following the definitive surgical resection (Item B-9).

2.6 Code “9 - Sequence unknown” when both systemic therapy and surgery were received by the patient, but the sequence is unknown and the dates are missing so the sequence cannot be determined

HER-2 (c-erbB-2, her2/neu): IHC

ITEM B-20

1. Code:
00 – Negative
01 – 1+
02 – 2+
03 – 3+
92 – Equivocal IHC, value not reported
93 – Equivocal, value not reported, type IHC or *in situ* hybridization (ISH) test unknown
94 – Positive IHC, specific value not reported
95 – Positive test, type IHC or ISH test unknown
96 – Negative IHC, value not reported
97 – Negative test, type IHC or ISH test unknown
98 – Not Done
99 – Unknown

2. Description:

2.1 Record the results of the measurement of HER-2 (also known as c-erbB-2 or her2/neu). When testing for her2/neu, the immunohistochemical (IHC) test may be used alone or followed by an ISH test including FISH (fluorescence *in situ* hybridization), SPoT-Light HER2 CISH (subtraction probe technology chromogenic *in situ* hybridization), or Inform HER2 Dual ISH (inform dual *in situ* hybridization) test. Please record the IHC in Item B-20 and the ISH in Item B-21. (It is possible that the HER-2 value may be entered into the record as 'Herceptest').

2.2 Code "00 - Negative" when the record indicates the test for her2/neu results were negative with the value given.

2.3 Code "01" when the IHC test value was reported as 1+.

2.4 Code "02" when the IHC test value was reported as 2+.

2.5 Code "03" when the IHC test value was reported as 3+.

2.6 Code "92" when the results of the her2/neu by IHC were stated as being equivocal and no value is given.

2.7 Code "93" when the results of the HER-2 value is equivocal, but the type of test (IHC or ISH) is unknown. Item B-21 should also be coded "93".

2.8 Code "94" when the HER-2 test is reported as positive by IHC, but the value is not reported.

HER-2 (c-erbB-2, her2/neu): IHC (continued)

ITEM B-20

2.9 Code “95” when the record indicates that the test for her2/neu was positive, but the type of test (IHC or ISH test) is unknown. Item B-21 should also be coded “95”.

2.10 Code “96” when the report states only that the IHC test was negative and does not provide the actual value.

2.11 Code “97” when the test is reported as negative, but the type of test (IHC or ISH) is unknown. Item B-21 should also be coded “97”.

2.12 If the test was not done, then code “98 - not done”.

2.13 If it is unknown whether the test was ordered, then code “99 – Unknown”.

HER-2 (c-erbB-2, her2/neu): *IN SITU* HYBRIDIZATION (ISH)

ITEM B-21

1. Code: 0.1…9.0 – Actual value
9.1 – 9.1 or higher
92 – Equivocal by ISH, value not reported
93 – Equivocal, value not reported, type IHC or ISH unknown
94 – Positive by ISH, value not reported
95 – Positive test, type IHC or ISH unknown
96 – Negative ISH, value not reported
97 – Negative test, type IHC or ISH unknown
98 – Not Done
99 – Unknown

ISH Tests:

- Fluorescence *in situ* hybridization (FISH)
- Subtraction probe technology chromogenic *in situ* hybridization (SPoT-Light HER2 CISH or CISH)
- Inform dual *in situ* hybridization (Inform HER2 Dual ISH or DISH)

2. Description:

2.1 Record the results of the measurement of HER-2 as reported when performed by *in situ* hybridization (ISH). These are more sensitive tests and a patient may have the IHC first, followed by ISH, or may have an ISH test alone. IHC should be reported in Item B-20. For ISH, code the actual value given which will be a 2-digit number. The decimal point between the two numbers need not be recorded because it is already written on the abstract form and in the abstracting utility. For example, the value of 0.5 should be recorded as "05".

2.2 Record the actual value from the laboratory test. The data are reported as a ratio of the number of her2 signals to 17 centromere signals. For ISH tests, a ratio >2.0 is consistent with amplification of HER-2 gene sequences or a positive test, a ratio of 1.8-2.0 is an equivocal finding and requires further testing and a ratio of <1.8 is within the normal limits (negative).

2.3 Code "92" when the record indicates that the test for HER-2 is equivocal by ISH, but the value is not reported.

2.4 Code "93" when the record indicates that the test for HER-2 was equivocal, but does not indicate the value nor the type of test (IHC or ISH). Item B-20 should also be coded "93".

HER-2 (c-erbB-2,her2/neu): *IN SITU* HYBRIDIZATION (ISH) (continued)

ITEM B-21

2.5 Code "94" when the record indicates that the test for HER-2 is positive by ISH, but the value is not reported.

2.6 Code "95" when the record indicates that the test for HER-2 is positive, but the type of test (IHC or ISH) is unknown. Item B-20 should also be coded "95".

2.7 Code "96" when the record indicates only that the ISH test was negative and does not provide the actual value.

2.8 Code "97" when the record indicates that the test for HER-*2* was negative, but the type of test (IHC or ISH) is unknown. Item B-20 should also be coded "97".

2.9 If the test was not done, then code "98 - Not done".

2.10 Code "99 - Unknown" if it is unknown whether the test was ordered.

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

GENE ASSAYS

ITEM B-22

1. Code: *Type*
   0 – No mention, not performed
   1 – Onco*type* DX™
   2 – Prosigna™ (PAM 50)
   3 – MammaPrint

   Score
   000-100 – Recurrence Score™
   200 – Low Risk
   300 – Intermediate Risk
   400 – High Risk
   555 – Not performed
   977 – Ordered, Results unknown
   999 – Unknown

2. Description:

FOR EACH TEST THE RECURRENCE SCORE IS PREFERRED TO THE RISK LEVEL.

2.1 Onco*type* DX™ is an FDA-approved 21-gene assay that is reported to provide an assessment of the likelihood of distant breast cancer recurrence. The company that developed the assay, Genomic Health, states that the test will "assist physicians in optimizing treatment plans." The assay was initially intended for use in newly diagnosed breast cancer patients with stage I or II, node negative, estrogen receptor-positive cancer, and who will be treated with tamoxifen. The assay uses formalin-fixed, paraffin-embedded tumor tissue. The use of the assay has now been expanded to women with other stages and ER status.

2.2 The results are expressed as a Recurrence Score™ (0-100). The Recurrence Score™ (RS) is supposed to correlate with the probability of distant recurrence at 10 years. The likelihood of distant recurrence at 10 years increases continuously with increase in RS, with RS risk groups defined as low-risk (RS < 18), intermediate-risk (RS 18-30), and high-risk (RS ≥ 31). Although an RS falls into a risk group, each RS score is specific to each patient. For example, within the intermediate-risk category, an RS of 18 is different from an RS of 30.[1] Genomic Health developed this assay and they run the ONLY laboratory that performs the assay. **Record the value provided by Genomic Health, between 0 and 100.** If you are unable to locate the assay or the exact value is unknown and there are written comments about the results, such as "RS is high," then code "400 – High".

GENE ASSAYS (continued)

ITEM B-22

2.3 Prosigna™ (PAM 50) is an FDA approved assay similar to Onco*type* DX™ and reports similar risk categories (low, intermediate, high) and a numerical score (0-100). The assay is used to assess the probability of distant recurrence of disease at 10 years for post-menopausal women with early stage, hormone-receptor positive, invasive breast cancer.

2.4 A third FDA approved assay is MammaPrint. It assays 70 genes and also is used to predict the risk of recurrence at 10 years. The results are presented as either low or high risk; it does not record intermediate risk. They do report probability in percentages, of recurrence with and without systemic therapy

2.5 These gene assays may be found in the hospital record. However, if it is ordered by the medical oncologist, it might be in the office record only.

2.6 If the test was ordered, but there is no record of the results, then code "977 – Ordered, Results unknown". If there are comments about whether the test was high, intermediate or low, then record those as appropriate instead of recording "Results unknown".

2.7 If there is no mention of whether the test was ordered, then code "555 – Not Performed" when it is know that the test was not performed

2.8 If it cannot be determined whether the test was ordered, record "999 – Unknown".

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

SYSTEMIC THERAPEUTIC AGENTS

ITEMS B-23 through B-41

1. Code: MM-DD-YYYY-Start date
00-00-0000 - Systemic therapy not given

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

Number of cycles completed/given/received

00- Not given
01- One cycle completed/given/received
02- Two cycles completed/given/received
…
…
77-Refused
96- Recommended, unknown if given
97- Unknown if given
98- Systemic agent is currently being given
99- Unknown number of cycles completed/given/received

B-23 Ado-trastuzumab emtansine (Kadcyla)

B-24 Capecitabine (Xeloda)

B-25 Carboplatin

B-26 Cyclophosphamide

B-27 Docetaxel (Taxotere, Docefrez)

SYSTEMIC THERAPEUTIC AGENTS (continued)

ITEMS B-23 through B-41

B-28 Doxorubicin (Adriamycin)

B-29 Eribulin (Halaven)

B-30 Fluorouracil (5-FU)

B-31 Gemcitabine (Gemzar)

B-32 Lapatinib (Tykerb)

B-33 Nab-Paclitaxel (Abraxane)

B-34 Paclitaxel (Taxol, Onxol)

B-35 Pertuzumab (Perjeta)

B-36 Trastuzumab (Herceptin)

B-37 Vinorelbine (Navelbine)

B-38 Tamoxifen (Nolvadex)

B-39 Aromatase Inhibitors [anastrozole (Arimidex), exemestane (Aromasin), letrozole (Femara)]

B-40 GnRH analogs [(goserelin acetate (Zoladex), leuprolide (Lupron, Lupron Depot), nafarelin (Synarel), degarelix (Firmagon), histrelin acetate (Vantas; Supprelin LA), triptorelin pamoate (Trelstar, Trelstar LA, Trelstar Depot), Gonadorelin (Factrel)]

B-41 Other Specify_____

SYSTEMIC THERAPEUTIC AGENTS (continued)

ITEMS B-23 through B-41

Examples of other chemotherapeutic agents which might have been given are:
Topotecan, Vinblastine (Velban), Mitoxantrone (Novantrone)

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

2. Description:

2.1 Enter the first date the therapy was given at any time following diagnosis.

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

2.3 Code "77-77-7777 - Patient/guardian refused systemic therapy" when systemic therapy was recommended, but not administered because of 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 "96-96-9696 - Recommended, unknown if given" when a patient was recommended to receive a systemic therapy agent, but it is unknown if it was actually received. When systemic therapy was recommended, but the treatment agents used were not documented, all agents must be coded "96-96-9696 - Recommended, unknown if given."

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

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

2.7 Record the number of cycles of systemic therapy completed/given/received. Please add all cycles from all courses of systemic therapy. Unless indicated on the physician verification form, do not record cycles for Items B-35, B-36, and B-38 through B-40.

POC DATA ACQUISITION MANUAL

SECTION IV

BREAST DATA SET

Partially adapted from previous manuals

SECTION IV - BREAST DATA SET

CONTENTS

HEIGHT / WEIGHT

ITEM B-1

1. Code:

Height

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

Units

1 = Inches
2 = Cm
3 = Other specify _____
9 = Unknown/not stated

Weight

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

Units

1 = Pounds
2 = Kilograms
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."

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.

DATE OF FIRST POSITIVE BIOPSY/ASPIRATION PROCEDURE

ITEM B-2

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

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

2. Description:

2.1 This item refers to the date of the first positive biopsy or aspiration procedure. This will be of interest for researchers interested in time from presentation to first diagnostic procedure. Code the date the specimen was obtained (NOT the date of the pathology/cytology report).

