POC DATA ACQUISITION MANUAL

2016 DIAGNOSIS

CORPUS UTERI CANCER
HEAD AND NECK CANCER
PANCREAS CANCER

Version 2016.5
3/7/2018

POC DATA ACQUISITION MANUAL

SECTION II

PATIENT ELIGIBILITY

SECTION II - PATIENT ELIGIBILITY

CONTENTS

PATIENT ELIGIBILITY

In addition to using a common set of data items and codes, it is important that the registries involved in this study adopt a uniform policy by which patients are selected for inclusion. This will ensure that the patient populations are comparable across registries and over time. Analyses will include the comparison of data collected for patients diagnosed with corpus uteri cancer in 1998, head and neck cancer in 1997, 2004 and 2009 and pancreatic cancer in 1998 and 2009.

1. PATIENT SELECTION

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

1.1.1 Women diagnosed with all invasive stages of corpus uteri cancer between January 1, 2016 and December 31, 2016 will be sampled by race/ethnicity.

1.1.2 Men and women diagnosed with all invasive stages of head and neck cancer (defined below) between January 1, 2016 and December 31, 2016 will be sampled by sex and race/ethnicity.

1.1.3 Men and women diagnosed with all invasive stages of pancreatic cancer between January 1, 2016 and December 31, 2016 will be sampled by sex, race/ethnicity and diagnostic confirmation.

2. SAMPLING

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

2.2 For registries using SEER*DMS, algorithms will be implemented within SEER*DMS to identify cases for the POC study. The POC SEER*Abs software will pull the data from SEER*DMS. Registry staff will be able to review the cases identified by the POC algorithms in SEER*DMS; and registry staff will use controls in SEER*Abs to pull cases for abstracting.

2.3 For registries not using SEER*DMS to sample cases, assign a random number between 0 and 1 to all eligible cases of the cancer of interest in your registry from January 1, 2016 through December 31, 2016. 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 stage I corpus uteri cancer is 0.63. All stage I corpus uteri 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.

2.4 At some point during the study, it is likely that cases will be added to the registry's database after sampling has already been completed. To give these additional cases an opportunity to be included in the study, the registries should identify such patients, 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). **If one or more of these additional cases is found to be ineligible after selection into the study, do not replace them with another case. If there are more than 10 cases found to be ineligible, please discuss with NCI whether additional cases should be sampled.**

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 microscopically confirmed cancer diagnosis of one of the following sites: corpus uteri and head and neck. Patients diagnosed with pancreatic cancer may be microscopically confirmed or not microscopically confirmed.

3.2.2 Patients must be age 20 or older.

3.2.3 Patient must have been initially diagnosed between January 1, 2016 and December 31, 2016.

3.2.4 Malignant neoplasms arising in the ICD-O Topography sites listed below are reportable to SEER POC study. See **SEER Program Coding and Staging Manual 2016** for a list of reportable terms.

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

3.2.9 Site-specific inclusion criteria are listed below.

4. CORPUS UTERI CASES

4.1 Corpus Uteri includes the following:

C54.0 Isthmus uteri
C54.1 Endometrium
C54.2 Myometrium
C54.3 Fundus uteri
C54.8 Overlapping lesion of corpus uteri
C54.9 Corpus uteri
C55.9 Uterus, NOS

4.1.1 Include only cases of CORPUS UTERI meeting the following criteria:

- Microscopically confirmed (diagnostic codes 1, 2, 4)
- Histology codes: ONLY Adenocarcinoma M-8140-8245, 8247-8384, 8440-8490, 8500-8543, 8550-8576
- Behavior code: /3 invasive

4.1.2 Exclude cases meeting any of the following criteria:

- No biopsy or aspiration performed for microscopic confirmation
- Males
- In situ
- Histology that is NOT Adenocarcinoma

4.2 Patients will be sampled separately by race/ethnicity.

4.3 Details of Sampling: Eligibility

Site	Race/Ethnicity
Corpus Uteri	NH-White
	NH-Black
	Hispanic
	Asian/Pacific Islander
	AI/AN

5. HEAD AND NECK CASES

5.1 Head and Neck includes the following:

ORAL CAVITY and PHARYNX

C01.9	Base of tongue, NOS
C02.0	Dorsal surface of tongue, NOS
C02.1	Border of tongue (Tip)
C02.2	Ventral surface of tongue, NOS
C02.3	Anterior 2/3 of tongue, NOS
C02.4	Lingual tonsil
C02.8	Overlapping lesion of tongue
C02.9	Tongue, NOS
C03.0	Upper gum
C03.1	Lower gum
C03.9	Gum, NOS
C04.0	Anterior floor of mouth
C04.1	Lateral floor of mount
C04.8	Overlapping lesion of floor of mouth
C04.9	Floor of mouth, NOS
C05.0	Hard palate
C05.1	Soft palate, NOS
C05.2	Uvula
C05.8	Overlapping lesion of palate
C05.9	Palate, NOS
C06.0	Cheek mucosa
C06.1	Vestibule of mouth
C06.2	Retromolar area (gingiva, trigone)
C06.8	Overlapping lesion of other and unspecified parts of the mouth
C06.9	Mouth, NOS
C09.0	Tonsillar fossa
C09.1	Tonsillar pillar
C09.8	Overlapping lesion
C09.9	Tonsil, NOS
C10.0	Vallecula
C10.1	Anterior surface of epiglottis
C10.2	Lateral wall of oropharynx
C10.3	Posterior wall of oropharynx
C10.4	Branchial cleft (site of neoplasm)
C10.8	Overlapping lesion of oropharynx
C10.9	Oropharynx, NOS
C11.0	Superior wall of nasopharynx
C11.1	Posterior wall of nasopharynx/Pharyngeal Tonsil
C11.2	Lateral wall of nasopharynx
C11.3	Anterior wall of nasopharynx
C11.8	Overlapping lesion of nasopharynx
C11.9	Nasopharynx, NOS

C12.9 Pyriform sinus
C13.0 Postcricoid region
C13.1 Hypopharyngeal aspect of aryepiglottic fold
C13.2 Posterior wall of hypopharynx
C13.8 Overlapping lesion of hypopharynx
C13.9 Hypopharynx, NOS (laryngopharynx)
C14.0 Pharynx, NOS
C14.2 Waldeyer ring
C14.8 Overlapping lesion of lip, oral cavity

LARYNX
C32.0 Glottis
C32.1 Supraglottis
C32.2 Subglottis
C32.3 Laryngeal cartilage
C32.8 Overlapping lesion of larynx
C32.9 Larynx, NOS

5.1.1 Include only cases of ORAL CAVITY, PHARYNX and LARYNX meeting the following criteria:

- Microscopically confirmed (diagnostic codes 1, 2, 4)
- Histology: ONLY Squamous cell carcinoma (M-8070 – 8078)
- Behavior: /3 invasive

5.1.2 Exclude cases meeting any of the following criteria:

- No biopsy or aspiration performed for microscopic confirmation
- In situ
- Cancer of the lip, paranasal sinuses and major salivary glands (C00.0-C00.9, C31.0-C31.9, C07.9-C08.9)
- Any histology other than squamous cell carcinoma

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

5.3 Details of Sampling: Eligibility

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

6. PANCREATIC CASES

6.1 Pancreatic cancer includes the following:

C25.0 Head of pancreas
C25.1 Body of pancreas
C25.2 Tail of pancreas
C25.3 Pancreatic duct
C25.4 Islets of Langerhans
C25.7 Other specified parts of pancreas
C25.8 Overlapping lesion of pancreas
C25.9 Pancreas, NOS

6.1.1 Include only cases of PANCREATIC CANCER meeting the following criteria:

- Microscopically confirmed (diagnostic codes 1, 2, 4) OR not microscopically confirmed (diagnostic codes 5,6,7)
- Histology: All except lymphoma/hematopoietic M-9590-9992
- Behavior: /3 invasive

6.1.2 Exclude cases meeting any of the following criteria:

- In situ
- Lymphoma/hematopoietic histology M-9590/3-9992/3

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

6.3 Details of Sampling: Eligibility

Site	Race/Ethnicity	Sex	Diagnostic Confirmation
Pancreas	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN	Male Female	Microscopically Confirmed Not Microscopically Confirmed

7. GENERAL NON-REPORTABLE CASES AND MALIGNANCIES

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

- Previous malignancies (except basal cell or squamous cell carcinoma of the skin)
- Simultaneously diagnosed cancers 60 days or less apart, either of the same site or two different sites. For example, a patient simultaneously diagnosed with primary corpus cancer and primary lung cancer a few weeks apart.
- Lymphoma/hematopoietic histology M-9590/3-9992/3
- Death certificate only diagnosis
- Autopsy only diagnosis
- Patient younger than adult (adult is 20+ years old)

8. REPORTABILITY SUMMARY BY SITE

8.1 Corpus Uteri

Include histology codes: ONLY Adenocarcinoma M-8140-8245, 8247-8384, 8440-8490, 8500-8543, 8550-8576
Include behavior code: 3 only
Include Diagnostic Confirmation codes 1, 2, 4
Include All stages
Include Females only
Exclude histology codes that are NOT Adenocarcinoma (see above)

8.2 Head and Neck

Include histology codes: ONLY Squamous cell carcinoma M-8070 – 8078
Include behavior code: 3 only
Include Diagnostic Confirmation codes 1, 2, 4
Include All stages
Exclude histology codes that are NOT Squamous cell carcinoma (see above)

8.3 Pancreas

Include histology codes: M8000-9589
Include behavior code: 3 only
Include Diagnostic Confirmation codes 1, 2, 4, 5, 6, 7
Include All stages
Exclude histology codes: Lymphoma/hematopoietic histology M-9590/3-9992/3

POC DATA ACQUISITION MANUAL

SECTION III

COMMON DATA SET

SECTION III - COMMON DATA SET

CONTENTS

SEER PARTICIPANT

ITEM A-1

1. Code: 2 digits

2. Description:

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

CASE NUMBER

ITEM A-2

1. Code: 8 digits

2. Description:

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

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

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

QUALITY CONTROL (QC)

ITEM A-3

1. Code: 0 = No
1 =Yes

2. Description:

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

2.2 Code "0" if this is **not** a re-abstracted QC case. Code "1" if it **is** a re-abstracted QC case.

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

2.4 Steps to be taken:

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

TUMOR RECORD NUMBER

ITEM A-4

1. Code: 2-digit code

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

2. Description:

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

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

SEQUENCE NUMBER

ITEM A-5

1. Code: 2 digits

2. Description:

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

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

PRIMARY SITE

ITEM A-6

1. Code: 3-digit code

2. Description:

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

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

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 for morphology coding instructions.

