

SECTION II: GENERAL ABSTRACTING INSTRUCTIONS

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It is the responsibility of every abstractor working in the state of Florida, including contract abstractors, to know the complete content of the latest FCDS Data Acquisition Manual (FCDS DAM) and to update it upon receiving any changes from FCDS. If you need training in cancer registry data collection, please visit the FLccSC Learning Management System and consider taking the FCDS Abstracting Basics Course to better understand the skills and training required to meet FCDS abstracting requirements and the national standards used when abstracting and coding cancer cases.

This manual is designed to explain in detail each data item required for the Florida Cancer Data System (FCDS) case reporting, specifically those labeled as Core in the Record Layout (see Appendix G). It should serve as the primary resource for any data item that must be coded and documented according to Florida cancer reporting rules and statutes. The descriptions aim to provide sufficient detail to achieve consensus when submitting the required data. This manual does not suggest any limitations on the type or degree of detailed information collected, classified, or studied within any healthcare facility-based cancer registry.

Basic Rules:

- 1) Always refer to the most current version of the *FCDS Data Acquisition Manual* when completing an abstract. The CoC STORE Manual may provide slightly different instructions for coding or abstracting of data items. However, the STORE Manual, the NAACCR Volume II Data Dictionary, and the SEER Coding and Staging Manual should be comparable in content, rules, instructions, and examples to ensure consistent coding across programs.
- 2) Always submit a separate abstract for each reportable primary neoplasm identified.
- 3) Text is required to justify all coded values adequately and to document supplemental information such as patient sex and family history of malignancy. Data items must be well documented in text field(s); specifically, Place of Diagnosis, Physical Exam, the Reason Why the Patient Came to Your Facility, Patient Sex, Imaging Studies including X-rays and Scans with Dates in Chronological Order, Diagnostic Endoscopy and Other Diagnostic Tools, Surgical Procedures and Operative Findings, Laboratory Tests and Pathology Reports (including: Dates of Specimen Collection, Primary Site, Histology, Behavior and Grade), Genetic Testing Results, Cancer Staging Information and Coding Rationale, and Site-Specific Data Items as Required.

The treatment details must also be documented in the Treatment Text fields, even if the treatment is non-standard or the case is non-analytic or historical. Dates should be included in each section's text to provide a chronology of events, imaging, lab tests, surgeries, and other anti-neoplastic treatments. Dates may be estimated and should be documented as estimated dates when necessary. Specifics of all treatments delivered are required, including chemotherapeutic and other anti-neoplastic agents, radiation therapy details, and treatment given outside your specific facility as noted in H&P, Consultation Reports, or other documentation. Please refer to Appendix L of this manual for specific text documentation instructions/examples.

Basic Rules For Date Fields:

- 1) FCDS no longer requires Date Flag Fields for any date flags beginning 1/1/2023.
- 2) Dates are transmitted in this format CCYYMMDD. However, this does not necessarily mean that the way dates are entered into your registry software has changed. Software providers are the primary resource for information about fields in their systems. Only valid portions of any date are to be transmitted.
- 3) FCDS requires every case you abstract (analytic, non-analytic, and historical grid cases) to include at least a valid year of diagnosis. All treatment (surgery, radiation, chemo, etc.) also requires a valid date consistent with the Date of Diagnosis, so the edits can validate that the treatment is within the parameters of the First Course of Therapy.

REGISTRY INFORMATION

The Registry Information section of the abstract includes the data items that identify the reporting facility, the case, the date of first contact or admission, the abstractor, and the date abstracted.

Data Items Included In This Section:

<u>NAACCR Item Number</u>	<u>Item Name</u>
540	Reporting Facility
550	Accession Number – Hospital
560	Sequence Number – Hospital
580	Date of First Contact
2300	Medical Record Number
2090	Date Case Completed/Date Abstracted
570	Abstracted By (FCDS Abstractor Code)
2152	CoC Accredited Flag
500	Type of Reporting Source

REPORTING FACILITY**NAACCR ITEM #540**

Identifies the facility reporting the case. This is a four-digit FCDS-assigned Facility Number. See Appendix A for hospital, surgery center, and free-standing radiation therapy center Facility Numbers.

The Reporting Facility (NAACCR Item #540), Accession Number (NAACCR Item #550), and Sequence Number (NAACCR Item #560) uniquely identify the facility, patient, and tumor(s). Each cancer patient in a facility is assigned a unique accession number, and each primary tumor diagnosed for that patient is assigned a sequence number to differentiate between primary cancers for the patient accessioned. See individual data item descriptions and coding instructions for more information on each data item noted.

Coding Instructions:

1. Enter the four-digit FCDS-assigned Facility Number from Appendix A.
2. The FCDS Facility Number differs from the FORDS Facility ID Number (FIN).
3. Each facility participating in a shared or network cancer registry must use the unique respective facility number unless the registry has been approved/designated an umbrella organization by FCDS.
4. Cases must be abstracted and reported separately for each facility according to Florida statute unless otherwise designated.
5. The four-digit reporting facility number must be right-justified.

ACCESSION NUMBER- HOSP**NAACCR ITEM #550**

Provides a unique identifier for the patient consisting of the year in which the patient was first seen at the reporting facility and the consecutive order in which the patient was abstracted.

The Reporting Facility (NAACCR Item #540), Accession Number (NAACCR Item #550), and Sequence Number (NAACCR Item #560) uniquely identify the facility, patient, and tumor(s). Each cancer patient in a facility is assigned a unique accession number, and each primary tumor diagnosed for that patient is assigned a sequence number to differentiate between primary cancers for the patient accessioned. See individual data item descriptions and coding instructions for more information on each data item noted.

Enter the nine-digit Accession Number as assigned by the reporting facility.

Format: The first four digits of the Accession Number specify the year the patient first had contact with the reporting facility in the format CCYY. The last five digits are the sequential/numeric order in which the registry entered the case into the database.

Each patient receives only one accession number from your facility for a lifetime, regardless of the facility's "reference date," number of primary cancers reported, or alternate numbering assignment. Accession numbers are never reassigned, even if a patient is removed from your facility registry.

Successive sequence numbers designate multiple primary reportable malignant neoplasms in one patient. Therefore, when submitting abstracts for multiple primary neoplasms for one patient simultaneously, use the same FCDS accession number for every cancer reported.

SEQUENCE NUMBER-HOSPITAL**NAACCR ITEM #560**

Enter the two-digit sequence number that corresponds to this primary tumor. This data item records the chronological appearance of each reportable primary malignant and non-malignant neoplasm over the

person's entire lifetime, regardless of where they were diagnosed or treated.

The Reporting Facility (NAACCR Item #540), Accession Number (NAACCR Item #550), and Sequence Number (NAACCR Item #560) uniquely identify the facility, patient, and tumor(s). Each cancer patient in a facility is assigned a unique accession number, and each primary tumor diagnosed for that patient is assigned a sequence number to differentiate between primary cancers for the patient accessioned. See individual data item descriptions and coding instructions for more information on each data item noted.

Codes 00–35 indicate neoplasms of in situ or malignant behavior (behavior equals 2 or 3).

A solitary reportable malignant neoplasm is not part of a sequence; therefore, enter **00** to indicate the lack of sequence.

If a patient was previously reported as sequence 00 and has since developed a subsequent reportable malignant neoplasm, the sequence should be designated by the appropriate number, 02, 03, etc. The original 00 will be changed to 01 automatically in the FCDS files.

If two or more independent primary malignant neoplasms are diagnosed simultaneously, the lowest sequence number should be assigned to the malignancy with the worst prognosis.

Codes 60–88 indicate neoplasms of non-malignant behavior (behavior equals 0 or 1).

A solitary reportable non-malignant neoplasm is not part of a sequence; therefore, enter 60 to indicate the lack of sequence.

If a patient was previously reported as sequence 60 and has since developed a subsequent reportable non-malignant neoplasm, the sequence should be designated by the appropriate number, 62, 63, etc. The original 60 will be changed to 61 automatically in the FCDS files.

If two or more non-malignant neoplasms are diagnosed at the same time, assign the lowest sequence number to the diagnosis with the worst prognosis.

A re-evaluation of all related sequence numbers is required whenever an additional neoplasm is identified.

Code	Description
00	One Malignant Primary Only (in-situ and malignant tumors)
01	First of two or more malignant primaries
02	Second of two or more malignant primaries
03	Third of three or more malignant primaries
60	One non-malignant primary (benign/borderline tumors)
61	First of two or more non-malignant primaries
62	Second of two or more non-malignant primaries

DATE OF FIRST CONTACT

NAACCR ITEM #580

Date of first patient contact, as inpatient or outpatient, with the reporting facility for the tumor diagnosis and/or treatment. The date may represent the date of an outpatient visit for a biopsy, x-ray, scan, or laboratory test. Enter the year, month, and day (CCYYMMDD) of the patient's first contact with the reporting facility for the tumor's diagnosis and/or treatment, whether as an inpatient or outpatient diagnosis

and/or first-course treatment. The date may represent the date of an outpatient visit for a biopsy, x-ray, scan, or laboratory test, the date of admission to the facility, or the date of a pathology specimen collected as part of surgical resection or biopsy performed during a long-term in-patient admission.

When a diagnosis of cancer is made during a patient's long-term stay for another condition, the date the patient was first examined for the cancer-related problem should be used as the Date of First Contact. If the case was initially diagnosed at autopsy, the Date of Death should be used as the Date of First Contact and the Date of Diagnosis.

An error is issued if the Date of First Contact precedes the Date of Diagnosis by more than thirty days.

The date of 1st Contact is one of several data items that can be used to measure the timeliness of reporting to central cancer registries by individual facilities. For tumors that are not diagnosed at the reporting facility following its Reference Date (Class of Case 20-22, 30-37), the Date of 1st Contact [580] can be used in conjunction with the Date Case Report Received [2111] to measure timeliness of reporting by individual facilities.

The CoC STORE Manual revised the definition of the Date of First Contact to allow registries to change the date to when the patient's case became 'analytic' for the facility. FCDS does not receive or allow Modify Records from all reporting facilities. If this is the case and registrars change the Date of First Contact, then FCDS would never know about it, nor would we know about the change in Class of Case. Please use your best judgment to resolve this inconsistency in instructions to fit reporting needs for Florida.

MEDICAL RECORD NUMBER

NAACCR ITEM #2300

Enter the patient's 15-character Medical Record Number (alpha/numeric) used by the facility to identify the patient. Do not use special characters in this field (i.e., *, -, /). If the patient has no Medical Record Number, you may enter the casefinding source (i.e. XRT, xyz CLINIC), any facility identification number, or billing number that will help locate the record at a future date.

DATE CASE COMPLETED/DATE ABSTRACTED

NAACCR ITEM #2090

Enter the date the case is being abstracted. The format for all dates is numeric (CCYYMMDD). An unknown date is not acceptable in this field.

Please wait until ALL first-course therapy has been completed before submitting the case to FCDS. FCDS continues to monitor the patient/cancer to ensure the first course of treatment is consistent with the stage of disease and specific biomolecular and genetic tumor markers for targeted therapies. For cases not yet completed by the June 30th deadline, you may code the treatment as recommended, unknown if administered. All cases are required to be reported to FCDS by June 30th. When treatment has not started but is a part of the treatment plan, and the FCDS Deadline to Report (June 30th) is upon you, but you do not have the information that treatment started, enter the treatment as 'recommended' and submit.

ABSTRACTED BY (FCDS ABTRACTOR CODE)

NAACCR ITEM #570

Enter the three-digit FCDS Abtractor Code of the person abstracting this case. Each abtractor submitting cases to FCDS must have their unique FCDS Abtractor Code. All abstracts submitted must have an approved and valid (current) FCDS Abtractor Code in this field. Validation of the FCDS Abtractor Code

is part of the FCDS EDITS process; therefore, if any Abstractor Code is incorrect, invalid, or expired, the batch will fail edits at the time of batch upload or record entry. If abstracts are submitted to FCDS with an expired Abstractor Code, the facility must update the abstracts with a valid Abstractor Code. Those abstracts should be reviewed for accuracy to validate the abstracted data.

Your FCDS Abstractor Code should never be shared with any other abstractor.

Refer to Section I of this manual for more information on the FCDS Abstractor Code requirement.

COC ACCREDITED FLAG

NAACCR ITEM #2152

CoC Accredited Flag is assigned at the point and time of data abstraction to label an abstract prepared for an analytic cancer case at a facility accredited by the Commission on Cancer (CoC). The flag may be assigned manually or defaulted by the registry's software.

CoC-accredited facilities are required to collect certain data items, including TNM staging. The flag incorporates the accredited status into abstracts at the time of abstraction by someone who knows the status. Thus, the flag simplifies and validates that CoC-accredited facilities have abstracted required items.

