POC DATA ACQUISITION MANUAL

2019 DIAGNOSIS

KIDNEY CANCER
URINARY BLADDER CANCER

Released December 30, 2021

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.

PATIENT SELECTION

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

1.1.1 Men and women diagnosed with Stage I-IV kidney cancer between January 1, 2019 and December 31, 2019 will be sampled by sex, race/ethnicity, and stage.

1.1.2 Men and women diagnosed with Stage 0a-IVb urinary bladder cancer between January 1, 2019 and December 31, 2019 will be sampled by sex and race/ethnicity.

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. Stage IV kidney cancer cases will also be oversampled.

2.2 For registries using SEER*DMS, algorithms will be implemented within SEER*DMS to identify cases for the POC study. Registry staff will be able to review the cases identified by the POC algorithms in SEER*DMS; and registry staff will use extracts in SEER*Abs to identify 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 kidney in your registry diagnosed from January 1, 2019 through December 31, 2019 and separately for all eligible cases of urinary bladder in your registry diagnosed from January 1, 2019 through December 31, 2019. The number of cases to be sampled divided by the total number of eligible cases will be your sampling fraction. If the case has a number less than or equal to your sampling fraction, X, the case will be included in the study. If the random number assigned is greater than your sampling fraction, the case will not be abstracted for the Patterns of Care study. For example, all kidney cancer cases eligible for inclusion in the study would have a random number between 0 and 1 assigned. If the sampling fraction for kidney cancer is 0.63 and case 10100001 were given the random number of 0.594, it would be included in the study. Its number is less than the sampling fraction number of 0.63. If case 10100001 were assigned the random number of 0.654, it would not be abstracted for this study because its number is greater than the 0.63 sampling fraction.

2.4 At some point during the study, it is possible that cases will be added to the registry's database after sampling has already been completed. If registries need to re-sample to identify additional cases to include in POC, these cases should have the opportunity to

be included. Registries using SEER*DMS can re-run the sampling extract. Registries not using SEER*DMS can add them to the appropriate Sampling File, and assign them random numbers between 0 and 1. If resampling is performed, all cases found after the initial sampling **MUST** be sampled in this way. These additional cases will not modify the sampling fractions already obtained for a given time interval. The basis for selection of these cases into the study will be the sampling fractions (i.e., if the fraction for a cancer site group or subgroup is 0.49, a case will be added to the appropriate SEER Patterns of Care file if the assigned random number is 0.49 or less). **If there are more than 9 cases found to be ineligible without replacement cases available, please discuss with NCI whether additional cases should be sampled.**

REPORTABLE CASES

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

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

3.2.1 Patient must have a microscopically confirmed invasive kidney cancer or in situ or invasive urinary bladder cancer diagnosis.

3.2.2 Patients must be age 20 or older.

3.2.3 Patient must have been diagnosed between January 1, 2019 and December 31, 2019.

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

3.2.5 For kidney cancer patients, this must be the first cancer diagnosed for this patient except for basal cell or squamous cell carcinoma of the skin. For urinary bladder cancer patients, patients with second primary bladder cancer cases are eligible (see SEER bladder cancer solid tumor rules M6 and M8, https://seer.cancer.gov/tools/solidtumor/Urinary_STM.pdf). Therefore, for urinary bladder cancer patients, this must be the first cancer diagnosed for this patient except for urinary bladder cancer or basal cell or squamous cell carcinoma of the skin. If a bladder cancer patient has two primary bladder cancers diagnosed in 2019, include only the first bladder cancer diagnosed in 2019 in POC.

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

3.2.7 Cases with previous neoplasms that had reportability changes: POC cases may have previous diagnoses that were once considered benign or borderline but are now considered malignant. The POC eligibility guidelines regarding previous neoplasms will follow the reportability guidelines that were in place at the time of

diagnosis of the previous neoplasm. For example, carcinoid NOS of the appendix changed from /1 to /3 in 2015. If a POC 2019 case had a previous diagnosis of /1 carcinoid tumor of the appendix in 2014, then that case would still be eligible for the POC study. However, if the previous diagnosis of /3 carcinoid tumor were in 2015, then the case would not be eligible for the POC 2019 study due to the 2019 kidney or bladder cancer not being the first diagnosed cancer. In other words, follow SEER reportability rules.

3.2.8 Site-specific inclusion criteria are listed below.

KIDNEY CANCER CASES

4.1 Include only cases meeting the following criteria:

- ICD-O-3 C64.9
- Histology codes 8260, 8310, 8312, 8316, 8317, 8319, 8480
- Behavior code 3 (malignant)
- Diagnostic Confirmation codes 1, 2, 4
- AJCC Stage I, II, III, IV (2018 8th edition)

4.2 Exclude kidney cancer cases with the following specifications:

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

4.3 Patients will be sampled separately by sex, race/ethnicity, and stage (I-III vs. IV).

4.4 Details of Sampling: Eligibility

Site	Race/Ethnicity	Sex	Stage
Kidney	NH-White NH-Black Hispanic Asian/Pacific Islander AI/AN	Male Female	I-III IV

URINARY BLADDER CASES

5.1 Include cases meeting the following criteria:

- ICD-O-3 C67.0-67.9
- Histology codes 8020, 8031, 8082, 8120, 8122, 8130, 8131
- Behavior code 2 (in situ) or 3 (malignant)

- Diagnostic Confirmation codes 1, 2, 4
- AJCC Stage 0a, 0is, I, II, IIIA, IIIB, IVA, IVB (2018 8th edition)

5.2 Exclude urinary bladder cases with the following specifications:

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

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

5.4 Details of Sampling: Eligibility

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

GENERAL NON-REPORTABLE CASES AND MALIGNANCIES

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

- Previous malignancies (except basal cell or squamous cell carcinoma of the skin for kidney cancer cases; except for urinary bladder or basal cell or squamous cell carcinoma of the skin for urinary bladder cancer cases)
- Simultaneously diagnosed cancers 60 days or less apart of two different sites or the same site (except bladder). For example, a patient simultaneously diagnosed with primary kidney cancer and primary lung cancer within 60 days.
- Non-histologically proven diagnosis (clinical diagnosis only)
- Neuroendocrine tumor (NET) histologies
- Lymphoma/hematopoietic histology M-9590/3-9992/3
- Unknown stage or unstaged cases
- Death certificate only diagnosis
- Autopsy only diagnosis
- Cases with age at diagnosis younger than 20 years old
- Cases with previously diagnosed neoplasms of uncertain or unknown behavior
- Cases that are identified for POC but upon abstraction are found to be improperly coded such that when corrected do not meet POC criteria
- Cases that were reported via out-of-state data exchange and for which there are no local (in-state) providers to contact and no medical records to access; cases reported via out-of-state data exchange but for which medical records are available should be included.
- Cases for which the registry has only a record of the cancer diagnosis or only pathology information and does not have any information on subsequent treatment

or outcomes

REPORTABILITY SUMMARY BY SITE

7.1 Kidney cancer

- Include primary sites ICD-O-3 C64.9
- Include histology codes: 8260, 8310, 8312, 8316, 8317, 8319, and 8480
- Include behavior code: 3 only
- Include Diagnostic Confirmation codes 1, 2, 4
- Include AJCC 8th Edition Stage I, II, III, IV

7.2 Urinary bladder cancer

- Include primary sites ICD-O-3 C67.0-67.9
- Include histology codes: 8020, 8031, 8082, 8120, 8122, 8130, 8131
- Include behavior code: 2 or 3 only
- Include Diagnostic Confirmation codes 1, 2, 4
- Include AJCC 8th Edition Stage 0a, 0is, I, II, IIIA, IIIB, IVA, IVB

POC DATA ACQUISITION MANUAL

SECTION III

COMMON DATA SET

SECTION III - COMMON DATA SET

CONTENTS

SEER PARTICIPANT

ITEM A-1

1. Code: 2 digits

2. Description:

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

CASE NUMBER

ITEM A-2

1. Code: 8 digits

2. Description:

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

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

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

QUALITY CONTROL

ITEM A-3

1. Code: 0 – No
1 – Yes

2. Description:

2.1 For each cancer site, a random 5% sample of cases to be re-abstracted should be selected by the registry. The procedure used by each registry for selecting this sample should be available if questions arise. 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 The QC abstraction must be performed ***after*** the original abstract is completed, to ensure the case is appropriate for inclusion in POC.

2.5 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 digits

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 kidney cancer cases, only “00” and “01” will be eligible since the kidney cancers will be first primary cancers. For bladder cancer cases, since second primary bladder cancer cases are eligible, codes other than “00” or “01” can be included.

HOSPITAL CODE

ITEM A-6

1. Code: 6 digits

2. Description:

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

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

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

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

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

2.6 The HOSPITAL CODE is comprised of the six components below. All components are listed on the American Hospital Directory entry for a hospital. If no information on any of the six components of the HOSPITAL CODE is available, code that component as 9 = Unknown. If a hospital is not listed in the American Hospital Directory, code the hospital as

9 9 9 9 9 9

HOSPITAL CODE (continued)

ITEM A-6

Digit 1: Bed size code:

1 = 1 - 49 beds
2 = 50 - 99 beds
3 = 100 - 199 beds
4 = 200 - 299 beds
5 = 300 - 399 beds
6 = 400 - 499 beds
7 = 500 or more beds
8 = OPD, including doctor's office or other non-hospital outpatient setting, including facilities with zero beds
9 = Unknown

Digit 2: Approved Residency training

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

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

Digit 3: Hospital Classification code:

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

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

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

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

9 = Unknown

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

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

HOSPITAL CODE (continued)

ITEM A-6

Digit 5: Patient Experience Rating:

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

Digit 6: Oncology Average Length of Stay:

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

2.7 Each hospital will have a six-digit code that will include one code for each of these items above. These codes will be assigned by the registry. For example, a 300 bed hospital with an approved residency program that is a not-for-profit, State University Hospital and has a TPS Quality Score of 35.0, a 3-star Patient Experience Rating, and an average length of stay for oncology of 4.62 days would be coded as:

5 1 1 3 3 2

2.8 There will be one code for each hospital/institution. However, these codes will not necessarily be unique. Your registry area may have several hospitals with the same characteristics. It is possible that there may be several 100-199 beds hospitals with no residency training program that are non-government/not-for- profit, have TPS Quality Scores between 39.7 and 47.3, have 4-star ratings, and have average length of stay for oncology between 5.25 and 8.48 days. The 6-digit code for all of these hospitals would be:

3 0 2 4 4 3

2.9 If a patient is seen only in a physician's office and is never treated in a hospital as an inpatient or outpatient, code the bed size as 8, OPD. The code would be:

8 0 3 9 9 9

2.10 In the unusual case that a patient received no surgery but received **palliative** radiation therapy and **non-palliative** (i.e., given with curative intent) systemic therapy at t**wo different hospitals**, the hospital administering the most definitive therapy and used for the HOSPITAL CODE will be the one that administered therapy first. For example, if radiation therapy was started before systemic therapy, code the hospital that administered radiation therapy in the HOSPITAL CODE.