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

2.3 If the positive biopsy/aspiration was performed on the same day as definitive surgery, then the biopsy date (Item B-2) will be the same as the Date of First Cancer-Directed Surgery to Primary Site (Item B-9). The first positive biopsy/aspiration may have been done as an outpatient, but must be no later than the Date of First Cancer-Directed Surgery to Primary Site.

2.4 If the exact date of the first positive biopsy/aspiration is unknown, then estimate. For example, if in history and physical, the physician states the patient had a biopsy two weeks ago, then code the date of biopsy as 14 days prior to date of admission. Coding closest approximation is preferable to coding unknown. If an estimate cannot be made, then code “99-99-9999”.

DATE OF FIRST POSITIVE BIOPSY/ASPIRATION PROCEDURE (continued)

ITEM B-2

3. Specifics:

3.1 Code the date of the PROCEDURE performed to obtain the specimen, NOT the date of the pathology/cytology report.

3.2 Histologic diagnoses are based upon microscopic examination of tissue specimens from biopsy, frozen section, aspiration (including aspiration biopsy) and surgical specimens.

3.3 Cytologic diagnoses are based upon microscopic examination of cells, as contrasted with tissues. Examples are breast aspiration cytology and cytologic examination of breast secretions.

DATE OF PATHOLOGIC CONFIRMATION REPORT

ITEM B-3

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

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

2. Description:

2.1 This item refers to the date of the REPORT of the pathologic confirmation of breast cancer by the biopsy or aspiration coded in Item B-2. This is NOT the date the specimen was obtained. This is NOT the date the breast cancer was suspected. Researchers are interested in the time from confirmation of breast cancer to treatment. If the pathology department has "real-time" reporting (the reports are sent electronically as they are completed to the physicians' offices), then the date of the report may be the same as the date of pathologic confirmation.

2.2 If the patient or guardian refused the biopsy, code "77-77-7777- Patient/guardian refused." This is unlikely for these patients because the diagnosis must be pathologically confirmed.

2.3 If the biopsy/aspiration was recommended but it is unknown if it was performed, code "96-96-9696 – Recommended, unknown if performed." This is unlikely for these patients because the diagnosis must be pathologically confirmed.

2.4 If it is unknown if biopsy/aspiration was offered or performed, code "97-97-9797 – Unknown if offered or performed." This is unlikely for these patients because the diagnosis must be pathologically confirmed.

2.5 If the exact date of the first positive biopsy/aspiration is unknown, then estimate. For example, if in history and physical, the physician states the patient had a biopsy two weeks ago, then code the date of biopsy as 14 days prior to date of admission. Coding closest approximation is preferable to coding unknown. If an estimate cannot be made, then code "99-99-9999". If the pathology department has real-time reporting, record the date the report was received.

SIZE OF PRIMARY TUMOR

ITEM B-4

1. Code:

000 -	No mass; no tumor found
001-988-	001-988 millimeters (exact tumor size)
989 -	989 millimeters or larger
990 -	Microinvasion; microscopic focus or foci only; no size given; described as less than 1 mm.
991 -	Described as less than 1 cm
992 -	Described as less than 2 cm
993 -	Described as less than 3 cm
994 -	Described as less than 4 cm
995 -	Described as less than 5 cm
996 -	Mammographic/xerographic diagnosis only, no size given; clinically not palpable
998 -	Diffuse
999 -	Not stated; unknown; not documented in medical record (palpable tumors only)

2. Description:

2.1 Code the size of the primary tumor as recorded in the pathology report, imaging report or physical examination **in priority order**. When multiple masses are present, code the longest diameter. Code the exact value from 001 (00.1 cm) through 989 (98.9 cm). Be certain that the units are correctly recorded. Do not confuse mm and cm. 5 mm and 5 cm are markedly different and have different therapies.

2.2 Code the tumor size recorded prior to initiation of therapy.

2.3 If the tumor was palpable, but no size is documented, then code "999 - Not stated".

2.4 When there was a biopsy followed by a more extensive resection with residual tumor removed, code the largest tumor size recorded, but do not add the dimensions of the excised tumor tissue together.

2.5 If the tumor was only diagnosed by mammography/xerography with no size given and is not clinically palpable, code “996-Mammography/xerography diagnosis only with no size given (clinically not palpable)”.

3. Examples: A tumor of 0.9 cm (9 mm) in size is coded as "009".
A tumor of 5.5 cm (55 mm) in size is coded as "055".
A tumor of 8.3 cm (83 mm) in size is coded as "083".

METHOD OF MEASUREMENT

ITEM B-5

1. Code:
0 - No mass; no tumor found
1 - Microscopic focus or foci only
2 - Mammography/xerography measurement
3 - Ultrasound
4 - Pathological specimen
5 - Other (specify _____)
9 - Size unknown/not stated

2. Description:

2.1 Code the method used to determine the tumor size coded in Item B-4. This will most often be the pathological specimen. However, if this is unavailable, other methods of measurement may be available. Use the CS Tumor Size coding hierarchy in the SEER Program Coding and Staging Manual 2015, Appendix C.

2.2 Code "0" when no mass or tumor is found. Item B-4 (Tumor Size) should be coded as "000".

2.3 Code "1" when only microscopic foci are found. Item B-4 (Tumor Size) should be coded as "990".

2.4 Code "2" when the measurement is from a mammogram or xerographic measurement. Item B-4 (Tumor Size) should be coded as the exact tumor size when a size is given, or as "996" when the tumor size is not given.

2.5 Code "3" when the measurement is taken at the time of an ultrasound.

2.6 The preferred measurement is one taken from the specimen obtained when the tumor is removed. This can usually be found in the path report. This measurement is preferred over others. Use the SEER coding hierarchy.

2.7 Code "9" when the size is unknown or not stated for palpable tumors. Item B-4 (Tumor Size) should be coded as "999".

METHOD OF DETECTION

ITEM B-6

1. Code:
1 – Signs/symptoms
2 – Physician's physical exam
3 – Self-discovered
4 – Screening Mammography
5 – Spouse or partner
6 – Other, specify_____
9 – Unknown/Not specified

2. Description:

2.1 Code the method by which the tumor was initially detected. This refers to the first notice of a breast tumor, NOT the diagnostic procedures that followed.

2.2 Code "1 – Signs/symptoms" when the patient had signs/symptoms such as changes in appearance (color, shape, or size) of the breast or nipple, nipple discharge other than breast milk, breast pain/discomfort.

2.3 Code "2 – Physician's physical exam" when the patient's breast abnormality was initially detected by a routine breast exam performed by her physician.

2.4 Code "3 – Self-discovered" when the patient found a breast abnormality herself while doing a breast self-exam or while in the shower.

2.5 Code "4 – Screening Mammography" when the tumor was first seen on a routine screening mammogram.

2.6 Code "5 – Spouse or Partner" if the woman's spouse or partner discovered a mass.

2.7 Code "6 – Other, specify" when the tumor was discovered by some other means. Specify the method of discovery.

2.8 Code "9 – Unknown/Not specified" when it cannot be determined from the records how the tumor was initially detected.

GRADE/TYPE

ITEM B-7

1. Code: GRADE

Breast Grading Conversion Table

BR Scores	BR Grade	Nuclear Grade	Terminology	Histologic Grade	SEER Code
3-5	Low	1/3; 1/2	Well differentiated	I/III; 1/3	**1**
6, 7	Intermediate	2/3	Moderately differentiated	II/III; 2/3	**2**
8, 9	High	2/2; 3/3	Poorly differentiated	III/III; 3/3	**3**

TYPE

1 = Bloom Richardson (BR) Score
2 = Bloom Richardson Grade
3 = Nuclear
4 = Terminology (well-diff, mod-diff, etc.)
5 = Histologic Grade
9 = Type not stated

2. Description:

GRADE

2.1 Use the Breast Grading Conversion Table to convert the score, grade or term into the SEER code.

2.2 Code grade, converted to SEER Code, in the following priority order:

1. Bloom-Richardson scores 3-9
2. Bloom Richardson grade (low, intermediate, high)
3. Nuclear grade only
4. Terminology
    a. Differentiation (well differentiated, moderately differentiated, etc).
5. Histologic grade
    a. Grade 1/I/i, grade 2/II/ii, grade 3/III/iii, grade 4/IV/iv

2.3 Bloom Richardson may also be called: modified Bloom-Richardson, Scarff-Bloom-Richardson, SBR grading, BR grading, Elston-Ellis modification of Bloom Richardson score, the Nottingham modification of Bloom Richardson score, Nottingham-Tenovus, or Nottingham grade.

GRADE/TYPE (continued)

ITEM B-7

2.4 BR may be expressed in **scores** (range 3-9).

2.5 The score is based on three morphologic features of "invasive no-special-type" breast cancers (degree of tubule formation/histologic grade, mitotic activity, nuclear pleomorphism of tumor cells).

2.6 BR may be expressed as a **grade** (low, intermediate, high).

2.7 BR grade is derived from the BR score. Note that the conversion of low, intermediate, and high for breast is different from the conversion used for all other tumors.

TYPE

2.8 Code which type of grade was used to convert to SEER grade.

REGIONAL NODE DISSECTION

ITEM B-8

1. Code:
0 – No nodal dissection
1 – Axillary nodal dissection only
2 – Sentinel node biopsy only
3 – Sentinel node biopsy followed by axillary node biopsy and/or dissection
4 – Internal mammary node biopsy or excision only
5 – Both axillary and internal mammary node biopsy or excision
6 – Other, specify_____
8 – Node dissection performed, type unknown
9 – Unknown/Not stated

NOTE: THESE ARE NOT THE SEER CODES.

2. Description:

2.1 Code "0 – No nodal dissection" when the woman did not have her nodes dissected/biopsied. If this item is coded as "0", then Item B-10 (Number of Regional Nodes Positive) should be coded as "98" and Item B-11 (Nodes Examined) should be coded "00".

2.2 Code "1 – Axillary nodal dissection only" when the surgeon performed the traditional axillary lymph node dissection.

2.3 Code "2 – Sentinel node biopsy only" when the surgeon injected dye or radioactive material into the tumor and removed the node(s) that took up the dye or radioactive material.

2.4 Code "3 – Sentinel node biopsy followed by axillary node biopsy" when the surgeon performed a sentinel node biopsy, but followed it with an axillary node biopsy. If the nodes were positive on frozen section, additional nodes might be removed through an axillary node dissection.

2.5 Code "6 – Other, specify" when a different type of nodal dissection is performed. Specify the type of nodal dissection.

2.6 Code "9 – Unknown/Not stated" if it cannot be determined whether a nodal dissection/biopsy was performed. If this item is coded as unknown, then B-10 (Number of Regional Nodes Positive) & Item B-11 (Nodes Examined) would also be unknown.

DATE OF CANCER-DIRECTED SURGERY TO PRIMARY SITE

ITEM B-9

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	
.	.	
.	.	
.	.	
77	77	7777 - Patient/guardian refused surgery
96	96	9696 – Recomm., unknown if performed
97	97	9797 - Unknown if recomm or performed
99 - Month Unknown	99 - Day Unknown	9999 - Year Unknown

2. Description:

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

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

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

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

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

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

NUMBER OF REGIONAL LYMPH NODES POSITIVE and EXAMINED

ITEM B-10 & B-11

1. Code: B-10 - Number of positive regional lymph nodes

00 - All nodes examined negative
01-89 1-89 positive nodes (exact number of positive nodes)
90 - 90 or more nodes positive
95 - Positive aspiration of lymph node(s)
97 - Positive nodes, number unspecified
98 - No nodes examined
99 - Unknown, if nodes are positive; not documented in patient record

B-11 - Number of regional lymph nodes examined

00 - No nodes examined
01-89 1-89 nodes examined (exact number of examined nodes)
90 - 90 or more regional lymph nodes examined
95 - No regional lymph node(s) removed, but aspiration or core biopsy of regional lymph node(s) was performed
96 - Regional lymph node removal documented as a sampling and number of lymph nodes unknown/not stated
97 - Regional lymph node removal documented as dissection and number of lymph 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 if nodes were examined; documented in patient record

2. Description:

2.1 For information on which nodes are considered regional, see SEER Program Coding and Staging Manual 2015.

2.2 Code the number of regional lymph nodes positive in Item B-10 and the number of regional lymph nodes examined in Item B-11. Include all axillary and/or other regional node dissection/biopsy procedure(s) done during the first course of therapy.