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

2.4 For a complete description of coding of GRADE/differentiation, use the Instructions for Coding Grade for 2014+. 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

2. Description:

2.1 Eligible codes include only microscopically confirmed diagnosis codes 1, 2, and 4 for corpus uteri and head and neck cancers. These cases must have their cancers microscopically confirmed. Patients diagnosed with pancreatic cancer may be microscopically confirmed (codes 1, 2, and 4) or not microscopically confirmed (codes 5, 6, and 7).

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

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

HOSPITAL CODE

ITEM A-9

1. **Code:** 3 digits

2. **Description:**

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

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 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.

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

TREATMENT PROTOCOL SPONSOR AND NUMBER (continued)

ITEM A-12

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

2.3 If the 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.

2.4 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."

2.5 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.**

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

HEIGHT / WEIGHT

ITEM A-14

1. Code: Height

030-998 = Actual height

999 = Unknown/not recorded

Units

1 = Inches (in)

2 = Centimeters (cm)

3 = Other specify _____

9 = Unknown/not stated

Weight

010-998 = Actual body weight

999 = Unknown/not recorded

Units

1 = Pounds (lbs)

2 = Kilograms (kg)

3 = Other specify _____

9 = Unknown/not stated

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

2. Description:

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

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

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.

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

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

ABSTRACTOR ID

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

DATE ABSTRACTED

1. Code: month | day | year

2. Description:

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

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

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

SEER POC DATA ACQUISITION MANUAL

SECTION IV

CORPUS UTERI CANCER DATA SET

SECTION IV – CANCER OF THE CORPUS UTERI DATA SET CONTENTS

DATE OF FIRST POSITIVE BIOPSY/ASPIRATION

ITEM B-1

1. Code: MM-DD-YYYY

Month	Day	Year
01 - January	01	Use 4-digit Year
02 - February	02	
.	.	
.	.	
12 - December	31	
99 - Month Unknown	99 - Day Unknown	9999 - Year Unknown

2. Description:

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

2.2 Code the date the first biopsy/aspiration was performed. If the biopsy/aspiration was performed on the same day as definitive surgery, the biopsy date (Item B-1) and the Date of First Cancer Directed Surgery to Primary Site (Item B-8) will be the same. The first positive biopsy/aspiration may have been done as an outpatient procedure, but must be no later than the Date of First Cancer-Directed Surgery to Primary Site.

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

3. Specifics:

3.1 Code the date of the procedure used to obtain the specimen, not the date of the pathology/cytology report.

3.2 Histologic diagnoses are based on 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 instead of tissues.

SIZE OF PRIMARY TUMOR

ITEM B-2

1. Code:

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

Type of Staging (see notes below for further guidance)

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

2. Description:

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

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

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

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

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

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

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

SIZE OF PRIMARY TUMOR (continued)

ITEM B-2

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

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

Note 3: The pathologic tumor size is recorded from the surgical resection specimen when surgery (including after neoadjuvant therapy) is administered as part of the first course treatment.

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

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

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

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

2.8 Refer to Section V for rules on rounding measurements, less than/greater than statements, priority order of reports and discrepancies between reports.

3. Examples:

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

CT/MRI/US OF PELVIS

ITEM B-3

1. Code
0 = None
1 = CT
2 = MRI
3 = Ultrasound
4 = CT and MRI
5 = CT and Ultrasound
6 = MRI and Ultrasound
7 = CT, MRI and Ultrasound
9 = Unknown

2. Description:

2.1 Code '0' if no CT, MRI or Ultrasound of the pelvis was performed prior to definitive therapy. If there is no mention of any of these tests in the hospital record, record "0."

2.2 Code "1" if only a CT of the pelvis was performed prior to definitive treatment.

2.3 Code "2" if only a MRI of the pelvis was performed prior to definitive treatment.

2.4 Code "3" if only a pelvic ultrasound was performed prior to definitive treatment.

2.5 If the record indicates one test was performed without any mention of the other tests, then code that test. For example, if the record states that the patient had an MRI, but there is no mention of a CT or pelvic ultrasound, code "2."

2.6 Use codes 4, 5, 6 and 7 in cases where the patient had more than one of the tests. For example, if the hospital chart indicates that a CT and an ultrasound was performed, code "5."

2.7 Code "9" if the chart indicates that a CT/MRI/US of the pelvis was ordered, but it is unclear whether any of these tests were performed.

EXTENSION OF PRIMARY TUMOR

ITEM B-4

1. Refer to: CS Extension Codes- CorpusCarcinoma
   CS Extension

Code	Description
000	In situ, intraepithelial, noninvasive, preinvasive
100	Invasive cancer confined to corpus uteri
110	Confined to endometrium (stroma)
120	Tumor invades less than one-half of myometrium Invasion of inner half of myometrium
123	Endocervical glandular involvement WITH tumor limited to endometrium or invading less than one-half of myometrium (See Note 3)
125	FIGO Stage IA
130	Tumor invades one-half or more of myometrium Invasion of outer half of myometrium (See Note 4)
133	Endocervical glandular involvement WITH tumor invading one-half or more of myometrium (See Note 3)
135	FIGO Stage IB
140	Invasion of myometrium, NOS
143	Endocervical glandular involvement WITH tumor invading myometrium, NOS
145	Endocervical glandular involvement and involvement of myometrium not specified
180	FIGO Stage I [NOS]
400	Localized, NOS
500	Cervix uteri, NOS, but not beyond uterus
520	Cervical stromal invasion
525	FIGO Stage II
540	Extension or metastasis to tunica serosa (visceral peritoneum of corpus, serosa covering the corpus) WITHOUT involvement of cervix
545	Extension or metastasis to tunica serosa of corpus WITH involvement of cervix
550	Extension or metastasis to: Adnexa: Fallopian tube(s) Ovary(ies)

Code	Description
630	FIGO Stage IIIA
635	Extension or metastasis to: Ligaments: Broad Round Parametrium, NOS Visceral peritoneum of pelvic organs excluding serosa of corpus
640	Extension or metastasis to vagina
645	Extension to: Ureter Vulva
655	Extension or metastasis to: Pelvic wall(s) Parietal serosa of pelvic wall
660	Extension or metastasis to: Bladder wall Bladder, NOS excluding mucosa Rectal wall Rectum, NOS excluding mucosa
662	Described clinically as "frozen pelvis", NOS
663	(660 or 662) + (640 or 645)
665	FIGO Stage IIIB
680	FIGO Stage III [NOS] based on tumor extension (See Note 4.)
715	Extension to bowel mucosa or bladder mucosa (excluding bullous edema)
800	Further contiguous extension Abdominal serosa (visceral or parietal peritoneum of abdomen) Cul de sac (rectouterine pouch or Pouch of Douglas) Sigmoid colon Small intestine
810	FIGO Stage IVA
820	FIGO Stage IV [NOS] based on tumor extension (See Note 4.)
950	No evidence of primary tumor
999	Unknown; extension not stated Primary tumor cannot be assessed Not documented in patient record

- **Note 1**: When both FIGO stage and extension detail are available, record the code with extension detail in preference to a statement of FIGO stage.

- **Note 2:** FIGO no longer includes Stage 0 (Tis) for this site.
- **Note 3:** To assign a T2 category, stromal connective tissue of the cervix must be involved; endocervical glandular involvement only is not considered a T2 tumor in AJCC 7. Use 123, 133, 143, or 145 if endometrial or myometrial involvement is described.
- **Note 4:** FIGO IIIA and IIIB are extension, whereas FIGO IIIC is nodal involvement. FIGO IVA is extension, whereas FIGO IVB is distant metastasis. FIGO Stage III, NOS and FIGO Stage IV, NOS are assigned based on tumor extension and/or metastasis. Code CS Extension based on a physician"s statement of FIGO Stage III, NOS or FIGO Stage IV, NOS only if it is known that the stage value is assigned because of tumor extension.
- **Note 5:** Positive cytology is reported separately (CS Site Specific Factor 2), and is not included as a staging element for AJCC 7 staging. It is included as a staging element for AJCC 6 and Summary Stage. Since "cancer cells in ascites or in peritoneal washings" was not specifically categorized in the 1977 Summary Staging Guide, it is unclear to which stage previous cases may have been coded in that staging system.
- **Note 6:** According to the AJCC, extension to the bowel or bladder mucosa must be proven by biopsy in order to rule out bullous edema.

NUMBER OF REGIONAL LYMPH NODES POSITIVE & EXAMINED

ITEMS B-5 & B-6

1. Code: B-5 – Number of positive regional lymph nodes

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

B-6 – Number of regional lymph nodes examined

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

2. Description:

2.1 For information on which nodes are considered regional, refer to CS Lymph Nodes or to the AJCC Staging Manual 7th Edition.

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

NUMBER OF REGIONAL LYMPH NODES POSITIVE & EXAMINED (continued)

ITEMS B-5 & B-6

2.3 Code the number of regional lymph nodes positive in Item B-5 and the number of regional lymph nodes examined in Item B-6. Include all node dissections done during the first course of therapy.