INSURANCE STATUS

ITEM A-7

1. Code: 0 – No
1 – Yes
2 – Patient died within 30 days of diagnosis (response option for >30 days after diagnosis only)
9 – Unknown

Code separately for:

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

- ☐ No insurance/Self pay
- ☐ Medicare fee-for-service (FFS), which may be listed as Part A, Part A/B, or Medicare unspecified
- ☐ Medicare HMO, which may be listed as Medicare Advantage, Medicare managed care, or Medicare Part C
- ☐ Medicare Part D or Medicare prescription drug plan (PDP)
- ☐ Supplemental private insurance with Medicare plan, which may be listed as Medigap insurance (select only if patient also has Medicare coverage)
- ☐ Medicaid
- ☐ Medicaid Pending
- ☐ Private Insurance/IPA Plan/HMO or Managed Care Plan Not Including Medicare or Medicaid
- ☐ Tricare/Other Military Not Including Veterans Affairs (VA)
- ☐ Veterans Affairs (VA)
- ☐ IHS (Indian Health Service)
- ☐ Other (specify)_____

2. Description:

2.1 This item is used to code information on all insurance coverage reported by the patient and has two parts; all insurance coverage reported **at or within 30 days** of diagnosis, and separately all insurance coverage reported **more than 30 days after** diagnosis. Cases may have more than one types of insurance. Code all appropriate insurance carriers on the abstract form. Please try to determine insurance status as accurately as possible because insurance status influences selection of therapy for cancer patients.

2.2 Patients may have codes of "1 – Yes" for multiple types of insurance. For example, a patient with both Medicare and Medicaid insurance would be coded as having "1 – Yes" for both their specific type(s) of Medicare insurance and for Medicaid insurance. If a patient has the same insurance at diagnosis and >30 days after diagnosis, it should be coded as "1 = Yes" for both the "at or within 30 days" as well as the "More than 30 days" fields.

INSURANCE STATUS (continued)

ITEM A-7

2.3 If a patient is listed as having a specific type or types of insurance (e.g., Medicaid), please code all other types of insurance as "0 = No". If a patient is listed as being insured but the type of insurance is not specified or is unknown, please code "No insurance/Self pay" as "0 = No", each other type of insurance as "9 = Unknown", and specify "insured, type unknown" under "Other (specify)".

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

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

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

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

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

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

INSURANCE STATUS (continued)

ITEM A-7

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

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

2.12 If a patient died within 30 days of diagnosis, code all insurance types for more than 30 days after diagnosis (> 30 days) as "2 = Patient died within 30 days of diagnosis".

Specifics:

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

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

2.15 Tricare/Other Military vs. VA: Tricare is a comprehensive insurance plan provided by the federal government for retired military and diplomatic personnel and their dependents. This form of health insurance was previously known as CHAMPUS. VA (Veterans Affairs) is different from Tricare; this coverage entitles patients to treatment at no cost at VA hospitals. Code Tricare/Other Military as "1 – Yes" if the patient has this type of insurance; code VA as "1 – Yes" if the patient received care at a VA facility.

INSURANCE STATUS (continued)

ITEM A-7

Examples:

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

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

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

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

TREATMENT PROTOCOL REGISTRATION

ITEM A-8

1. Code:

0 – Not registered on treatment protocol
1 – Registered on treatment protocol during first course of therapy
2 – Registered on treatment protocol during after course of therapy
3 – Registered on treatment protocol during and after first course of therapy
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 at any time following cancer diagnosis. This includes treatment protocols sponsored by cooperative groups, clinical cancer centers, comprehensive cancer centers, and drug companies. This includes registration in protocols to treat cancer or to treat cancer-related symptoms (e.g. fatigue).

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

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

2.4 Code "1 - Registered on treatment protocol during first course of therapy" when the patient was registered on a treatment protocol during the first course of therapy. Code "2 - Registered on treatment protocol after the first course of therapy" when the patient was registered on a treatment protocol after the first course of therapy. Code "3 - Registered on treatment protocol during and after first course of therapy" when the patient was registered on two or more different treatment protocol, at least one during the first course of therapy and at least one after 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-9

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 first clinical trial in which the patient was enrolled. 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. If the patient was enrolled in more than one treatment protocol, code only the first.

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-8 is coded “0”, “7”, “8”, or “9”, then A-9 should be coded with a single “9” in the left most box and the other boxes in A-9 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-9 should be coded with a single “9” in the left most box and the other boxes in A-9 should be left blank.

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

Examples:

2.9 SWOG 8711 is coded:

A-9 S W O G 8 7 1 1 _ _ _ _
Sponsor: SWOG
Number: 8711

2.10 Local protocol is coded:

A-9 L O C A L _ _ _ _ _ _ _

TREATMENT PROTOCOL SPONSOR AND NUMBER (continued)

ITEM A-9

2.11 Drug company protocol is coded:

A-9 ASTRAZENECA _
Sponsor: AstraZeneca

CASE INFORMATION VERIFIED WITH PHYSICIAN OR OFFICE STAFF

ITEM A-10

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

2. Description:

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

2.2 Unified medical record refers to a medical record **that has all inpatient plus outpatient cancer diagnosis or treatment-related medical records from a single hospital, health care organization, or health care system**. A medical record that includes cancer treatment information from more than one health care system or organization, such as from an oncology or urology practice that isn't affiliated with the hospital or health care system where inpatient treatment occurred, is **not** considered a unified medical record and should instead be coded using option "1 – Yes, physician or office staff." If you have reviewed a unified medical record, there is no need to send a physician verification form. Code "2 = Unified record review" should take priority. That is, if a unified medical record is reviewed, code "2 = Unified record review" should always be indicated for A-10. A Central Registry Abstract is not a unified medical record.

2.3 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 these cases as "2 – Unified record review."

2.4 If a unified medical record was not available **and** the medical record indicates the patient was hospitalized prior to initiation of cancer therapy and died during this hospitalization, code this Item as "3 = Death prior to discharge from hospitalization for initial cancer treatment ".

2.5 If a unified medical record was not available **and** the patient was not hospitalized and died prior to initiation of cancer therapy (code "3") **and** the medical record indicates that the patient was hospitalized prior to initiation of cancer therapy and was then discharged to hospice, code this item as "4 = Discharge from hospitalization for initial cancer treatment to hospice". For codes "3" or "4", physician verification is not required and the abstraction is in the same category as if a unified medical record was used.

CASE INFORMATION VERIFIED WITH PHYSICIAN OR OFFICE STAFF (continued)

ITEM A-10

2.6 If a case is not verified with a unified medical record, death prior to hospital discharge, or discharge to hospice (codes “2”, “3”, or “4”) and the patient was diagnosed and/or treated at more than one hospital, attempts should be made to obtain medical records from all treating hospitals regardless of location (i.e., both in-state and out-of-state). If a patient was diagnosed at one hospital and treated at another hospital, the treating hospital may have copies of the diagnosis records; therefore, it may not be necessary to obtain these records from the diagnosing hospital.

2.7 If a case is verified with a medical record that includes complete inpatient and outpatient cancer treatment information, and this information comes from more than one health care system or organization, code “1 – Yes, physician or office staff.” For example, if a hospital record includes copies of notes/records from the treating oncologist(s) or urologist(s) who are not affiliated with the hospital, this should be coded as “1 – Yes, physician or office staff.”

2.8 If the case information was verified through contact with the physician or office staff, code "1 – Yes, physician or office staff.” **The contact may be the physician’s response to a letter, a telephone contact with the physician or his/her office staff, or a review of the physician's office records by a POC abstractor.**

2.9 If a case is not verified with a unified medical record, death prior to hospital discharge, or discharge to hospice (i.e., options 2, 3, or 4 do not apply) and the patient was treated by more than one oncologist, verification forms should be sent to all treating oncologists regardless of location (i.e., both in-state and out-of-state). If at least one of the treating oncologists completes and returns the verification form, this item can be coded as being verified “1= Yes, physician or office staff”, and a comment should be included with the item (in the comment field that goes to NCI) indicating the number of treating oncologists/oncology practices and the number of oncologists/oncology practices who returned verification forms.

2.10 If the case information was not verified by the physician or office staff, there was no review of the patient’s unified record, and the patient neither died during a hospitalization prior to initial treatment nor was discharged to hospice after a hospitalization prior to initial treatment, then code this item as "0 – No outpatient verification and unified record not available.” This might be the case if the hospital medical record cannot be found. Also use code “0” if the individual was a “VA patient only” and access to the medical records has been denied by the VA. (Some registries are allowed access while other VA systems will not provide information to the registry.) Please document in the “comment” column of the POC abstracting software if you were not allowed access to medical records.

HEIGHT / WEIGHT

ITEM A-11

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.

PRESENTING SYMPTOMS/METHOD OF CANCER DETECTION

ITEM A-12

1. Code: **Mark all that apply** for the presenting symptom(s) or initial method of cancer detection. Code each as "1 - Yes", "2 - No", or "9 - Unknown".

- ☐ Hematuria/Blood in urine
- ☐ Pain upon urination
- ☐ Other urinary tract symptoms (e.g., increased urinary frequency, difficulty urinating)
- ☐ Other pain (e.g., back pain)
- ☐ Other symptoms not listed above (do not need to specify symptom)
- ☐ Physical exam (e.g., abdominal mass)
- ☐ Finding on imaging for another issue (incidental finding)
- ☐ Other, specify _____

2. Description:

2.1 This is a pilot item to assess whether information on presenting symptom or method or cancer detection can be collected from the medical record. For this item, please review outpatient urologist or medical oncologist notes if those are available. If those outpatient notes are not available and information on presenting symptoms/method of cancer detection is not provided from a physician verification form, please code each item as "9 - Unknown".