2.3 If more than one dissection/biopsy was done during the first course of therapy, code the total number of regional lymph nodes positive and examined.

NUMBER OF REGIONAL LYMPH NODES POSITIVE and EXAMINED (continued)

ITEM B-10 & B-11

2.4 If the number of nodes positive was 90 or greater, then code Item B-10 as "90". If the number of nodes examined was 90 or greater, then code Item B-11 as “90”.

2.5 If regional lymph nodes were known to be positive, but the exact number is unknown, then code Item B-10 as "97" and Item B-11 as “96”, “97” or “98”.

2.6 If no regional nodes were examined, then code Item B-10 as "98" and Item B-11 as “00”.

2.7 If it is unknown or not stated whether any nodes were positive or examined, then code "99" in Item B-10 and/or Item B-11.

3. Specifics:

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

EXTENSION OF PRIMARY TUMOR

ITEM B-12

1. Code: Breast
CS Extension

Code	Description
000	In situ: noninfiltrating; intraepithelial Intraductal WITHOUT infiltration Lobular neoplasia
050	Paget disease of nipple WITHOUT underlying tumor
070	Paget Disease disease of nipple WITHOUT underlying invasive carcinoma pathologically
100	Confined to breast tissue and fat including nipple and/or areola Localized, NOS
110	Stated as T1mi with no other information on extension
120	Stated as T1a with no other information on extension
130	Stated as T1b with no other information on extension
140	Stated as T1c with no other information on extension
170	Stated as T1 [NOS] with no other information on extension or size
180	Stated as T2 with no other information on extension or size
190	Stated as T3 with no other information on extension or size
200	Invasion of subcutaneous tissue Local infiltration of dermal lymphatics adjacent to primary tumor involving skin by direct extension Skin infiltration of primary breast including skin of nipple and/or areola
300	Attachment or fixation to pectoral muscle(s) or underlying tissue Deep fixation Invasion of (or fixation to) pectoral fascia or muscle
400	Invasion of (or fixation to): Chest wall Intercostal or serratus anterior muscle(s) Rib(s) See codes 610 (obsolete), 612-615, and 620 (obsolete) for combinations with this code
410	Stated as T4a with no other information on extension

Code	Description
510	OBSOLETE DATA RETAINED V0200 Extensive skin involvement, including: Satellite nodule(s) in skin of primary breast Ulceration of skin of breast Any of the following conditions described as involving not more than 50% of the breast, or amount or percent of involvement not stated: Edema of skin En cuirasse Erythema Inflammation of skin Peau d'orange ("pigskin")
512	Extensive skin involvement, including: Satellite nodule(s) in skin of primary breast Ulceration of skin of breast
514	Any of the following conditions described as involving less than one-third (33%) of the breast WITHOUT a stated diagnosis of inflammatory carcinoma WITH or WITHOUT dermal lymphatic infiltration: Edema of skin En cuirasse Erythema Inflammation of skin Peau d'orange ("pigskin")
516	514 + 512
518	Any of the following conditions described as involving one third (33%) or more but less than or equal to half (50%) of the breast WITHOUT a stated diagnosis of inflammatory carcinoma WITH or WITHOUT dermal lymphatic infiltration: Edema of skin En cuirasse Erythema Inflammation of skin Peau d'orange ("pigskin")
519	518 + 512
520	Any of the following conditions described as involving more than 50% of the breast WITHOUT a stated diagnosis of inflammatory carcinoma WITH or WITHOUT dermal lymphatic infiltration: Edema of skin En cuirasse Erythema Inflammation of skin Peau d'orange ("pigskin")
575	520 + 512

Code	Description
580	Any of the following conditions with amount or percent of breast involvement not stated and WITHOUT a stated diagnosis of inflammatory carcinoma WITH or WITHOUT dermal lymphatic infiltration: Edema of skin En cuirasse Erythema Inflammation of skin Peau d'orange ("pigskin")
585	580 + 512
600	Diagnosis of inflammatory carcinoma WITH a clinical description of inflammation, erythema, edema, peau d'orange, etc., involving less than one-third (33%) of the skin of the breast, WITH or WITHOUT dermal lymphatic infiltration
605	Stated as T4b with no other information on extension
610	OBSOLETE DATA RETAINED V0200 (400) + (510)
612	Any of (512-516) + 400
613	Any of (518-519) + 400
615	Any of (520-585) + 400
620	OBSOLETE DATA RETAINED V0200 (400) + (520)
680	Stated as T4c with no other information on extension
710	OBSOLETE DATA RETAINED V0200 Diagnosis of inflammatory carcinoma WITH a clinical description of inflammation, erythema, edema, peau d'orange, etc., involving not more than 50% of the skin of the breast, WITH or WITHOUT dermal lymphatic infiltration Inflammatory carcinoma, NOS Previous wording (V0100): Diagnosis of inflammatory carcinoma WITHOUT a clinical description of inflammation, erythema, edema, peau d'orange, etc., of more than 50% of the breast, WITH or WITHOUT dermal lymphatic infiltration Inflammatory carcinoma, NOS
715	OBSOLETE DATA RETAINED V0202 Diagnosis of inflammatory carcinoma WITH a clinical description of inflammation, erythema, edema, peau d'orange, etc., involving not more than one-third (33%) of the skin of the breast, WITH or WITHOUT dermal lymphatic infiltration

Code	Description
725	Diagnosis of inflammatory carcinoma WITH a clinical description of inflammation, erythema, edema, peau d'orange, etc., involving one-third (33%) or more but less than or equal to one-half (50%) of the skin of the breast, WITH or WITHOUT dermal lymphatic infiltration
730	Diagnosis of inflammatory carcinoma WITH a clinical description of inflammation, erythema, edema, peau d'orange, etc., involving more than one-half (50%) of the skin of the breast, WITH or WITHOUT dermal lymphatic infiltration
750	Diagnosis of inflammatory carcinoma WITH a clinical description of inflammation, erythema, edema, peau d'orange, etc., but percent of involvement not stated, WITH or WITHOUT dermal lymphatic infiltration. Note: If percentage is known, code to 600, 725, or 730. Diagnosis of inflammatory carcinoma WITHOUT a clinical description of inflammation, erythema, edema, peau d'orange, etc., WITH or WITHOUT dermal lymphatic infiltration Inflammatory carcinoma, NOS
780	Stated as T4d with no other information on extension
790	Stated as T4 [NOS] with no other information on extension
950	No evidence of primary tumor
999	Unknown; extension not stated Primary tumor cannot be assessed Not documented in patient record

- Note 1: Changes such as dimpling of the skin, tethering, and nipple retraction are caused by tension on Cooper's ligament(s), not by actual skin involvement. They do not alter the classification.

- Note 2: Consider adherence, attachment, fixation, induration, and thickening as clinical evidence of extension to skin or subcutaneous tissue, code 200.

- Note 3: Consider fixation, NOS as involvement of pectoralis muscle, code 300.

- Note 4: If CS Extension code is 000, then Behavior code must be 2; if CS Extension code is 050 or 070, then Behavior code may be 2 or 3; and if CS Extension code is 100, then Behavior code must be 3.

EXTENSION OF PRIMARY TUMOR (continued)

ITEM B-12

- Note 5: Inflammatory Carcinoma: AJCC includes the following text in the Cancer Staging Manual 7th Edition: "Inflammatory carcinoma is a clinicopathologic entity characterized by diffuse erythema and edema (peau d'orange) of the breast, often without an underlying palpable mass. These clinical findings should involve the majority of the skin of the breast. Classically, the skin changes arise quickly in the affected breast. Thus the term of inflammatory carcinoma should not be applied to a patient with neglected locally advanced cancer of the breast presenting late in the course of her disease. On imaging, there may be a detectable mass and characteristic thickening of the skin over the breast. This clinical presentation is due to tumor emboli within dermal lymphatics, which may or may not be apparent on skin biopsy. The tumor of inflammatory carcinoma is classified T4d. It is important to remember that inflammatory carcinoma is primarily a clinical diagnosis. Involvement of the dermal lymphatics alone does not indicate inflammatory carcinoma in the absence of clinical findings. In addition to the clinical picture, however, a biopsy is still necessary to demonstrate cancer either within the dermal lymphatics or in the breast parenchyma itself."

- Note 6: For CS coding, the abstractor should record a stated diagnosis of inflammatory carcinoma, and also record any clinical statement of the character and extent of skin involvement in the text area. Code 600 should be used if there is a stated diagnosis of inflammatory carcinoma and a clinical description of the skin involvement is less than one-third (33%) of the skin of the breast. Code 725 should be used if there is a stated diagnosis of inflammatory carcinoma and a clinical description of the skin involvement is greater than or equal to one-third (33%) and less than or equal to one-half (50%) of the skin of the breast. Code 730 should be used if there is a stated diagnosis of inflammatory carcinoma and a clinical description of the skin involvement in more than one-half (50%) (majority or diffuse) of the skin of the breast. Cases with a stated diagnosis of inflammatory carcinoma but no such clinical description should be coded 750. A clinical description of inflammation, erythema, edema, peau d'orange, or other terms describing skin changes without a stated diagnosis of inflammatory carcinoma should be coded 512-585 depending on described extent of the condition.

PATHOLOGICAL MARGINS

ITEM B-13

1. Code:
0 – No definitive surgery performed
1 – Margins of resection pathologically free of tumor
2 – Tumor at margins of surgical specimen, or residual tumor in area of primary
3 – Margins not stated in pathology report--surgeon reports no residual tumor
8 – Resection recommended, unknown if performed.
9 – Unknown, not stated

2. Description:

2.1 This item records the pathological margin status for a patient's most definitive surgical treatment.

2.2 Code "0 – No definitive surgery" when a patient did not have definitive surgery performed.

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

2.4 Code "3 – Margins not stated in path 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.

2.5 Code "8 – Resection recommended unknown if performed" if the physician recommended but it is unknown whether or not the patient had a resection.

2.6 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.

PROPHYLACTIC CONTRALATERAL MASTECTOMY

ITEM B-14

1. Code: 0 – No prophylactic contralateral mastectomy
1 – Prophylactic contralateral mastectomy
2 – Contralateral mastectomy, unclear whether prophylactic
9 – Unknown whether prophylactic contralateral mastectomy

2. Description:

2.1 A prophylactic contralateral mastectomy is a mastectomy on the contralateral (opposite) breast although there is no indication that there is cancer in that breast. If a patient had a mastectomy on the contralateral (opposite) breast because the contralateral (opposite) breast had cancer, this would not be prophylactic and the patient would be ineligible due to simultaneous diagnosis.

2.2 Code "0 – No prophylactic contralateral mastectomy" when there was no prophylactic contralateral mastectomy performed.

2.2 Code "1 - Prophylactic contralateral mastectomy" when the patient received a prophylactic contralateral mastectomy.

2.3 Code "2 - Contralateral mastectomy, unclear whether prophylactic" when the woman received a contralateral mastectomy, but it is not clear if there was cancer in the removed breast.

2.4 Code "9- Unknown whether prophylactic contralateral mastectomy" if it is unknown whether prophylactic contralateral mastectomy was performed.