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

2.5 If the number of nodes positive was 90 or greater, code Item B-5 as “90”. If the number of nodes examined was 90 or greater, code Item B-6 as “90”.

2.6 If lymph nodes were known to be positive, but the exact number is unknown, code Item B-5 as “97” and Item B-6 as “96”, “97”, or “98”.

2.7 If no regional lymph nodes were positive, and the number examined is at least one, but the total is unknown, code B-5 “00” and B-6 “96”, “97” or “98”.

2.8 If no regional node dissection was done, code Item B-5 “98” and B-6 “00”.

2.9 If it is unknown or not stated whether any nodes were either positive or examined, then code “99” in Items B-5 and B-6.

2.10 If there was no lymph node removal or aspiration, code Item B-6 “00 - No regional lymph nodes examined” and Item B-5 must be coded “98 - No nodes examined”.

2.11 If regional lymph nodes were aspirated, code Item B-5 either “00” for negative or “95” if positive and code Item B-6 as “95”.

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

METASTASIS AT DIAGNOSIS

ITEM B-7

1. Code

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

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

2. Description:

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

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

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

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

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

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

METASTASIS AT DIAGNOSIS (continued)

ITEM B-7

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

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

2.9 Refer to Section V of the SEER Manual for interpretation of ambiguous terminology.

3. **Specifics**

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

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

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

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

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

3.6 Other sites include distant involvement of sites other than bone, brain, distant lymph nodes, liver, and lung. It includes involvement of other more specific sites and more generalized metastasis (ex. Adrenal gland, bone marrow, pleura, peritoneum, malignant pleural effusion)

DATE OF CANCER-DIRECTED SURGERY TO PRIMARY SITE

ITEM B-8

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

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

2. Description:

2.1 Enter the date the first definitive Cancer-Directed Surgery to Primary Site was performed. Refer to the SEER Program Coding and Staging Manual Section VII for definition of first course of therapy. If the biopsy/aspiration was performed on the same day as definitive surgery, the biopsy date (Item B-1) and the Date of Cancer-Directed Surgery to Primary Site (Item B-8) will be the same.

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

2.3 If the patient or patient"s guardian refused cancer-directed surgery, code "77-77-7777 – Patient/guardian refused".

2.4 If cancer-directed surgery was recommended but it is unknown if it was done, code "96-96-9696 – Recommended, unknown if performed".

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

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

SITE-SPECIFIC SURGERY

ITEM B-9

1. Codes: Refer to the Corpus Uteri Surgery Codes

00 None; no cancer-directed surgery of primary site

19 Local tumor destruction or excision, NOS **(UNKNOWN if specimen sent to pathology)**

10 Local tumor destruction, NOS **(WITHOUT PATHOLOGY SPECIMEN)**
- 11 Photodynamic therapy (PDT)
- 12 Electrocautery; fulguration (includes use of hot forceps for tumor destruction)
- 13 Cryosurgery
- 14 Laser
- 15 Loop Electrocautery Excision Procedure (LEEP)

WITH PATHOLOGY SPECIMEN FOR CODES 20-79

20 Local tumor excision, NOS; simple excision, NOS
- 24 Excisional biopsy
- 25 Polypectomy
- 26 Myomectomy

Any combination of 20 or 24-26 WITH
- 21 Electrocautery
- 22 Cryosurgery
- 23 Laser ablation or excision

Note: margins of resection may have microscopic involvement

30 Subtotal hysterectomy/supracervical hysterectomy/fundectomy WITH or WITHOUT removal of tube(s) and ovary(ies).
- 31 WITHOUT tube(s) and ovary(ies)
- 32 WITH tube(s) and ovary(ies)

Note: For these procedures, the cervix is left in place

40 Total hysterectomy (simple, pan-) WITHOUT removal of tube(s) and ovary(ies)
Removes both the corpus and cervix uteri. It may also include a portion of the vaginal cuff.

50 Total hysterectomy (simple, pan-) WITH removal of tube(s) and/or ovary(ies)
Removes both the corpus and cervix uteri. It may also include a portion of the vaginal cuff.

60 Modified radical or extended hysterectomy; radical hysterectomy; extended radical hysterectomy
- 61 Modified radical hysterectomy
- 62 Extended hysterectomy

SITE-SPECIFIC SURGERY (continued)

ITEM B-9

63 Radical hysterectomy; Wertheim"s procedure
Note: Use code 63 for "Type III" hysterectomy
64 Extended radical hysterectomy

65 Hysterectomy, NOS, WITH or WITHOUT removal of tube(s) and ovary(ies)
71 WITHOUT removal of tube(s) and ovary(ies)
72 WITH removal of tube(s) and ovary(ies)

75 Pelvic exenteration
76 Anterior exenteration
Includes bladder, distal ureters, and genital organs WITH their ligamentous attachments and pelvic lymph nodes.
Note: Do not code removal of pelvic lymph nodes under Surgical Procedure/Other Site

77 Posterior exenteration
Includes rectum and rectosigmoid WITH ligamentous attachments and pelvic lymph nodes
Note: Do not code removal of pelvic lymph nodes under Surgical Procedure/Other Site

78 Total exenteration
Includes removal of all pelvic contents and pelvic lymph nodes
Note: Do not code removal of pelvic lymph nodes under Surgical Procedure/Other Site

79 Extended exenteration
Includes pelvic blood vessels or bony pelvis

90 Surgery, NOS

99 Unknown if cancer-directed surgery performed; death certificate ONLY

2. Description:

2.1 Code as directed in the Corpus Uteri surgery codes.

2.2 Code the most extensive surgery of the primary site.

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

DATE OF RADIATION TO PRIMARY SITE

ITEM B-10

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

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

2. Description:

2.1 Enter the date of first radiation to the primary site at any time following diagnosis.

2.2 If there was no radiation given, then code "00-00-0000 – No radiation".

2.3 If the patient/guardian refused radiation therapy, then code "77-77-7777 – Patient/guardian refused radiation".

2.4 If radiation was recommended, but it is unknown if it was given, then code "96-96-9696 – Recommended, unknown if given".

2.5 If it is unknown whether or not the patient had radiation therapy, then code "97-97-9797 – Unknown if given".

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

TYPE OF RADIATION TO PRIMARY SITE

ITEM B-11

1. Code:
0 – No radiation received
1 – Uterine brachytherapy
2 – Vaginal brachytherapy
3 – External beam radiation therapy (EBRT)
4 – EBRT + vaginal brachytherapy
5 – Other, specify type(s) and site(s) _____
8 – 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-10.

2.2 Code "1 – Uterine brachytherapy" when the patient received radiation therapy with placement of radioactive materials at the cancer site.

2.3 Code "2 – Vaginal brachytherapy" when the patient received radiation therapy through radioactive materials inserted into the vagina.

2.4 Code "3 – External beam radiation therapy" when the patient received radiation therapy from a machine outside of the body

2.5 Code "4 – EBRT + vaginal brachytherapy" when the patient received both EBRT and vaginal brachytherapy

2.6 Code "5 – Other" when the patient received a different kind of radiation or radiation to a different site(s). Specify the type(s) of radiation and site(s).

2.7 Code "8 – Radiation, type unknown" when the patient received radiation but the type of radiation is not specified.

RADIATION SEQUENCE WITH SURGERY

ITEM B-12

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.

2.2 Code “0 – No/unknown radiation and/or no/unknown cancer-directed surgery” when the patient did not receive radiation (Item B-10) and/or cancer directed surgery (Item B-8), or if it is unknown whether the patient received radiation and/or cancer-directed surgery (Item B-8 and/or B-10 are coded “00-00-000”, “77-77-7777”, “96-96-9696”, or “97-97-9797”).

2.3 Code "2 - Radiation before surgery" when the patient received radiotherapy prior to the most extensive cancer-directed surgery coded in Item B-8.

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

2.4 Code "3 - Radiation after surgery" when the patient received radiotherapy following the definitive surgery coded in Item B-8.

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

2.5 Code "4 - Radiation both before and after surgery" is used when the radiation therapy was given both prior to and following the definitive surgical resection coded in Item B-8.

2.6 Code "5 - Intraoperative radiation" when the patient received radiation directly to the tumor bed during the definitive surgical resection coded in Item B-8.

RADIATION SEQUENCE WITH SURGERY (continued)

ITEM B-12

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 definitive surgical resection coded in Item B-8.

2.8 Code “9 - Sequence unknown, but both surgery and radiation were given” when it is known that the patient received both surgery and radiation, but the order is unknown.

RADIATION SEQUENCE WITH SYSTEMIC THERAPY

ITEM B-13

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

Note:

Radiation and systemic therapy are concurrent if:

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

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

2. Description:

2.1 This item is used to record information on patients who were treated with BOTH radiation therapy and systemic therapy.

2.2 Code "0 - No/unknown radiation and/or no/unknown systemic therapy" when the patient did not receive radiation (Item B-10) and/or systemic therapy (Items B-15 to B-32), or if it is unknown whether the patient received radiation or systemic therapy (for example, Items B-15 to B-32 are coded "00-00-0000", "77-77-7777", "96-96-9696", or "97-97-9797").

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

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

RADIATION SEQUENCE WITH SYSTEMIC THERAPY (continued)

ITEM B-13

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

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

2.5 Code "4 - Radiation both before and after systemic therapy" is used when the radiation therapy was given both prior to and following the systemic therapy.

2.6 Code "5 - Concurrent radiation" is used when the patient received radiation during the time that she was also receiving systemic therapy.

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

2.8 Code “7 – Systemic therapy before and after radiation” when the patient received systemic therapy before and after radiation.

2.9 Code “8 – Concurrent radiation and systemic therapy with other systemic therapy given before and/or after radiation” when the patient received both 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 given” when it is known the patient received both systemic therapy and radiation but the sequence is unknown.