2.2 This item refers does **not** refer to biopsy or cytology performed to definitively diagnose kidney or urinary bladder cancer. Other POC items collect information on biopsy or cytology used for cancer diagnosis.

2.3 Please choose the item(s) on the above list mentioned on the earliest date in the medical record. If multiple items listed above are mentioned on the same date, please code all of those items at "1 – Yes".

2.4 Code "Finding on imaging for another issue (incidental finding)" as "1 – Yes" when the cancer was detected following an imaging test or scan (e.g., x-ray, CAT scan, MRI, etc.) that was performed for a clinical reason unrelated to the bladder or kidney (e.g., an MRI of the liver, which also identified a potential issue with the bladder or kidney) and there were no symptoms suggesting urinary bladder or kidney cancer. Reports suggest that a substantial proportion of bladder and kidney cases are identified as "incidental findings" from imaging scans performed for other reasons.

2.5 If the medical record indicates another presenting method of cancer detection, code "Other, specify" and briefly indicate the method. This field should be used rarely; attempt to code in the other categories first.

2.6 If no information is presented on the presenting symptom of method of cancer detection, code all items "9 - Unknown".

CARE COORDINATION, MULTIDISCIPLINARY CARE, AND SUPPORTIVE CARE

ITEM A-13

1. Code:

i) Note(s) present in medical record from care coordinators, managers, and/or navigators:

Mark all that apply if notes from multiple types of care coordinators/managers/navigators are present in the 12 months following diagnosis. Code as not applicable (N/A) if no care coordinator/ manager/navigator notes are present in the medical record.

- ☐ Care Coordinator
- ☐ Client Coordinator
- ☐ Care Navigator
- ☐ Patient Navigator
- ☐ Client Navigator
- ☐ Nurse Navigator
- ☐ Clinical Navigator
- ☐ Cancer Navigator
- ☐ Lay Navigator
- ☐ Financial Navigator
- ☐ Financial Counselor
- ☐ Case Manager
- ☐ Care Manager
- ☐ Other _____
- ☐ N/A

ii) Date of **FIRST** coordinator/manager/ navigator note in medical record:

MM-DD-YYYY
00-00-0000 – No coordinator/manager/navigator note in medical record
99-99-9999 – Date not available for first note in medical record

Month	Day	Year
01	01	Use 4-digit year
02	02	
..	..	
12	31	

CARE COORDINATION, MULTIDISCIPLINARY CARE, AND SUPPORTIVE CARE (cont)

ITEM A-13

iii) Degree or credentials of individual(s) who completed the **FIRST** coordinator/manager/ navigator note in medical record:

Mark all that apply for the **FIRST** note from a coordinator/manager/navigator in the medical record in the 12 months following diagnosis. Code as not applicable (N/A) if no care coordinator/manager/ navigator notes are present in the medical record.

- ☐ Nurse/nurse specialist/nurse practitioner
- ☐ Social worker
- ☐ Pharmacist/pharmacy technician
- ☐ Physician Assistant
- ☐ Physician
- ☐ Other health care provider (specify) _____
- ☐ Medical office/hospital/health care facility staff (non-health care provider)
- ☐ Financial counselor
- ☐ Lay person (non-health care professional)
- ☐ Other (specify) _____
- ☐ Unknown/not specified
- ☐ N/A

iv) In first year following diagnosis, case presented at a multidisciplinary rounds?

Mark all that apply for the names/types of multidisciplinary rounds at which the case was presented in the 12 months following diagnosis. Code as not applicable (N/A) if the case was not presented at any multidisciplinary rounds in the 12 months following diagnosis.

- ☐ Multidisciplinary care rounds/conference/team meeting
- ☐ Interdisciplinary team conference/meeting
- ☐ Molecular tumor board
- ☐ Virtual tumor board
- ☐ Other type of tumor board, including in-person (do not need to specify type)
- ☐ Other _____
- ☐ N/A

CARE COORDINATION, MULTIDISCIPLINARY CARE, AND SUPPORTIVE CARE (cont)

ITEM A-13

v) In first year following diagnosis, type(s) of physicians involved in the treatment for this patient's cancer:

Mark all that apply for the types of physicians involved in the treatment of this patient's cancer in the 12 months following diagnosis. Code as not applicable (N/A) if no physicians were involved in treatment of the patient's cancer in the 12 months following diagnosis.

- ☐ Urologist
- ☐ Medical oncologist
- ☐ Radiation oncologist
- ☐ Surgeon other than a urologist
- ☐ Other _____
- ☐ N/A

vi) Type(s) of supportive care services provided:

Mark all that apply for the types of supportive care services provided in the 12 months following diagnosis. Code as not applicable (N/A) if no supportive care services were provided.

- ☐ Physical therapy/exercise therapy/rehabilitation
- ☐ Occupational therapy
- ☐ Enterostomal therapy/ostomy care
- ☐ Mental health/psychosocial therapy
- ☐ Nutrition counseling
- ☐ Financial counseling
- ☐ Spiritual counseling/spiritual support/pastoral care
- ☐ Other _____
- ☐ N/A

2. Description:

2.1 Item A-13 is a pilot test to assess whether information on care coordination, multidisciplinary care, and supportive care can be collected from the medical record in the 12 months following diagnosis. For item A-13, review only sections of the medical records that would normally be reviewed for POC. Do not include portions of the medical record that are not commonly reviewed to abstract information for POC.

CARE COORDINATION, MULTIDISCIPLINARY CARE, AND SUPPORTIVE CARE (cont)

ITEM A-13

2.2 For item (i), indicate whether there are notes by coordinators, managers, and/or navigators in the medical record. Separately record notes by each type of coordinator, manager, or navigator. This does not require reviewing other notes in the medical record (e.g., physician or nursing notes) to see if a coordinator, manager, or navigator is mentioned.

2.3 For item (ii), record the date of the first coordinator/manager/navigator note in the medical record. Code this as 00-00-0000 if no coordinator, manager, or navigator note appears in the medical record. Code this as 99-99-9999 if the date of the first note in the medical record is unknown.

2.4 In item (iii), code the degree(s) or credential(s) of the individual(s) who completed the first coordinator/manager/navigator note in the medical record. If the individual(s) completing this note correspond to more than one type, code each type separately. If the type of individual(s) who completed the first note is not specified or cannot be determined, code as "Unknown/not specified". Code this as N/A if no coordinator, manager, or navigator note appears in the medical record.

2.5 Item (iv) records the type(s) of multidisciplinary care rounds, interdisciplinary team conference, tumor board, or similar events that includes health care providers from multiple disciplines where the case was presented. This does not include presentation as part of standard medical rounds, Grand Rounds. or a "Morbidity and Mortality (M&M) Conference". Mark all that apply if the case was presented at more than one multidisciplinary event. There does not need to be a note from this conference/meeting in the medical record, only a listing that the case was or will be presented.

2.6 Item (v) records the type(s) of physicians involved in the treatment of this patient's cancer in the 12 months following diagnosis. Separately code all physicians involved in treatment of the patient's cancer. This is treatment only for the patient's cancer, not for other medical conditions affected by the cancer. This does not include care not directly part of cancer treatment. For example, even if a patient with diabetes had their diabetes medicine changed due to cancer or cancer treatment by an endocrinologist, don't include the endocrinologist as an answer to this question. Code as not applicable (N/A) if no physicians were involved in treatment of the patient's cancer in the 12 months following diagnosis.

2.7 Item (vi) records the type(s) or supportive care services provided to the patient. Separately mark all types of services provided. Do not code palliative care services in this item, including pain management; palliative care services should be coded as part of item A-14. Code as not applicable (N/A) if the patient did not receive any supportive care services.

PALLIATIVE CARE

ITEM A-14

1. Code:

0 No palliative care provided (Code date as 00-00-0000)

1 Surgery (which may involve a bypass procedure) to alleviate symptoms, but no attempt to diagnose, stage, or treat the primary tumor is made.

2 Radiation therapy to alleviate symptoms, but no attempt to diagnose, stage, or treat the primary tumor is made.

3 Chemotherapy, hormone therapy, or other systemic drugs to alleviate symptoms, but no attempt to diagnose, stage, or treat the primary tumor is made.

4 Patient received or was referred for pain management therapy with no other palliative care.

5 Any combination of codes 1, 2, and/or 3 without code 4.

6 Any combination of codes 1, 2, and/or 3 with code 4.

7 Palliative care was performed or referred, but no information on the type of procedure is available in the patient record.

8 Palliative care was provided that does not fit the descriptions for codes 1–6.

9 It is unknown if palliative care was performed or referred; not stated in patient record (Code date as 00-00-0000).

Date palliative care FIRST appears in record

Month	Day	Year
01	01	Use 4-digit year
02	02	
..	..	
12	31	
00	00	0000 – Palliative Care not listed in medical record or not given
99	99	9999 – Date not available for first listing of palliative care in medical record

2. Description:

2.1 Record the type of palliative care provided at any time after diagnosis. This item is based on NAACCR Item #3280.

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

2.3 Palliative care is not used to diagnose or stage the primary tumor or for potentially curative treatment. All surgery, radiation therapy, and systemic therapy administered for patients with stage IV (metastatic) disease and/or indicated as "non-curative" can be assumed to be palliative care.

PALLIATIVE CARE (continued)

ITEM A-14

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

2.5 A palliative care consult should be considered palliative care, even if no other palliative care is received. Code as "8: Palliative care was provided that does not fit the descriptions for codes 1–6."