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

DATE RADIATION TO PRIMARY SITE BEGAN - COMPLETED

ITEM B-15

1. Code: MM-DD-YYYY
00-00-0000 - No radiation
0, 1, 2, 9 – Radiation completion

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

Radiation course completion status

0 – No, not completed
1 – Yes, completed
2 – No radiation given to primary site
9 – Unknown whether radiation was given or completed

2. Description:

2.1 Enter the date the patient was first given radiation to the primary site (breast/chest wall) at any time after diagnosis.

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

2.3 Code “96-96-9696 - Unknown" if radiation was recommended but it is unknown whether the recommended radiation was performed.

2.4 If a patient or guardian refuses radiation code “77-77-7777 - Patient/guardian refused.”

2.5 If it cannot be determined whether radiation was recommended and given, then code “97-97-9797 – Unknown if offered/given”.

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

DATE RADIATION TO PRIMARY SITE BEGAN – COMPLETED (continued)

ITEM B-15

2.6 If the exact date of radiation is unknown, then an estimate should be made. Otherwise, code "99-99-9999 - Date Unknown".

2.7 Code whether the full course of radiation was completed (Code 1– Yes, completed) or if the patient received less than a full course of radiation (Code 0 – No, not completed).

2.8 If the patient did not receive radiation to the primary site (breast/chest wall), code date as "00-00-0000" and completion as "2 – No radiation given to primary site."

2.9 If it is unknown whether radiation to the primary site (breast/chest wall) was given or completed, then code completion as "9 - unknown."

RADIATION THERAPY RECEIVED

ITEM B-16

1. Code:
0 – No radiation received
1 – Received whole breast radiation
2 – Received chest wall radiation
3 – Received accelerated partial breast irradiation (Brachytherapy)
4 – Received breast and regional nodal radiation
5 – Received chest wall and regional nodal radiation
6 – Other, Specify _____
8 – Received radiation, type unknown
9 – Unknown whether radiation received

2. Description:

2.1 Code "0 – No radiation received" if the patient did not receive radiation in Item B-15.

2.2 Code "1 – Whole breast radiation" when the patient received traditional external beam radiation to the entire breast region.

2.3 Code "2 – Chest wall radiation" when the patient received radiation to the chest wall, the mastectomy scar and the drain sites (when present).

2.4 Code "3 – Accelerated partial breast irradiation" when the patient received radiation therapy targeted just to the tumor site. This is often referred to as conformal, 3-D radiation, or brachytherapy

2.5 Code "4 – Breast and regional nodal radiation" When the patient received external beam radiation to the breast AND to lymph nodes including the paraclavicular, axillary, and internal mammary nodes.

2.6 Code "5 – Chest wall and regional nodal radiation" when the patient received radiation to the chest wall, the mastectomy scar and the drain sites (when present) to lymph nodes including the paraclavicular, axillary, and internal mammary nodes.

2.7 Code "6 – Other, specify" when the patient received a different kind of radiation or radiation to a different site. Specify the type of radiation and site.

2.8 Code "8 – Received radiation, type unknown" when the woman received radiation but the type of radiation is not specified.

RADIATION THERAPY SEQUENCE WITH SURGERY

ITEM B-17

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

2. Description:

2.1 This item is used to record information on patients who were treated with BOTH radiation therapy and cancer-directed surgery at any time after diagnosis. If only one was given, then this item is sequenced as “0”.

2.2 Code "0 - No/unknown radiation and/or no/unknown cancer-directed surgery" when radiation (Item B-15) and/or cancer-directed surgery status (Item B-9) 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 before surgery" when the patient received radiation therapy (Item B-15) prior to cancer-directed surgery (Item B-9).

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

2.4 Code "3 - Radiation after surgery" when the patient received radiotherapy (Item B-15) following surgery (Item B-9).

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

2.5 Code "4 - Radiation both before and after surgery" when the radiation therapy (Item B-15) was given both prior to and following the surgical resection (Item B-9).

RADIATION THERAPY SEQUENCE WITH SURGERY (continued)

ITEM B-17

2.6 Code "5 - Intraoperative radiation" when the patient received radiation therapy (Item B-15) directly to the tumor bed during the surgical resection (Item B-9).

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

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

RADIATION THERAPY SEQUENCE WITH SYSTEMIC THERAPY

ITEM B-18

1. Code:

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

2. Description:

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

2.2 Code "0 - No/unknown radiation and/or no/unknown systemic therapy" when radiation therapy (Item B-15) and/or systemic therapy status (Items B-23 to B-41) 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 (Item B-15) prior to systemic therapy (Items B-23 to B-41).

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-18

2.4 Code "3 - Radiation after systemic therapy" when the patient received radiation therapy (Item B-15) following systemic therapy (Items B-23 to B-41).

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

2.5 Code "4 - Radiation both before and after systemic therapy" when radiation therapy (Item B-16) was given both prior to and following systemic therapy (Items B-23 to B-41), but not concurrently.

2.6 Code "5 - Concurrent radiation and systemic therapy" when the patient received radiation (Item B-15) during the time that she was receiving systemic therapy (Items B-23 to B-41).

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

2.8 Code "7 - Systemic therapy before and after radiation" when the patient received systemic therapy (Items B-23 to B-41) prior to and following radiation therapy (Item B-16), 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 radiation and systemic therapy, but it is unclear in which order they were given.

SYSTEMIC THERAPY SEQUENCE WITH SURGERY

ITEM B-19

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
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 was given, then this item is sequenced as “0”.

2.2 Code "0 – No/unknown systemic therapy and/or no/unknown cancer-directed surgery" when systemic therapy (Items B-23 to B-41) and/or Cancer-Directed surgery status (Item B-19) 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 (Items B-23 to B-41) prior to the most extensive cancer-directed surgery (Item B-9).

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

2.4 Code "3 - Systemic therapy after surgery" when the patient received systemic therapy (Items B-23 to B-41) following the definitive surgery (Item B-9).

For example: A patient who had a biopsy, followed by a modified radical mastectomy, 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 systemic therapy (Items B-23 to B-41) was given both prior to and following the definitive surgical resection (Item B-9).

2.6 Code “9 - Sequence unknown” when both systemic therapy and surgery were received by the patient, but the sequence is unknown and the dates are missing so the sequence cannot be determined

HER-2 (c-erbB-2, her2/neu): IHC

ITEM B-20

1. Code:
00 – Negative
01 – 1+
02 – 2+
03 – 3+
92 – Equivocal IHC, value not reported
93 – Equivocal, value not reported, type IHC or *in situ* hybridization (ISH) test unknown
94 – Positive IHC, specific value not reported
95 – Positive test, type IHC or ISH test unknown
96 – Negative IHC, value not reported
97 – Negative test, type IHC or ISH test unknown
98 – Not Done
99 – Unknown

2. Description:

2.1 Record the results of the measurement of HER-2 (also known as c-erbB-2 or her2/neu). When testing for her2/neu, the immunohistochemical (IHC) test may be used alone or followed by an ISH test including FISH (fluorescence *in situ* hybridization), SPoT-Light HER2 CISH (subtraction probe technology chromogenic *in situ* hybridization), or Inform HER2 Dual ISH (inform dual *in situ* hybridization) test. Please record the IHC in Item B-20 and the ISH in Item B-21. (It is possible that the HER-2 value may be entered into the record as 'Herceptest').

2.2 Code "00 - Negative" when the record indicates the test for her2/neu results were negative with the value given.

2.3 Code "01" when the IHC test value was reported as 1+.

2.4 Code "02" when the IHC test value was reported as 2+.

2.5 Code "03" when the IHC test value was reported as 3+.

2.6 Code "92" when the results of the her2/neu by IHC were stated as being equivocal and no value is given.

2.7 Code "93" when the results of the HER-2 value is equivocal, but the type of test (IHC or ISH) is unknown. Item B-21 should also be coded "93".

2.8 Code "94" when the HER-2 test is reported as positive by IHC, but the value is not reported.

HER-2 (c-erbB-2, her2/neu): IHC (continued)

ITEM B-20

2.9 Code “95” when the record indicates that the test for her2/neu was positive, but the type of test (IHC or ISH test) is unknown. Item B-21 should also be coded “95”.

2.10 Code “96” when the report states only that the IHC test was negative and does not provide the actual value.

2.11 Code “97” when the test is reported as negative, but the type of test (IHC or ISH) is unknown. Item B-21 should also be coded “97”.

2.12 If the test was not done, then code “98 - not done”.

2.13 If it is unknown whether the test was ordered, then code “99 – Unknown”.

HER-2 (c-erbB-2, her2/neu): *IN SITU* HYBRIDIZATION (ISH)

ITEM B-21

1. Code: 0.1…9.0 – Actual value
9.1 – 9.1 or higher
92 – Equivocal by ISH, value not reported
93 – Equivocal, value not reported, type IHC or ISH unknown
94 – Positive by ISH, value not reported
95 – Positive test, type IHC or ISH unknown
96 – Negative ISH, value not reported
97 – Negative test, type IHC or ISH unknown
98 – Not Done
99 – Unknown

ISH Tests:

- Fluorescence *in situ* hybridization (FISH)
- Subtraction probe technology chromogenic *in situ* hybridization (SPoT-Light HER2 CISH or CISH)
- Inform dual *in situ* hybridization (Inform HER2 Dual ISH or DISH)

2. Description:

2.1 Record the results of the measurement of HER-2 as reported when performed by *in situ* hybridization (ISH). These are more sensitive tests and a patient may have the IHC first, followed by ISH, or may have an ISH test alone. IHC should be reported in Item B-20. For ISH, code the actual value given which will be a 2-digit number. The decimal point between the two numbers need not be recorded because it is already written on the abstract form and in the abstracting utility. For example, the value of 0.5 should be recorded as "05".

2.2 Record the actual value from the laboratory test. The data are reported as a ratio of the number of her2 signals to 17 centromere signals. For ISH tests, a ratio >2.0 is consistent with amplification of HER-2 gene sequences or a positive test, a ratio of 1.8-2.0 is an equivocal finding and requires further testing and a ratio of <1.8 is within the normal limits (negative).

2.3 Code "92" when the record indicates that the test for HER-2 is equivocal by ISH, but the value is not reported.

2.4 Code "93" when the record indicates that the test for HER-2 was equivocal, but does not indicate the value nor the type of test (IHC or ISH). Item B-20 should also be coded "93".

HER-2 (c-erbB-2,her2/neu): *IN SITU* HYBRIDIZATION (ISH) (continued)

ITEM B-21

2.5 Code “94” when the record indicates that the test for HER-2 is positive by ISH, but the value is not reported.

2.6 Code “95” when the record indicates that the test for HER-2 is positive, but the type of test (IHC or ISH) is unknown. Item B-20 should also be coded “95”.

2.7 Code “96” when the record indicates only that the ISH test was negative and does not provide the actual value.

2.8 Code “97” when the record indicates that the test for HER-*2* was negative, but the type of test (IHC or ISH) is unknown. Item B-20 should also be coded “97”.

2.9 If the test was not done, then code “98 - Not done”.

2.10 Code “99 - Unknown” if it is unknown whether the test was ordered.

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

GENE ASSAYS

ITEM B-22

1. Code: *Type*
   0 – No mention, not performed
   1 – Onco*type* DX™
   2 – Prosigna™ (PAM 50)
   3 – MammaPrint

   Score
   000-100 – Recurrence Score™
   200 – Low Risk
   300 – Intermediate Risk
   400 – High Risk
   555 – Not performed
   977 – Ordered, Results unknown
   999 – Unknown

2. Description:

FOR EACH TEST THE RECURRENCE SCORE IS PREFERRED TO THE RISK LEVEL.