Code	Description
0	Abstract prepared at a facility WITHOUT CoC accreditation of its cancer program.
1	ANALYTIC abstract prepared at facility WITH CoC accreditation of its cancer program (Includes Class of Case codes 10-22)
2	NON-ANALYTIC abstract prepared at facility WITH CoC accreditation of its cancer program (Includes Class of Case codes 30-43 and 99, plus code 00, which CoC considers analytic but does not require to be staged)
Blank	Not applicable; DCO

TYPE OF REPORTING SOURCE

NAACCR ITEM #500

Enter the Type of Reporting Source code that identifies the source of information used to abstract the case.

Code	Description
1	Hospital Inpatient; managed health plans with comprehensive, unified medical records
2	Radiation Treatment Centers or Medical Oncology Centers (hospital-affiliated or independent)
3	Laboratory only (hospital-affiliated or independent)
4	Physician's Office/Private Medical Practitioner (LMD)
5	Nursing/Convalescent Home/Hospice
6	Autopsy Only
7	Death Certificate Only (DCO) - FCDS Use Only
8	Other hospital outpatient units/surgery centers

When multiple source documents are used to abstract a case, use the following priority order to assign a code for Type of Reporting Source: Priority order of codes 1, 2, 8, 4, 3, 5, 6, 7.

Code	Label	Source Documents	Priority
1	Hospital inpatient; Managed health plans with comprehensive, unified medical records	<ul style="list-style-type: none"> Hospital inpatient ; Includes outpatient services of HMOs and large multi-specialty physician group practices with unit record. <ul style="list-style-type: none"> Offices/facilities with unit record HMO physician office or group HMO affiliated free-standing laboratory, surgery, radiation or oncology clinic 	1
2	Radiation Treatment Centers or Medical Oncology Centers (hospital-affiliated or independent)	<ul style="list-style-type: none"> Facilities with serial record (not a unit record) Radiation treatment centers Medical oncology centers (hospital affiliated or independent) <p>There were no source documents from code 1.</p>	2
3	Laboratory Only (hospital-affiliated or independent)	<ul style="list-style-type: none"> Laboratory with serial record (not a unit record) <p>There were no source documents from codes 1, 2, 8, or 4.</p>	5
4	Physician's Office/Private Medical Practitioner	<ul style="list-style-type: none"> Physician's office that is NOT an HMO or large multi-specialty physician group practice. <p>There were no source documents from codes 1, 2 or 8</p>	4
5	Nursing/Convalescent Home/Hospice	<ul style="list-style-type: none"> Nursing or convalescent home or a hospice. <p>There were no source documents from codes 1, 2, 8, 4, or 3.</p>	6
6	Autopsy Only	<ul style="list-style-type: none"> Autopsy <p>The cancer was first diagnosed on autopsy.</p> <p>There are no source documents from codes 1, 2, 8, 4, 3 or 5.</p>	7
7	Death Certificate Only	<p>Death certificate is the only source of information; follow-back activities did not identify source documents from codes 1, 2, 8, 4, 3, 5 or 6. If another source document is subsequently identified, the Type of Reporting Source code must be changed to the appropriate code in the range of 1, 2, 8, 4, 3 or 6</p>	
8	Other hospital outpatient units/surgery centers	<ul style="list-style-type: none"> Other hospital outpatient units/surgery centers. Includes, but not limited to, outpatient surgery and nuclear medicine services. <p>There are no source documents from codes 1 or 2.</p>	3

PATIENT DEMOGRAPHICS

The Patient Demographics section of the abstract includes the data items used to describe personal information about the patient. When grouped, these data can be used to study how cancer rates differ by geographic location and what groups are at a higher risk of certain types of cancer. Much of this section's information is confidential and can be used to identify individual patients.

Data Items Included in this Section (CONFIDENTIAL):

<u>NAACCR Item Number</u>	<u>Item Name</u>
2230	Name – Last
2240	Name – First
2250	Name – Middle
2280	Name – Alias
2232	Name – Birth Surname
2315	Medicare Beneficiary ID
2320	Social Security Number
240	Date of Birth
252	Birthplace State
254	Birthplace Country
220	Sex
160	Race 1
161	Race 2
162	Race 3
163	Race 4
164	Race 5
190	Spanish/Hispanic Origin
150	Marital Status
344	Tobacco Use Smoking Status
9960	Height at Diagnosis (inches)
9961	Weight at Diagnosis (lbs.)
2335	Addr at DX - Supplemental
2330	Addr at DX – No & Street
70	Addr at DX – City
80	Addr at DX – State
102	Addr at DX – Country
100	Addr at DX – Postal Code
90	County at DX
2350	Addr Current – No & Street
1810	Addr Current – City
1820	Addr Current – State
1832	Addr Current – Country
1830	Addr Current – Postal Code
1840	County--Current
2360	Telephone Current
630	Primary Payer at DX
2460	Physician – Managing
2465	NPI – Managing Physician
2475	NPI – Following Physician
2485	NPI – Primary Surgeon
2495	NPI – Physician #3 (Radiation Oncologist)
2505	NPI – Physician #4 (Medical Oncologist)
310	Text – Usual Occupation
320	Text – Usual Industry

NAME – LAST**NAACCR ITEM #2230**

Enter the patient's full last name. Blanks, spaces, hyphens, and apostrophe marks are allowed. However, FCDS software will strip off these special characters during upload to the FCDS database.

*Example:*Mc Donald is entered McDonald. O'Hara is entered OHara.

NAME – FIRST**NAACCR ITEM #2240**

Enter the patient's full first name with no special characters (e.g., no periods). Do not enter the patient's middle name or initial in this field. If you encounter an edit failure that the Patient Name does not match a previously submitted neoplasm, contact your Field Coordinator to correct any Demographic discrepancies before resubmission.

NAME – MIDDLE**NAACCR ITEM #2250**

Enter the patient's middle name or middle initial with no special characters (e.g., no periods). If the patient does not have a middle name or if the middle name is unknown, leave this field blank.

NAME – ALIAS**NAACCR ITEM #2280**

Enter the patient's alternate name or "AKA" (also known as), if known. You may also enter postscripts in this field such as "Junior", "Senior", etc. Note that the maiden name is entered in the Name-Maiden field.

NAME – BIRTH SURNAME**NAACCR ITEM #2232**

This new data item is similar to Maiden Name but not the same. Enter the patient's last name (surname) of patient at birth, regardless of gender or marital status. Leave this field blank if the birth surname is unknown or not applicable. Do not enter Mr, Mrs, Ms, Unknown, Unk or other non-surnames in this field.

MEDICARE BENEFICIARY ID (MBI)**NAACCR ITEM #2315**

The Centers for Medicare and Medicaid removed Social Security Number (SSN), based Health Insurance Claim Numbers (HICNs), from Medicare cards in 2020; and are now using Medicare Beneficiary Identifiers (MBIs) for Medicare transactions like billing, eligibility status, and claim status.

Every Medicare beneficiary has been assigned an MBI. Like the SSN, the MBI is confidential and should be protected as Personally Identifiable Information.

The Medicare Beneficiary Identifier (MBI) is randomly generated and has 11 characters, consisting of numbers and letters, entered without dashes. This number has replaced the Social Security Number for patients receiving Medicare/Medicaid and patients with Federal Medical Insurance. When available, enter the patient's 11-digit Medical Beneficiary Identifier. You may leave this field blank if the Medical Beneficiary Identifier is unavailable, the patient is a non-Medicare patient, or the number is unknown.

- | | |
|----------------------------|--|
| Coding Requirements | <ol style="list-style-type: none"> 1. Conditional 2. Value must be an 11-character string 3. Character 1 must be numeric values 1 thru 9 4. Character 2 must be alphabetic values A thru Z (minus S,L,O,I,B,Z) 5. Character 3 must be alphanumeric values 0 thru 9 or A thru Z (minus S,L,O,I,B,Z) 6. Character 4 must be numeric values 0 thru 9 7. Character 5 must be alphabetic values A thru Z (minus S,L,O,I,B,Z) 8. Character 6 must be alphanumeric values 0 thru 9 or A thru Z (minus S,L,O,I,B,Z) 9. Character 7 must be numeric values 0 thru 9 10. Character 8 must be alphabetic values A thru Z (minus S,L,O,I,B,Z) 11. Character 9 must be alphabetic values A thru Z (minus S,L,O,I,B,Z) 12. Character 10 must be numeric values 0 thru 9 13. Character 11 must be numeric values 0 thru 9 14. Value must not contain a pipe or asterisk symbols |
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SOCIAL SECURITY NUMBER (SSN)

NAACCR ITEM #2320

SOCIAL SECURITY NUMBER IS STILL A FLORIDA REQUIREMENT ON ALL CASES.

Coding Instructions:

1. Please reference APPENDIX Q - FLORIDA DEPARTMENT OF HEALTH LETTER regarding patient Social Security Number – A Florida Mandated Data Item printed on Florida DOH Letterhead.
2. Enter the patient's complete nine-digit Social Security Number.
3. The Social Security Number is entered without dashes and a letter suffix.
4. If the patient's Social Security Number is unknown, not applicable or incomplete, enter 999999999.
5. Do not use computer-generated hospital-specific billing numbers in this field.
6. Do not enter a partial Social Security Number with a valid last 4-digits. This is not a valid number.
7. Sequential numbers such as 123456789 and other contrived numbers will not be accepted as valid.
8. If you cannot access the patient social security number through your electronic medical record you must work with your in-house IT security and records access contacts to ensure you have access to this item. It is required in the Florida Statute for Reporting Cancers to FCDS.

Note: The Centers for Medicare and Medicaid removed Social Security Number (SSN)-based Health Insurance Claim Numbers (HICNs) from Medicare cards in 2020; and are now using Medicare Beneficiary Identifiers (MBIs) for Medicare transactions like billing, eligibility status, and claim status.

Every person with Medicare has been assigned an MBI. The MBI is confidential, like the SSN, and should be protected as Personally Identifiable Information. See the MBI Data Item for more information on MBI.

DATE OF BIRTH

NAACCR ITEM #240

Identifies the date of birth of the patient.

Coding Instructions:

1. Record the patient's date of birth as indicated in the patient record. For single-digit day or month, record with a lead 0 (for example, September is 09). Use the full four-digit year for year.
2. Record the actual date of birth for in utero diagnosis and treatment.
3. If only the patient age is available, calculate the year of birth from age and the year of diagnosis and leave day and month of birth unknown (for example, a 60 year old patient diagnosed in 2010 is calculated to have been born in 1950).
4. If month is unknown, the day is coded unknown. If the year cannot be determined, the day and month are coded unknown.

BIRTHPLACE STATE

NAACCR ITEM #252

Enter the two-character United States Postal Service abbreviation (Appendix B) for the state, commonwealth, U.S. possession; or Canadian province/territory in which the patient was born. Do not use State Code XX, YY, or ZZ for Canadian-born patients or patients born in a US Territory, US Possession, or while deployed out of the United States as part of the military or other federal service. Each tumor's birth state is the same if the patient has multiple primaries.

This data item in combination with BIRTHPLACE COUNTRY is a modification of the historical data item Birthplace [250].

BIRTHPLACE COUNTRY

NAACCR ITEM #254

Enter the three-character International Organization for Standardization (ISO) Country Code abbreviation (Appendix B) for the country where the patient was born.

If the patient has multiple primaries, the country of birth must be the same for each tumor.

This data item in combination with BIRTHPLACE STATE is a modification of the historical data item Birthplace [250].

Please refer to Appendix B for specific ISO Country Codes.

SEX**NAACCR ITEM #220**

Enter the appropriate Sex code.

Code	Description
1	Male
2	Female
3	Other (intersex, disorders of sexual development/DSD)
4	Transsexual, NOS
5	Transsexual, natal male
6	Transsexual, natal female
9	Unknown/not stated

RACE 1, RACE 2- 5**NAACCR ITEMS 160, 161, 162, 163, 164**

Item Name	NAACCR Item #
Race 1	160
Race 2	161
Race 3	162
Race 4	163
Race 5	164

For guidance, refer to the Race Coding Instructions Supplement and Appendix D (Race and Nationality Descriptions from the 2000 Census and Bureau of Vital Statistics).

Code	Label	Code	Label
01	White	20	Micronesian, NOS
02	Black or African American	21	Chamorro
03	American Indian or Alaska Native	22	Guamanian, NOS
04	Chinese	25	Polynesian, NOS
05	Japanese	26	Tahitian
06	Filipino	27	Samoan
07	Native Hawaiian	28	Tongan
08	Korean	30	Melanesian, NOS
		31	Fiji Islanders
10	Vietnamese	32	Papua New Guinean
11	Laotian	96	Other Asian, including Asian, NOS
12	Hmong	97	Pacific Islander, NOS
13	Cambodian	98	Some other race
14	Thai	99	Unknown by patient
15	Asian Indian, NOS or Pakistani, NOS		
16	Asian Indian		
17	Pakistani		

SPANISH/ HISPANIC ORIGIN**NAACCR ITEM #190**

Enter the patient's designated Spanish or Hispanic origin. This term identifies persons of Spanish/ Hispanic surname or ethnicity. (See Appendix E for a list of Spanish surnames and for instructions for using the list to determine ethnicity). Accurate determination of Hispanic ethnicity is important for purposes for calculating cancer rates for Hispanics. All records for a patient must contain the same code.