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

SMOKING

ITEM A-15

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

00.0 – Never smoked
00.5 – Half a pack or less per day (≤0.5 ppd
00.9 – More than half a pack to less than 1 pack per day (>0.5 to <1 ppd)
01.0 – 1 pack per day
02.0 – 2 packs per day
03.0 – 3 packs per day
...
...
55.5 – Light or occasional smoker
66.6 – Moderate smoker
77.7 – Heavy smoker
88.8 – Smoked, number of packs unknown
90.1 – Never smoked cigarettes; reported use of e-cigarettes and/or vaping
90.2 – Never smoked cigarettes; reported use of cigars, pipes, or other inhaled forms of tobacco
90.3 – Never smoked cigarettes; reported use of chewing tobacco
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
90 – Never smoked cigarettes; reported use of e-cigarettes, vaping, cigars, pipes, or other inhaled forms of tobacco
99 – Unknown, not stated whether patient smoked

SMOKING (continued)

ITEM A-15

Smoking Status at Diagnosis

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

2. Description:

2.1 This item is to be coded for **any information** known about the patient's smoking status. Code the number of packs per day, the number of years smoked and/or the pack years smoked, as well as smoking status at diagnosis. If the patient never smoked, code "00.0" in Packs Per Day, the Number of Years Smoked and the Pack Years, and code Smoking Status at Diagnosis as "0". When multiple values for years, packs, or pack-years of smoking history are listed, record the lowest value presented. If a patient **never** smoked cigarettes but used e-cigarettes (i.e., "vaping") or smoked cigars, a pipe, or some other form of tobacco, please use the codes corresponding to that form of tobacco specified for "Number of packs per day" (codes 90.1, 90.2, or 90.3) and for "pack years" (code 90). Please also code the number of years the patient used that other form of tobacco under "Number of years". If a patient smoked cigarettes **AND** another form of tobacco, please code information on cigarette smoking **only**.

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

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

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

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

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

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

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

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

PASSIVE SMOKING EXPOSURE

ITEM A-16

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

2. Description:

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

2.2 Passive smoking is coded separately from "active" smoking history (item A-15). That is, even when a patient is listed as a current smoker, if they are also described as having passive smoking exposure, that should be recorded separately. However, do not code a current smoker as having passive smoking exposure only because they are exposed to their own smoking. A patient is coded as having passive smoking exposure only if exposed to someone else's smoking.

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

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

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

CO-MORBID CONDITIONS

ITEM C

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

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.

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: 5 digits

DATE ABSTRACTED

1. Code: month, day, year

2. Description:

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

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

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

POC DATA ACQUISITION MANUAL

SECTION IV

KIDNEY CANCER DATA SET

SECTION IV – KIDNEY CANCER DATA SET

CONTENTS

DATE OF FIRST POSITIVE BIOPSY OR CYTOLOGY

ITEM B-1

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

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

2. Description:

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

2.2 If the biopsy/cytology was performed on the same day as definitive surgery, the biopsy date and the Date of Cancer Directed Surgery to Primary Site (Item B-3) will be the same. The first positive biopsy/cytology may have been done as an outpatient procedure but must be no later than the Date of Fist Cancer-Directed Surgery to Primary Site.

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

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

DATE OF FIRST POSITIVE BIOPSY OR CYTOLOGY (continued)

ITEM B-1

2.5 Code "77-77-7777" if patient or the patient's guardian refused biopsy/cytology.

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

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

2.8 If it is unknown whether a biopsy/cytology was performed, code "97-97-9797".

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

LAPAROSCOPIC SURGERY

ITEM B-2

1. Code: 0 – No surgical removal of tissue
1 – Yes, surgery performed laparoscopically
2 – Open surgical procedure
9 – Unknown

2. Description:

2.1 This item refers to surgery of the primary site (kidney). 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 or more incisions 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, or cryoablation, then code "0 – No surgical removal of tissue."

PRIMARY SITE SURGERY AND DATE

ITEM B-3

1. Code: Kidney Surgery Code: 00-99
Refer to *SEER Program Coding and Staging Manual 2018, Appendix C.*

Surgery Date: MM-DD-YYYY
00-00-0000 – No Surgery

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

2. Description:

2.1 Enter the site-specific surgery code as defined in *SEER Program Coding and Staging Manual 2018, Appendix C* (https://seer.cancer.gov/archive/manuals/2018/AppendixC/Surgery_Codes_Kidney_2018.pdf). This is only for the initial (first course) surgery to the primary site.

2.2 Enter the date on which the most definitive surgery of the **primary site** was performed. Code "00-00-0000" if no surgery to the primary site was performed.

2.3 If the patient or patient's guardian refused surgery to the primary site, then code "77-77- 7777 – Patient/guardian refused".

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

2.5 If surgery to the primary site was recommended, but it is unknown if it was performed, then code "96-96-9696 – Recommended, unknown if given".

2.6 If it is unknown whether the patient had surgery to the primary site, then code "97-97-9797-Unknown if performed".

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

PATHOLOGICAL MARGINS

ITEM B-4

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

2. Description:

2.1 This item records the pathological margin status following the most definitive surgery performed after diagnosis (Item B-3). This refers to pathological margins only for the initial surgery at the primary site.

2.2 Code "0 – No resection/surgery performed" when no cancer-directed surgery or only a biopsy was performed. Cryoablation or other destruction of tumor should be coded 0.

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

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

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

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

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

SIZE OF PRIMARY TUMOR

ITEM B-5

1. Code:

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

Type of Staging (see notes below for further guidance)

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

2. Description:

2.1 Refer to the 2018 SEER Program Coding and Staging Manual for complete details. **Code information about both clinical and pathologic tumor size for each patient**. This information should not be taken from autopsy records.

2.2 For clinical tumor size, record the largest measurement of the primary tumor from the priority list below before any form of treatment. Use information available within four months of the date of diagnosis, in the absence of disease progression when no treatment is administered.

Record largest size according to the following priority order:

1. Operative report from surgical exploration without resection
2. Imaging-guided tissue biopsy (i.e., incisional biopsy done under imaging)
3. Diagnostic imaging
4. Physical exam

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.
Note 3: A smaller size from a higher priority source should be coded.

SIZE OF PRIMARY TUMOR (continued)

ITEM B-5

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 before adjuvant treatment. 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. Using 2018 SEER rules, code pathologic tumor size even when neoadjuvant therapy was given before surgery.
b. Code the size from the synoptic report (also known as CAP protocol or pathologyreport checklist) when there is a discrepancy among tumor size measurements in the various sections of the pathology report.
c. Use final diagnosis, microscopic, or gross examination, in that order,when only a pathology report is available.

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

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

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

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

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

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

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

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

SIZE OF PRIMARY TUMOR (continued)

ITEM B-5

2.9 **Examples**:

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

NUMBER OF REGIONAL LYMPH NODES POSITIVE and EXAMINED

ITEMS B-6 & B-7

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

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

B-7 – Number of regional lymph nodes examined

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

2. Description:

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

2.2 Record the number of regional nodes **examined by a pathologist** and found to contain metastasis. These should be coded based only on data from lymph nodes that are pathologically examined, not from lymph nodes that are clinically examined or examined using imaging procedures.

NUMBER OF REGIONAL LYMPH NODES POSITIVE & EXAMINED (continued)

ITEMS B-6 & B-7

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

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

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

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

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

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

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

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

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

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

METASTASIS AT DIAGNOSIS

ITEM B-8

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

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

2. Description:

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

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-8

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

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

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

Specifics:

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

2.11 Bone involvement does NOT include bone marrow involvement.

2.12 Distant lymph node involvement does NOT include regional lymph nodes.

MUTATIONS AND TESTING

ITEM B-9

1. Code: 0 – Test not performed/no mention
1 – One or more of specified test performed, all positive
2 – One or more of specified test performed, all negative
3 – More than one of specified test performed, initially positive and subsequently negative
4 – More than one of specified test performed, initially negative and subsequently positive
8 – Test performed, result unknown
9 – Unknown if test performed

Tests
MSI/Microsatellite instability
MMR deficiency/Mismatch repair deficiency
NGS/Next-Generation Sequencing

2. Description:

2.1 Molecular marker or mutations status information can come from either the primary tumor or from metastases; if tests are performed using either, the specified marker/mutation should be coded using the values indicated.

2.2 Microsatellites are short, repeated sequences of DNA. Microsatellite instability-high (MSI-H) cancer cells may have a defect in the ability to correct mistakes that occur when DNA is copied in the cell.

2.3 Mismatch repair (MMR) deficiency describes cells that have mutations (changes) in certain genes that are involved in correcting mistakes made when DNA is copied in a cell. MMR deficient cells usually have many DNA mutations, which may lead to cancer. Knowing if a tumor is MMR deficient may help plan treatment or predict how well the tumor will respond to treatment.

2.4 Next-generation sequencing (NGS) is a method used to determine a portion of the nucleotide sequence of an individual's genome. This technique utilizes DNA sequencing technologies that are capable of processing multiple DNA sequences in parallel. Examples of NGS tests include Foundation One, MSK IMPACT, Oncomine, Caris Molecular Intelligence, Trusight Oncology, Guandant360, and Myriad MYCHOICE. The type of NGS test used does not matter for this item, only whether or not NGS was performed. If the only positive result from Next Generation Sequencing is "variants of unknown significance" (VUS), code this as a negative test result. Different NGS platforms have different definitions of VUS, so it is hard to interpret whether VUS has any meaning. If there are any other positive results from Next Generation Sequencing, code it as a positive test result.

2.5 If the test was not performed or there is no mention in any of the records, then code "0 – Test not performed/no mention".

MUTATIONS AND TESTING (continued)

ITEM B-9

2.6 If a test was performed one or more times and all test results were positive, code that test as "1 – One or more of specified test performed, all positive".

2.7 If a test was performed one or more times and all test results were negative, code that test as "2 – One or more of specified test performed, all negative".

2.8 If a test was performed more than one time and the test results were positive the first time but were negative for any subsequent test, code that test as "3 – More than one of specified test performed, initially positive and subsequently negative".

2.9 If a test was performed more than one time and the test results were negative the first time but were positive for **any** subsequent test, code that test as "4 – More than one of specified test performed, initially negative and subsequently positive".

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

2.11 If a patient received a panel of multiple tests (also called a "gene panel") and the specified mutation is listed as being part of the panel, assume that it was tested for. However, if the result is not listed, don't assume the test result was negative. If the specified test result is not listed, coded this as "8 – One or more test performed, result unknown".