2.1 Onco*type* DX™ is an FDA-approved 21-gene assay that is reported to provide an assessment of the likelihood of distant breast cancer recurrence. The company that developed the assay, Genomic Health, states that the test will "assist physicians in optimizing treatment plans." The assay was initially intended for use in newly diagnosed breast cancer patients with stage I or II, node negative, estrogen receptor-positive cancer, and who will be treated with tamoxifen. The assay uses formalin-fixed, paraffin-embedded tumor tissue. The use of the assay has now been expanded to women with other stages and ER status.

2.2 The results are expressed as a Recurrence Score™ (0-100). The Recurrence Score™ (RS) is supposed to correlate with the probability of distant recurrence at 10 years. The likelihood of distant recurrence at 10 years increases continuously with increase in RS, with RS risk groups defined as low-risk (RS < 18), intermediate-risk (RS 18-30), and high-risk (RS ≥ 31). Although an RS falls into a risk group, each RS score is specific to each patient. For example, within the intermediate-risk category, an RS of 18 is different from an RS of 30.[1] Genomic Health developed this assay and they run the ONLY laboratory that performs the assay. **Record the value provided by Genomic Health, between 0 and 100.** If you are unable to locate the assay or the exact value is unknown and there are written comments about the results, such as "RS is high," then code "400 – High".

GENE ASSAYS (continued)

ITEM B-22

2.3 Prosigna™ (PAM 50) is an FDA approved assay similar to Onco*type* DX™ and reports similar risk categories (low, intermediate, high) and a numerical score (0-100). The assay is used to assess the probability of distant recurrence of disease at 10 years for post-menopausal women with early stage, hormone-receptor positive, invasive breast cancer.

2.4 A third FDA approved assay is MammaPrint. It assays 70 genes and also is used to predict the risk of recurrence at 10 years. The results are presented as either low or high risk; it does not record intermediate risk. They do report probability in percentages, of recurrence with and without systemic therapy

2.5 These gene assays may be found in the hospital record. However, if it is ordered by the medical oncologist, it might be in the office record only.

2.6 If the test was ordered, but there is no record of the results, then code "977 – Ordered, Results unknown". If there are comments about whether the test was high, intermediate or low, then record those as appropriate instead of recording "Results unknown".

2.7 If there is no mention of whether the test was ordered, then code "555 – Not Performed" when it is know that the test was not performed

2.8 If it cannot be determined whether the test was ordered, record "999 – Unknown".

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

SYSTEMIC THERAPEUTIC AGENTS

ITEMS B-23 through B-41

1. Code: MM-DD-YYYY-Start date
00-00-0000 - Systemic therapy not given

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

Number of cycles completed/given/received

00- Not given
01- One cycle completed/given/received
02- Two cycles completed/given/received
…
…
77-Refused
96- Recommended, unknown if given
97- Unknown if given
98- Systemic agent is currently being given
99- Unknown number of cycles completed/given/received

B-23 Ado-trastuzumab emtansine (Kadcyla)

B-24 Capecitabine (Xeloda)

B-25 Carboplatin

B-26 Cyclophosphamide

B-27 Docetaxel (Taxotere, Docefrez)

SYSTEMIC THERAPEUTIC AGENTS (continued)

ITEMS B-23 through B-41

B-28 Doxorubicin (Adriamycin)

B-29 Eribulin (Halaven)

B-30 Fluorouracil (5-FU)

B-31 Gemcitabine (Gemzar)

B-32 Lapatinib (Tykerb)

B-33 Nab-Paclitaxel (Abraxane)

B-34 Paclitaxel (Taxol, Onxol)

B-35 Pertuzumab (Perjeta)

B-36 Trastuzumab (Herceptin)

B-37 Vinorelbine (Navelbine)

B-38 Tamoxifen (Nolvadex)

B-39 Aromatase Inhibitors [anastrozole (Arimidex), exemestane (Aromasin), letrozole (Femara)]

B-40 GnRH analogs [(goserelin acetate (Zoladex), leuprolide (Lupron, Lupron Depot), nafarelin (Synarel), degarelix (Firmagon), histrelin acetate (Vantas; Supprelin LA), triptorelin pamoate (Trelstar, Trelstar LA, Trelstar Depot), Gonadorelin (Factrel)]

B-41 Other Specify_____

SYSTEMIC THERAPEUTIC AGENTS (continued)

ITEMS B-23 through B-41

Examples of other chemotherapeutic agents which might have been given are:
Topotecan, Vinblastine (Velban), Mitoxantrone (Novantrone)

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

2. Description:

2.1 Enter the first date the therapy was given at any time following diagnosis.

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

2.3 Code "77-77-7777 - Patient/guardian refused systemic therapy" when systemic therapy was recommended, but not administered because of 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 "96-96-9696 - Recommended, unknown if given" when a patient was recommended to receive a systemic therapy agent, but it is unknown if it was actually received. When systemic therapy was recommended, but the treatment agents used were not documented, all agents must be coded "96-96-9696 - Recommended, unknown if given.”

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

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

2.7 Record the number of cycles of systemic therapy completed/given/received. Please add all cycles from all courses of systemic therapy. Unless indicated on the physician verification form, do not record cycles for Items B-35, B-36, and B-38 through B-40.

SEER POC DATA ACQUISITION MANUAL

SECTION V

NON-SMALL CELL LUNG DATA SET

SECTION V - NON-SMALL CELL LUNG DATA SET

CONTENTS

METASTASIS

ITEM B-1

1. Code: CS Mets at DX

Code	Description
00	None
15	Malignant pleural effusion, ipsilateral or same lung
16	Malignant pleural effusion, contralateral or other lung
17	Malignant pleural effusion, ipsilateral and contralateral lungs (bilateral pleural effusion)
18	Malignant pleural effusion, unknown if ipsilateral or contralateral lung
20	Malignant pericardial effusion
21	20 + (16 or 17) Malignant pericardial effusion plus contralateral or bilateral pleural effusion
23	Extension to: Contralateral lung Contralateral main stem bronchus Separate tumor nodule(s) in contralateral lung Pleural tumor foci or nodules on contralateral lung
24	Pleural tumor foci or nodules on the ipsilateral lung separate from direct invasion
25	23 + any of [15, 16, 17, 18, 20, 21, 24] Extension to contralateral lung plus pleural or pericardial effusion or separate pleural tumor foci
26	Stated as M1a with no other information on distant metastases
30	Distant lymph node(s), including cervical nodes
32	30 + any of (15, 16, 17, 18, 20, 21) Distant lymph nodes plus pleural or pericardial effusion
33	30 + 24 Distant lymph nodes plus pleural tumor foci
35	Obsolete data retained V0200 Separate tumor nodules now coded in SSF #1 in AJCC 7th Edition Separate tumor nodule(s) in different lobe, same lung
36	30 + 23 Distant lymph nodes plus extension to contralateral lung
37	Extension to: Skeletal muscle Sternum Skin of chest

Code	Description
38	37 + 23 Extension in code 37 plus extension to contralateral lung
40	Abdominal organs Distant metastasis, except distant lymph node(s) and extension specified in codes 23 and 37, including: Separate lesion in chest wall or diaphragm Distant metastasis, NOS Carcinomatosis
41	40+ 23 Distant mets plus extension to contralateral lung
42	(37 or 40) + any of (15, 16, 17, 18, 20, 21) Distant metastasis plus pleural or pericardial effusion
43	(37 or 40) + 24 Distant metastasis plus pleural tumor foci
50	Obsolete data retained V0200 Distant metastases + Distant node(s) (10) + any of [(35) to (40)]
51	(37 or 40) + 30 Distant metastasis plus distant lymph node(s)
52	51 + any of (15, 16, 17, 18, 20, 21) Distant metastasis plus distant lymph nodes plus pleural or pericardial effusion
53	51 + 24 Distant metastases plus distant lymph nodes plus pleural tumor foci
70	Stated as M1b with no other information on distant metastases
75	Stated as M1[NOS] with no other information on distant metastases
99	Unknown if distant metastasis Distant metastasis cannot be assessed Not documented in patient record

2. Description:

2.1 Use the general instructions and lung site-specific instructions for "Mets at Diagnosis" in the Collaborative Staging Manual to identify distant metastasis. See http://web2.facs.org/cstage0205/lung/Lungschema.html for more information.

PET SCAN / DATE

ITEM B-2

1. Code: 0 – No PET scan for cancer / no mention
1 – PET scan of whole body
2 – PET scan of chest
3 – PET scan of brain
4 – PET scan of abdomen
5 – PET scan of extremity
6 – PET scan done, unknown site
9 – Unknown whether PET scan was performed

MM-DD-YYYY
00-00-0000 - No PET scan

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

2. Description:

2.1 Positron emission tomography, or PET, is a diagnostic examination usually performed in a nuclear medicine department. It is sometimes used to detect cancer and/or metastasis, but can be used for other purposes such as heart disease, neurological disorders and Alzheimer's disease. A radioactive substance is administered as an intravenous injection. A PET scanner is used for imaging.

2.2 **The PET scan should only be recorded if it was done for the purpose of diagnosing or staging cancer.** If it is clear that the scan was done for another reason, i.e. Alzheimer's disease, then record "0 - No PET scan for cancer".

2.3 If no PET scan was performed for cancer or there is no mention of a PET scan in the medical record, then code "0 – No pet scan for cancer / no mention". The date should be coded "00-00-0000".

PET SCAN / DATE (continued)

ITEM B-2

2.4 If a PET scan was performed, then determine the site of the body that was scanned. It is possible to perform a whole body scan. For example, if only the chest was scanned, then code "2 – PET scan of chest".

2.5 If you cannot determine whether a PET scan was done, then code "9 – Unknown whether PET scan was performed". The date should be coded either "96-96-9696-Recommended, unknown if performed" or "97-97-9797-Unknown if performed".

2.6 If there are multiple PET scans, then code the PET scan site and date of the PET scan closest to the date of diagnosis.

2.7 If a PET scan was recommended, but it is unknown if it was performed, then code "96-96-9696".

2.8 If the exact date of the PET scan is unknown, estimate the date if possible. An estimate is preferable to coding unknown.

DATE OF CANCER-DIRECTED SURGERY TO PRIMARY SITE

ITEM B-3

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	
.	.	
.	.	
.	.	
77	77	7777-Patient/guardian refused
96	96	9696-Recommended, unknown if performed
97	97	9797-Unknown if surgery performed
99 - Month Unknown	99 - Day Unknown	9999-Year Unknown

2. Description:

2.1 Enter the date of the ***most definitive*** cancer-directed surgery to the primary site. This does not include biopsy.

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

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

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

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

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

MUTATIONS

ITEM B-4

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

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-4

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 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”.

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

2.10 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”.