SYSTEMIC THERAPY SEQUENCE WITH SURGERY

ITEM B-14

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

2. Description:

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

2.2 Code "0 – No/unknown systemic therapy and/or no/unknown cancer-directed surgery" when systemic therapy (Items B-15 to B-32) and/or Cancer-Directed surgery status (Item B-8) 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-15 to B-32) prior to the most extensive cancer-directed surgery (Item B-8).

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-15 to B-32) following the definitive surgery (Item B-8).

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-15 to B-32) was given both prior to and following the definitive surgical resection (Item B-8).

2.6 Code "5 - Intraoperative systemic therapy" when the patient received systemic therapy (Items B15 - B32) during the cancer-directed surgical procedure (Item B-8).

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

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

SYSTEMIC THERAPY AGENTS

ITEMS B-15 through B-32

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

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

B-15 Aromatase Inhibitors (Anastrozole, Exemestane, Letrozole)

B-16 Bevacizumab (Avastin)

B-17 Carboplatin (Paraplat)

B-18 Cisplatin (CDDP, Platinol)

B-19 Docetaxel (Taxotere)

B-20 Doxorubicin (Adriamycin)

B-21 Everolimus (Afinitor)

B-22 Gonadotropin-Releasing Hormone (GnRH) agonists (Lupron, Trelstar, Zoladex)

B-23 Levonorgestrel IUD (Plan B)

B-24 Liposomal doxorubicin (Doxil)

B-25 Medroxyprogestone Acetate (Provera, Depo-provera)

SYSTEMIC THERAPY AGENTS (continued)

ITEMS B-15 through B-32

B-26 Megestrol acetate (Megace)

B-27 Nab-Paclitaxel (Abraxane)

B-28 Paclitaxel (Taxol)

B-29 Ridaforolimus (Deforolimus)

B-30 Tamoxifen (Nolvadex)

B-31 Temsirolimus (Torisel)

B-32 Other (specify)_____

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

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

2. Description:

2.1 Code month, day and year for all agents received at any time following diagnosis.

2.2 Code "00-00-0000 - Not given" for each agent not given to the patient. Also, use this code when the agent was considered or recommended, and it is known that the patient did not receive it. (See also "77-77-7777 - Refused".)

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

2.4 Code "96-96-9696 - Recommended, unknown if given" when a patient was recommended to receive an agent, but it is unknown if it was actually received. When therapy was recommended, but the agents used were not documented, all agents in Items B-15 through B-32 must be coded "96-96-9696 – Recommended, unknown if given".

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

SYSTEMIC THERAPY AGENTS (continued)

ITEMS B-15 through B-32

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

POC DATA ACQUISITION MANUAL

SECTION V

PANCREATIC CANCER DATA SET

SECTION V - PANCREATIC CANCER DATA SET CONTENTS

DATE OF FIRST POSITIVE BIOPSY/ASPIRATION

ITEM B-1

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	
.	.	
.	.	
12 - December	31	
77	77	7777 – Patient/guardian refused
96	96	9696 – Recommended, unk. 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 diagnosis of this tumor confirmed by biopsy or aspiration. This may be a biopsy of the primary site, lymph node or metastatic site that confirmed the diagnosis of pancreatic cancer. 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, code "00-00-0000" (unless the biopsy/aspiration was refused; see code "77-Refused").

2.3 Code the date the first biopsy/aspiration was performed. If the biopsy/aspiration was performed on the same day as definitive surgery, the biopsy date (Item B-1) and the Date of First Cancer-Directed Surgery to Primary Site (Item B-7) will be the same. The first positive biopsy/aspiration may have been done as an outpatient procedure, but must be no later than the Date of First Cancer-Directed Surgery to Primary Site.

2.4 If the patient or patient's guardian refused a biopsy or aspiration, code "77-77-7777 – Patient/guardian refused."

2.5 If a biopsy or aspiration was recommended but it is unknown if it was done, code "96-96-9696 – Recommended, unknown if performed."

2.6 If it is unknown whether a biopsy or aspiration was performed or recommended, code "97-97-9797 – Unknown."

DATE OF FIRST POSITIVE BIOPSY/ASPIRATION (continued)

ITEM B-1

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

3. Specifics:

3.1 Code the date of the procedure used to obtain the specimen, not the date of the pathology/cytology report.

3.2 Histologic diagnoses are based on 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 instead of tissues.

CA 19-9

ITEM B-2

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

2. Description:

2.1 No tumor-specific markers exist for pancreatic cancer. Markers such as serum cancer (CA) 19-9 have low specificity. CA 19-9 is known as Cancer antigen GI, CA GI, carbohydrate antigen 19-9, or CA 19-9. Most patients with pancreatic cancer will have an elevated CA 19-9 at diagnosis. However, it is not useful as a diagnostic or screening test for pancreatic cancer because there are non-cancerous conditions that cause elevated CA 19-9. CA 19-9 can be measured at any time and it is often measured more than once over time to follow tumor growth, response to treatment and recurrence. This item is concerned with whether the test was performed **at any time** NOT the test result.

2.2 Code "0 – Not performed/No mention" if there is no mention of the test being performed at any time in the medical record and there are no laboratory results for the test.

2.3 Code "1 – Performed" if there is evidence of the test being performed at any time in the medical record and or laboratory results.

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

SIZE OF PRIMARY TUMOR

ITEM B-3

1. Code:

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

Type of Staging (see notes below for further guidance)

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

2. Description:

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

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

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

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

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

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

a. Code the size from the synoptic report (also known as CAP protocol or pathology report checklist) when there is a discrepancy among tumor size measurements in the various sections of the pathology report.

SIZE OF PRIMARY TUMOR (continued)

ITEM B-3

b. Use final diagnosis, microscopic, or gross examination, in that order, when only a pathology report is available.

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

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

Note 3: The pathologic tumor size is recorded from the surgical resection specimen when surgery (including after neoadjuvant therapy) is administered as part of the first course treatment.

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

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

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

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

2.8 Refer to Section V for rules on rounding measurements, less than/greater than statements, priority order of reports and discrepancies between reports.

3. Examples:

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

METASTASIS AT DIAGNOSIS

ITEM B-4

1. Code

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

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

2. Description:

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

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

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

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

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

METASTASIS AT DIAGNOSIS (continued)

ITEM B-4

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

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

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

2.9 Refer to Section V of the SEER Manual for interpretation of ambiguous terminology.

3. **Specifics**

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

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

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

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

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

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

NUMBER OF REGIONAL LYMPH NODES POSITIVE AND EXAMINED

ITEMS B-5 & B-6

1. Code: B-5 – Number of positive regional lymph nodes

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

B-6 – Number of regional lymph nodes examined

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

2. Description:

2.1 For information on which nodes are considered regional, refer to CS Lymph Nodes or to the AJCC Staging Manual 7th Edition.

2.2 Record the number of regional nodes **examined by a pathologist** and found to contain metastasis. Code as appropriate for the location of the tumor within the pancreas.

2.3 Code the number of regional lymph nodes positive in Item B-5 and the number of regional lymph nodes examined in Item B-6. Include all node dissections done during the first course of therapy.

NUMBER OF REGIONAL LYMPH NODES POSITIVE AND EXAMINED (continued)

ITEMS B-5 & B-6

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

2.5 If the number of nodes positive was 90 or greater, code Item B-5 as "90". If the number of nodes examined was 90 or greater, code Item B-6 as "90".

2.6 If lymph nodes were known to be positive, but the exact number is unknown, code Item B-5 as "97" and Item B-6 as "96", "97", or "98".

2.7 If no regional lymph nodes were positive, and the number examined is at least one, but the total is unknown, code B-5 "00" and B-6 "96", "97" or "98".

2.8 If no regional node dissection was done, code Item B-5 "98" and B-6 "00".

2.9 If it is unknown or not stated whether any nodes were either positive or examined, then code "99" in Items B-5 and B-6.

2.10 If there was no lymph node removal or aspiration, code Item B-6 "00 - No regional lymph nodes examined" and Item B-5 must be coded "98 - No nodes examined". If regional lymph nodes were aspirated, code Item B-5 either "00" for negative or "95" if positive and code Item B-6 as "95".

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

DATE OF CANCER-DIRECTED SURGERY TO PRIMARY SITE

ITEM B-7

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

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

2. Description:

2.1 Enter the date the first definitive Cancer-Directed Surgery to Primary Site was performed. Refer to the SEER Program Coding and Staging Manual Section VII for definition of first course of therapy. If the biopsy/aspiration was performed on the same day as definitive surgery, the biopsy date (Item B-1) and the Date of Cancer-Directed Surgery to Primary Site (Item B-7) will be the same.

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

2.3 If the patient or patient's guardian refused cancer-directed surgery, code "77-77-7777 – Patient/guardian refused".

2.4 If cancer-directed surgery was recommended but it is unknown if it was done, code "96-96-9696 – Recommended, unknown if performed".

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

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

STENT

ITEM B-8

1. Code 0 - No
1 - Yes
9 - Unknown

2. Description:

2.1 Stents can be inserted to relieve blockages that occur as a result of the pancreatic cancer. If the biliary ducts become blocked, a thin tube may be inserted to help keep the duct open. Stents can be placed through the skin or during an endoscopic procedure.

2.2 If the patient had a stent placed, then code "1–Yes.".

2.3 If there is no indication that the patient had a stent placed, then code "0 – No."

2.4 If it is unclear whether the patient had a stent placed, then code "9 – Unknown."

SITE-SPECIFIC SURGERY

ITEM B-9

1. Codes: Refer to Pancreas Surgery Codes

00 None; no surgery of primary site; autopsy ONLY

25 Local excision of tumor, NOS

30 Partial pancreatectomy, NOS; example: distal

35 Local or partial pancreatectomy and duodenectomy

- 36 WITHOUT distal/partial gastrectomy
- 37 WITH partial gastrectomy (Whipple)

40 Total pancreatectomy

60 Total pancreatectomy and subtotal gastrectomy or duodenectomy

70 Extended pancreatoduodenectomy

80 Pancreatectomy, NOS

90 Surgery, NOS

99 Unknown if surgery performed; death certificate ONLY

[Note: Assign code 90 for NanoKnife, or irreversible electroporation (IRE)]

2. Description:

2.1 Code the most extensive surgery of the primary site as directed in the Pancreas Surgery Codes.

2.2 The surgery code should reflect the surgical procedure that was actually done as described in the body of the surgeon/operative report rather than relying only on the name of the procedure.