Persons of Spanish or Hispanic origin may be of any race. Categories are not used for Native American, Filipinos, etc., who may have Spanish names. The use of code 9 is discouraged. If the medical record does not indicate Hispanic ethnicity and the name does not appear in Appendix E, code 0 non-Hispanic.

If a patient has a Hispanic name but there is reason to believe they are not Hispanic (e.g. the patient is Filipino, or the patient is a woman known to be non-Hispanic who has a Hispanic married name) the code in this field should be 0, Non-Spanish, Non- Hispanic.

Code	Label
0	Non-Spanish; non-Hispanic (including Portuguese and Brazilian)
1	Mexican (includes Chicano)
2	Puerto Rican
3	Cuban
4	South or Central American (except Brazil)
5	Other specified Spanish/Hispanic origin (includes European; excludes Dominican Republic)
Code	Label
6	Spanish, NOS; Hispanic, NOS; Latino, NOS (There is evidence other than surname or r maiden name that the person is Hispanic, but he/she cannot be assigned to any category of 1-5.)
7	Spanish surname only (The only evidence of the person's Hispanic origin is surname or maiden name and there is no contrary evidence that the person is not Hispanic.)
8	Dominican Republic
9	Unknown whether Spanish or not

MARITAL STATUS**NAACCR ITEM #150**

Enter the patient's Marital Status at the time of diagnosis of the primary being reported. If the patient has multiple primaries, marital status may differ for each primary. If a patient is younger than 15, assume he/she is single and code 1.

Code	Description
1	Single (never married)
2	Married (including common law)
3	Separated
4	Divorced
5	Widowed
6	Unmarried or Domestic Partner (same sex or opposite sex, registered or unregistered)
9	Unknown

HEIGHT AT DIAGNOSIS**NAACCR ITEM #9960**

Enter the patient's height at the time of diagnosis for all sites in inches. Historical cases may not have this information available. Different tumors for the same patient may have different values. Therefore, height at DX should be collected from source records once for each cancer. Height should be taken from the Nursing Interview Guide, Flow Chart, or Vital Stats section from the patient's hospital medical or physician office records. See Appendix J for converting feet to inches.

Coding Instructions:

Code height as 2 digit numbers and measured in inches (note that 1 foot=12 inches).

Code "98" for 98 inches or greater.

Code "99" for unknown height.

Code "99" for historical cases.

All inches values should be rounded to the nearest whole number; values with decimal place x .5 and greater should be rounded up (e.g., 62.5 inches would be 63 inches).

The height entered should be that listed at or around the time of diagnosis. If no height was listed on the date of diagnosis, please use the height recorded on the date closest to the date of diagnosis and before treatment was started.

You can use the following on-line conversion calculator: http://manuelweb.com/in_cm.htm

If you have trouble opening this link from this file, copy and paste the address into your browser.

WEIGHT AT DIAGNOSIS**NAACCR ITEM #9961**

Enter the patient's weight at the time of diagnosis for all sites. Historical cases may not have this information available. Different tumors for the same patient may have different values. It should be collected from source records once for each cancer. Weight should be taken from the Nursing Interview Guide, Flow Chart, or Vital Stats section from the patient's hospital medical or physician office records. See Appendix -K for converting kilograms to pounds.

Coding Instructions:

Code weight as 3-digit numbers and measured in pounds (note that 1 kg = 2.2 pounds).

Code "999" for unknown weight.

Code "999" for historical cases.

All pound values should be rounded to the nearest whole number; values with decimal place x.5 and greater should be rounded up (e.g., 155.5 pounds would be 156 pounds).

Patients with less than 100 pounds should be recorded with a leading 0.

TOBACCO USE SMOKING STATUS**NAACCR ITEM #344**

This data item indicates the patient's past or current smoking use of tobacco (cigarette, cigar and/or pipe). Cigarette smoking is the leading preventable cause of death in the US and a major risk factor for cancer.

Reducing tobacco use is a CDC's National Center for Chronic Disease Prevention and Health Promotion focus. Reliable registry-based tobacco use data will help public health planners and clinicians target populations of cancer survivors for tobacco cessation.

Individual states have reported smoking data on patients are a useful covariate risk factor for cancer cluster investigations. Some state central cancer registries collect tobacco use data, but these variables are not standardized among registries.

Coding Instructions:

- Record cigarette, cigar and/or pipe use only. Tobacco Use Smoking Status does not include marijuana, chewing tobacco, e-cigarettes, or vaping devices.
- Tobacco smoking history can be obtained from sections such as the Nursing Interview Guide, Flow Chart,
- Vital Stats, Nursing Assessment section, or other sources from the patient's hospital medical or physician office records.
- **Use code 1** (Current smoker) if there is evidence in the medical record that the patient quit smoking within 30 days prior to diagnosis. The 30 days prior information is intended to differentiate patients who may have quit recently due to symptoms that led to a cancer diagnosis.
- **Use code 2** (Former smoker) if the medical record indicates the patient smoked tobacco in the past but does not smoke now. The patient must have quit 31 or more days prior to cancer diagnosis to be coded as 'Former smoker' (see above instruction).
- **Use code 3** (Ever Smoked, current status unknown) if it cannot be determined whether patient currently smokes or formerly smoked. For example, the medical record only indicates "Yes" for smoking without further information.
- **Use code 9** (Unknown if ever smoked) rather than code 0 (Never used),
 - if the medical record only indicates "No" for tobacco use
 - smoking status is not stated or provided
 - the method (cigarette, pipe, cigar) used cannot be verified in the chart.

Codes	
0	Never smoker
1	Current Smoker
2	Former Smoker
3	Smoker, current status unknown
9	Unknown if ever smoked

ADDRESS AT DX – SUPPLEMENTAL

NAACCR ITEM #2335

Enter the name of the place where the patient lived at the time of diagnosis, such as, a nursing home, or the name of an apartment complex. This field may also be used to record if the patient is homeless, a transient patient, or a foreign resident.

The Supplemental address field is to be used to record the name of a place, not an address.

For example, "WEST WOOD RETIREMENT HOME" would be entered in the Supplemental Address field and is not acceptable in the standard address fields.

ADDRESS AT DX – NO & STREET**NAACCR ITEM #2330**

Enter the number and street or the rural mailing address of the patient's residence at the time of diagnosis, including apartment number. Leave blanks between numbers and words. If the patient has multiple primaries, the address may differ for subsequent primaries. Do not abbreviate street names.

If the patient is a resident of the United States, the address must be a properly formed USPS street address. Following is a list of acceptable spellings:

“RR” is acceptable—no RURAL ROUTE, STAR ROUTE or RURAL DELIVERY

“HCR” is acceptable—no HC or HIGHWAY CONTRACT

“PO BOX” is acceptable—no POB or POST OFFICE BOX

“HOMELESS” is not allowed

“GENERAL DELIVERY” is acceptable

Enter “UNKNOWN” if the patient's address at diagnosis is not known.

“UNKNOWN” is acceptable—no UNK or UK. The word “UNKNOWN” must be spelled out.

The address at diagnosis will usually be the patient's current address for analytic cases.

For non-analytic cases, the address at diagnosis may not be the patient's current address. Reviewing the patient's medical record may reveal information regarding the patient's residence at the time of diagnosis. This information may be limited to city or state, but may include the actual street address in some instances. Any information available should be entered in the appropriate address field.

Avoid the use of post office box number and rural routes whenever possible. Do not use a temporary address. The Census Bureau definition of residence is “the place where he or she lives and sleeps most of the time or the place the person considers to be his or her usual home.”

Persons with More than One Residence (summer and winter homes, “snowbirds”): Use the street address the patient specifies if a usual residence is not apparent.

Persons with No Usual Residence (transients, homeless): Use the street address of the patient's residence when the cancer was diagnosed. This could be a shelter or the diagnosing facility.

Persons Away at School: College students are residents of the school area. Boarding school children below college level are residents of their parents' home.

Persons in Custodial Care Facilities: The Census Bureau states “Persons under formally authorized, supervised care or custody” are facility residents.

Persons in the Armed Forces and on Maritime Ships: Members of the armed forces are residents of the installation area. Use the stated street address for military personnel and their family. Military personnel may use the installation street address or the surrounding community's address. The Census Bureau has detailed residency rules for Navy personnel, Coast Guard, and maritime ships. Refer to Census Bureau publications for detailed rules.

ADDRESS AT DX – CITY**NAACCR ITEM #70**

Enter the name of the city or town where the patient resides at the time of diagnosis. If the patient resides in a rural area, record the name of the city used in their mailing address. If the patient has multiple primaries, the city of residence may differ for each primary. If the name of the city or town is not known at the time of diagnosis enter “UNKNOWN”. Do not abbreviate.

Persons with More than One Residence (summer and winter homes, “snowbirds”): Use the city address the patient specifies if a usual residence is not apparent.

Persons with No Usual Residence (transients, homeless): Use the city address of the place the patient was staying when the cancer was diagnosed. This could be a shelter or a diagnosing facility.

Person Away at School: College students are residents of the school area. Boarding school children below college level are residents of their parents’ homes.

Persons in Custodial Care Facilities: The Census Bureau states “Persons under formally authorized, supervised care or custody” are facility residents.

Persons in the Armed Forces and or Maritime Ships: Members of the armed forces are residents of the installation area. Use the stated city address for military personnel and their family. Military personnel may use the installation address or the surrounding community’s address.

The Census Bureau has detailed residency rules for Navy personnel, Coast Guard, and maritime ships. Refer to Census Bureau publications for detailed rules.

ADDRESS AT DX – STATE**NAACCR ITEM #80**

USPS abbreviation for the state, territory, commonwealth, U.S. possession, or Canada Post abbreviation for the Canadian province/territory where the patient resides when the reportable tumor is diagnosed.

If the patient has multiple primaries, each tumor's state of residence may differ.

Codes (in addition to USPS abbreviations):

CD	Resident of Canada, NOS (province/territory unknown)
US	Resident of United States, NOS (state/commonwealth/territory/possession/unknown)
XX	Resident of a country other than the United States (including its territories, commonwealths, or possessions) or Canada, and the country is known
YY	Resident of a country other than the United States (including its territories, commonwealths, or possessions) or Canada, and the country is unknown
ZZ	Residence unknown

FCDS Address field requirements:

Address At Dx - State	Class of Case	Address Status	County	Zip Code
FL	00-30,34-43	Full Address Required	Valid FL	Valid FL

FL	31-33	Full Address allowed but Unknown is permitted	Valid FL,999	Valid FL,99999
Non-FL exclude XX,YY,ZZ, US Possessions and Canada	00-14,34,35,38,40,41,42	Full Known Address Required	998	State Zip
Non-FL exclude XX,YY,ZZ, US Possessions and Canada	20-33,36-37,43	Full Address allowed but Unknown is permitted	998	State Zip, 99999
XX,YY	00-99	Unknown Permitted	998	88888
ZZ	00-99	Unknown Permitted	999	99999
US Possessions and Canada	00-99	Unknown Permitted	998	99999

ADDRESS AT DX – COUNTRY**NAACCR ITEM #102**

Enter the three-character International Organization for Standardization (ISO) Country Code abbreviation (Appendix B) for the country where the patient lived at the time of diagnosis.

If the patient has multiple primaries, the diagnosis address may differ for each tumor/abstract.

Refer to Appendix B for specific ISO Country Codes.

ADDRESS AT DX – POSTAL CODE**NAACCR ITEM #100**

Identifies the postal code of the patient's address at diagnosis

For United States residents, enter either the 5-digit or the extended 9-digit Zip code. When the 9-digit extended Zip code is unavailable, enter the 5-digit Zip code followed by zeros.

For Canadian residents, use 999999999. If using the FCDS IDEA Upload program only, Canadian valid Zip codes (ANANAN format) will be replaced with 999999999 at time of upload. For Single Entry users, Canadian residents must have 999999999 in the Zip code.

Current Zip (Postal) Code and postal directories are available from the National Information Data Center, PO Box 96523, Washington, DC 200900-6523 or call (301) 287-2347. Most major cities have a telephone listing, which you may call for Zip (Postal) Code information. Many mailing address look-up services are available online, including http://www.usps.com/ncsc/lookups/lookup_zip+4.html.

COUNTY AT DIAGNOSIS**NAACCR ITEM #90**

Enter the code for the county of the patient's residence when the tumor was diagnosed. For U.S. residents, standard codes are those of the FIPS publication — *Counties and Equivalent Entities of the United States, Its Possessions, and Associated Areas*. If the patient has multiple tumors, each tumor's county codes may differ.

FCDS only allows Florida County Codes. If a residence is NOT in Florida, the code must be 998 or 999.

Codes (in addition to FIPS):

998 Known town, city, state, or country of residence but county code not known AND a resident outside of the state of reporting institution (must meet all criteria). CANADIAN Residents.