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

EOD OF PRIMARY TUMOR

ITEM B-10

1. Code: Kidney parenchyma

Code	Description	SS2018 T
000	In situ, intraepithelial, noninvasive	IS
100	Any size tumor • Invasion of renal capsule • Invasive cancer confined to kidney cortex and/or medulla Confined (limited) to the kidney, NOS Localized, NOS	L
200	Blood vessel(s) (major) • Extrarenal portion of renal vein or segmental (muscle containing branches) • Hilar blood vessel • Perirenal vein • Renal artery • Renal vein, NOS • Tumor thrombus in a renal vein, NOS • Invasion of perirenal and/or renal sinus fat but not beyond Gerota's fascia Pelvicalyceal system Perinephric tissue invasion WITHOUT extension beyond the Gerota's fascia Renal pelvis or calyces involved Separate focus of tumor in renal pelvis/calyx	RE
300	Inferior vena cava (IVC) below diaphragm	RE
400	IVC above diaphragm or invades wall of IVC	RE
500	Tumor extends into major veins (excluding ipsilateral adrenal gland) Not beyond Gerota's fascia (see code 600) IVC, NOS	RE

EOD OF PRIMARY TUMOR (continued)

ITEM B-10

Code	Description	SS2018 T
600	Extension beyond Gerota's fascia to • Adrenal gland (ipsilateral) (contiguous metastasis) • Ascending colon from right kidney • Beyond Gerota's fascia, NOS • Descending colon from left kidney • Diaphragm • Duodenum from right kidney • Peritoneum • Psoas muscle • Quadratus lumborum muscle • Retroperitoneal soft tissue • Tail of pancreas Ureter (ipsilateral), including implant(s)	RE
700	Aorta Liver from right kidney Ribs Spleen from left kidney Stomach Further contiguous extension	D
800	No evidence of primary tumor	U
999	Unknown; extension not stated Primary tumor cannot be assessed Not documented in patient record Death Certificate Only	U

Note 1: Gerota's fascia is a fibrous tissue sheath surrounding the kidney and suprarenal or adrenal gland. The perirenal fat, renal capsule, and renal parenchyma lie below the fascia.

Note 2: The most common site for renal parenchymal cancer to develop is in the proximal convoluted tubule. Tumor extension from one of these structures into another is coded 100 and is dependent on size in the absence of further involvement.

2. Description:

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

GRADE

ITEM B-11

1. Code: 3 digits

Clinical Grade	1 digit
Pathological Grade	1 digit
Post-therapy Grade	1 digit

2. Description:

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

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

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

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

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

GRADE (continued)

ITEM B-11

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

DATE RADIATION TO PRIMARY SITE BEGAN

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

2. Description:

2.1 Enter the date the patient first received radiation TO THE PRIMARY SITE at any time after diagnosis.

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

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

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

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

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

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

METASTASIS OR LOCAL RECURRENCE AFTER DIAGNOSIS

ITEM B-13

1. Code: i) Metastasis or local recurrence after diagnosis

0 – Patient had metastatic disease at diagnosis
1 – No evidence of metastasis or local recurrence after diagnosis
2 – Yes, metastasis at a distant site identified after diagnosis
3 – Yes, local recurrence at primary tumor site identified after diagnosis
4 – Yes, both metastasis and local recurrence identified after diagnosis
9 – Unknown if metastasis or local recurrence after diagnosis

ii) Date first metastasis or local recurrence identified after diagnosis

MM-DD-YYYY
00-00-0000-No evidence of metastasis or local recurrence; Patient had metastatic disease at diagnosis; or Unknown if metastasis or local recurrence after diagnosis

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

2. Description:

2.1 This item collects information on whether a cancer metastasis or local recurrence is identified four months or more **after** the initial tumor diagnostic work-up. Metastasis refers to the presence of the same cancer at a site distant from the primary tumor. Local recurrence refers to the presence of the same cancer at the primary tumor site **after** the primary tumor has been removed. If the primary tumor is not removed, there cannot be a local recurrence.

2.2 For item (i), Code "0 - Patient had metastatic disease at diagnosis" if at initial diagnosis the patient was diagnosed with metastatic disease (M-stage M1 or coded as "Yes" in Item B-8, "METASTASIS AT DIAGNOSIS").

2.3 Code "1 – No" if there is no evidence of metastasis or local recurrence in the medical record or imaging reports **after** the initial tumor diagnosis work-up. The initial tumor diagnostic work-up is not just the initial biopsy but also includes subsequent imaging studies to determine the initial stage of the patient's cancer. **This option should be selected only if the patient did not have metastatic disease at diagnosis.** If the patient had metastatic disease at diagnosis (M-stage M1 or coded as "Yes" in item B-8), instead use code "0 - Patient had metastatic disease at diagnosis".

METASTASIS OR LOCAL RECURRENCE AFTER DIAGNOSIS (continued)

ITEM B-13

2.4 If there was no metastasis to distant sites after diagnosis **and** there was no removal of primary tumor, then code "1—No evidence of metastasis or local recurrence after diagnosis".

2.5 Code "2 – Yes, metastasis at a distant site identified after diagnosis" when there is clinical or pathologic evidence of distant metastasis **after** diagnosis for patients who did not have an initial diagnosis of metastatic cancer.

2.6 Code "3 – Yes, local recurrence at primary tumor site identified after diagnosis" when there was surgery to completely remove the primary tumor and after the surgery there is clinical or pathologic evidence of a new cancer of the same type at the site of the primary tumor.

2.7 Code "4 – Yes, both metastasis and local recurrence identified after diagnosis" when there is clinical and pathologic evidence of distant metastasis after diagnosis **AND** clinical or pathologic evidence of local recurrence at the primary tumor site.

2.8 Code "9 - Unknown" if it is unknown whether there is metastasis or local recurrence after diagnosis.

2.9 For item (ii), code the first date that the metastasis or local recurrence after initial diagnosis listed in the medical record. If the patient had metastatic disease at diagnosis (item (i) coded "0"), no evidence of metastasis or local recurrence (item (i) coded "1"), or unknown whether there is metastasis or local recurrence after diagnosis (item (i) coded "9"), code item (ii) "00-00-0000".

2.10 For this item, identification of new positive regional lymph nodes more than four months following diagnosis should be coded as metastasis after diagnosis.

SYSTEMIC THERAPY AGENTS

ITEMS B-14 through B-30

1. Code: i) Date of start of therapy

MM-DD-YYYY
00-00-0000 — No systemic therapy given

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

ii) Mode of administration:
Oral (O)
Parenteral (P)
Unknown (U)
N/A (N)

B-14 Avelumab (Bavencio)

B-15 Axitinib (Inlyta)

B-16 Bevacizumab (Avastin)

B-17 Bortezomib (Velcade)

B-18 Cabozantinib (Cometriq)

B-19 Everolimus (Afinitor)

B-20 Interferon or interferon-alpha

B-21 IL-2 (Interleukin-2, ETAF, Ril-2, TCGF)

B-22 Ipilimumab (Yervoy)

B-23 Lenvatinib (Lenvima)

B-24 Nivolumab (Opdivo)

B-25 Pazopanib (Votrient)

SYSTEMIC THERAPY AGENTS (continued)

ITEMS B-14 through B-30

B-26 Pembrolizumab (Keytruda)

B-27 Sorafenib (Nexavar)

B-28 Sunitinib (Sutent)

B-29 Temsirolimus (Torisel)

B-30 Other, specify: _____

This list is by no means complete and if other agents are found, please list them as well under B-30.

Please be sure to record all systemic therapy agents. SEER*Rx is useful for looking up chemotherapy, 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 Enter information for each agent separately. If therapy agents are present in the medical record that are not included in this list, please include these under B-30, "Other". Please record information on all systemic therapy, from diagnosis to end of available medical records, not just the first course of systemic therapy

2.2 For item (i), code the date therapy started for each systemic therapy agent given at any time following diagnosis.

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

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

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

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

SYSTEMIC THERAPY AGENTS (continued)

ITEMS B-14 through B-30

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

2.8 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 Bevacizumab beginning two weeks ago, code date of first Bevacizumab as 14 days prior to that date. If the record states that the Bevacizumab was given recently, code the month and year, but not the day. Code the day as “99”. Coding the closest approximation is preferable to coding unknown.

2.9 When a systemic therapy is administered as one or more arms of a clinical trial and it is not known whether the patient was in that arm, this therapy should be coded as “Unknown if given” (97-97-9797). For example, if a patient were in a trial of new investigational agent vs. bevacizumab, bevacizumab should be coded as “Unknown if given”. The new investigational agent should also be listed as “Unknown if given”. However, if a patient was in a trial of bevacizumab plus new investigational agent in one arm vs. bevacizumab plus placebo in the other arm, bevacizumab should be coded as given since it is part of both arms. Do not include “placebo” as part of systemic therapies.

2.10 For item (ii), code the mode of administration for each therapy administered. This can be coded as O = Oral (by mouth), P = Parenteral, U = Unknown/not specified, or N = N/A. Parenteral administration is general intravenous (IV), but can also include intramuscular (IM), subcutaneous (SC or SQ), or administration via an angiocatheter; Broviac, Groshong, or Hickman catheter; PICC line; or port-a-cath. If a therapy was not administered (date of administration in item (i) coded as 00-00-0000, 77-77-7777, or 95-95-9595), code model of administration as N = N/A. If it is unknown if a therapy was administered (date of administration in item (i) coded as 96-96-9696 or 97-97-9797) or a therapy was administered but date of administration is unknown (date of administration in item (i) coded as 99-99-9999), code mode of administration using any available information in the medical chart, including specified recommendations regarding mode of administration.

POC DATA ACQUISITION MANUAL

SECTION V

URINARY BLADDER CANCER DATA SET

SECTION V – URINARY BLADDER CANCER DATA SET

CONTENTS

DATE OF FIRST POSITIVE BIOPSY OR CYTOLOGY

ITEM B-1

1. Code: MM-DD-YYYY

00-00-0000-No biopsy or cytology done.

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

2. Description:

2.1 This item refers to the date of the first diagnosis of this tumor confirmed by biopsy/cystoscopy/cytology for this current diagnosis. This may be a biopsy of the primary site, lymph node, or metastatic site that confirmed the diagnosis of urinary bladder cancer; cystoscopic examination of the bladder; or analysis of cells in a urine sample (cytology) that confirmed the diagnosis of urinary bladder cancer. Code the date the specimen was obtained (NOT the date of the pathology/cytology report).