Example: If a surgical procedure is called a “whipple” but the description in the surgeon/operative report only includes pancreatectomy and duodenectomy, use code 36.

LAPAROSCOPIC SURGERY

ITEM B-10

1. Code:
0 – No surgical removal of tissue
1 – Yes, laparoscopic tissue removal
2 – Open surgical procedure to remove tissue
9 – Unknown

2. Description:

2.1 This item refers to surgery of the primary site. An individual may have surgery performed via laparoscope. This is performed using scopes and instruments inserted through very small incisions instead of the more typical surgery in which there is a large surgical opening (laparotomy).

2.2 Code "0 – No surgical removal of tissue" if the patient did not have surgery to remove tissue from the primary site.

2.3 Code "1 – Yes, surgery performed laparoscopically" if the patient had their surgery performed laparoscopically.

2.4 Code "2 – Open surgical procedure" if the patient had the typical surgery with one incision large enough for the surgeon to view the organs/fields necessary. If there is no mention in the operative report that the surgery was performed laparoscopically, then code "2 – Open surgical procedure".

2.5 Code "9 – Unknown" if it is unclear from the operative report how the surgery was performed.

2.6 If the patient had non-surgical treatment, such as photodynamic therapy, then code "0 – No surgical removal of tissue".

PATHOLOGICAL MARGINS

ITEM B-11

1. Code:
0 – No cancer-directed surgery
1 – Margins of resection free of tumor
2 – Pathology report indicates tumor at margins of resection
3 – Margins not stated in pathology report; surgeon indicates no residual tumor
4 – No mention in pathology report; surgical report indicates tumor at margins of resection, or residual tumor in area of primary tumor
9 – Unknown, not stated

2. Description:

2.1 Code status of pathological margins from the pathology report of the most extensive surgical procedure performed during the first course of therapy (Item B-7).

2.2 Code "0 - No cancer-directed surgery" when no resection was performed.

2.3. If there was a more extensive surgery following an excisional biopsy, and there was no residual in the resection specimen, code "1 - Margins of resection free of tumor".

2.4 Code "2 – Tumor at margins of resection" when the pathology report shows 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 pathological margin status, but the surgeon states in the operative report that no tumor was left in the area from which the primary tumor was resected.

2.6 Code "4 – No mention in pathology report; surgical report indicates tumor at margins" when there is no mention of the margins in the pathology report but the surgical report indicates tumor at the margins of resection or there is residual tumor in the area of the primary tumor.

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.

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

2.9 If Item B-7 is coded "Unknown whether surgery performed", then code pathological margins as "9 - Unknown".

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DATE OF RADIATION TO PRIMARY SITE

ITEM B-12

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

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

2. Description:

2.1 Enter the date of first radiation to the primary site at any time following diagnosis.

2.2 If there was no radiation given, then code "00-00-0000 – No radiation".

2.3 If the patient/guardian refused radiation therapy, then code "77-77-7777 – Patient/guardian refused radiation".

2.4 If radiation was recommended, but it is unknown if it was given, then code "96-96-9696 – Recommended, unknown if given".

2.5 If it is unknown whether or not the patient had radiation therapy, then code "97-97-9797 – Unknown if given".

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

RADIATION SEQUENCE WITH SURGERY

ITEM B-13

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.

2.2 Code "0 – No/unknown radiation and/or no/unknown cancer-directed surgery" when the patient did not receive radiation (Item B-12) and/or cancer directed surgery (Item B-7), or if it is unknown whether the patient received radiation or cancer-directed surgery (e.g. Item B-7 is coded "00-00-000", "77-77-7777", "96-96-9696", or "97-97-9797").

2.3 Code "2 - Radiation before surgery" when the patient received radiotherapy prior to the most extensive cancer-directed surgery coded in Item B-7.

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

2.4 Code "3 - Radiation after surgery" when the patient received radiotherapy following the definitive surgery coded in Item B-7.

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

2.5 Code "4 - Radiation both before and after surgery" when the radiation therapy was given both prior to and following the definitive surgical resection coded in Item B-7.

2.6 Code "5 - Intraoperative radiation" when the patient received radiation therapy directly to the tumor bed during the definitive surgical resection coded in Item B-7.

RADIATION SEQUENCE WITH SURGERY (continued)

ITEM B-13

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 definitive surgical resection coded in Item B-7.

2.8 Code “9 – Sequence unknown, but both surgery and radiation were given” when it is known that patient received both surgery and radiation but the order is unknown.

RADIATION SEQUENCE WITH SYSTEMIC THERAPY

ITEM B-14

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 or after systemic therapy
7 – Systemic therapy before and after radiation
8 – Concurrent radiation and systemic therapy with other systemic therapy given before and/or after radiation
9 – Sequence unknown, but both systemic therapy and radiation were given

Note:
Radiation and systemic therapy are concurrent if:

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

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

2. Description:

2.1 This item is used to record information on patients who were treated with BOTH radiation therapy and systemic therapy.

2.2 Code "0 – No/unknown radiation and/or no/unknown systemic therapy" when the patient did not receive radiation (Item B-12) and/or systemic therapy (Items B-16 through B-34), or if it is unknown whether the patient received radiation or systemic therapy (for example, all systemic therapy agents are coded "00-00-0000", "77-77-7777", "96-96-9696", or "97-97-9797").

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

For example: A patient with a biopsy, followed by radiation, followed by 5-FU, is coded "2 - Radiation before systemic therapy".

RADIATION SEQUENCE WITH SYSTEMIC THERAPY (continued)

ITEM B-14

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

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

2.5 Code "4 - Radiation both before and after systemic therapy" is used when the radiation therapy was given both prior to and following the systemic therapy.

2.6 Code "5 - Concurrent radiation" is used when the patient received radiation therapy during the time he/she was also receiving systemic therapy.

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

2.8 Code "7 – Systemic therapy before and after radiation" when the patient received systemic therapy before and after radiation.

2.9 Code "8 – Concurrent radiation and systemic therapy with other systemic therapy given before and/or after radiation" when the patient received both 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 given" when it is known the patient received both systemic therapy and radiation but the sequence is unknown.

SYSTEMIC THERAPY SEQUENCE WITH SURGERY

ITEM B-15

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

2. Description:

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

2.2 Code "0 – No/unknown systemic therapy and/or no/unknown cancer-directed surgery" when systemic therapy (Items B-16 to B-34) and/or Cancer-Directed surgery status (Item B-7) 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-16 to B-34) prior to the most extensive cancer-directed surgery (Item B-7).

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-16 to B-34) following the definitive surgery (Item B-7).

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-16 to B-34) was given both prior to and following the definitive surgical resection (Item B-7).

2.6 Code "5 - Intraoperative systemic therapy" when the patient received systemic therapy (Items B16 - B34) during the cancer-directed surgical procedure (Item B-7).

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

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

SYSTEMIC THERAPY AGENTS

ITEMS B-16 through B-34

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

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

B-16 Capecitabine (Xeloda)

B-17 CAPOX

B-18 Cisplatin (CDDP, Platinol)

B-19 Docetaxel (Taxotere)

B-20 Erlotinib (Tarceva)

B-21 Everolimus (Afinitor)

B-22 Fluorouracil (5-FU)

B-23 FOLFIRINOX

B-24 FOLFOX

B-25 Folinic Acid (Leucovorin)

B-26 Gemcitabine (Gemzar)

B-27 Irinotecan (Camptosar)

B-28 Irinotecan Liposomal (Onivyde)

B-29 Mitomycin C (Mutamycin)

B-30 Nab-Paclitaxel (Abraxane)

B-31 Oxaliplatin

B-32 Paclitaxel (Taxol)

B-33 Sutinib Malate (Sutent)

B-34 Other, specify: _____

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

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

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

2. Description:

2.1 Code month, day and year for all systemic therapy agents received at any time following diagnosis of pancreatic cancer.

2.2 Code "00-00-0000 - Not given" when the patient did not receive the systemic therapy agents. Also use this code when the systemic therapy agent was considered or recommended, and it is known that the patient did not receive it. If the patient or patient's guardian refused systemic therapy, see code "77-77-7777 - Patient or patient's guardian refused systemic therapy".

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

2.4 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 in Items B-16 through B-34 must be coded "96-96-9696 - Unknown if given".

SYSTEMIC THERAPY AGENTS (continued)

ITEMS B-16 through B-34

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

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

POC DATA ACQUISITION MANUAL

SECTION VI

HEAD AND NECK CANCER DATA SET

CONTENTS

DATE OF FIRST POSITIVE BIOPSY/ASPIRATION

ITEM B-1

1. Code: MM-DD-YYYY

Month	Day	Year
00	00	0000 – Not given
01 - January	01	Use 4-digit year
02 - February	02	
.	.	.
.	.	.
12 - December	31	
99 - Month Unknown	99 - Day Unknown	9999 - Year Unknown

2. Description:

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

2.2 Code the date the first biopsy/aspiration was performed. If the biopsy/aspiration was performed on the same day as definitive surgery, the biopsy date (Item B-1) and the Date of First Cancer-Directed Surgery to Primary Site (Item B-8) will be the same. The first positive biopsy/aspiration may have been done as an outpatient procedure, but must be no later than the Date of First Cancer-Directed Surgery to Primary Site.

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

3. Specifics:

3.1 Code the date of the procedure used to obtain the specimen, not the date of the pathology/cytology report.

3.2 Histologic diagnoses are based on microscopic examination of tissue specimens from biopsy, fine needle aspiration (including aspiration biopsy) and surgical specimens.