999 COUNTY UNKNOWN

FCDS Address field requirements:

Address At Dx - State	Class of Case	Address Status	County	Zip Code
FL	00-30,34-43	Full Address Required	Valid FL	Valid FL
FL	31-33	Full Address allowed but Unknown is permitted	Valid FL,999	Valid FL,99999
Non-FL exclude XX,YY,ZZ,US Possessions and Canada	00-14,34,35,38,40,41,42	Full Known Address Required	998	State Zip
Non-FL exclude XX,YY,ZZ,US Possessions and Canada	20-33,36-37,43	Full Address allowed but Unknown is permitted	998	State Zip, 99999
XX,YY	00-99	Unknown Permitted	998	88888
ZZ	00-99	Unknown Permitted	999	99999
Canada and US Possessions	00-99	Unknown Permitted	998	99999

ADDRESS CURRENT – NO & STREET**NAACCR ITEM #2350**

Enter the address number & street of the patient's current and usual residence. Leave a blank between numbers and words.

The Census Bureau definition of residence is “the place where he or she lives and sleeps most of the time or the place the person considers to be his or her usual home.”

Do not abbreviate street names.

If the patient has multiple primaries, the address may differ for subsequent primaries.

Avoid the use of post office box numbers and rural routes whenever possible. Do not use a temporary address.

Persons with More than One Residence (summer and winter homes, “snowbirds”): Use the city address the patient specifies if a usual residence is not apparent.

Persons with No Usual Residence (transients, homeless): Use the city address of the place the patient was staying when the cancer was diagnosed. This could be a shelter or the diagnosing facility.

Person Away at School: College students are residents of the school area. Boarding school children below college level are residents of their parents' home.

Persons in Custodial Care Facilities: The Census Bureau states “Persons under formally authorized, supervised care or custody” are facility residents.

Persons in the Armed Forces and or Maritime Ships: Members of the armed forces are residents of the installation area. Use the stated city address for military personnel and their family. Military personnel may use the installation address or the surrounding community’s address.

The Census Bureau has detailed residency rules for Navy personnel, Coast Guard, and maritime ships. Refer to Census Bureau publications for detailed rules.

ADDRESS CURRENT – CITY

NAACCR ITEM #1810

Enter the name of the city or town of the patient’s current and usual residence. If the patient resides in a rural area, record the name of the city used in their mailing address.

Persons with More than One Residence (summer and winter homes, “snowbirds”): Use the city address the patient specifies if a usual residence is not apparent.

Persons with No Usual Residence (transients, homeless): Use the city address of the place the patient was staying when the cancer was diagnosed. This could be a shelter or the diagnosing facility.

Person Away at School: College students are residents of the school area. Boarding school children below college level are residents of their parents’ home.

Persons in Custodial Care Facilities: The Census Bureau states “Persons under formally authorized, supervised care or custody” are facility residents.

Persons in the Armed Forces and or Maritime Ships: Members of the armed forces are residents of the installation area. Use the stated city address for military personnel and their family. Military personnel may use the installation address or the surrounding community’s address.

The Census Bureau has detailed residency rules for Navy personnel, Coast Guard, and maritime ships. Refer to Census Bureau publications for detailed rules.

ADDRESS CURRENT – STATE

NAACCR ITEM #1820

Enter the USPS abbreviation for the state, territory, commonwealth, U.S. possession, or Canada Post abbreviation for the Canadian province/territory of the patient’s current residence. If the patient has multiple tumors, the current state of residence should be the same for all tumors.

Codes (in addition to the U.S. and Canadian postal service abbreviations):

CD	Resident of Canada, NOS (province/territory unknown)
US	Resident of United States, NOS (state/commonwealth/territory/possession unknown)
XX	Resident of country other than the United States (including its territories, commonwealths, or possessions) or Canada, and country is known
YY	Resident of country other than the United States (including its territories, commonwealths, or

possessions) or Canada, and country is unknown
 ZZ Residence unknown

FCDS Address field requirements:

Address Current - State	Class of Case	Address Status	County	Zip Code
FL	00-99	Full Known Address Required	Valid FL	Valid FL
Non-FL exclude XX,YY,ZZ, US Possessions and Canada	00-99	Full Known Address Required	998	State Zip
XX,YY	00-99	Unknown Permitted	998	88888
ZZ (NOT ALLOWED)				
US Possessions and Canada	00-99	Unknown Permitted	998	99999

ADDRESS CURRENT – COUNTRY

NAACCR ITEM #1832

Enter the three-character International Organization for Standardization (ISO) Country Code abbreviation (Appendix B) for the country where the patient lived at the time of last known contact.

If the patient has multiple primaries, the current address at diagnosis is the same for each tumor/abstract.

Refer to Appendix B for specific ISO Country Codes.

ADDRESS CURRENT – POSTAL CODE

NAACCR ITEM #1830

For United States residents, enter either the 5-digit or the extended 9-digit Zip code. When the 9-digit extended Zip code is unavailable, enter the 5-digit Zip code followed by zeros.

For residents of countries other than the United States, U.S. possessions or territories, or Canada enter 888888888.

For Canadian residents, enter 999999999. If using the FCDS IDEA Upload program only, Canadian valid Zip codes (ANANAN format) will be replaced with 999999999 at time of upload. For Single Entry users, Canadian residents must have 999999999 in the Zip code.

Current Zip (Postal) Code and postal directories are available from the National Information Data Center, PO Box 96523, Washington, DC 200900-6523 or call (301) 287-2347. Most major cities have a telephone listing, which you may call for Zip (Postal) Code information. Many mailing address look-up services are available online, including http://www.usps.com/ncsc/lookups/lookup_zip+4.html.

COUNTY – CURRENT

NAACCR ITEM #1840

Enter the code for county of patient's current residence. For U.S. residents, standard codes are those of the FIPS publication – *Counties and Equivalent Entities of the United States, Its Possessions, and Associated Areas*. Florida FIPS County Codes can be found in Appendix B.

FCDS only allows Florida FIPS County Codes. The county code must be 998 or 999 if any residence is out of Florida.

Codes (in addition to FIPS):

998 Known town, city, state, or country of residence but county code not known AND a resident outside of the state of reporting institution (must meet all criteria). Use this code for Canadian residents.

999 COUNTY UNKNOWN

FCDS Address field requirements:

Address Current - State	Class of Case	Address Status	County	Zip Code
FL	00-99	Full Known Address Required	Valid FL	Valid FL
Non-FL exclude XX,YY,ZZ, US Possessions and Canada	00-99	Full Known Address Required	998	State Zip
XX,YY	00-99	Unknown Permitted	998	88888
ZZ (NOT ALLOWED)				
Canada and US Possessions	00-99	Unknown Permitted	998	99999

TELEPHONE CURRENT

NAACCR ITEM #2360

Enter the current telephone number with area code for the patient. Do not enter dashes or spaces.

0000000000 Patient does not have a telephone

9999999999 Telephone number unavailable or unknown

PRIMARY PAYER AT DX

NAACCR ITEM #630

Enter the Primary Payer code corresponding to the patient's primary payment method or medical insurance coverage at the time of initial diagnosis and/or treatment. If more than one payer or insurance carrier is listed on the patient's admission page record the first.

Code	Label	Description
01	Not Insured	Patient has no insurance and is declared a charity write-off
02	Not Insured, self-pay	Patient has no insurance and is declared responsible for charges.
10	Insurance, NOS	Type of insurance unknown or other than those listed in codes 20, 21, 31, 35, 60-68.
20	Private Insurance: Managed care, HMO, PPO	Patient has insurance with a managed care provider health maintenance organization [HMO] preferred provider organization [PPO]

Code	Label	Description
21	Private Insurance: Fee-for-Service	An insurance plan that does not have negotiated fee structure with the participating hospital. Type of insurance plan not coded as 20.
31	Medicaid	State government-administered insurance for uninsured persons below the poverty level, or covered under entitlement programs. Medicaid other than described in code 35.
35	Medicaid administered through a Managed Care plan	State government-administered insurance through a managed care plan. State government insurance that is administered through a commercial managed care plan such as an HMO or PPO for uninsured persons, below the poverty level, or covered under entitlement programs
60	Medicare/Medicare, NOS	Federal government funded insurance for persons who are 62 years of age or older, or are chronically disabled (social security insurance eligible). Not described in codes 61, 62, or 63.
61	Medicare with supplement, NOS	Patient has Medicare and another type of unspecified insurance to pay costs not covered by Medicare. State government administered Medicaid insurance with Federal Medicare supplement.
62	Medicare administered through a Managed Care plan	Patient is enrolled in Medicare through a Managed Care plan (e.g. HMO or PPO). The Managed Care plan pays for all incurred costs. Federal government insurance for persons who are retired or disabled.
63	Medicare with private supplement	Patient has Medicare and private insurance to pay costs not covered by Medicare. Medicare with supplement. Patient has Medicare and another insurance to pay costs not covered by Medicare
64	Medicare with Medicaid eligibility	Federal government Medicare insurance with State Medicaid administered supplement. Patient has Medicare and another insurance to pay costs not covered by Medicare
65	TRICARE	Department of Defense program providing supplementary civilian-sector hospital and medical services beyond a military treatment facility to military personnel, retirees, and their dependents. Formally CHAMPUS (Civilian Health and Medical Program of the Uniformed Services).
66	Military	Military personnel or their dependents who are treated in a military facility
67	Veterans Affairs	Veterans who are treated in Veterans Affairs facilities
68	Indian/Public Health Service	Patient who receives care at an Indian Health Service facility, a Public Health Service facility or at another facility, and the medical costs are reimbursed by the Indian Health Service or the Public Health Service.
99	Insurance status unknown	It is unknown from the patient's medical record whether or not the patient is insured.

PHYSICIAN – MANAGING**NAACCR ITEM #2460**

Enter the appropriate identifying code for the managing or attending physician responsible for the patient at the reporting facility. Generally, each facility assigns its coding scheme to physicians on staff. If the physician is no longer on staff, enter the FCDS facility number or the physician's last name. Use leading zeros when necessary to right-justify.

NPI – MANAGING PHYSICIAN**NAACCR ITEM #2465**

Identifies the physician responsible for the patient's overall management during diagnosis and/or treatment of this cancer. You may search for NPI standard provider ID numbers at <https://nppes.cms.hhs.gov/nppes/npiregistrysearch.do?subaction=reset&searchtype=ind>

Coding Instructions:

1. Record the 10-digit NPI for the physician responsible for managing the patient's care.
2. Check with the billing or health information departments to determine the physician's NPI or search. at <https://nppes.cms.hhs.gov/NPPES/NPIRegistrySearch.do?subAction=reset&searchType=ind>.
3. NPI should be recorded as available.
4. NPI may be left blank.

FCDS encourages all registries and vendors to attempt to identify, capture, and code all data items, including the "as available" and the 5 "NPI-Physician" data items.

Code	Definition
(fill Spaces)	10-digit NPI number for the managing physician.
(leave blank)	NPI for the managing physician is unknown or not available.

NPI – FOLLOWING PHYSICIAN**NAACCR ITEM #2475**

Records the NPI for the physician currently responsible for the patient's medical care.

Coding Instructions:

1. Record the 10-digit NPI for the physician currently responsible for the patient's medical care.
2. Check with the billing or health information departments to determine the physician's NPI or search at <https://nppes.cms.hhs.gov/NPPES/NPIRegistrySearch.do?subAction=reset&searchType=ind>.
3. NPI should be recorded as available
4. NPI may be left blank.

Code	Definition
(fill Spaces)	10-digit NPI number for the following physician.
(leave blank)	NPI for the following physician is unknown or not available.

NPI – PRIMARY SURGEON**NAACCR ITEM #2485**

Identifies the physician who performed the most definitive surgical procedure.

Coding Instructions:

1. Record the 10-digit NPI for the physician who performed the most definitive surgical procedure.
2. Check with the billing or health information departments to determine the physician's NPI or search at <https://nppes.cms.hhs.gov/NPPES/NPIRegistrySearch.do?subAction=reset&searchType=ind>.
3. NPI should be recorded as available for all cases diagnosed January 1, 2008, and later.
4. NPI may be left blank.

Code	Definition
(fill Spaces)	10-digit NPI number for the primary surgeon.
(leave blank)	The patient did not have surgery. NPI for the primary surgeon is unknown or not available. The physician who performed the surgical procedure was not a surgeon (for example, general practitioner).

NPI – PHYSICIAN #3 – (RADIATION ONCOLOGIST)**NAACCR ITEM #2495**

Records the NPI for a physician involved in the care of the patient. It is recommended that this item identify the physician who performed the most definitive radiation therapy.

Coding Instructions:

1. Record the 10-digit NPI for the physician.
2. Check with the billing or health information departments to determine the physician's NPI or search at <https://nppes.cms.hhs.gov/NPPES/NPIRegistrySearch.do?subAction=reset&searchType=ind>.
3. NPI should be recorded as available.
4. NPI may be left blank.

Code	Definition
(fill Spaces)	10-digit NPI number for the primary radiation oncologist.
(leave blank)	NPI for the primary radiation oncologist is unknown or not available.

NPI – PHYSICIAN #4 (MEDICAL ONCOLOGIST)**NAACCR ITEM #2505**

Records the NPI for a physician involved in the care of the patient. It is recommended that this data item identify the physician who gives the most definitive systemic therapy.