EXTENSION OF PRIMARY TUMOR

ITEM B-5

1. Code: Lung
CS Extension

Code	Description	TNM 7	TNM 6	SS77	SS2000
000	In situ, intraepithelial, noninvasive	^	*	#	**
100	Tumor confined to one lung WITHOUT extension or conditions described in codes 200-800 EXCLUDING primary in main stem bronchus EXCLUDING superficial tumor as described in code 110	^	*	L	**
110	Superficial tumor of any size with invasive component limited to bronchial wall, with or without proximal extension to the main stem bronchus	^	*	L	**
115	Stated as T1a with no other information on extension	^	*	L	**
120	Stated as T1b with no other information on extension	^	*	L	**
125	Stated as T1[NOS] with no other information on extension	^	*	L	**
200	Extension from other parts of lung to main stem bronchus, NOS EXCLUDING superficial tumor as described in code 110 Tumor involving main stem bronchus greater than or equal to 2.0 cm from carina (primary in lung or main stem bronchus)	^	*	L	**
210	Tumor involving main stem bronchus, NOS (Distance from carina not stated and no surgery as described in Note 2)	^	*	L	**
220	Direct tumor invasion into an adjacent ipsilateral lobe	^	*	L	**
230	Tumor confined to hilus	^	*	L	**
300	Localized, NOS	^	*	L	**
400	Atelectasis/obstructive pneumonitis that extends to the hilar region but does not involve the entire lung Or atelectasis/obstructive pneumonitis, NOS	^	*	RE	**

Code	Description	TNM 7	TNM 6	SS77	SS2000
410	Extension to but not into pleura, including invasion of elastic layer BUT not through the elastic layer.	^	*	RE	**
420	Invasion of pleura, including invasion through the elastic layer	^	*	RE	**
430	Invasion of pleura, NOS	^	*	RE	**
440	Pulmonary ligament	^	*	RE	**
455	Stated as T2a with no other information on extension	^	*	RE	**
460	Stated as T2b with no other information on extension	^	*	RE	**
465	Stated as T2 [NOS] with no other information on size or extension	^	*	RE	**
500	Tumor of/involving main stem bronchus less than 2.0 cm from carina	^	*	L	**
520	500 + 400	^	*	RE	**
540	500 + any of (410-440)	^	*	RE	**
550	Atelectasis/obstructive pneumonitis involving entire lung	^	*	RE	**
560	Parietal pericardium or pericardium, NOS	^	*	RE	**
570	Stated as T3 with no other information on extension	^	*	RE	**
590	Invasion of phrenic nerve	^	*	RE	**
600	Direct extension to: Brachial plexus, inferior branches or NOS, from superior sulcus Chest (thoracic) wall Diaphragm Pancoast tumor (superior sulcus syndrome), NOS Parietal pleura Note: For separate lesion in chest wall or diaphragm, see CS Mets at DX.	^	*	D	**
610	Superior sulcus tumor WITH encasement of subclavian vessels OR WITH unequivocal involvement of superior branches of brachial plexus (C8 or above)	T4	*	D	**
680	Tumor confined to carina	T4	*	L	**

Code	Description	TNM 7	TNM 6	SS77	SS2000
700	Blood vessel(s), major (EXCEPT aorta and inferior vena cava, see codes 740 and 770) Azygos vein Pulmonary artery or vein Superior vena cava (SVC syndrome) Carina from lung/mainstem bronchus Compression of esophagus or trachea not specified as direct extension Esophagus Mediastinum, extrapulmonary or NOS Nerve(s): Cervical sympathetic (Horner syndrome) Recurrent laryngeal (vocal cord paralysis) Vagus Trachea	T4	*	RE	**
705	700 + (600 or 610)	T4	*	D	D
710	Heart Visceral pericardium	T4	*	D	D
730	Adjacent rib See also code 785	^	*	D	D
740	Aorta	T4	*	D	**
745	740 + 710	T4	*	D	D
748	740 + 730	T4	*	D	D
750	Vertebra(e) Neural foramina	T4	*	D	D
770	Inferior vena cava	T4	*	D	D
785	730 + (700 or 710)	T4	*	D	D
800	Further contiguous extension (Except to structures specified in CS Mets at DX codes 23 and 37)	T4	*	D	D
810	Stated as T4 with no other information on extension	T4	*	D	D
950	No evidence of primary tumor	^	*	#	**
980	Tumor proven by presence of malignant cells in sputum or bronchial washings but not visualized by imaging or bronchoscopy; "occult" carcinoma	^	*	#	**
999	Unknown; extension not stated Primary tumor cannot be assessed Not documented in patient record	^	*	#	**

EXTENSION OF PRIMARY TUMOR (Continued)

ITEM B-5

* The T category is assigned based on the value of the tumor size, extension and Site Specific Factor #1, as shown in the extension size table for 6th edition.
^ The T category is assigned based on the value of the tumor size, extension and Site Specific Factor #1, as shown in the extension size table for 7th edition
(See http://web2.facs.org/cstage0205/lung/Lung_baj.html for more information)

Note 1: Direct extension to or other involvement of structures considered M1 in AJCC staging is coded in the data item CS Mets at DX. This includes: sternum; skeletal muscle; skin of chest; contralateral lung or mainstem bronchus; separate tumor nodule(s) in contralateral lung.
Note 2: Distance from Carina. Assume tumor is greater than or equal to 2 cm from carina if lobectomy, segmental resection, or wedge resection is done.
Note 3: Opposite Lung. If no mention is made of the opposite lung on a chest x-ray, assume it is not involved.
Note 4: Bronchopneumonia. "Bronchopneumonia" is not the same thing as "obstructive pneumonitis" and should not be coded as such.
Note 5: Pulmonary Artery/Vein. An involved pulmonary artery/vein in the mediastinum is coded to 700 (involvement of major blood vessel). However, if the involvement of the artery/vein appears to be only within lung tissue and not in the mediastinum, it would not be coded to 700.
Note 6: Vocal cord paralysis (resulting from involvement of recurrent branch of the vagus nerve), superior vena cava obstruction, or compression of the trachea or the esophagus may be related to direct extension of the primary tumor or to lymph node involvement. The treatment options and prognosis associated with these manifestations of disease extent fall within the T4-Stage IIIB category; therefore, generally use code 700 for these manifestations. HOWEVER, if the primary tumor is peripheral and clearly unrelated to vocal cord paralysis, vena cava obstruction, or compression of the trachea or the esophagus, code these manifestations as mediastinal lymph node involvement (code 200) in CS Lymph Nodes unless there is a statement of involvement by direct extension from the primary tumor.
Note 7: Pleural effusion and pericardial effusion are coded under CS Mets at DX.
Note 8: In some cases, the determination of the T category for TNM 6th or 7th is based on this field and CS Mets at DX or SSF #1.
Note 9: Code to the highest applicable code for extension and then code the absence or presence of separate ipsilateral tumor nodules in SSF 1: Separate Tumor Nodules/Ipsilateral lung. Code separate tumor nodules in contralateral lung in Mets at Dx.
Note 10: The visceral pleura invasion is captured in codes 410-430. This is due to introduction of elastic layer involvement that was found to have prognostic factor in lung cancer cases per AJCC 7th edition

EXTENSION OF PRIMARY TUMOR (Continued)

ITEM B-5

2. Description:

2.1 USE SEER CODING RULES.

2.2 The data collected in the Collaborative Staging System are limited to information gathered through completion of surgery(ies) in the first course of treatment OR all information available within four months of the date of diagnosis in the absence of disease progression--whichever is ***longer***.

2.3 Use the Collaborative Staging Manual general guidelines and lung site-specific guidelines to assign CS extension. See http://web2.facs.org/cstage0205/lung/Lungschema.html for more information.

PATHOLOGICAL MARGINS

ITEM B-6

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 at any time 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.

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

DATE RADIATION TO PRIMARY SITE BEGAN

ITEM B-7

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

Month	Day	Year
01 - January	01	Use 4-digit year
02 - February	02	
.	.	
.	.	
.	.	
77	77	7777-Patient/guardian refused radiation
96	96	9696-Recommended, unknown if given
97	97	9797-Unknown if given
99 - Month Unknown	99 - Day Unknown	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 “96-96-9696 – Recommended, unknown if given" if it is unknown whether the recommended radiation was performed.

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

2.5 If it cannot be determined whether radiation was recommended and given, code “97-97-9797 – Unknown if radiation given”.

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

RADIATION THERAPY (PRIMARY SITE) SEQUENCE WITH SURGERY

ITEM B-8

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-7) and/or cancer-directed surgery status (Item B-3) 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 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 surgical resection.

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

RADIATION THERAPY SEQUENCE WITH SURGERY (continued)

ITEM B-8

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 the 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-9

1. Code:

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

2. Description:

2.1 This item is used to record information on patients who were treated with BOTH radiation therapy 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-7) and/or systemic therapy (Items B-12 to B-31) 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 ".

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.

RADIATION THERAPY SEQUENCE WITH SYSTEMIC THERAPY (continued)

ITEM B-9

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

2.7 Code "6 - Concurrent radiation and systemic therapy with other radiation given before and/or after 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 chemotherapy 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-10

1. Code: 0 – No/unknown systemic therapy and/or no/unknown cancer-directed surgery
2 - Systemic therapy before surgery
3 - Systemic therapy after surgery
4 - Systemic therapy both before and after surgery
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-12 to B-31) and/or Cancer-Directed surgery status (Item B-3) 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 extensive 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 definitive 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 surgical resection.

2.6 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.

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

DATE RADIATION TO OTHER SITE BEGAN

ITEM B-11

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	
.	.	
.	.	
.	.	
77	77	7777 - Patient/guardian refused
96	96	9696 - Recommended, unknown if given
97	97	9797 - Unknown if given
99 - Month Unknown	99 - Day Unknown	9999 - Year Unknown

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-7).

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

2.3 Code "96-96-96 – Unknown" if it is unknown whether the recommended prophylactic or palliative radiation was performed.

2.4 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".

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

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

SYSTEMIC THERAPY AGENTS

ITEMS B-12 through B-31

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

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

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

B-12 Alectinib (Alecensa)

B-13 Bevacizumab (Avastin)

B-14 Carboplatin

B-15 Ceritinib (Zykadia)

B-16 Cisplatin (CDDP, Platinol)

B-17 Docetaxel (Taxotere)

B-18 Erlotinib (Tarceva)

B-19 Etoposide (Vepesid)

B-20 Gefitinib (Iressa)

B-21 Gemcitabine (Gemzar)

B-22 Necitumumab (Portrazza)

SYSTEMIC THERAPY (continued)

ITEMS B-12 through B-31

B-23 Nivolumab (Opdivo)

B-24 Osimertinib (Tagrisso)

B-25 Paclitaxel (Taxol)

B-26 Panitumumab (Vectibix)

B-27 Pembrolizumab (Keytruda)

B-28 Pemetrexed (Alimta)

B-29 Ramucirumab (Cyramza)

B-30 Vinorelbine (Navelbine)

B-31 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.

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

SYSTEMIC THERAPY (continued)

ITEMS B-12 through B-31

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 "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.

2.5 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 - Unknown" when there is no documentation regarding systemic therapy date in the medical records reviewed. Estimate the date of systemic therapy if possible. For example, use the statement that systemic therapy began two months ago to estimate the month and year.

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

MAINTENANCE THERAPY

ITEM B-32

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

2. Description:

2.1 Information on maintenance therapy will be collected on the physician verification form.

2.2 Code the information provided by the physician about whether or not the patient received maintenance therapy. 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.

2.3 If the physician does not indicate the patient had maintenance therapy and there is no indication in the hospital record that maintenance was given, code "9 – Unknown."

SMOKING

ITEM B-33

1. Code: **Number of packs per day**
00.0 - Never smoked
00.5 – Half a pack per day
00.9 - less than 1 pack per day
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 (continued)

ITEM B-33

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. If the patient never smoked, code "00.0" in packs per day, the number of years smoked and the pack years smoked.

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, and "99" in years and pack years.

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-34

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-35

1. Code: 0 – Not exposed to asbestos
1 – Exposed to asbestos
9 – Unknown 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 or if there is no mention of asbestos exposure.

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

2.4 If it is unclear whether the patient was exposed to asbestos, then code "9 – Unknown". If asbestos exposure is not mentioned in the record, then code "0 – Not exposed to asbestos".

SEER POC DATA ACQUISITION MANUAL

SECTION VI

COLON/RECTUM DATA SET

Partially adapted from the Community Cancer Care Evaluation - Patterns of Care Study Data Acquisition Manual 1984, the SEER Program Code Manual 1988, and the Community Clinical Oncology Program II Evaluation - Practice Patterns Study Data Acquisition Manual 1988, SEER Patterns of Care Study 1995.