3.3 Cytologic diagnoses are based upon microscopic examination of cells, instead of tissues. Aspiration biopsies may be done on the primary site and/or lymph nodes.

SIZE OF PRIMARY TUMOR

ITEM B-2

1. Code:

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

Type of Staging (See notes below for further guidance)

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

2. Description:

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

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

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

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

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

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

a. Code the size from the synoptic report (also known as CAP protocol or pathology report checklist) when there is a discrepancy among tumor size measurements in the various sections of the pathology report.

SIZE OF PRIMARY TUMOR (continued)

ITEM B-2

b. Use final diagnosis, microscopic, or gross examination, in that order, when only a pathology report is available.

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

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

Note 3: The pathologic tumor size is recorded from the surgical resection specimen when surgery (including after neoadjuvant therapy) is administered as part of the first course treatment.

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

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

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

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

2.8 Refer to Section V for rules on rounding measurements, less than/greater than statements, priority order of reports and discrepancies between reports.

3. Examples:

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

REGIONAL LYMPH NODES

ITEM B-3

1. Code:
0 – No regional lymph node involvement
1 – Single ipsilateral lymph node
2 – Multiple ipsilateral lymph nodes
3 – Single contralateral or bilateral lymph node
4 – Multiple contralateral or bilateral lymph nodes
5 – Ipsilateral lymph node, not stated if single or multiple
6 – Single lymph node; not stated if ipsilateral, bilateral, or contralateral
7 – Multiple lymph nodes; not stated if ipsilateral, bilateral, or contralateral
8 – Regional lymph nodes involved, unknown laterality and/or unknown number of involved nodes
9 – Unknown; Not applicable

Type of Staging

Clinical – regional lymph node status **before** definitive treatment

Pathologic – For head and neck cancer, pathologic lymph node status requires resection of the primary tumor

2. Description:

2.1 Refer to Section V of the SEER Program Coding and Staging Manual for more information on clinical vs pathologic evaluation of regional nodes and terms of involvement. **Code information about both clinical and pathologic lymph nodes for each patient.**

2.2 Staging of head and neck cancer includes detailed information not only about whether regional lymph nodes are positive, but also the size of the lymph nodes and whether the lymph nodes were positive only on one side or on both. All of this information will be used to stage the patient.

2.3 Clinical lymph node status is based on all clinical evaluations done *prior* to definitive therapy, including surgery. Clinical evaluation includes: physical examination, imaging examination or other non-invasive clinical evidence, endoscopic examination, diagnostic biopsy, including fine needle aspiration biopsy, excision of regional or sentinel lymph nodes without removal of the primary tumor, or invasive techniques, including surgical observation without biopsy. Information on regional lymph nodes from imaging/radiographic techniques can be used to assign clinical N.

2.4 Pathologic lymph node status is based on all clinical evaluations done prior to definitive surgery, plus all information through completion of definitive surgery(ies) in the first course of treatment. When pathologic T is available, any microscopic evaluation of lymph nodes is pathologic except for excision of a lymph node when there is no resection of the primary site.

REGIONAL LYMPH NODES (continued)

ITEM B-3

2.5 For information on which nodes are considered regional for Head and Neck, refer to CS Lymph Nodes or to the AJCC Staging Manual 7th Edition.

2.6 For pathologic lymph nodes status, if there is discrepancy between clinical information and pathologic information about the same lymph nodes, pathologic information takes precedence if no neoadjuvant (preoperative) treatment was given.

2.7 If all regional lymph nodes are negative, code "0 – No regional lymph node involvement".

2.8 If a single ipsilateral lymph node is involved, code "1 – Single ipsilateral lymph node".

2.9 If multiple ipsilateral lymph nodes are involved, code "2 – Multiple ipsilateral lymph nodes".

2.10 If a single contralateral or bilateral lymph node is involved, code "3 – Single contralateral or bilateral lymph node".

2.11 If multiple contralateral or bilateral lymph nodes are involved, code "4 – Multiple contralateral or bilateral lymph nodes".

2.12 If there is ipsilateral lymph node involvement but the number of nodes is unknown, code "5 – Ipsilateral lymph node involvement; not stated if single or multiple".

2.13 If an ipsilateral lymph node is involved but laterality is unknown, code "6– Single lymph node; not stated if ipsilateral, bilateral, or contralateral".

2.14 If multiple lymph nodes are involved but laterality is unknown, code "7 – Multiple lymph nodes; not stated if ipsilateral, bilateral, or contralateral".

2.15 If lymph nodes are involved, but it is unknown if they are ipsilateral or bilateral and/or it is unknown if a single node is involved or multiple nodes are involved, code "8 – Regional lymph nodes involved, unknown laterality and/or unknown number of involved nodes".

2.16 If there is no clinical or pathologic information available regarding the regional lymph nodes, code "9 –Unknown; Not Applicable".

SIZE OF REGIONAL LYMPH NODES

ITEM B-4

1. Code:

000	No regional lymph nodes involved
001-979	Actual size of lymph nodes in mm (Exact size of lymph node to nearest mm)
980	980 millimeters or larger
990	Microscopic focus or foci only and no size of focus given
991	Described as "less than 1 centimeter (cm)"
992	Described as "less than 2cm" or "greater than 1cm" or "between 1cm and 2cm"
993	Described as "less than 3cm" or "greater than 2cm" or "between 2cm and 3cm"
994	Described as "less than 4cm" or "greater than 3cm" or "between 3cm and 4cm"
995	Described as "less than 5cm" or "greater than 4cm" or "between 4cm and 5cm"
996	Described as "less than 6cm" or "greater than 5cm" or "between 5cm and 6cm"
997	Described as "more than 6cm"
998	No resection of the primary tumor was performed
999	Regional lymph node(s) involved, size not stated; Unknown if regional lymph nodes involved; Not documented in patient record

2. Description:

2.1 Staging of head and neck cancer includes detailed information not only about whether regional lymph nodes were positive, but also the size of the lymph nodes and whether the lymph nodes were positive only on one side or on both will be used to stage the patient.

2.2 Code the **largest diameter** of any involved regional lymph node based on positive **pathologic confirmation**. For head and neck cancer pathologic lymph node status requires resection of the primary tumor.

2.3 When pathologic T is available, any microscopic evaluation of lymph nodes is pathologic except for excision of a lymph node when there is no resection of the primary site.

2.4 For pathologic N, record the size of the metastasis if known. If the size of the metastasis is not known, record the size of the entire lymph node.

2.5 If the size given is described only as a mass or nodule, record the size of the mass or nodule.

SIZE OF REGIONAL LYMPH NODES (continued)

ITEM B-4

2.6 For information on which nodes are considered regional for Head and Neck, refer to CS Lymph Nodes or to the AJCC Staging Manual 7th Edition.

2.7 If all regional lymph node(s) were negative, code "000 – No regional lymph nodes involved".

2.8 Code the **greatest dimension** of involved regional lymph node(s). Code the actual size reported in the medical records.

2.9 If the lymph node(s) size was described in terms of "more than, less than", use the appropriate code 991 – 996.

2.10 If the lymph node(s) was described in terms of "greater than 6 cm", use code "997 – Described as more than 6 cm".

2.11 If the primary head and neck tumor was not resected, use code "998- no resection of the primary tumor performed."

2.12 If the size of the lymph node(s) was not stated, use code "999 – Size not stated, Unknown if nodes involved, not documented in the patient record".

NUMBER OF REGIONAL LYMPH NODES POSITIVE & EXAMINED

ITEMS B-5 & B-6

1. Code: B-5 – Number of positive regional lymph nodes

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

B-6 – Number of regional lymph nodes examined

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

2. Description:

2.1 For information on which nodes are considered regional for Head and Neck, refer to CS Lymph Nodes or to the AJCC Staging Manual 7th Edition.

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

NUMBER OF REGIONAL LYMPH NODES POSITIVE & EXAMINED (continued)

ITEMS B-5 & B-6

2.3 Code the number of regional lymph nodes positive in Item B-5 and the number of regional lymph nodes examined in Item B-6. Include all node dissections done during the first course of therapy.

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

2.5 If the number of nodes positive was 90 or greater, code Item B-5 as"90". If the number of nodes examined was 90 or greater, code Item B-6 as "90".

2.6 If lymph nodes were known to be positive, but the exact number is unknown, code Item B-5 as "97" and Item B-6 as "96", "97", or "98".

2.7 If no regional lymph nodes were positive, and the number examined is at least one, but the total is unknown, code B-5 "00" and B-6 "96", "97" or "98".

2.8 If no regional node dissection was done, code Item B-5 "98" and B-6 "00".

2.9 If it is unknown or not stated whether any nodes were either positive or examined, then code "99" in Items B-5 and B-6.

2.10 If there was no lymph node removal or aspiration, code Item B-6 "00 - No regional lymph nodes examined" and Item B-5 must be coded "98 - No nodes examined". If regional lymph nodes were aspirated, code Item B-5 either "00" for negative or "95" if positive and code Item B-6 as "95".

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

METASTASIS AT DIAGNOSIS

ITEM B-7

1. Code

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

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

2. Description:

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

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

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

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

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

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

METASTASIS AT DIAGNOSIS (continued)

ITEM B-7

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

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

2.9 Refer to Section V of the SEER Manual for interpretation of ambiguous terminology.

3. **Specifics**

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

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

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

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

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

3.6 Other sites include distant involvement of sites other than bone, brain, distant lymph nodes, liver, and lung. It includes involvement of other more specific sites and more generalized metastasis (ex. Adrenal gland, bone marrow, pleura, peritoneum, malignant pleural effusion)

DATE OF CANCER-DIRECTED SURGERY TO PRIMARY SITE

ITEM B-8

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

Month	Day	Year
00	00	0000 – Not performed
01 - January	01	Use 4-digit year
02 - February	02	
.	.	.
.	.	.
12 - December	31	
77	77	7777 - Patient/guardian refused surgery
96	96	9696 - Recommended, unk. 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 on which the most definitive cancer-directed surgery to primary site was performed. Refer to the SEER Program Coding and Staging Manual Section VII for definition of first course of therapy. If the biopsy/aspiration was performed on the same day as definitive surgery, the biopsy date (Item B-1) and the Date of Cancer-Directed Surgery to Primary Site (Item B-8) will be the same.