Coding Instructions:

1. Record the 10-digit NPI for the physician.
2. Check with the billing or health information departments to determine the physician's NPI or search at <https://nppes.cms.hhs.gov/NPPES/NPIRegistrySearch.do?subAction=reset&searchType=ind>.
3. NPI should be recorded as available.
4. NPI may be left blank.

Code	Definition
(fill Spaces)	10-digit NPI number for the primary medical oncologist.
(leave blank)	NPI for the primary medical oncologist is unknown or not available.

TEXT – USUAL OCCUPATION**NAACCR ITEM #310**

Provide enough details to document the patient's usual occupation, referring to the type of job or work performed during most of the patient's working life before a cancer diagnosis. The occupation is the job the patient held for the longest duration prior to a cancer diagnosis. It is not necessarily the highest-paying job nor the one deemed most prestigious, but rather the one that accounted for the greatest number of working years.

Example: Registered nurse

“Retired” is not an occupation. Do not enter “retired” when the only information available is that the patient is retired. When all the information available is “retired,” enter “unknown” in this field.

Enter “Unknown” when no information is available.

Record “never worked” as the Usual Occupation if the patient has never worked.

If the patient was a housewife/househusband and also worked outside the home during most of his/her adult life, record the Usual Occupation outside of the home.

If the patient was a housewife/househusband and did NOT work outside of the home for most of his/her adult life, record “housewife” or househusband.”

The reference guide, “A Cancer Registrar’s Guide to Collecting Industry and Occupation”, DHHS (NIOSH) Publication No. 2011-173, is available free of charge in PDF format from CDC and NIOSH at <http://www.cdc.gov/niosh/docs/2011-173/pdfs/2011-173.pdf> and includes Tips on capturing these data.

TEXT – USUAL INDUSTRY**NAACCR ITEM #320**

Industry is the type of business or industry where the patient worked in his or her usual occupation. Example: Healthcare. Industry is a broader term than occupation. It encompasses the environment in which the occupation took place. Enter sufficient text to document the patient's usual occupation.

Be sure to distinguish among “manufacturing,” “wholesale,” “retail,” and “service” components of an industry, that performs more than one of these components. If the face sheet identifies the employer, and the chart does not specify the industry, enter the employer's name instead of the industry.

The reference guide, “A Cancer Registrar’s Guide to Collecting Industry and Occupation”, DHHS (NIOSH) Publication No. 2011-173, is available free of charge in PDF format from CDC and NIOSH at <http://www.cdc.gov/niosh/docs/2011-173/pdfs/2011-173.pdf> and includes Tips on capturing these data.

TUMOR INFORMATION

The Tumor Information section includes data items used to describe the cancer or tumor being reported. It includes when and where the cancer was first diagnosed, the anatomic location and type of cancer, staging and other descriptive information used to characterize the cancer at the time of diagnosis.

Data Items Included in This Chapter:

<u>NAACCR Item Number</u>	<u>Item Name</u>
390	Date of Diagnosis
2690	Text – Place of Diagnosis
610	Class of Case
490	Diagnostic Confirmation
400	Primary Site
2580	Text- Primary Site Title
410	Laterality
522	Histologic Type ICD-O-3 – See Appendix R
2590	Text- Histology Title
523	Behavior ICD-O-3
3843	Grade Clinical
3844	Grade Pathological
1068	Grade Post Therapy Clin (yc)
3845	Grade Post Therapy Path (yp)
756	Tumor Size Summary
820	Regional Lymph Nodes Positive
830	Regional Lymph Nodes Examined
1182	Lymph-Vascular Invasion

DATE OF INITIAL DIAGNOSIS**NAACCR ITEM #390**

Records the first date of diagnosis of cancer as noted by any physician for the tumor reported whether clinically or microscopically confirmed. This includes radiologist diagnosis on imaging, pathologist diagnosis on review of biopsy, tissue or resection, or any other physician statement.

Unknow Date of Initial Diagnosis is not accepted by FCDS.

An error is issued when the Date of First Contact precedes the Date of Diagnosis by more than thirty days.

FCDS Requirement for Unknown Date of Diagnosis for all cases:

FCDS has long recognized that medical record history and physical exams often include mention of a ‘history of cancer’ but provide little if any information regarding when or where the diagnosis or initial treatment occurred. This is why for many years FCDS has allowed registrars to enter blanks, 9’s, or use the Date of Admission as a proxy for the Date of Initial Diagnosis when no information was available in the medical record. This generally applied to non-analytic cases seen at your facility with current evidence of cancer and historical-only cases with no evidence of cancer reported to FCDS in the historical grid when a new cancer has been diagnosed (multiple primaries diagnosed over patient’s lifetime). This is no longer the case.

FCDS requires every case that you abstract (analytic, non-analytic and historical grid cases) to include at a minimum a valid year of diagnosis. The FCDS EDITS Metafile will reinforce this requirement.

All Treatment (surgery, radiation, chemo, etc.) will also require a valid date consistent with the Date of Diagnosis so the edits can validate the treatment is indeed within the parameters of first course of therapy.

Without a valid year of diagnosis, FCDS EDITS cannot determine which set of diagnosis year specific standards to apply. This has led to complicated Florida-only rules for EDITS to point to which standards the EDITS must apply when trying to stage and grade cases (and the site-specific data items), and based on the Date of First Contact. Date of First Contact has proven not to be a very good proxy for Date of Diagnosis.

Below is a revised set of instructions and guidelines for estimating the Date of Diagnosis when no information or limited information is available in a medical record. See Instruction 23 below.

Estimating the Date of Diagnosis When No Information is Available in the Medical Record

Registrars must use every resource available at the reporting facility to determine the best date of diagnosis. In the absence of an exact date of initial diagnosis, you must estimate at least the year of diagnosis using your best approximation from the information available in the record. Documentation that the exact date of diagnosis was not available in the medical record must be included in a text field. When an exact date of diagnosis is identified after a case has been completed, contact FCDS.

Often, the History and Physical or a Consultation Report will provide clues to aid in estimating a date of diagnosis. Keywords and phrases such as recently, a few months ago, or in the distant past can provide hints as to when a patient was diagnosed without providing an exact year or date. However, registrars can use these keywords and phrases to guide them when determining an estimated date of diagnosis. Some medical record histories provide no clues as to when the patient was diagnosed with cancer. These can be the most difficult cases to estimate the date of diagnosis. Guidelines for estimating dates are provided

below bearing in mind that the clues in the record should be used first and will always override the guidelines. These are guidelines. No specific rules are available.

The date of initial diagnosis is the earliest date a medical practitioner recognizes this primary reportable neoplasm. It may be diagnosed clinically, by imaging, or microscopically. The date is the FIRST DATE, regardless of whether the diagnosis was made at the reporting facility or elsewhere. Please do not use the Date of Admission as a proxy for Date of Diagnosis.

The initial diagnosis date may be from a clinical diagnosis or another acceptable diagnostic method; for example, when a radiologist reviews a CT Scan or chest x-ray, and the diagnosis is lung cancer or suspicious for lung cancer. When a diagnosis is confirmed later on biopsy/resection, the (clinical or other acceptable testing) date of diagnosis remains the date of the initial diagnosis.

Date of Diagnosis Coding Instructions:

1. Use the first date of diagnosis whether clinically or histologically established.
2. Refer to the list of Ambiguous Terminology Section I for language that represents a diagnosis of cancer.
 - a. When the first diagnosis includes reportable ambiguous terminology, record the date of that diagnosis.

Example: Area of microcalcifications in breast suspicious for malignancy on 02/13/2025.
Biopsy positive for ductal carcinoma on 02/28/2025. The date of diagnosis is 02/13/2025.
3. **PI Rads, BI Rads, LI Rads alone are not reportable to FCDS. PI Rads, BI Rads, LI Rads confirmed with biopsy or physician statement are reportable to FCDS. The Date of Diagnosis is the date of the positive biopsy or definitive statement from a physician. This FCDS rule was updated to align with CoC.**
4. If the physician states that, in retrospect, the patient had cancer at an earlier date, use the earlier date as the date of diagnosis. When this occurs and the Date of Diagnosis is confirmed as earlier than previously reported, the registrar should contact FCDS to update the Date of Diagnosis.
5. A “Definitive Term” always supersedes any “Ambiguous Term” when making coding decisions.
6. Refer to the list of “Ambiguous Terms” in Section I for language that represents a diagnosis of cancer when only ambiguous terms are used to describe the abnormality or neoplasm.
7. The date of diagnosis based on a pathology report should be the date the specimen was taken, not the date the pathology report was read or created. Imaging often identifies a neoplasm prior to biopsy.
8. The date of death is the date of diagnosis for a *Class of Case 38* (diagnosed at autopsy) - NAACCR Item #610. However, if the patient is suspected of having cancer prior to death/autopsy and the autopsy simply confirms the presence of malignancy, the date of the first diagnosis for the suspected malignancy should be used. These patients were not actually diagnosed at autopsy, but rather the suspected cancer was confirmed at the time of death when the autopsy was performed.
9. For patients diagnosed prior to the date of first contact with the reporting facility, record the date of diagnosis as given in the medical record. This can usually be found in the patient history or in a resection, laboratory, or consultation report.
10. Suspicious Cytology should never be used as a basis for diagnosis when ‘suspicious’ or other ambiguous terms are used. Ambiguous cytology is not diagnostic of cancer. Any suspicious cytology must be confirmed by biopsy, resection or a statement by the physician that the patient has cancer. Cytology is the examination of cells rather than tissue. It includes sputum smears, bronchial brushings, bronchial washings, prostatic secretions, breast secretions, gastric fluids, spinal fluid, peritoneal fluid, urinary sediment, and cervical and vaginal smears. It does not include FNA. Use the date of clinical, histologic, or positive cytologic confirmation as the date of diagnosis.
11. If a date is not recorded and if the patient was seen at the reporting facility within one month of the diagnosis, then the date of first contact may be used as the date of diagnosis.

12. If a date is not recorded and if the date of the first cancer-directed therapy or treatment is known then the date of the first cancer-directed therapy or treatment may be used as the date of diagnosis.
13. Treatment dates may not be coded to unknown.
14. When a diagnosis of cancer is made during the patient's long-term stay for another condition, adjust the date of first contact as outlined under Date of First Contact.
15. If the only information is "Spring of," "Middle of the year," "Fall," approximate these as April, July, and October, respectively. For "Winter of," it is important to determine whether the beginning of the year or the end of the year is meant before approximating the month.
16. If the only information is "recently," the date of diagnosis should be estimated as one month prior to month and year of admission. You may estimate the day as the 15th of the month.
17. If the only information is "several months ago," the date of diagnosis should be estimated as three months prior to the month and year of admission. You may estimate the day as the 15th of the month.
18. Use the actual date of diagnosis for an in utero diagnosis (For cases diagnosed before January 1, 2009, assign the date of birth).
19. In the absence of a definitive diagnosis date for patient undergoing first course therapy at the reporting facility, the date of first cancer-directed therapy may be recorded as the date of diagnosis.
20. If the year of diagnosis cannot be identified, the year of diagnosis must be approximated based on information from the H&P. Only the month and day of diagnosis can be left blank.

21. FINAL RESORT FOR ESTIMATING DATE OF DIAGNOSIS:

- a. Always take into account the chronology of previous diagnosis of cancer and adjust the below recommendations to take the age of the patient and the chronology of diagnoses into account.
- b. FCDS Cancer Site-Specific Estimates when no information available except 'history of xyz cancer'. The below estimates are suggestions for a date of diagnosis of last resort and must take the chronology of the other cancers, initial course of therapy, and other factors into account.
- c. FCDS Cancer Site-Specific estimates are loosely based on the Solid Tumor Rules, estimated time to recurrence or progression, expected lifespan, and/or FCDS experience applying the Solid Tumor Rules over many years and as available. These estimates are far from perfect and must always be used with caution, considering all other factors available in the patient's age and medical history.
 - i. Head and Neck Sites – at least 3 years prior to admission
 - ii. Colon/Rectosigmoid/Rectum Sites – at least 5 years prior to admission
 - iii. Lung – at least 3 years prior to admission
 - iv. Kidney – at least 5 years prior to admission
 - v. Cutaneous Melanoma – at least 1 year prior to admission
 - vi. Breast – at least 5 years prior to admission
 - vii. GYN Sites – at least 5 years prior to admission
 - viii. Urinary Sites – at least 3 years prior to admission
 - ix. Prostate – at least 5 years prior to admission
 - x. Malignant Lymphoma – at least 3 years prior to admission
 - xi. Chronic Leukemia – at least 5 years prior to admission
 - xii. Myeloproliferative/Myelodysplastic Neoplasms – at least 5 years prior to admission AND diagnosed after 2001 which is the year these cancers became reportable to FCDS
 - xiii. Benign Brain Tumors – at least 5 years prior to admission AND diagnosed after 2004 which is the year these cancers became reportable to FCDS.
 - xiv. Malignant Brain Tumors – at least 1 year prior to admission
 - xv. Other Sites – at least 5 years prior to admission
 - xvi.