2.2 If a cystoscopy was done with no specimen collected at time of cystoscopy, and a later biopsy or cytology is performed to confirm the tumor diagnosis, code the date of the later biopsy or cytology in Item B1. If a cystoscopy was done with no specimen collected at time of cystoscopy, and a TURBT or other surgery is performed later to remove the tumor that was visualized during the cystoscopy WITH NO BIOPSY OR CYTOLOGY PERFORMED TO CONFIRM THE TUMOR

2.3 If a cystoscopy was done with no specimen collected at time of cystoscopy, and no surgery is performed later at the site of the tumor, then do not code the date of cystoscopy in Item B1.If the biopsy/cystoscopy/cytology was performed on the same day as definitive surgery, the biopsy/cystoscopy/cytology date and the Date of Cancer Directed Surgery to Primary Site (Item B-2) will be the same. The first biopsy/cystoscopy/ cytology may have been done as an outpatient procedure but must be no later than the Date of Fist Cancer-Directed Surgery to Primary Site.

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

DATE OF FIRST POSITIVE BIOPSY OR CYTOLOGY (continued)

ITEM B-1

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

2.6 Code "77-77-7777" if patient or the patient's guardian refused biopsy/cystoscopy/cytology.

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

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

2.9 If it is unknown whether a biopsy/cystoscopy/cytology was performed, code "97-97-9797".

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

PRIMARY SITE SURGERY AND DATE

ITEM B-2

1. Code: Bladder Surgery Code: 00-99
Refer to *SEER Program Coding and Staging Manual 2018, Appendix C.*

Surgery Date: MM-DD-YYYY
00-00-0000 – No Surgery

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

2. Description:

2.1 Enter the site-specific surgery code as defined in SEER Program Coding and Staging Manual 2018, Appendix C (https://seer.cancer.gov/archive/manuals/2018/AppendixC/Surgery_Codes_Bladder_2018.pdf). This is only for the initial (first course) surgery to the primary site.

2.2 Enter the date on which the most definitive surgery of the primary site was performed. Code "00-00-0000" if no surgery to the primary site was performed.

2.3 If the patient or patient's guardian refused surgery to the primary site, then code "77-77- 7777 – Patient/guardian refused".

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

2.5 If surgery to the primary site was recommended, but it is unknown if it was performed, then code "96-96-9696 – Recommended, unknown if given".

2.6 If it is unknown whether the patient had surgery to the primary site, then code "97-97-9797-Unknown if performed".

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

PATHOLOGICAL MARGINS

ITEM B-3

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

2. Description:

2.1 This item records the pathological margin status following the most definitive surgery performed after diagnosis (Item B-2). This refers to pathological margins only for the initial surgery at the primary site.

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

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

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

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

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

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

SIZE OF PRIMARY TUMOR

ITEM B-4

1. Code:

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

Type of Staging (see notes below for further guidance)

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

2. Description:

2.1 Refer to the 2018 SEER Program Coding and Staging Manual for complete details. Code information about both clinical and pathologic tumor size for each patient. This information should not be taken from autopsy records.

2.2 For clinical tumor size, record the largest measurement of the primary tumor from the priority list below before any form of treatment. Use information available within four months of the date of diagnosis, in the absence of disease progression when no treatment is administered.

Record largest size according to the following priority order:

1. Operative report from surgical exploration without resection
2. Imaging-guided tissue biopsy (i.e., incisional biopsy done under imaging)
3. Diagnostic imaging
4. Physical exam

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.
Note 3: A smaller size from a higher priority source should be coded.

SIZE OF PRIMARY TUMOR (continued)

ITEM B-4

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 before adjuvant treatment. 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. Using 2018 SEER rules, code pathologic tumor size even when neoadjuvant therapy was given before surgery.
b. Code the size from the synoptic report (also known as CAP protocol or pathologyreport checklist) when there is a discrepancy among tumor size measurements in the various sections of the pathology report.
c. Use final diagnosis, microscopic, or gross examination, in that order,when only a pathology report is available.

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

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

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

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

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

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

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

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

SIZE OF PRIMARY TUMOR (continued)

ITEM B-4

2.9 **Examples**:

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

NUMBER OF REGIONAL LYMPH NODES POSITIVE and EXAMINED

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; nodes examined but number unknown
99 – Unknown/not stated whether nodes examined

2. Description:

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

2.2 Record the number of regional nodes examined by a pathologist and found to contain metastasis. These should be coded based only on data from lymph nodes that are pathologically examined, not from lymph nodes that are clinically examined or examined using imaging procedures.

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 positive is unknown, code Item B-5 as “97”.

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

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

2.9 If no regional node dissection was done or no regional lymph nodes were removed/examined, code Item B-5 “98” and B-6 “00”.

2.10 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.

2.11 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

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

2. Description:

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

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 lung, distant lymph node, bone, peritoneum, and liver as "9 – unknown" and code other (Specify) as "1 – Yes." Enter the other site in the text field.

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

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

Specifics:

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

2.11 Bone involvement does NOT include bone marrow involvement.

2.12 Distant lymph node involvement does NOT include regional lymph nodes.

MULTIPLE BLADDER TUMORS

ITEM B-8

1. Code: 0 – Single bladder tumor
1 – Multiple bladder tumors present (multi-focal)
9 – Unknown if multiple bladder tumors present

2. Description:

2.1 Code "0 – Single bladder tumor" if only one bladder tumor is present. The tumor may be present in one site or may overlap multiple sites/subsites.

2.2 Code "1 – Multiple bladder tumors present (multi-focal)" if multiple, discontinuous bladder tumors are present in either the same site or in multiple sites in the bladder. This includes multiple foci or discrete tumors, as well as areas of in situ bladder cancer in addition to invasive cancer. The path report may note that there are multiple sites of bladder tumor.

2.3 If there is no mention by either the pathologist or the urologist of multiple bladder tumors, then code "0 – Single bladder tumor".

2.4 If it is unclear whether there are multiple tumors, then code "9 – Unknown if multiple bladder tumors present".

2.5 Only tumors within the bladder are coded in this data item. Discontinuous extension to the upper urinary tract is coded in a subsequent data item.

Tis/CIS PRESENT

ITEM B-9

1. Code: 0 – No Tis/CIS present
1 – Yes, Tis/CIS present
9 – Unknown if Tis/CIS was present

2. Description:

2.1 Code "0 – no Tis/CIS present" if the record indicates that only invasive tumor is present.

2.2 Code "0 – no Tis/CIS present" if the record indicates that non-invasive papillary tumor is present and there is no mention of the flat, sessile CIS/Tis tumor.

2.3 Code "0 – no Tis/CIS present" if there is no mention of Tis/CIS in the pathology report.

2.4 Code "1 – yes, Tis/CIS present" if IN SITU cancer that is flat or sessile is found in the bladder. This would be a flat or sessile tumor Tis/CIS tumor confirmed by pathology.

2.5 Code "9 – unknown" if it is not clear whether Tis/CIS is present.

UPPER URINARY TRACT INVOLVEMENT

ITEM B-10

1. Code: 0 – No evidence of upper urinary tract involvement
1 – Yes, evidence of upper urinary tract involvement
9 – Unknown if upper urinary tract involvement is present

2. Description:

2.1 After reviewing the record, code "0 – No evidence of upper urinary tract involvement" if there is no evidence or no mention of cancer in the upper urinary tract.

2.2 Code "1 – Yes, evidence of upper urinary tract involvement" if there is an indication of cancer in the upper urinary tract.

2.3 If there is a positive cytology from the ureters, code "1 – Yes, evidence of upper urinary tract involvement".

2.4 Code "1 – Yes, evidence of upper urinary tract involvement" if the IVP is positive for ureteral or renal pelvis masses.

2.5 Code "9 – Unknown if upper urinary tract involvement is present" if it is unclear whether the upper urinary tract is involved.

2.6 The upper urinary tract would include such structures as the ureters, and renal pelvis.

2.7 Note that based on SEER Urinary Solid Tumor Rule M11, urothelial carcinoma bladder cancer with involvement of the upper urinary tract is coded as a single primary.

MUTATIONS AND TESTING

ITEM B-11

1. Code: 0 – Test not performed/no mention
1 – One or more of specified test performed, all positive
2 – One or more of specified test performed, all negative
3 – More than one of specified test performed, initially positive and subsequently negative
4 – More than one of specified test performed, initially negative and subsequently positive
8 – Test performed, result unknown
9 – Unknown if test performed

Tests
MSI/Microsatellite instability
MMR deficiency/Mismatch repair deficiency
NGS/Next-Generation Sequencing
FGFR/fibroblast growth factor receptor
ERCC2

2. Description:

2.1 Molecular marker or mutations status information can come from either the primary tumor or from metastases; if tests are performed using either, the specified marker/mutation should be coded using the values indicated.

2.2 Microsatellites are short, repeated sequences of DNA. Microsatellite instability-high (MSI-H) cancer cells may have a defect in the ability to correct mistakes that occur when DNA is copied in the cell. Molecular marker or mutations status information can come from either the primary tumor or from metastases; if tests are performed using either, the specified marker/mutation should be coded using the values indicated.

2.3 Mismatch repair (MMR) deficiency describes cells that have mutations (changes) in certain genes that are involved in correcting mistakes made when DNA is copied in a cell. MMR deficient cells usually have many DNA mutations, which may lead to cancer. Knowing if a tumor is MMR deficient may help plan treatment or predict how well the tumor will respond to treatment.

MUTATIONS AND TESTING (continued)

ITEM B-11

2.4 Next-generation sequencing (NGS) is a method used to determine a portion of the nucleotide sequence of an individual's genome. This technique utilizes DNA sequencing technologies that are capable of processing multiple DNA sequences in parallel. Examples of NGS tests include Foundation One, MSK IMPACT, Oncomine, Caris Molecular Intelligence, Trusight Oncology, Guandant360, and Myriad MYCHOICE. The type of NGS test used does not matter for this item, only whether NGS was performed. If the only positive result from Next Generation Sequencing is "variants of unknown significance" (VUS), code this as a negative test result. Different NGS platforms have different definitions of VUS, so it is hard to interpret whether VUS has any meaning. If there are any other positive results from Next Generation Sequencing, code it as a positive test result.