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

2.3 If the patient or patient's guardian refused cancer-directed surgery, code "77-77-7777 – Patient/guardian refused".

2.4 If cancer-directed surgery was recommended but it is unknown if it was done, code "96-96-9696 – Recommended, unknown if performed".

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

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

SITE-SPECIFIC SURGERY

ITEM B-9

1. Code:
00 – No surgery of the primary site performed
10 – 90 Site-specific surgery codes
99 – Unknown if surgery performed

2. Description:

2.1 Refer to Appendix C of the SEER Manual for site-specific surgery of primary site codes.

2.2 If surgery of the primary site was not performed, code "00 – No surgery of primary site".

2.3 Use codes 10-90 to assign the site-specific surgery of the primary site code.

2.4 If it is unknown if surgery of the primary site was performed, code "99 – Unknown".

PATHOLOGICAL MARGINS

ITEM B-10

1. Code:
0 – No cancer-directed surgery
1 – Margins of resection pathologically free of tumor
2 – Pathology report indicates tumor at margins of resection
3 – Margins not stated in pathology report; surgeon indicates no residual tumor
4 – No mention in pathology report; surgical report indicates tumor at margins of resection, or residual tumor in area of primary tumor
9 – Unknown, not stated

2. Description:

2.1 Code status of pathologic margins from the pathology report of the most extensive procedure performed during the first course of therapy (Item B-8).

2.2 Code "0 - No cancer-directed surgery" when no resection was performed.

2.3 If there was more extensive surgery than excisional biopsy, and there was no residual in the resection specimen, code "1 - Margins of resection pathologically free of tumor".

2.4 Code "2 - Tumor at margins of resection" 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 from which the primary tumor was resected.

2.6 Code "4 – No mention in pathology report; surgical report indicates tumor at margins" when there is no mention of the margins in the pathology report but the surgical report indicates tumor at the margins of resection or there is residual tumor in the area of the primary tumor.

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.

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

2.9 If Item B-8 is coded "Unknown whether surgery performed", then code pathological margins as "9 - Unknown".

DATE OF RADIATION TO PRIMARY SITE

ITEM B-11

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

Month	Day	Year
00	00	0000 – No radiation
01 - January	01	Use 4-digit year
02 - February	02	
.	.	.
.	.	.
12 - December	31	
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 date of first radiation to the primary site at any time following diagnosis.

2.2 If there was no radiation given, then code "00-00-0000 – No radiation".

2.3 If the patient/guardian refused radiation therapy, then code "77-77-7777 – Patient/guardian refused radiation".

2.4 If radiation was recommended, but it is unknown if it was given, then code "96-96-9696 – Recommended, unknown if given".

2.5 If it is unknown whether or not the patient had radiation therapy, then code "97-97-9797 – Unknown if given".

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

RADIATION HYPERFRACTIONATION

ITEM B-12

1. Code:
0 – No external beam radiation given
1 – Usual External Beam radiation
2 – Conventional Hyperfractionation (twice per day)
3 – Accelerated Hyperfractionation (more than twice/day)
4 – Radiation given, unknown if hyperfractionated
7 – Patient/guardian refused radiation hyperfractionation
8 – Radiation hyperfractionation recommended, unknown if administered
9 – Unknown

2. Description:

2.1 Hyperfractionation is a method of giving radiation therapy in smaller-than-usual doses two or three times a day instead of once a day. This is done with external beam radiation.

2.2 Code "0 – No external beam radiation given" if no external beam radiation was used.

2.3 Code "1 – Usual external beam radiation" for external beam radiation directed to cancer tissue in the usual manner, once per day, regardless of source of radiation.

2.4 Code "2 – Conventional hyperfractionation" when the radiation therapy is given twice per day.

2.5 Code "3 – Accelerated hyperfractionation" when the radiation is given more than twice per day.

2.6 Code "4 – Radiation given, unknown if hyperfractionated" when the patient received radiation, but it is not known whether it is hyperfractionated radiation.

2.7 Code "7 – Patient/guardian refused" when the patient or patient's guardian refused radiation hyperfractionation therapy.

2.8 Code "8 – Recommended, unknown if administered" when it is known that radiation hyperfractionation therapy was recommended, but it is unknown if it was given.

2.9 Code "9 – Unknown" when it is unknown if radiation or hyperfractionation of radiation therapy was recommended AND unknown if given.

TYPE OF RADIATION

ITEM B-13

1. Code:
0 – No radiation given
1 – External beam radiation therapy (EBT), NOS
2 – Intensity-modulated radiation therapy (IMRT)
3 – Image-guided radiation therapy (IGRT)
4 – Three-Dimensional Conformal Radiation Therapy (3D-CRT)
5 – 4-D radiation therapy (4D)
6 – IGRT and IMRT
7 – Other (specify)_____
9 – Unknown

2. Description:

2.1 Radiation therapy is often given to patients with head and neck cancer. The standard EBT is the most common. However, newer treatments are increasing.

2.2 Code the type of radiation given for the treatment of head and neck cancer.

2.3 IMRT is an advanced mode of high-precision radiotherapy that utilizes computer-controlled x-ray accelerators to deliver precise radiation doses to a malignant tumor or specific areas within the tumor. The radiation dose is designed to conform to the three-dimensional (3-D) shape of the tumor by modulating—or controlling—the intensity of the radiation beam to focus a higher radiation dose to the tumor while minimizing radiation exposure to surrounding normal tissues. Code "2 – IMRT" if the patient received intensity-modulated radiation therapy.

2.4 Radiation oncologists use IGRT, to help better deliver the radiation to the cancer since tumors can move between treatments due to differences in organ filling or movements while breathing. IGRT involves conformal radiation treatment guided by imaging, such as CT, ultrasound or X-rays, taken in the treatment room just before the patient is given the radiation treatment. All patients first undergo a CT scan as part of the planning process. The imaging information from the CT scan is then transmitted to a computer in the treatment room to allow doctors to compare the earlier image with the images taken just before treatment. During IGRT, doctors compare these images to see if the treatment needs to be adjusted. This allows doctors to better target the cancer while avoiding nearby healthy tissue. In some cases, doctors will implant a tiny marker in or near the tumor to pinpoint it for IGRT. Code "3 – IGRT" if patient received image-guided radiation therapy.

TYPE OF RADIATION (continued)

ITEM B-13

2.5 Tumors are not regular — they come in different shapes and sizes. 3D-CRT, uses computers and special imaging techniques to show the size, shape and location of the tumor. Computer assisted tomography (CT or CAT scans), magnetic resonance imaging (MR or MRI scans) and/or positron emission tomography (PET scans) are used to create detailed, three-dimensional representations of the tumor and surrounding organs. The radiation oncologist can then precisely tailor the radiation beams to the size and shape of the tumor with multileaf collimators or custom fabricated field shaping blocks. Because the radiation beams are very precisely directed, nearby normal tissue receives less radiation and can heal quickly. Code "4 – 3D - Conformal" if patient received 3D conformal radiation therapy.

2.6 4-D radiation therapy also considers the movement of a tumor with respiration. This technique and requires CT scans for the planning of the therapy. 4-D radiation therapy is synchronized with respiration-induced motion and therefore delivers a dose more exactly to the tumor. Code "5 – 4D" if patient received 4D radiation therapy.

2.7 If IGRT and IMRT were both used, code "6 – IGRT and IMRT."

2.8 If more than one type of radiation therapy other than IGRT and IMRT was provided, then code the dominant modality.

2.9 Code "7 – Other" if the patient had another type of radiation therapy and specify the type of therapy the patient received.

2.10 Code "9 – Unknown, not stated" when the patient received radiation therapy but type of radiation given cannot be determined.

RADIATION SEQUENCE WITH SURGERY

ITEM B-14

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.

2.2 Code "0 – No/unknown radiation and/or no/unknown cancer-directed surgery" when the patient did not receive radiation (Item B-11) and/or cancer directed surgery (Item B-8), or if it is unknown whether the patient received radiation or cancer-directed surgery (Item B-8 and/or B-11 are coded "00-00-000", "77-77-7777", "96-96-9696", or "97-97-9797").

2.3 Code "2 - Radiation before surgery" when the patient received radiotherapy prior to the most extensive cancer-directed surgery coded in Item B-8.

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

2.4 Code "3 - Radiation after surgery" when the patient received radiotherapy following the definitive surgery coded in Item B-8.

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

2.5 Code "4 - Radiation both before and after surgery" when the radiation therapy was given both prior to and following the definitive surgical resection coded in Item B-8.

2.6 Code "5 - Intraoperative radiation" when the patient received radiation therapy directly to the tumor bed during the definitive surgical resection coded in Item B-8.

RADIATION SEQUENCE WITH SURGERY (continued)

ITEM B-14

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 definitive surgical resection coded in Item B-8.

2.8 Code “9 - Sequence unknown, but both surgery and radiation were given” when it is known that the patient received both surgery and radiation, but the order is unknown.

RADIATION SEQUENCE WITH SYSTEMIC THERAPY

ITEM B-15

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

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

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

2. Description:

2.1 This item is used to record information on patients who were treated with BOTH radiation therapy and systemic therapy.

2.2 Code "0 – No/unknown radiation and/or no/unknown systemic therapy" when the patient did not receive radiation (Item B-11) and/or systemic therapy (Items B-17 through B-41), or if it is unknown whether the patient received radiation or systemic therapy (for example, Items B-17 through B-41are coded "00-00-0000", "77-77-7777", "96-96-9696", or "97-97-9797").