Date of Initial Diagnosis – Estimating a Best Date of Diagnosis	
Spring	Use April (04) for the month
Summer	Use July (07) for the month
Fall/Autumn	Use October (10) for the month
Winter	Determine if this means the beginning or the end of the year. Use December (12) or January (01) for the month as determined.
Early in Year	Use January (01) for the month
Middle of Year	Use July (07) for the month
Late in Year	Use December (12) for the month
Recently	Use the year and month of admission and leave the day blank. If patient was admitted during the first week of a month, use the previous month.
Several Months Ago	If the patient was not previously treated or if first course treatment started elsewhere was continued at the reporting facility, assume the case was first diagnosed three months before admission with day unknown (blank).
A Couple of Years	Code to two years earlier
A Few Years	Code to three years earlier

TEXT – PLACE OF DIAGNOSIS

NAACCR ITEM #2690

Enter text information about the facility, city, state, or county where the diagnosis was made, even if at your facility. If the patient was diagnosed in a physician's office, please enter the physician's name and any other identifying information.

Text is needed to justify the codes selected for the related data item(s) and to allow for the recording of information that is not coded at all. Text is also used for quality control and for special studies.

Text information should be retrieved from the medical record and should not be generated electronically from coded values.

CLASS OF CASE

NAACCR ITEM #610

The Class of Case reflects the facility's role in managing the cancer, whether the cancer is required to be reported by CoC, and whether the case was diagnosed after the program's Reference Date.

Enter the appropriate Class of Case. Use the code from the accompanying table which best describes the level of involvement by the reporting facility with the initial diagnosis and treatment of the reported cancer.

- Code 00 applies only when it is known the patient went elsewhere for treatment. If it is not known that the patient actually went somewhere else, code *Class of Case* 10.
- A staff physician (codes 10-12, 41) is a physician who is employed by the reporting facility, under contract with it, or a physician who has routine practice privileges there. Treatment provided in a staff physician's office is provided "elsewhere". That is because care given in a physician's office is not within the hospital's realm of responsibility.

- If the hospital has purchased a physician practice, it will be necessary to determine whether the practice is now legally considered part of the hospital (their activity is coded as the hospital's) or not. If the practice is not legally part of the hospital, it will be necessary to determine whether the physicians involved are staff physicians or not, as with any other physician.
- “In-transit” care is care given to a patient who is temporarily away from the patient’s usual practitioner for continuity of care. If these cases are abstracted, they are *Class of Case 31*. If a patient begins first course radiation or chemotherapy elsewhere and continues at the reporting facility, and the care is not in-transit, then the case is analytic (*Class of Case 21*).

Analytic Classes of Case	
<i>Initial diagnosis at reporting facility</i>	
00	Initial diagnosis at the reporting facility AND all treatment or a decision not to treat was done elsewhere.
10	Initial diagnosis at the reporting facility or in a staff physician’s office AND part or all of first course Treatment or a decision not to treat was at the reporting facility, NOS. If it is not known that the patient actually went somewhere else , code <i>Class of Case 10</i>
11	Initial diagnosis in staff physician’s office AND part of first course treatment was done at the reporting facility.
12	Initial diagnosis in staff physician’s office AND all first course treatment or a decision not to treat was done at the reporting facility.
13	Initial diagnosis at the reporting facility AND part of first course treatment was done at the reporting facility; part of first course treatment was done elsewhere.
14	Initial diagnosis at the reporting facility AND all first course treatment or a decision not to treat was done at the reporting facility
<i>Initial diagnosis elsewhere</i>	
20	Initial diagnosis elsewhere AND all or part of first course treatment was done at the reporting facility, NOS..
21	Initial diagnosis elsewhere AND part of first course treatment was done at the reporting facility.
22	Initial diagnosis elsewhere AND all first course treatment or a decision not to treat was done at the reporting facility.

Non-Analytic Classes of Case	
<i>Patient appears in person at reporting facility</i>	
30	Initial diagnosis and all first course treatment elsewhere AND reporting facility participated in diagnostic workup (for example, consult only) NOTE: The 2010 FORDS Manual changed the definition Class of Case = 30 the CoC added a new component to what previously had been “consult only.” The addition is for cases where the facility is part of the “staging workup after initial diagnosis elsewhere.” These cases are “analytic” to FCDS and in Florida a “consult only” case only refers to a case where the facility provides a second opinion without additional testing.
31	Initial diagnosis and all first course treatment elsewhere AND reporting facility provided in-transit care.
32	Diagnosis AND all first course treatment provided elsewhere AND patient presents at reporting facility with disease recurrence or persistence (active disease).
33	Diagnosis AND all first course treatment provided elsewhere AND patient presents at reporting facility with disease history only (disease not active).
34	Type of case not required by CoC to be accessioned (for example, a benign colon tumor) AND

	initial diagnosis AND part or all of first course treatment by reporting facility.
35	Case diagnosed before program's Reference Date AND initial diagnosis AND all or part of first course treatment by reporting facility.
36	Type of case not required by CoC to be accessioned (for example, a benign colon tumor) AND initial diagnosis elsewhere AND all or part of first course treatment by reporting facility.
37	Case diagnosed before program's Reference Date AND initial diagnosis elsewhere AND all or part of first course treatment by facility.
38	Initial diagnosis established by autopsy at the reporting facility, cancer not suspected before death.
<i>Patient does not appear in person at reporting facility</i>	
40	Diagnosis AND all first course treatment given at the same staff physician's office..
41	Diagnosis and all first course treatment given in two or more different staff physician offices
<i>Patient appears in person at reporting facility</i>	
42	Non-staff physician or non-CoC accredited clinic or other facility, not part of reporting facility, accessioned by reporting facility for diagnosis and/or treatment by that entity (for example, hospital abstracts cases from an independent radiation facility).
43	Pathology or other lab specimens only.
49	Death certificate only.
99	Non-analytic case of unknown relationship to facility (not for use by CoC accredited cancer programs for analytic cases).

DIAGNOSTIC CONFIRMATION

NAACCR ITEM #490

Records the best method of diagnostic confirmation of the cancer being reported at any time in the patient's history.

Coding Instructions for Solid Tumors (all tumors *except* ICD-O-3 Histology Codes M9590-9993):

1. The codes are in **priority order**; code 1 has the highest priority. Always code the procedure with the lower numeric value when presence of cancer is confirmed with multiple diagnostic methods. This data item must be changed to the lower (higher priority) code if a more definitive method confirms the diagnosis *at any time during* the course of the disease.
2. Code 1 when the microscopic diagnosis is based on tissue specimens from biopsy, frozen section, surgery, autopsy or D&C or from aspiration of biopsy of bone marrow specimens. Code 1 is the preferred coding for Fine Needle Aspiration (FNA). Code 1 is also used for bone marrow biopsy, peripheral blood smears and other diagnostic methods for many leukemia cases (or Code 3). Leukemia can also be diagnosed with CBC or wbc PLUS OR MINUS Immunophenotyping, genetic testing, or JAK2 testing. Code 1 or Code 3 should be used depending on result of special testing.

NOTE: Pathologists may refer to FNA as 'FNA Cytology' – however, 'cytology' for cancer registry purposes indicates cells suspended in body fluids such as washings, spinal fluid, pleural fluid or peritoneal fluid. FNA does not meet this definition.

3. Code 2 when the microscopic diagnosis is based on cytologic examination of *cells suspended in body fluids* such as sputum smears, bronchial brushings, bronchial washings, prostatic secretions, breast secretions, gastric fluid, spinal fluid, peritoneal fluid, pleural fluid, urinary sediment, cervical smears and vaginal smears, or from paraffin block specimens from concentrated spinal, pleural, or peritoneal

fluid. FNA is not classified as ‘cytology’ in cancer registry. FNA is treated as a biopsy Code 1.

4. DO NOT USE Code 3 for ANY Solid Tumors. Code 3 is only for Myeloid/Lymphoid Neoplasms. There are some solid tumors such as non-small cell lung cancer and several brain tumors can have genetic testing to identify histologic type and subtype. However, code 3 is not used in these cases.
5. Code 4 when there is information that the diagnosis of cancer was microscopically confirmed, but the type of confirmation is unknown.
6. Code 5 when the cancer diagnosis is based on laboratory tests or marker studies which are clinically diagnostic for that specific cancer.

Example: If the workup for a prostate cancer patient is limited to a highly elevated PSA (no DRE and no imaging) and the physician diagnoses and/or treats the patient based only on that PSA, code the diagnostic confirmation to 5.

7. Code 6 when the diagnosis is based only on the surgeon’s operative report from a surgical exploration or endoscopy or from gross autopsy findings in the absence of tissue or cytological findings.
8. Code 7 when the only confirmation of malignancy was diagnostic imaging such as computerized axial tomography (CT scans), magnetic resonance imaging (MRI scans), or ultrasounds/sonography
 - a. Note: Intraductal papillary mucinous neoplasm with high grade dysplasia (8453/2) of the pancreas is reportable based on imaging alone; histologic confirmation is not required.
9. Assign code 8 when the case was diagnosed by any clinical method not mentioned in preceding codes. The diagnostic confirmation is coded 8 when the only confirmation of disease is a physician’s clinical diagnosis.

Example: CT diagnosis is possible lung cancer. Patient returns to the nursing home with a Do Not Resuscitate (DNR) order. Physician enters a diagnosis of lung cancer in the medical record. Code the diagnostic confirmation to 8: there is a physician’s clinical diagnosis – clinical diagnosis made by the physician using the information available for the case.
10. Code 9 should not be used unless there is absolutely no information or inference of confirmation method used to confirm the patient’s cancer. Do not use this code.

Codes for Solid Tumors (all tumors *except* ICD-O-3 Histology Codes M9590-9993):

Code	Description	Definition
1	Positive histology – INCLUDES FNA, bone marrow, peripheral blood smear, CBC, WBC, tissue, core biopsy	Histologic confirmation (tissue microscopically examined) (includes FNA) FNA is comparable to a bone marrow aspiration/bx. It is not an examination of body cavity fluid, a fluid suspension, washings, or cells in urine.
2	Positive cytology – NOT FNA – body fluid	Cytologic confirmation (no tissue microscopically examined; fluid suspension with cells microscopically examined – urine, washings, body cavity fluids).

Code	Description	Definition
4	Positive microscopic confirmation, method not specified	Microscopic confirmation is all that is known. It is unknown if the cells were from histology or cytology.
5	Positive laboratory test/marker study	A clinical diagnosis of cancer is based on laboratory tests/marker studies which are clinically diagnostic for cancer. Examples include alpha-fetoprotein for liver cancer and abnormal electrophoretic spike for multiple myeloma. Elevated PSA is not diagnostic of cancer. If the physician uses the PSA as a basis for diagnosing prostate cancer with no other workup, record as code 5.
6	Direct visualization without microscopic confirmation	The tumor was visualized during a surgical or endoscopic procedure only with no tissue resected for microscopic examination.
7	Radiography and other imaging techniques without microscopic confirmation	The malignancy was reported by the physician from an imaging technique report only.
8	Clinical diagnosis only, other than 5, 6 or 7	The malignancy was reported by the physician in the medical record.
9	Unknown whether or not microscopically confirmed <u>Note: DO NOT USE THIS CODE</u>	A statement of malignancy was reported in the medical record, but there is no statement of how the cancer was diagnosed (usually nonanalytic).

Coding Instructions for Hematopoietic/Lymphoid Neoplasms (Histology Codes M9590-9993):

1. There is no priority hierarchy for coding *Diagnostic Confirmation* for hematopoietic and lymphoid tumors. Most commonly, the specific histologic type is diagnosed by immunophenotyping or genetic testing. See the online *Hematopoietic Database (DB)* for information on the definitive diagnostic confirmation for specific types of tumors.
2. Code 1 when the microscopic diagnosis is based on tissue specimens from biopsy, frozen section, surgery, autopsy or D&C or from aspiration of biopsy of bone marrow specimens. Code 1 is the preferred coding for Fine Needle Aspiration (FNA). Code 1 is also used for bone marrow biopsy, peripheral blood smears and other diagnostic methods for many leukemia cases (or Code 3). Leukemia can also be diagnosed with CBC or wbc PLUS OR MINUS Immunophenotyping, genetic testing, or JAK2 testing. Code 1 or Code 3 should be used depending on result of special testing.

NOTE: Pathologists may refer to FNA as 'FNA Cytology' – however, 'cytology' for cancer registry purposes indicates cells suspended in body fluids such as washings, spinal fluid, pleural fluid or peritoneal fluid. FNA does not meet this definition.

3. For leukemia only, code 1 when the diagnosis is based only on the complete blood count (CBC), white blood count (WBC) or peripheral blood smear. Use code 1 for FNA cytology, bone marrow, peripheral blood, or blood smear for leukemia. Do not use code 1 if the diagnosis was based on immunophenotyping or genetic testing using tissue, bone marrow, or blood.
4. Code 2 when the microscopic diagnosis is based on cytologic examination of *cells* (rather than tissue)

including but not limited to spinal fluid, peritoneal fluid, pleural fluid, urinary sediment, cervical smears and vaginal smears, or from paraffin block specimens from concentrated spinal, pleural, or peritoneal fluid. These methods are rarely used for hematopoietic or lymphoid tumors.