2.5 Fibroblast growth factor receptor (FGFR) are receptor tyrosine kinases that can be activated in tumor cells. FGFR inhibitors are a new class of systemic treatment for selected patients with urothelial cancers.

2.6 Mutations in ERCC2, a nucleotide excision repair gene, is associated with response to cisplatin chemotherapy among individuals with urinary bladder cancer.

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

2.8 If a test was performed one or more times and all test results were positive, code that test as "1 – One or more of specified test performed, all positive".

2.9 If a test was performed one or more times and all test results were negative, code that test as "2 – One or more of specified test performed, all negative".

2.10 If a test was performed more than one time and the test results were positive the first time but were negative for any subsequent test, code that test as "3 – More than one of specified test performed, initially positive and subsequently negative".

2.11 If a test was performed more than one time and the test results were negative the first time but were positive for any subsequent test, code that test as "4 – More than one of specified test performed, initially negative and subsequently positive".

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

2.13 If a patient received a panel of multiple tests (also called a "gene panel") and the specified mutation is listed as being part of the panel, assume that it was tested for. However, if the result is not listed, don't assume the test result was negative. If the specified test result is not listed, coded this as "8 – One or more test performed, result unknown".

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

EOD OF PRIMARY TUMOR

ITEM B-12

1. Code: Bladder

Code	Description	SS2018 T
000	Papillary (8130/2, 8131/2, other histologies, see code 050) • Non-infiltrating or non-invasive papillary transitional cell carcinoma • Non-infiltrating or non-invasive papillary urothelial carcinoma • Papillary transitional cell carcinoma, with inferred description of non-invasion • Papillary urothelial carcinoma, with inferred description of non-invasion	IS
050	Nonpapillary • Carcinoma in situ, NOS • Sessile (flat) (solid) carcinoma in situ • Transitional cell carcinoma in situ • Urothelial carcinoma (in situ, non-infiltrating, non-invasive) Multifocal papillary and nonpapillary non-invasive tumors (see Note 4)	IS
100	Confined to mucosa, NOS	L
130	Lamina propria Stroma Subepithelial connective tissue Submucosa Subserosa Tunica propria	L
150	Localized, NOS	L
170	Extension to distal ureter • Subepithelial connective tissue of bladder and/or distal ureter	RE

EOD OF PRIMARY TUMOR (continued)

ITEM B-12

Code	Description	SS2018 T
200	Muscle (muscularis propria) of bladder only • Superficial muscle - inner half	L
250	Extension to distal ureter Superficial muscle of bladder and/or distal ureter	RE
300	Muscle (muscularis propria) of bladder only • Deep muscle--outer half Extension through full thickness of bladder wall BUT still contained within bladder wall	L
350	Extension to distal ureter Deep muscle or extension through wall of bladder and/or distal ureter	RE
370	Muscle (muscularis propria) invaded, NOS of bladder only	L
400	Extension to distal ureter Muscle (muscularis propria) invaded, NOS of bladder and/or distal ureter	RE
450	Extension to perivesical fat/tissues (MICROSCOPIC) including • Adventitia • Distal periureteral tissue • Periprostatic tissue • Peritoneum • Serosa (mesothelium) (to/through) Tunica serosa (to/through)	RE
500	Extravesical mass (Clinically or grossly apparent extravesical mass) Extension to perivesical fat/tissues (MACROSCOPIC) including • Adventitia • Distal periureteral tissue • Periprostatic tissue • Peritoneum • Serosa (mesothelium) (to/through) Tunica serosa (to/through)	RE

EOD OF PRIMARY TUMOR (continued)

ITEM B-12

Code	Description	SS2018 T
550	Extension to perivesical fat/tissues, NOS (UNKNOWN if MICROSCOPIC or MACROSCOPIC), including • Adventitia • Distal periureteral tissue • Periprostatic tissue • Peritoneum • Serosa (mesothelium) (to/through) Tunica serosa (to/through)	RE
600	Extravesical tumor with extension to • Parametrium • Prostate, NOS • Prostatic stroma • Rectovesical/Denonvilliers' fascia • Seminal vesicle • Ureter (excluding distal ureter) • Urethra (including prostatic urethra) • Uterus • Vagina Vas deferens	RE
650	Extravesical tumor with extension to • Large intestine • Rectum (male) Small intestine	D
700	Bladder is "fixed"	RE

EOD OF PRIMARY TUMOR (continued)

ITEM B-12

Code	Description	SS2018 T
720	Bladder is "fixed" with extension to structures in code 650 OR Extravesical tumor with extension to • Abdominal wall • Bone • Colon • Pelvic wall • Pubic bone • Rectum (female) Further contiguous extension	D
750	Extravesical tumor, NOS	RE
800	No evidence of primary tumor	U
999	Unknown; extension not stated Primary tumor cannot be assessed Not documented in patient record Death Certificate Only	U

Note 1: The two main types of bladder cancer are the flat (sessile) variety and the papillary type. The flat (sessile) variety is called in situ when tumor has not penetrated the basement membrane. Papillary tumor that has not penetrated the basement membrane is called noninvasive.

Note 2: Noninvasive papillary transitional carcinoma: Pathologists use many different descriptive terms for noninvasive papillary transitional cell carcinoma. Frequently, the pathology report does not contain a definite statement of non-invasion; however, non-invasion can be inferred from the microscopic description.

Definite statements of non-invasion for papillary transitional cell carcinomas (Ta) include

Noninfiltrating
Noninvasive
No evidence of invasion
No extension into lamina propria
No stromal invasion
No extension into underlying supporting tissue
Negative lamina propria and superficial muscle
Negative muscle and (subepithelial) connective tissue
No infiltrative behavior/component

EOD OF PRIMARY TUMOR (continued)

ITEM B-12

Inferred descriptions of non-invasion for papillary transitional cell carcinomas include

No involvement of muscularis propria and no mention of subepithelium/submucosa
No statement of invasion (microscopic description present)
(Underlying) Tissue insufficient to judge depth of invasion
No invasion of bladder wall
No involvement of muscularis propria
Benign deeper tissue
Microscopic description problematic (non-invasion versus superficial invasion)
Frond surfaced by transitional cell
No mural infiltration
No evidence of invasion (no sampled stroma)
Confined to mucosa

Note 3: Noninvasive (in situ) flat transitional cell carcinoma: Careful attention must be given to the use of the term "confined to mucosa" for flat bladder carcinomas. Historically, carcinomas described as "confined to mucosa" were coded as localized. However, pathologists use this designation for non-invasion as well. Pathologists also vary in their use of the terms "invasion of mucosa, grade 1" and "invasion of mucosa, grade 2" to distinguish between noninvasive and invasive carcinomas. In order to accurately code tumors described as "confined to mucosa", abstractors should determine

- If the tumor is confined to the epithelium: then it is noninvasive (000).
- If the tumor has penetrated the basement membrane to invade the lamina propria: then it is invasive and coded to 100 for localized. The lamina propria and submucosa tend to merge when there is no muscularis mucosa, so these terms may be used interchangeably, along with stroma and subepithelial connective tissue.
- If the distinction between involvement of the epithelium and lamina propria cannot be made, then the tumor should be coded as "confined to mucosa, NOS" (100).
- Statements meaning confined to mucosa, NOS for flat transitional cell carcinomas include
  - Confined to mucosal surface
  - Limited to mucosa, no invasion of submucosa and muscularis
  - No infiltration/invasion of fibromuscular and muscular stroma
  - Superficial, NOS

Note 4: In case of multifocal papillary noninvasive tumors (code 000) and nonpapillary in situ tumors (code 050), code 050

Note 5: Code 300 if the only description of extension is through full thickness of bladder wall, and there is no clear statement as to whether or not the cancer has extended into fat.

EOD OF PRIMARY TUMOR (continued)

ITEM B-12

Note 6: An associated in situ component of tumor extending into the prostatic ducts, prostatic glands, or ureter without invasion is disregarded in staging classification. Assign the code that best describes depth of bladder wall invasion.

Note 7: Direct invasion of the distal ureter is classified by the depth of greatest invasion in the bladder or ureter. Code 100 if the distal ureter is defined as below the iliac vessel, within the pelvic brim is involved.

Note 8: Code 130 when there is extension from the bladder into the subepithelial tissue of prostatic urethra.

2. Description:

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

GRADE

ITEM B-13

1. Code: 3 digits

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

2. Description:

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

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

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

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

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

GRADE (continued)

ITEM B-13

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

DATE RADIATION TO PRIMARY SITE BEGAN

ITEM B-14

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

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

2. Description:

2.1 Enter the date the patient first received radiation TO THE PRIMARY SITE at any time after diagnosis.

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

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

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

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

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

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

SHORTAGE OF BACILLUS CALMETTE-GUERIN (BCG)

ITEM B-15

1. Code: i). Did the medical record or physician office information indicate a shortage of Bacillus Calmette-Guerin (BCG) or any difficulty obtaining BCG for treatment of this patient?

1 – Yes. The medical record or physician office information listed a shortage of BCG or difficulty obtaining/acquiring BCG for bladder cancer treatment.
2 – No. BCG was part of the treatment plan but no mention in the medical record or physician office information of BCG shortage or difficulty obtaining BCG for bladder cancer treatment.
9 – Unknown. Shortage or difficulty obtaining BCG is unknown or BCG was not part of the treatment plan.

ii). Date BCG shortage or difficulty obtaining BCG was first listed in medical record:

Month	Day	Year
00	00	0000 – No BCG Shortage, or unknown
01 - January	01	Use 4-digit Year
02 - February.	02	
..	..	
12 - December	31	
99 - Month Unk	99 - Day Unk	9999-Year Unknown

iii). Effect of BCG shortage of patient's treatment:

Mark all that apply if multiple effects of BCG shortage or difficulty obtaining BCG are listed in the medical record or physician office information. Code as 'No effect of BCG shortage listed' if no effects from BCG shortage/difficulty obtaining BCG are listed in the medical record or physician office information. Code as not applicable (N/A) if no BCG shortage or BCG shortage unknown was indicated in section (i).