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

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

RADIATION SEQUENCE WITH SYSTEMIC THERAPY (continued)

ITEM B-15

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

For example: A patient who had a biopsy, followed by systemic therapy, then treated with radiation therapy would be coded "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.

2.6 Code "5 - Concurrent radiation and systemic therapy" when the patient received radiation during the time that he/she was also receiving systemic therapy.

2.7 Code "6 - Concurrent radiation and systemic therapy with other radiation given before and/or after systemic therapy" when the patient received both 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.

2.9 Code "8 - Concurrent radiation and systemic therapy with other systemic therapy given before and/or after radiation" when the patient received both 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 systemic therapy and radiation but the sequence is unknown.

SYSTEMIC THERAPY SEQUENCE WITH SURGERY

ITEM B-16

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

2. Description:

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

2.2 Code "0 – No/unknown systemic therapy and/or no/unknown cancer-directed surgery" when the patient did not receive systemic therapy (Items B-17 through B-41) and/or cancer directed surgery (Item B-8), or if it is unknown whether the patient received systemic therapy or cancer-directed surgery (e.g. Item B-8 is coded "00-00-000", "77-77-7777", "96-96-9696", or "97-97-9797").

2.3 Code "2 – Systemic therapy before surgery" when the patient received systemic therapy coded in Items B-17 through B-41prior to the most definitive cancer-directed surgery coded in Item B-8.

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

2.4 Code "3 – Systemic therapy after surgery" when the patient received systemic therapy coded in Items B-17 through B-41, following the definitive surgery coded in Item B-8.

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

2.6 Code "5 - Intraoperative systemic therapy" when the patient received systemic therapy (Items B17 – B41) during the cancer-directed surgical procedure (Item B-8).

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

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

SYSTEMIC THERAPY AGENTS

ITEMS B-17 through B-41

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

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

B-17 Afatinib (Gilotrif)

B-18 Bevacizumab (Avastin)

B-19 Bleomycin (Blenoxane)

B-20 Capecitabine (Xeloda)

B-21 Carboplatin (Paraplat)

B-22 Cetuximab (Erbitux)

B-23 Cisplatin (Platinol)

B-24 Cyclophosphamide (Cytoxan)

B-25 Docetaxel (Taxotere)

B-26 Doxorubicin (Adriamycin)

B-27 Epirubicin (Ellence)

B-28 Fluorouracil (5-FU)

SYSTEMIC THERAPY AGENTS (continued)

ITEMS B-17 through B-41

B-29 Gemcitabine (Gemzar)

B-30 Hydroxyurea (Hydrea)

B-31 Ifosfamide (Ifex)

B-32 Isotretinoin (Accutane)

B-33 Leucovorin (Citrovorum factor)

B-34 Methotrexate (Abitrexate)

B-35 Nab-Paclitaxel (Abraxane)

B-36 Nivolumab (Opdivo)

B-37 Paclitaxel (Taxol)

B-38 Pembrolizumab (Keytruda)

B-39 Vinblastine (Velban)

B-40 Vinorelbine (Navelbine)

B-41 Other, specify: _____

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

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

2. Description:

2.1 Code the month, day, and year when a particular systemic therapy agent was first given at any time following the diagnosis of head and neck cancer. These questions refer to therapy which is administered for head and neck cancer. (Include dates of ancillary drugs Isotretinoin and Leucovorin).

SYSTEMIC THERAPY AGENTS (continued)

ITEMS B-17 through B-41

2.2 Code the date as “00-00-0000 - Not given” when the patient did not receive systemic therapy following the diagnosis of head and neck cancer, unless the patient or patient's guardian refused systemic therapy. (See also code “77-77-7777 - Refused.”)

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

2.4 Code “96-96-9696 - Recommended, unknown if given” when a patient was recommended to receive a systemic agent, but it is unknown if it was actually received. When systemic therapy was recommended, but the treatment agents used were not documented, all agents in Items B-17 through B-41 must be coded “96-96-9696 - Recommended, unknown if given.”

2.5 Code “97-97-9797 – Unknown if agent given” when there is no documentation regarding systemic therapy recommendation or receipt in the medical records 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 in history and physical, the physician states the patient had Cisplatin beginning two weeks ago, code date of first Cisplatin as 14 days prior to that date. If the record states that the Cisplatin was given recently, code the month and year, but not the day. Code the day as “99.” Coding the closest date approximation is preferable to coding unknown.

SMOKING

ITEM B-42

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-42

2. Description

2.1 This item is to be coded for **any information** known about the patient's **cigarette** 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. **Cigars should not be coded in this item.**

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 the individual smoked 40 cigarettes/day for 10 years, then code *02.0* packs in the packs/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", 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."

2.10 If only a range is given (1-2 packs per day), code the highest number in the range.

HUMAN PAPILLOMA VIRUS (HPV)

ITEM B-43

1. Code:
0 – HPV testing not performed/no mention
2 – HPV negative
3 – HPV positive for high-risk type 16
4 – HPV positive for high-risk type(s) not including type 16
5 – HPV positive, NOS, risk and type(s) not stated
7 – Test ordered, results not in chart
9 – Unknown if HPV test performed

Notes:
High Risk (hrHPV or HR-HPV) types: 16 and 18, 26, 31, 33, 35, 36, 45, 51, 52, 53, 56, 58, 59, 66, 67, 68, 69, 70, 73, 82, and 85.

2. Description:

2.1 Human papillomavirus (HPV) is a risk factor for head and neck cancer. However, it is associated with a more favorable response to therapy. It is also thought to be partially responsible for the increase in head and neck cancer. HPV testing may be performed for prognostic purposes; testing may also be performed on metastatic sites to aid in determination of the primary site. Record the results of any HPV testing performed on pathologic specimens from the primary tumor or a metastatic site, including lymph nodes in which **high risk** HPV types were detected (see list above). Do not record the results of blood tests or serology.

2.2 Code "0 – Not performed/No mention"-If it is known the test was not performed or if there is no mention of the test being performed at any time in the medical record, no pathologic specimen available for HPV testing and there are no laboratory results for the test.

2.3 Code "2 – HPV negative" if the test was performed and results show the patient does not have HPV

2.4 Code "3 – HPV positive for high-risk type 16" if the test was performed and results show the patient is positive for HPV type 16. Note: The patient may be positive for multiple HPV types. Code 3 if there is any mention of positivity for HPV type 16. See the list of high risk types above.

2.5 Code "4 – HPV positive for high-risk types not including type 16" if the test was performed and results show the patient is positive for a high risk type but not type 16. If the patient is positive for type 16 code 3.

HUMAN PAPILLOMA VIRUS (HPV) (continued)

ITEM B-43

2.6 Code "5 – HPV positive, NOS, risk and type(s) not stated" if the test was performed and results show the patient is positive for HPV but the risk and type are not stated.

2.7 Code "7 – Test ordered, results not in chart" if there is indication in the medical record that the test was ordered but the test results are not stated.

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

p16 IMMUNOHISTOCHEMISTRY (IHC)

ITEM B-44

1. Code: 000-100 – Percentage of tumor cells expressing p16 (% stained)
200 – 1+
300 – 2+
400 – 3+
500 – >3+
600 – Positive
700 – Negative
800 – Equivocal
555 – Test not done/No mention
977 – Test ordered, Results unknown
999 – Unknown if test performed at any time

Note: ***THE % OF TUMOR CELLS EXPRESSING p16 IS PREFERRED.***

2. Description:

2.1 Human papillomavirus (HPV) is a risk factor for head and neck cancer. In the US, more than half of cancers diagnosed in the oropharynx are linked to HPV type 16. Studies show p16 IHC expression appears to be a reliable surrogate marker for clinically and biologically relevant HPV infection. The NCCN recommends testing for p16 expression with immunohistochemistry (IHC) or for tumor HPV DNA positivity. Not all p16 positive tumors are HPV-DNA positive. However, p16-positive and HPV-positive tumors have the best prognosis. HPV/p16 status is associated with tumor control and survival. HPV testing is collected in Item B-43. For this item please review the medical record for any mention of p16 IHC testing.

2.2 Code results of p16 IHC testing. There is no consensus regarding what defines HPV positivity for p16 IHC.

2.3 Record the percentage of tumor cells expressing p16. Percent of tumor cells stained is the preferred method, followed by 1+, 2+, etc, followed by test results summarized as positive, negative or equivocal. For example, if the record shows 5% of cells express p16, then record as ‘005’; if 10%, then record as ‘010’.

2.4 If there is no mention of the test being performed in the medical record and there are no laboratory results for the test, code “555 – Test not done/No mention”.

2.5 If the test was ordered, but there is no record of the results, then code “977 – Test ordered, Results unknown”. If there are comments about test results, then record results as appropriate instead of recording “Results unknown”.

2.6 If there is mention of the test in the records but no indication that the test was performed, then code “999 – Unknown if test performed at any time.”

EPSTEIN-BARR VIRUS (EBV)

ITEM B-45

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

2. Description:

2.1 The Epstein Barr Virus (EBV) has been associated with certain cancers, including nasopharyngeal cancer. A blood test or an in situ hybridization test for EBV may be done in the work up for nasopharyngeal cancer. The blood test checks for antibodies to EBV and DNA markers of EBV which are found in the blood of patients who have been infected with EBV. The in situ hybridization test checks for EBV in nuclei of cells by staining tissue removed from the nasopharynx. In situ hybridization test information may be found in pathology reports. This item is concerned with whether any EBV test was performed NOT the test result.

2.2 Code "0 – Not performed/No mention" if there is no mention of an EBV test being performed at any time in the medical record and there are no laboratory or pathology results for EBV tests.

2.3 Code "1 – Performed" if there is evidence of an EBV test being performed at any time in the medical record and or laboratory or pathology results.

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