SECTION VI - COLON/RECTUM DATA SET

CONTENTS

HEIGHT / WEIGHT

ITEM B-1

1. Code:

Height

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

Units

1 = Inches
2 = Cm
3 = Other specify _____
9 = Unknown/not stated

Weight

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

Units

1 = Pounds
2 = Kilograms
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 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."

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.

PERFORATION

ITEM B-2

1. Code:
0 – No bowel perforation, no mention
1 – Bowel perforation present in operative or pathology report(s) only
2 – Bowel perforation clinically evident only
3 – Bowel perforation on clinical report and operative or pathology report(s)
9 – Unknown

2. Description:

2.1 Bowel perforation, also known as ruptured bowel, is a hole in the wall of the colon. Information on the presence of a bowel perforation should come from the operative report or pathology report and clinical records. Examine these records carefully for statements about the presence or absence of a bowel perforation.

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

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

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

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

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

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

OBSTRUCTION

ITEM B-3

1. Code:
0 – No bowel obstruction, no mention
1 – Partial bowel obstruction
2 – Complete bowel obstruction
3 – Bowel obstruction; Partial or complete not specified
9 – Unknown

2. Description:

2.1 Bowel obstruction, also known as intestinal obstruction, is a mechanical or functional obstruction of the intestines which prevents the normal movement of the products of digestion. **Information on the presence of a bowel obstruction should come from the operative or pathology reports only**. Examine the record carefully for statements about the presence or absence of a bowel obstruction in the colon.

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

2.3 Code "1 – Partial bowel obstruction" when the operative or pathology record states there is a partial bowel obstruction. A "stricture" is a partial bowel obstruction.

2.4 Code "2 – Complete bowel obstruction" when a separate operation for decompressing colostomy was performed prior to the procedure to remove the tumor, or when the operative report indicates there was a complete bowel obstruction.

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

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

3. Specifics:

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

RAS MUTATION

ITEM B-4

1. Code:
0 – Not performed/No mention
1 – Negative for mutation
2 – Positive for mutation
8 – Performed, results unknown
9 – Unknown if performed

2. Description:

2.0 RAS (KRAS or NRAS) is a gene that encodes proteins in the epidermal growth factor receptor (EGFR) signaling pathway and is important for the development and progression of cancer. The RAS status of a tumor, identified as normal (wild-type) or mutated, may indicate the prognosis and response of the tumor to therapeutic drugs.

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

2.2 Code "0 – Not performed/No mention" if the RAS test was not performed or there is no mention in any of the records.

2.3 Code "1 – Negative for mutation" when the medical records indicate the RAS test was performed and results indicate the gene is negative for mutation. When there is no mutation, the medical record may also state that the RAS status is normal or wild-type.

2.4 Code "2 – Positive for mutations" when the medical record states the RAS test was performed and results indicate the gene is positive for mutation. When a mutation is found, the medical record may also state the RAS status is abnormal or non-wild-type.

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

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

BRAF STATUS

ITEM B-5

1. Code:
0 – Not performed/No mention
1 – Negative for mutation
2 – Positive for mutation
8 – Performed, results unknown
9 – Unknown if performed

2. Description:

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

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

2.2 Code "0 – Not performed/No mention" if the BRAF test was not performed or there is no mention in any of the records.

2.3 Code "1- Negative for mutation" when the medical records indicate the BRAF test was performed and results indicate the gene is negative for mutation. When there is no mutation, the medical record may also state that the BRAF status is normal.

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

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

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

DEFECTIVE MISMATCH REPAIR

ITEM B-6

1. Code: 0 – Not performed/ No mention
1 – Microsatellite stable (MSS); proficient mismatch repair (pMMR)
2 – Microsatellite unstable (MSI high); deficient mismatch repair (dMMR)
8 – Performed, results unknown
9 – Unknown if performed

2. Description:

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

2.2 Code "0 – Not performed/No mention" if the microsatellite instability test was not performed or there is no mention in any of the records.

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

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

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

2.6 Code "9 – Unknown if performed" if there is mention of the microsatellite instability test in the records but no indication that the test was performed

NEXTGEN SEQUENCING (NGS)

ITEM B-7

1. Code: 0 – Not performed/No mention
1 – Performed
9 – Unknown if performed

2. Description:

2.1 NGS is suitable for individuals with a clinical history of hereditary gastrointestinal cancers. This test especially aids in a differential diagnosis of similar phenotypes, rules out particular syndromes, and provides the analysis of multiple genes simultaneously. Individuals with multiple gastrointestinal tumors, multifocal, recurrent, family history, and early onset (e.g. <50 years) tumors should be assessed with this panel. NGS is specifically designed for heritable germline mutations and is not appropriate for the detection of somatic mutations in tumor tissue.

2.2 Code "0 – Not performed/No mention" if the NGS test was not performed or there is no mention in any of the records.

2.3 Code "1 – Performed" when the NGS test was performed.

2.4 Code "9 – Unknown if performed" if there is mention of the NGS test in the records but no indication that the test was performed.

LAPAROSCOPIC COLECTOMY (COLON ONLY)

ITEM B-8

1. Code: 0 – No laparoscopic colectomy (or rectal cancer patient)
1 – Laparoscopic colectomy performed
9 – Unknown if laparoscopic colectomy performed

2. Description:

2.1 Code "0 – No laparoscopic colectomy" if the patient did not have surgery or had surgical removal of tumor and resection of colon through an abdominal incision. Also code "0 – No laparoscopic colectomy (or rectal cancer patient)" for all rectal cancer patients.

2.2 Code "1 – Laparoscopic colectomy performed" if the patient had the tumor removed and the colon resected using laparoscopic surgery at any time after diagnosis.

2.3 Code "9 – Unknown" if it cannot be determined which surgical method was used.

2.4 **This information should be available in the operative report.**

DATE OF CANCER-DIRECTED SURGERY TO PRIMARY SITE

ITEM B-9

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

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

2. Description:

2.1 Enter the date of the most definitive cancer-directed surgery to the primary site at any time after diagnosis.

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

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

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

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

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

NUMBER OF REGIONAL LYMPH NODES POSITIVE and EXAMINED

ITEMS B-10 & B-11

1. Code: B-10 - Number of positive regional lymph nodes

00 - All nodes examined negative
01-89 1-89 positive nodes (exact number of positive nodes)
90 - 90 or more nodes positive
95 - Positive aspiration of lymph node(s)
97 - Positive nodes, number unspecified
98 - No nodes examined
99 - Unknown if nodes examined; not stated if nodes are positive

B-11 - Number of regional lymph nodes examined

00 - No node dissection done
01-89 1-89 nodes examined (exact number of examined nodes)
90 - 90 or more regional lymph nodes examined
95 - No regional lymph node(s) removed, but aspiration of regional lymph node(s) was performed
96 - Regional lymph node removal documented as a sampling and number of lymph nodes unknown/not stated
97 - Regional lymph node removal documented as dissection and number of lymph 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 if nodes were examined; not applicable or negative

2. Description:

2.1 For information on which nodes are considered regional, see SEER Program Coding and Staging Manual 2015. **Cases involving metastases to distant lymph nodes are NOT eligible for this study.**

2.2 Code the number of **pathologically** positive regional lymph nodes in Item B-10 and the number of regional lymph nodes examined **pathologically** in Item B-11. Include all regional node dissection(s) done at any time after diagnosis.

2.3 If more than one dissection was done, code the total number of regional lymph nodes positive and examined.

NUMBER OF REGIONAL LYMPH NODES POSITIVE and EXAMINED (continued)

ITEM B-10 & B-11

2.4 If the number of nodes positive was 90 or greater, then code Item B-10 (Nodes Positive) as "90". If the number of nodes examined was 90 or greater, then code Item B-11 (Nodes Examined) as “90”.

2.5 Code Item B-10 (Nodes Positive) as “97” when regional lymph nodes were known to be positive, but the exact number is unknown.

2.6 Code Item B-11 (Nodes Examined) as "96, 97, or 98" when the exact number of nodes examined is unknown.

2.7 If no regional node dissection was done, then code Item B-10 (Nodes Positive) as "98" and Item B-11 (Nodes Examined) as “00”.

2.8 If it is unknown or not stated whether any nodes were either positive or examined, code "99" in both items.

3. Specifics:

3.1 When there is a difference between the number of nodes positive and/or examined in the sign-out diagnosis and the body of the pathology report, code the information found in the sign-out diagnosis.

3.2 There may be cases that have a clinical diagnosis of positive regional lymph nodes followed by neoadjuvant therapy and removal of pathologically negative regional lymph nodes. In these cases, make a note in the abstractors comment to reflect the clinical diagnosis followed by neoadjuvant therapy and resulting pathologically negative regional lymph nodes.

EXTENSION OF PRIMARY TUMOR

ITEM B-12

1. Code: Colon
CS Extension

Code	Description	TNM 7	TNM6	SS77	SS2000
130	Confined to head of polyp, NOS	T1	T1	L	L
140	Confined to stalk of polyp, NOS	T1	T1	L	L
150	Invasive tumor in polyp, NOS	T1	T1	L	L
160	Invades submucosa (superficial invasion), including submucosa in the stalk of a polyp	T1	T1	L	L
170	Stated as T1[NOS] with no other information on extension	T1	T1	L	L
200	Muscularis propria invaded Stated as T2[NOS] with no other information on extension	T2	T2	L	L
300	Localized, NOS Confined to colon, NOS	T1	T1	L	L
400	Extension through wall, NOS Invasion through muscularis propria or muscularis, NOS Non-peritonealized pericolic tissues invaded Perimuscular tissue invaded Subserosal tissue/(sub)serosal fat invaded Transmural, NOS	T3	T3	L	L
450	Extension to: All colon sites: Adjacent tissue(s), NOS Connective tissue Mesenteric fat Mesentery Mesocolon Pericolic fat Ascending and descending colon Retroperitoneal fat Transverse colon/flexures Gastrocolic ligament Greater omentum	T3	T3	RE	RE

Code	Description	TNM 7	TNM6	SS77	SS2000
470	Stated as T3 with no other information on extension	T3	T3	RE	RE
458	Fat, NOS	T3	T3	RE	RE
500	Invasion of/through serosa (mesothelium) (visceral peritoneum)	T4a	T4	RE	RE
550	500 + (450 or 458)	T4a	T4	RE	RE
560	Stated as T4a with no other information on tension	T4a	T4	RE	RE
565	Adherent to other organs or structures nically with no microscopic examination umor found in adhesion(s) if microscopic amination performed	T4b	T4	RE	RE
570	Adherent to other organs or structures, NOS	T4b	T4	RE	RE
600	All colon sites: Small intestine Cecum and appendix: Greater omentum Ascending colon: Greater omentum Liver, right lobe Transverse colon and flexures: Gallbladder/bile ducts Kidney Liver Pancreas Spleen Stomach Descending colon: Greater omentum Pelvic wall Spleen Sigmoid colon: Greater omentum Pelvic wall	T4b	T4	RE	RE
655	All colon sites: Abdominal wall All colon sites excluding sigmoid: Retroperitoneum (excluding fat)	T4b	T4	RE	RE

Code	Description	TNM 7	TNM6	SS77	SS2000
660	Ascending colon: Right kidney Right ureter Descending colon: Left kidney Left ureter	T4b	T4	RE	RE
675	Sigmoid colon: Retroperitoneum (excluding fat)	T4b	T4	D	RE
700	Cecum, appendix, ascending, descending and sigmoid colon: Fallopian tube Ovary Uterus	T4b	T4	D	D
750	All colon sites unless otherwise stated above: Adrenal (suprarenal) gland Bladder Diaphragm Fistula to skin Gallbladder Other segment(s) of colon via serosa	T4b	T4	D	D
800	Further contiguous extension: Cecum: Kidney Liver Ureter Transverse colon and flexures: Ureter Sigmoid colon: Cul de sac (rectouterine pouch) Ureter	T4b	T4	D	D
850	Stated as T4b with no other information on extension	T4b	T4	RE	RE
900	Stated as T4[NOS] with no other information on extension	T4NOS	T4	RE	RE
950	No evidence of primary tumor	T0	T0	U	U
999	Unknown extension Primary tumor cannot be assessed Not documented in patient record	TX	TX	U	U

Note 1: Ignore intraluminal extension to adjacent segment(s) of colon/rectum or to the ileum from the cecum; code depth of invasion or extracolonic spread as indicated.