- ☐ Delayed treatment until BCG was available
- ☐ Substituted a different intravesical drug for BCG due to shortage
- ☐ Used a different systemic drug or drugs due to BCG shortage
- ☐ Reduced dose of BCG due to shortage
- ☐ Reduced number of BCG administrations due to shortage
- ☐ Stopped treatment due to shortage
- ☐ Obtained BCG from a more expensive supplier
- ☐ Sent patient to a different institution/site to receive BCG treatment
- ☐ Obtained BCG from a different source
- ☐ No effect of BCG shortage listed
- ☐ Unknown/effect of BCG shortage on treatment not specified
- ☐ Other, specify _____
- ☐ N/A

SHORTAGE OF BACILLUS CALMETTE-GUERIN (BCG) (continued)

ITEM B-15

2. Description:

2.1 This item is a pilot test to assess whether information on shortages or difficulties obtaining Bacillus Calmette-Guerin (BCG), an intravesical (intra-bladder) therapy for bladder cancer, can be collected from the medical record. Shortages in BCG are regularly reported in the U.S. but no national study has attempted to document the effects of these shortages on patterns of care.

2.2 For item (i), record whether the medical record or physician office information indicates a shortage of BCG or difficulty obtaining BCG to treat this patient's current episode of bladder cancer. Code this item as "1 – Yes" if the medical record or physician office information indicates a shortage or difficulty obtaining BCG to treat bladder cancer. Code this item as "2 – No" if BCG was part of the treatment plan but there was no indication in the medical record or physician office information of a shortage or difficulty obtaining BCG. Use code "9 – Unknown" if the medical record indicates that there was no planned treatment for this patient's bladder cancer; or if BCG was not part of the patient's treatment plan; or if the patient died before a treatment plan was prepared. Also use code "9 – Unknown" if BCG was part of the treatment plan, but it is unknown whether there was a shortage of BCG.

2.3 For item (ii), record the date when the BCG shortage or difficulty obtaining BCG was first mentioned in the medical record. If no BCG shortage was listed (i.e., code "2 – No" was applied in item i) or BCG shortage was unknown (i.e., code "9 - Unknown" was applied in item i), code item (ii) as "00-00-0000". If item i) is coded "1-Yes, BCG shortage" but the date the shortage was first documented is unknown, then use code "99-99-9999".

2.4 For item (iii), record the effect(s) of the BCG shortage or difficulty obtaining BCG on the patient's urinary bladder cancer treatment pattern of care. Mark all effects that were indicated in the medical record. If there was an effect indicated in the medical record that isn't listed in item (iii), record it in the "Other, specify" field. If the medical record indicates that the BCG shortage or difficulty obtaining BCG did not affect the patient's cancer treatment patterns, code as "No effect of BCG shortage listed." If the medical record does not specify whether the BCG shortage or difficulty obtaining BCG had any effect on the patient's treatment pattern, code as "Unknown/effect of BCG shortage on treatment not specified." If no BCG shortage was listed (i.e., code "2 – No" was applied in item i) or BCG shortage was unknown (i.e., code "9 – Unknown" was applied in item i), code item (iii) as "N/A".

METASTASIS OR LOCAL RECURRENCE AFTER DIAGNOSIS

ITEM B-16

1. Code: i) Metastasis or local recurrence after diagnosis

0 – Patient had metastatic disease at diagnosis
1 – No evidence of metastasis or local recurrence after diagnosis
2 – Yes, metastasis at a distant site identified after diagnosis
3 – Yes, local recurrence at primary tumor site identified after diagnosis
4 – Yes, both metastasis and local recurrence identified after diagnosis
9 – Unknown if metastasis or local recurrence after diagnosis

ii) Date first metastasis or local recurrence identified after diagnosis

MM-DD-YYYY
00-00-0000-No evidence of metastasis or local recurrence; Patient had metastatic disease at diagnosis; or Unknown if metastasis or local recurrence after diagnosis

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

2. Description:

2.1 This item collects information on whether a cancer metastasis or local recurrence is identified four months or more **after** the initial tumor diagnostic work-up. Metastasis refers to the presence of the same cancer at a site distant from the primary tumor. Local recurrence refers to the presence of the same cancer at the primary tumor site **after** the primary tumor has been removed. If the primary tumor is not removed, there cannot be a local recurrence.

2.2 For item (i), Code "0 - Patient had metastatic disease at diagnosis" if at initial diagnosis the patient was diagnosed with metastatic disease (M-stage M1 or coded as "Yes" in Item B-7, "METASTASIS AT DIAGNOSIS").

2.3 Code "1 – No" if there is no evidence of metastasis or local recurrence in the medical record or imaging reports **after** the initial tumor diagnosis work-up. The initial tumor diagnostic work-up is not just the initial biopsy but also includes subsequent imaging studies to determine the initial stage of the patient's cancer. **This option should be selected only if the patient did not have metastatic disease at diagnosis.** If the patient had metastatic disease at diagnosis (M-stage M1 or coded as "Yes" in item B-7), instead use code "0 - Patient had metastatic disease at diagnosis".

METASTASIS OR LOCAL RECURRENCE AFTER DIAGNOSIS (continued)

ITEM B-16

2.4 If there was no metastasis to distant sites after diagnosis, **and** there was no removal of primary tumor, then code "1—No evidence of metastasis or local recurrence after diagnosis".

2.5 Code "2 – Yes, metastasis at a distant site identified after diagnosis" when there is clinical or pathologic evidence of distant metastasis **after** diagnosis for patients who did not have an initial diagnosis of metastatic cancer.

2.6 Code "3 – Yes, local recurrence at primary tumor site identified after diagnosis" when there was surgery to completely remove the primary tumor and after the surgery there is clinical or pathologic evidence of a new cancer of the same type at the site of the primary tumor.

2.7 Code "4 – Yes, both metastasis and local recurrence identified after diagnosis" when there is clinical and pathologic evidence of distant metastasis after diagnosis **AND** clinical or pathologic evidence of local recurrence at the primary tumor site.

2.8 Code "9 - Unknown" if it is unknown whether there is metastasis or local recurrence after diagnosis.

2.9 For item (ii), code the first date that the metastasis or local recurrence after initial diagnosis listed in the medical record. If the patient had metastatic disease at diagnosis (item (i) coded "0"), no evidence of metastasis or local recurrence (item (i) coded "1"), or unknown whether there is metastasis or local recurrence after diagnosis (item (i) coded "9"), code item (ii) "00-00-0000".

2.10 For this item, identification of new positive regional lymph nodes more than four months following diagnosis should be coded as metastasis after diagnosis.

SYSTEMIC AND INTRAVESICAL THERAPY AGENTS

ITEMS B-17 through B-40

1. Code: i) Date of start of therapy

MM-DD-YYYY
00-00-0000 — No systemic or intravesical therapy given

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

ii) Mode of administration:
Intravesical (I)
Oral (O)
Parenteral (P)
Unknown (U)
N/A (N)

B-17 Atezolizumab (Tecentriq)

B-18 Avelumab (Bavencio)

B-19 Bacillus Calmette-Guérin (BCG)

B-20 Cisplatin

B-21 Carboplatin

B-22 Cyclophosphamide

B-23 Docetaxel

B-24 Doxorubicin (Adriamycin)

B-25 Durvalumab (Imfinzi)

B-26 Enfortumab vedotin (Pacdev)

B-27 Erdafitinib (Balversa)

SYSTEMIC AND INTRAVESICAL THERAPY AGENTS (continued)

ITEMS B-17 through B-40

B-28 Epirubicin

B-29 Gemcitabine

B-30 Interferon or interferon-alpha

B-31 Methotrexate

B-32 Mitomycin C (Mutamycin)

B-33 Nivolumab (Opdivo)

B-34 Paclitaxel

B-35 Pembrolizumab (Keytruda)

B-36 Thiotepa (ThioTEPA)

B-37 Valrubicin (Valstar)

B-38 Vinblastine

B-39 Vincristine

B-40 Other, specify: _____

This list is by no means complete and if other agents are found, please list them as well under B-40.

Please be sure to record all systemic therapy agents. SEER*Rx is useful for looking up chemotherapy, 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 Enter information for each agent separately. If systemic or intravesical therapy agents are present in the medical record that are not included in this list, please include these under B-40, "Other". Please record information on all systemic and intravesical therapy, from diagnosis to end of available medical records, not just the first course of systemic and/or intravesical therapy

2.2 For item (i), code the date therapy started for each systemic or intravesical (intra-bladder) therapy agent given at any time following diagnosis.

SYSTEMIC AND INTRAVESICAL THERAPY AGENTS (continued)

ITEMS B-17 through B-40

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

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

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

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

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

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

2.9 When a systemic or intravesical therapy is administered as one or more arms of a clinical trial and it is not known whether the patient was in that arm, this therapy should be coded as “Unknown if given” (97-97-9797). For example, if a patient were in a trial of new investigational agent vs. cisplatin, cisplatin should be coded as “Unknown if given”. The new investigational agent should also be listed as “Unknown if given”. However, if a patient was in a trial of cisplatin plus new investigational agent in one treatment arm vs. cisplatin plus placebo in the other treatment arm, cisplatin should be coded as given since it is part of both treatment arms. Do not include “placebo” as part of systemic therapies.

SYSTEMIC AND INTRAVESICAL THERAPY AGENTS (continued)

ITEMS B-17 through B-40

2.10 For item (ii), code the mode of administration for each therapy administered. This can be coded as I = Intravesical (or intra-bladder), O = Oral (by mouth), P = Parenteral, administration U = Unknown/not specified, or N = N/A. Parenteral administration is general intravenous (IV), but can also include intramuscular (IM), subcutaneous (SC or SQ), or administration via an angiocatheter; Broviac, Groshong, or Hickman catheter; PICC line; or port-a-cath. If a therapy was not administered (date of administration in item (i) coded as 00-00-0000, 77-77-7777, or 95-95-9595), code model of administration as N = N/A. If it is unknown if a therapy was administered (date of administration in item (i) coded as 96-96-9696 or 97-97-9797) or a therapy was administered but date of administration is unknown (date of administration in item (i) coded as 99-99-9999), code mode of administration using any available information in the medical chart, including specified recommendations regarding mode of administration.