5. Code 3 can be used for cases diagnosed 2010+ with histologic confirmation (see code 1) AND immunophenotyping, genetic testing, immunophenotype, flow cytometry, microarray, FISH, NGS genetic panel, multi-gene panel test, PCR testing, IHC testing, or JAK2 confirmation.

- a) Did the patient have one or more molecular pathology tests performed on blood, lymph, bone marrow and/or tissue biopsy/resection (traditional anatomic microscopy/pathology)?

✓ Immunophenotype

- Flow cytometry for cluster of designation or CD marker analysis,
- IHC (immunohistochemistry) for CD marker analysis,
- PCR testing (polymerase chain reaction) for CD marker analysis,

✓ Molecular pathology studies to analyze DNA or other genetic material using;

- Single gene test,
- Genetic panel test,
- Multi-gene panel test,
- DNA Microarray,
- Biomolecular marker(s),
- FISH (fluorescent in-situ hybridization),
- Other Immunofluorescence testing,
- Next-generation sequencing (NGS) gene panel, or
- Other DNA/RNA/gene testing

- b) Did the additional molecular pathology test(s) result in one or more of the following; a) confirm the diagnosis, b) clarify the type of neoplasm (clarify specific histologic type or subtype), or 3) identify a target drug or specific biological, molecular or immunotherapy (BRM)?

- c) Cases with positive histology for the neoplasm being abstracted (including acceptable ambiguous terminology and provisional diagnosis) AND immunophenotyping, genetic testing, or JAK2 is listed in the Definitive Diagnosis in the Heme DB AND the testing:

- i. Confirms the neoplasm OR
- ii. Identifies a more specific histology (not preceded by ambiguous terminology)
 Note 1: Do not use code 3 for positive immunophenotyping or genetic testing identifying a more specific histology when preceded by ambiguous terminology.
 Note 2: Do not use code 3 for positive immunophenotyping or genetic testing identifying a more specific histology when the test result is preceded by "patchy weak staining."
- iii. Peripheral blood smear followed by flow cytometry (most commonly done with CLL/SLL, 9823/3)
 Note: Flow cytometry studies are typically done based on an abnormal blood smear. If unable to find documentation that a peripheral blood smear was done first, assume that it was and code 3

Note 1: The following histologies are diagnosed based on immunophenotyping or genetics and therefore should only be diagnostic confirmation 3: 9806/3, 9807/3, 9808/3, 9809/3, 9812/3, 9813/3, 9814/3, 9815/3, 9816/3, 9817/3, 9818/3, 9819/3,

9865/3, 9866/3, 9869/3, 9871/3, 9877/3, 9878/3, 9879/3, 9896/3, 9897/3, 9911/3, 9912/3, 9965/3, 9966/3, 9967/3, 9968/3, 9986/3.

Note 2: The following histologies should never be assigned diagnostic confirmation 3 since they are non specific codes and neither genetic testing or immunophenotyping are listed as Definitive Diagnostic Methods for these histologies. If there is immunophenotyping or genetics available, then a more specific histology code may be able to be assigned: 9590/3, 9655/3, 9800/3, 9820/3, 9860/3, 9863/3, 9980/3, 9982/3, 9989/3, 9991/3.

6. Code 5 when the diagnosis of cancer is based on laboratory tests or marker studies which are clinically diagnostic for that specific cancer, but no positive histologic confirmation.
7. Code 6 when the diagnosis is based only on the surgeon's report from a surgical exploration or endoscopy or from gross autopsy findings without tissue or cytological findings. Code 6 is used for direct visualization of a neoplasm either through an endoscope or viewed with physician eyes.
8. Code 7 is used rarely for hematopoietic neoplasms. However, some neoplasms (brain, lung) may be diagnosed on imaging without additional confirmation of the neoplasm. Use this code sparingly.
9. Code 8 for when the hematopoietic neoplasms are 'diagnosis by exclusion' when tests for the disease are negative and the physician makes a diagnosis based on information from the clinical presentation and negative tests.
10. Code 8 when the case was diagnosed by any clinical method that cannot be coded as 5, 6 or 7.
11. Code 9 should not be used unless there is absolutely no information or inference of confirmation method used to confirm the patient's cancer. DO NOT USE THIS CODE EVEN ON HISTORICAL CASES

Codes Hematopoietic or Lymphoid Neoplasms (ICD-O-3.2 Histology Codes M9590-9993):

Code	Description	Definition
1	Positive histology – INCLUDES FNA, bone marrow biopsy, peripheral blood smear, CBC, WBC	Histologic confirmation (tissue microscopically examined). Includes FNA Cytology.
2	Positive cytology – NOT FNA	Cytologic confirmation – cells suspended in body fluids (no tissue microscopically examined; fluid cells microscopically examined).
3	Positive histology PLUS • Positive immunophenotyping AND/OR • Positive genetic studies SEE LIST OF POSSIBLE TESTS ABOVE TO RULE OUT CODE 3	Histology is positive for cancer, and there are also positive immunophenotyping and/or genetic test results to refine or confirm a specific diagnosis. For example, bone marrow examination is positive for acute myeloid leukemia. (9861/3) Genetic testing shows AML with inv(16)(p13.1q22) (9871/3).
4	Positive microscopic confirmation, method not specified	Microscopic confirmation is all that is known. It is unknown if the cells were from histology or cytology.

Code	Description	Definition
5	Positive laboratory test/marker study Note: DO NOT USE THIS CODE	A clinical diagnosis of cancer is based on laboratory tests/marker studies which are clinically diagnostic for cancer.
6	Direct visualization without microscopic confirmation	The tumor was visualized during a surgical or endoscopic procedure only with no tissue resected for microscopic examination.
7	Radiography and other imaging techniques without microscopic confirmation	The malignancy was reported by the physician from an imaging technique report only.
8	Clinical diagnosis only, other than 5, 6 or 7	The malignancy was reported by the physician in the medical record.
9	Unknown whether or not microscopically confirmed Note: DO NOT USE THIS CODE	A statement of malignancy was reported in the medical record, but there is no statement of how the cancer was diagnosed (usually nonanalytic).

PRIMARY SITE**NAACCR ITEM #400**

Enter the topography code for the site of origin of the primary tumor from the *International Classification of Diseases for Oncology* (ICD-O-3). The terms primary site, site, and topography are used synonymously.

Coding Instructions:

1. Record the ICD-O-3 topography code for the site of origin. You can still use the ICD-O-3 purple book for Topography (Primary Site) Coding. None of the Topography Codes have changed.
2. Consult the physician advisor to identify the primary site or the most definitive site code if the medical record does not contain that information.
3. Topography codes are indicated by a “C” preceding the three-digit code number. Do not record the decimal point.
4. Follow the Coding Instructions in ICD-O-3 and in the most current version of the *SEER Solid Tumor Rules* to assign primary site for solid tumors.
5. Avoid assigning unknown/ill-defined site topography codes; they are general terms/vague anatomy. Unknown/Ill-Defined Sites Include: C069, C189, C260-269, C328-329, C390-399, C409, C419, C479, C499, C559, C579, C639, C760-769, C809.

When the medical record does not contain enough information to assign a primary

- a. Consult a physician advisor to assign the site code
- b. Use the NOS category for the organ system or the Ill-Defined Sites (C760-C768) if the physician advisor cannot identify a primary site
- c. Occult Tumors of the Head and Neck
 - i. Assign primary site C119 (nasopharynx) for occult head and neck tumors with cervical lymph node metastasis in Levels I-VII, and other group lymph nodes positive for Epstein–Barr virus (EBV+) (regardless of p16 status) encoded

- small RNAs (EBER) identified by in situ hybridization
 - ii. Assign primary site C109 (oropharynx) for occult head and neck tumors with cervical lymph node metastasis in Levels I-VII, and other group lymph nodes, p16 positive with histology consistent with HPV-mediated oropharyngeal carcinoma (OPC)
 - iii. Assign C760 for Occult Head and Neck primaries with positive cervical lymph nodes. Schema Discriminator 1: Occult Head and Neck Lymph Nodes is used to discriminate between these cases and other uses of C760
- 6. Follow the instructions in *Hematopoietic and Lymphoid Neoplasm Case Reportability and Coding Manual* and the Hematopoietic and Lymphoid Neoplasms Database (Hematopoietic DB) in the most current version for assigning site for lymphomas, leukemia and other hematopoietic neoplasms (M-9590-9993) and to determine whether multiple conditions represent one or more tumors to be abstracted for myeloid and lymphoid neoplasm cases diagnosed on or after January 1, 2010.
- 7. Use subcategory 8 for single tumors that overlap the boundaries of two or more sub-sites and the unknown point of origin.
- 8. Use subcategory 9 for multiple tumors that originate in different subsites of one organ.

Rules for Specific Tissues with Ill-Defined Sites:

1. Use the alphabetic index in ICD-O-3 to assign the most specific site if only a general location is specified in the record.
2. DO NOT USE TOPOGRAPHY CODES IN THE C76.* SERIES for soft tissue neoplasms or neoplasms of unknown primary. Use the specific soft tissue/connective tissue primary site codes.
3. Use the table below to assign primary site when the only information available is the histologic type of tumor and the patient has metastatic disease without an identifiable primary site. The primary site is presumed to be the NOS or “not otherwise specified” primary site code when the histology is known but for which no primary can be found. Do not code these cases to C80.9.

Histologic Type Codes	Histologic Types	Preferred Site Codes for Ill-Defined Primary Sites
8720-8790	Melanoma	C44. _, Skin
8800-8811, 8813-8830, 8840-8921, 9040-9044	Sarcoma except periosteal fibrosarcoma and dermatofibrosarcoma	C49. _, Connective, Subcutaneous and Other Soft Tissues
8990-8991	Mesenchymoma	C49. _, Connective Subcutaneous and Other Soft Tissues
8940-8941	Mixed tumor, salivary gland type	C07. _, for Parotid Gland; C08. _, for Other and Unspecified Major Salivary glands

9120-9170	Blood vessels tumors, Lymphatic vessel tumors	C49. __, Connective Subcutaneous and other Soft tissues
9240-9252	Mesenchymal chondrosarcoma and giant cell tumors	C40. __, C41. __ for bone and cartilage C49. __, Connective, Subcutaneous, and Other Soft tissues
9580-9582	Granular cell tumor and alveolar soft part sarcoma	C49. __, Connective, Subcutaneous and Other Soft Tissues

IMPOSSIBLE PRIMARY SITE/HISTOLOGY COMBINATIONS

Combinations of primary sites and histologies are designated as “impossible” because the combination of site and histology type is biologically impossible, i.e., the particular form of cancer does not arise in the specified site.

Checking medical references or discussing problem cases with the registry’s medical advisors is helpful. The suggestions below are a starting point for analyzing an impossible site and histology combination but are not a substitute for a medical decision. Reference to the original medical record is always required.

1. Retroperitoneum/Peritoneum and Melanomas: If melanoma is identified in peritoneal or retroperitoneal tissue, it is almost certainly metastatic to that site. Try to identify the primary site of the melanoma. If no primary can be determined, the standard convention in cancer registries is to code the primary site as skin, NOS, C44.9, which puts the case in the most likely site group for analysis. Most histologic type codes for melanomas in ICD-O-3 list skin, C44. __, as the appropriate primary site.
2. Nasal Cavity/Middle Ear/Accessory Sinuses and Osteosarcomas: Osteosarcomas arise in bone, and the specified site code in ICD-O-3 is C40. __ or C41. __. Osteosarcomas arising in the nose, middle ear, and sinuses should be assumed to have arisen in the bone of the skull and their primary site coded C41.0.
3. Pleura/Mediastinum and Carcinomas or Melanomas: If a carcinoma or melanoma is identified in the pleura or mediastinum, it is almost certainly metastatic to that site. Try to identify the primary site of the carcinoma or melanoma. If no primary can be determined for a carcinoma, code unknown primary site, C80.9. For melanoma, if no primary can be determined, the standard convention in cancer registries is to code the primary site as skin, NOS, C44.9, which puts the case in the most likely site group for analysis. Most histologic type codes for melanomas in ICD-O-3 list skin, C44. __, as the appropriate primary site.
4. Peripheral Nerves/Connective Tissue and Carcinomas or Melanomas: If a carcinoma or melanoma is identified in peripheral nerves or connective tissue, it is almost certainly metastatic to that site. Try to identify the primary site of the carcinoma or melanoma. For a carcinoma, if no primary can be determined, code unknown primary site, C80.9. For a melanoma, if no primary can be determined, the standard convention in cancer registries is to code the primary site as skin, NOS, C44.9, which puts the case in the most likely site group for analysis. Most histologic type codes for melanomas in ICD-O-3 list skin, C44. __, as the appropriate primary site.
5. Meninges/Brain/Other CNS and Carcinomas: If a carcinoma is identified in the brain, meninges, or other central nervous system, it is metastatic to that site. Try to identify the true primary site of the carcinoma.
6. Bone and Carcinomas or Melanomas: If a carcinoma or melanoma is defined in the pleura or mediastinum, it is almost certainly metastatic to that site. Try to identify the primary site of the carcinoma or melanoma. For a carcinoma, if no primary can be determined, code unknown primary site, C80.9. For a melanoma, if

no primary can be determined, the standard convention in cancer registries is to code the primary site as skin NOS, C44.9, which puts the case in the most likely site group for analysis. Most histologic type codes for melanomas in ICD-O-3 list skin, C44., as the appropriate primary site.