Note 2: Codes 600-800 are used for contiguous extension from the site of origin. Discontinuous involvement is coded in CS Mets at DX.

Note 3: Tumor that is adherent to other organs or structures, macroscopically, is classified T4b. However, if no tumor is present in the adhesion, microscopically, the classification should be pT3.

Note 4: High grade dysplasia and severe dysplasia are generally not reportable in cancer registries, but if a registry does collect it, code 000 should be used.

Rectosigmoid, Rectum
CS Extension

Code	Description	TNM 7	TNM 6	SS77	SS2000
000	In situ, intraepithelial, noninvasive	Tis	Tis	IS	IS
050	(Adeno)carcinoma, noninvasive, in a polyp or adenoma	Tis	Tis	IS	IS
100	Invasive tumor confined to mucosa, NOS including intramucosal, NOS	Tis	Tis	L	L
110	Invades lamina propria, including lamina propria in the stalk of a polyp	Tis	Tis	L	L
120	Confined to and not through the muscularis mucosae, including muscularis mucosae in the stalk of a polyp.	Tis	Tis	L	L
130	Confined to head of polyp, NOS	T1	T1	L	L
140	Confined to stalk of polyp, NOS	T1	T1	L	L
150	Invasive tumor in polyp, NOS	T1	T1	L	L
160	Submucosa (superficial invasion), including submucosa in the head or stalk of a polyp	T1	T1	L	L
165	For rectum: Tumor invading submucosa with intraluminal extension to colon and/or anal canal/anus	T1	T1	L	L
170	Stated as T1 with no other information on extension	T1	T1	L	L
200	Muscularis propria invaded	T2	T2	L	L
210	For rectum: Tumor invading muscularis propria with intraluminal extension to colon and/or anal canal/anus	T2	T2	RE	L
250	Stated as T2 with no other information on extension	T2	T2	L	L
300	Confined to rectosigmoid junction, NOS Confined to rectum, NOS Localized, NOS	T1	T1	L	L
400	Extension through wall, NOS	T3	T3	L	L

Code	Description	TNM 7	TNM 6	SS77	SS2000
	Invasion through muscularis propria or muscularis, NOS Non-peritonealized perirectal tissues invaded Perimuscular tissue invaded Subserosal tissue/(sub)serosal fat invaded Transmural, NOS				
415	For rectum: Tumor invading through muscularis propria with intraluminal extension to colon and/or anal canal/anus	T3	T3	RE	L
455	Adjacent (connective) tissue: For all sites: Perirectal fat For rectosigmoid: Mesentery (including mesenteric fat, mesocolon) Pericolic fat For rectum: Rectovaginal septum	T3	T3	RE	RE
458	Fat, NOS	T3	T3	RE	RE
470	Stated as T3 with no other information on extension	T3	T3	RE	RE
500	Invasion of/through serosa (mesothelium) (visceral peritoneum) Tumor penetrates visceral peritoneum	T4a	T4	RE	RE
555	500 + (165, 210, 415, 455 or 458)	T4a	T4	RE	RE
560	Stated as T4a with no other information on extension	T4a	T4	RE	RE
565	Adherent to other organs or structures clinically with no microscopic examination Tumor found in adhesion(s) if microscopic examination performed	T4b	T4	RE	RE
570	Adherent to other organs or structures, NOS	T4b	T4	RE	RE
610	For rectosigmoid: Cul de sac (rectouterine pouch) Pelvic wall/pelvic plexuses Small intestine For rectum: Anal canal/anus extraluminally Bladder for males only Cul de sac (rectouterine pouch) Ductus deferens Pelvic wall Prostate Rectovesical fascia for males only Seminal vesicle(s) Skeletal muscle of pelvic floor Vagina	T4b	T4	RE	RE

Code	Description	TNM 7	TNM 6	SS77	SS2000
700	For rectosigmoid: Bladder Colon via serosa Fallopian tube(s) Prostate Skeletal muscles of pelvic floor Ureter(s) Vagina For rectum: Bladder for females only Bone(s) of pelvis Cervix Perineum, perianal skin Sacrum Sacral plexus Urethra	T4b	T4	D	D
800	Further contiguous extension	T4b	T4	D	D
850	Stated as T4b with no other information on extension	T4b	T4	RE	RE
900	Stated as T4 [NOS] with no other information on extension	T4NOS	T4	RE	RE
950	No evidence of primary tumor	T0	T0	U	U
999	Unknown; extension not stated Primary tumor cannot be assessed Not documented in patient record	TX	TX	U	U

Note 1: Ignore intraluminal extension to adjacent segment(s) of colon/rectum and code depth of invasion or extracolonic spread as indicated.

Note 2: Codes 600-800 are used for contiguous extension from the site of origin. Discontinuous involvement is coded in CS Mets at DX.

Note 3: Tumor that is adherent to other organs or structures, macroscopically, is classified T4b. However, if no tumor if present in the adhesion, microscopically, the classification should be pT3.

Note 4: High grade dysplasia and severe dysplasia are generally not reportable in cancer registries, but if a registry does collect it, code 000 should be used.

2. Description:

2.1 The data collected in the Collaborative Staging System are limited to information gathered through completion of surgery(ies) in the first course of treatment OR to all information available within four months of the date of diagnosis in the absence of disease progression, whichever is ***longer.***

2.2 Use the Collaborative Staging Manual general guidelines and colon/rectum site-specific guidelines to assign CS extension.
For more information, see http://web2.facs.org/cstage0205/colon/Colonschema.html (for colon) and http://web2.facs.org/cstage0205/rectum/Rectumschema.html (for rectum).

PATHOLOGICAL MARGINS

ITEM B-13

1. Code:
0 - No resection or cancer directed surgery
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 path report--surgeon indicates no residual tumor
9 - Unknown, not stated

2. Description:

2.1 Information on pathological margins should be found in the pathology report of the most definitive procedure performed at any time after diagnosis.

2.2 Code "0 - No resection" when Item B-9 (Cancer-Directed Surgery) is coded "00-Not done", "77-Refused", "96-Recommended, unknown if performed", or "97-Unknown".

2.3 Code "1 - Margins of resection free of tumor" when there was a more extensive surgery than an incisional biopsy and there was no residual in the resection specimen.

2.4 Code "2 - Tumor at margins of resection, or residual tumor in area of primary" when the pathology report documents involvement of the surgical resection margins.

2.5 Code "3 - Margins not stated in path 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 "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.

2.7 If the most definitive surgery to primary was cryosurgery, electrocautery, fulguration, or laser surgery resulting in no tissue from the margins being examined by the pathologist, then code "9 - Unknown, not stated".

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

DATE RADIATION TO PRIMARY SITE BEGAN

ITEM B-14

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

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

2. Description:

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

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

2.3 Code "96-96-9696 – Unknown" if it is unknown whether radiation was performed.

2.4 If the exact date of radiation is unknown, then an estimate should be made. Otherwise, code "99-99-9999 - Date Unknown".

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

2.6 Code "77-77-7777 – Patient/guardian refused" when the patient or patient's guardian refused the recommended radiation.

RADIATION THERAPY SEQUENCE WITH SURGERY

ITEM B-15

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

2. Description:

2.1 This item is used to record information on patients who were treated with BOTH radiation therapy 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 and/or no/unknown cancer-directed surgery" when radiation (Item B-14) and/or cancer-directed surgery status (Item B-9) 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, 77, 97 or 96”).

2.3 Code "2 - Radiation before surgery" when the patient received radiation therapy (Item B-14) prior to cancer-directed surgery (Item B-9).

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

2.4 Code "3 - Radiation after surgery" when the patient received radiation therapy (Item B-14) following surgery (Item B-9).

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

2.5 Code "4 - Radiation both before and after surgery" when the radiation therapy (Item B-14) was given both prior to and following the surgical resection (Item B-9).

RADIATION THERAPY SEQUENCE WITH SURGERY (continued)

ITEM B-15

2.6 Code "5 - Intraoperative radiation" when the patient received radiation therapy (Item B-14) directly to the tumor bed during the surgical resection (Item B-9). This is likely to be very rare.

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

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

RADIATION THERAPY SEQUENCE WITH SYSTEMIC THERAPY

ITEM B-16

1. Code:

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

2. Description:

2.1 This item is used to record information on patients who were treated with BOTH radiation therapy 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-14) and/or systemic therapy status (Items B-18 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 (Item B-14) prior to systemic therapy (Items B-18 to B-35).

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-16

2.4 Code "3 - Radiation after systemic therapy" when the patient received radiation therapy (Item B-14) following systemic therapy (Items B-18 to B-35).

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

2.5 Code "4 - Radiation both before and after systemic therapy" when radiation therapy (Item B-14) was given both prior to and following systemic therapy (Items B-18 to B-35), but not concurrently.

2.6 Code "5 - Concurrent radiation and systemic therapy" when the patient received radiation (Item B-14) during the time that they were receiving systemic therapy (Items B-18 to B-35).

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

2.8 Code "7 - Systemic therapy before and after radiation" when the patient received systemic therapy (Items B-18 to B-35) prior to and following radiation therapy (Item B-14), 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-17

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
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-18 to B-35) and/or Cancer-Directed surgery status (Item B-9) 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 (Items B-18 to B-35) prior to the most extensive cancer-directed surgery (Item B-9).

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

2.4 Code "3 - Systemic therapy after surgery" when the patient received systemic therapy (Items B-18 to B-35) following the definitive surgery (Item B-9).

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

2.5 Code "4 - Systemic therapy both before and after surgery" is used when systemic therapy (Items B-18 to B-35) was given both prior to and following the definitive surgical resection (Item B-9).

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

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

SYSTEMIC THERAPY AGENTS

ITEMS B-18 through B-35

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

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

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

B-18 CAPOX

B-19 FOLFOX

B-20 FOLFOXIRI

B-21 FOLFIRI

B-22 Fluorouracil (5-FU)

B-23 Bevacizumab (Avastin)

B-24 Capecitabine (Xeloda)

B-25 Cetuximab (Erbitux)

B-26 Folinic acid (Leucovorin) (Ancillary drug)

B-27 Irinotecan (CPT-11, Camptosar)

SYSTEMIC THERAPY AGENTS (continued)

ITEMS B-18 through B-35

B-28 Levamisole (Ergamisol)

B-29 Oxaliplatin (Eloxatin)

B-30 Panitumumab (Vectibix)

B-31 Ramucirumab

B-32 Regorafenib

B-33 Trifluridine & Tipiracic (Lonsurf)

B-34 Ziv-Aflibercept

B-35 Other, specify:_____

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

Mitomycin C (Mutamycin)

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

2. Description:

2.1 Code information on all systemic therapeutic agents received at any time after diagnosis. Code the first date the systemic therapy was given.

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

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

SYSTEMIC THERAPY AGENTS (continued)

ITEMS B-18 through B-35

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

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

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

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