7. Ill-defined Sites and Various Histologies: Some histologic types are by convention more appropriately coded to a code representing the tissue in which such tumors arise rather than the ill-defined region of the body, which contains multiple tissues. The table below shows for the histologic types which site should be used instead of an ill-defined site in the range C76.0-C76.8.

IMPOSSIBLE PRIMARY SITE/HISTOLOGY COMBINATIONS

SITE	HISTOLOGY
C480-C488 Retroperitoneum and peritoneum	8720-8790 Melanomas
C300 Nasal Cavity C301 Middle ear C310-C319 Accessory sinuses	9250-9342 Osteosarcoma (Giant cell Ewing's odontogenic)
C381-C388 Pleura and mediastinum	8010-8245 8247-8671 8940-8941 8720-8790 Melanomas
C470-C479 Peripheral nerves C490-C499 Connective tissue	8010-8671 Carcinomas 8940-8941 8720-8790 Melanomas
C700-C709 Meninges C710-C719 Brain C720-C729 Other central nervous system	8010-8671 Carcinomas 8940-8941
C400-C419 Bone	8010-8060 Carcinoma (except squamous cell) 8075-8671 8940-8941 8720-8790 Melanomas
C760-C768 Ill-defined Sites	8720-8790 Melanoma 8800-8811 Sarcoma except myeloid sarcoma 8813-8830 Fibromatous neoplasms 8840-8921 Fibrosarcoma 9040-9044 Dermatofibrosarcoma 8990-8991 mesenchymoma 8940-8941 Mixed tumor, salivary gland type 9120-9170 Blood vessel tumor lymphatic vessel tumor 9240-9252 Mesenchymal chondrosarcoma, and giant cell tumors 9540-9560 Nerve Sheath tumor 9580-9582 Granular cell tumor and alveolar soft part sarcoma

Cancer PathCHART Site-Morphology Combination Standards

Source: SEER Program Coding and Staging Manual 2024

About Cancer PathCHART: The Cancer Pathology Coding Histology and Registration Terminology (Cancer PathCHART) initiative is a ground-breaking collaboration of North American and global registrar, registry, pathology, and clinical organizations. The main goal of Cancer PathCHART is to improve cancer surveillance data quality by updating standards for tumor site, histology, and behavior code combinations and associated terminology. This initiative involves a substantial, multifaceted review process of histology and behavior codes (and associated terminology) by tumor site that includes expert pathologists and tumor registrars. The results of these in-depth reviews are incorporated into the Cancer PathCHART database, which serves as the single source of truth standards for tumor site, histology, and behavior coding across all standard setters. See the Cancer PathCHART website for further information:

<https://seer.cancer.gov/cancerpathchart/>.

Cancer PathCHART Standards for cases diagnosed January 1, 2024 and forward: Tumor site-morphology combinations are designated as valid, unlikely, or impossible. Valid tumor entities can be abstracted without any issues. For cases diagnosed as of January 1, 2024 and forward, Impossible tumor entities will trigger an error on the Primary Site, Morphology-Type, Beh ICDO3 2024 (N7040) edit and cannot be abstracted. An alternative site, histology, and behavior combination will need to be coded for the tumor. Unlikely entities will also trigger an error on the N7040 edit. For these combinations, confirm the primary site, histology and behavior code by thoroughly reviewing the medical record. If the information is determined to be correct as coded, the Site/Type Interfield Review override flag will need to be set for the abstract. The 2024 Cancer PathCHART ICD-O-3 Site Morphology Validation List: **The 2024 Cancer PathCHART ICD-O-3 Site Morphology Validation List (CPC SMVL), output directly from the Cancer PathCHART database, is a comprehensive table that replaces both the ICD-O-3 SEER Site/Histology Validation List and the list of impossible site and histology combinations included in the Primary Site, Morphology-Imposs ICDO3 (SEER IF38) edit.** The 2024 CPC SMVL is freely available to cancer registration software vendors and any other end users in easily consumed, computer-readable formats (CSV, XLSX, XML, and JSON). The downloadable list can be found at <https://seer.cancer.gov/cancerpathchart/products.html>.

Cancer PathCHART SVMML Search Tool: a web tool is available on the Cancer PathCHART website that will allow searches for tumor topography, histology, and behavior codes and terms and whether the site-morphology combinations are biologically valid, impossible, or unlikely.

TEXT- PRIMARY SITE TITLE

NAACCR ITEM #2580

Enter the location of the primary site of the tumor being reported. Include available information on tumor laterality. Do not use vendor-driven auto-coding of primary site title in this field. Enter free text.

LATERALITY

NAACCR ITEM #410

Laterality identifies the side of a paired organ or the side of the body in which the reportable tumor originated. This applies to the primary site only. It must be recorded for the following paired organs as 1-5 or 9. Organs that are not paired, for which you have not recorded right or left laterality, are coded 0. Midline origins are coded 5. "Midline" in this context refers to the point where the "right" and "left" sides of paired organs come into direct contact and a tumor forms at that point. Most paired sites cannot develop midline tumors. For example, skin of the trunk can have a midline tumor, but the breasts cannot.

Coding Instructions:

1. Code laterality for all paired sites. (See Section One for additional information.)
2. For the sites C300, C340, C413, C414, the laterality can be coded 04, or 9.
3. Do not code metastatic sites as bilateral involvement.
4. Assign code 5 when the tumor originates only in the midline of a site listed in 4a. "Midline" in this context refers to the point where the "right" and "left" sides of paired organs come into direct contact and a tumor forms at that point.
 - a. C700, C710-C714, C722-C725, C443, C444, C445
5. Organs not paired, unless they are recorded "right" or "left" laterality, are coded 0.

Code	Description
0	Organ is not a paired site.
1	Origin of primary is right.
2	Origin of primary is left.
3	Only one side involved, right or left origin unspecified. For in situ cases, if laterality unknown use '3'
4	Bilateral involvement at time of diagnosis, lateral origin unknown for a single primary; or both ovaries involved simultaneously, single histology; bilateral retinoblastoma, bilateral Wilms tumor. A bilateral laterality (4) should be assigned when there are multiple nodules in both lungs
5	Paired site: midline tumor ONLY for C700, C710-C714, C722-C725, C443, C444, C445
9	Paired site, but no information concerning laterality.

PRIMARY SITES REQUIRING LATERALITY

ICD-O-3	SITES
C07.9	Parotid gland
C08.0	Submandibular gland
C08.1	Sublingual gland
C09.8	Overlapping lesion of tonsil
C09.9	Tonsil, NOS
C30.1	Middle ear
C31.0	Maxillary sinus
C31.2	Frontal sinus
C34.1 – C34.9	Lung
C38.4	Pleura
C40.0	Long bones of upper limb and scapula
C40.1	Short bones of upper limb
C40.2	Long bones of lower limb
C40.3	Short bones of lower limb

ICD-O-3	SITES
C44.1	Skin of eyelid
C44.2	Skin of external ear
C44.3	Skin of other and unspecified parts of face (midline code “9”)
C44.4	Skin of Scalp and Neck
C44.5	Skin or trunk (midline code “9”)
C44.6	Skin of upper limb and shoulder
C44.7	Skin of lower limb and hip
C47.1	Peripheral nerves and autonomic nervous system of upper limb shoulder
C47.2	Peripheral nerves and autonomic nervous system of lower limb and hip
C49.1	Connective, subcutaneous and other soft tissues of upper limb and shoulder
C49.2	Connective, subcutaneous and other soft tissues of lower limb and hip
C50.0 – C 50.9	Breast
C56.9	Ovary
C57.0	Fallopian tube
C62.0 – C62.9	Testis
C63.0	Epididymis
C63.1	Spermatic cord
C64.9	Kidney, NOS
C65.9	Renal pelvis
C66.9	Ureter
C69.0 – C69.9	Eye and lacrimal gland
C70.0	Cerebral meninges, NOS (excluding diagnoses prior to 2004)
C71.0	Cerebrum (excluding diagnoses prior to 2004)
C71.1	Frontal lobe (excluding diagnoses prior to 2004)
C71.2	Temporal lobe (excluding diagnoses prior to 2004)
C71.3	Parietal lobe (excluding diagnoses prior to 2004)
C71.4	Occipital lobe (excluding diagnoses prior to 2004)
C72.2	Olfactory nerve (excluding diagnoses prior to 2004)
C72.3	Optic nerve (excluding diagnoses prior to 2004)
C72.4	Acoustic nerve (excluding diagnoses prior to 2004)
C72.5	Cranial nerve, NOS (excluding diagnoses prior to 2004)
C74.0 – C74.9	Adrenal gland
C75.4	Carotid body

HISTOLOGIC TYPE ICD-O-3**NAACCR ITEM #522**

Numerous resources are required to code Histologic Type ICD-O-3. See Appendix R and all references to code histology.

International Classification of Diseases for Oncology, 3rd ed. Geneva, World Health Organization: 2000	The World Health Organization WHO Publications Center USA; 49 Sheridan Avenue; Albany, NY 12210 ISBN 9241545348 Order Number 11503350 http://www.who.int/classifications/icd/en/index.html
Current Hematopoietic and Lymphoid Neoplasm Case Reportability and Coding Manual and Hematopoietic Database (desktop or web-based versions available)	https://seer.cancer.gov/tools/heme/
Current NAACCR ICD-O-3 Coding Guidelines – Annotated Histology List	https://www.naaccr.org/icdo3/
ICD-O-3.2 Excel Table downloaded from the IACR/WHO Website	Downloadable Excel File Version of ICD-O-3.2 http://www.iacr.com.fr/index.php?option=com_content&view=article&id=149:icd-o-3-2&catid=80&Itemid=545

Histologic Type identifies the microscopic anatomy of cells, is a basis for staging and the determination of treatment options, and affects the patient's prognosis and course of disease.

Code the final pathologic diagnosis for solid tumors.

Use the Hematopoietic Rules and online Database for coding myeloid and lymphoid neoplasms (lymphoma, leukemia, myeloma, myelodysplastic syndromes or myeloproliferative diseases).

The printed versions of the ICD-O-3 Manual is no longer current and should be used as a last resort. However, the basic rules for using these codes are still valid and included in early chapters of the manual.

Use the most current version of the Solid Tumor Rules (<https://seer.cancer.gov/tools/solidtumor/>) when coding the histology for all reportable solid tumors. And, use the WHO official ICD-O-3.2 Tables for official ICD-O-3.2 histology codes. You may also use the NAACCR Annotated Histology List with care.

For lymphomas, leukemias and other hematopoietic tumors (any histology 9590 or greater), follow the instructions in Hematopoietic and Lymphoid Neoplasm Case Reportability and Coding Manual and the Hematopoietic and Lymphoid Neoplasms Database (Hematopoietic DB) <https://seer.cancer.gov/tools/heme/>.

Site-Associated/Site-Related Codes: Some histology/behavior terms in ICD-O-3 have a related or associated primary site code in parenthesis next to the histology code; for example Hepatoma (C22.0). This indicates that this particular histology is usually associated with the primary site C22.0 (liver). Use specific histology codes associated with specific primary site topography codes. Use the site code suggested by ICD-O-3 when the primary site is the same as the site code suggested or when the primary site is unknown and the histology is known.

Code the site documented in the record and ignore the suggested ICD-O-3 code when a primary site is specified in the medical record and there is no evidence of neoplasm in the suggested site.

2018 Site-Restricted Codes: New histology codes were introduced in 2018 that are restrictive to certain sites, particularly lung cancers, pancreato-hepat-biliary cancers, and HPV-associated cancers. These new site-restrictive codes can only be used under certain conditions and for certain primary sites. Exercise caution when determining the difference between site-associated, site-related, and site-restricted histology codes in the Excel File from IACR/WHO.

TEXT – HISTOLOGY TITLE

NAACCR ITEM #2590

Enter the histologic type, behavior, and grade of the tumor being reported. Do not use vendor-drive auto-coding of the histologic type, behavior, or grade of the tumor in this field. Enter free text.

BEHAVIOR ICD-O-3

NAACCR ITEM #523

Enter the behavior that best describes the tumor. The fifth digit of the morphology code listed in the *International Classification of Diseases for Oncology*, 2000, Third Edition (ICD-O-3), pages 27-28, 66 which appears after the slash (/) is the behavior code and ICD-O-3 Updates. If the only specimen was from a metastatic site, code the histologic type of the metastatic site and code **3** for the Behavior code.

NOTE: There have been many behavior code changes for many histology codes over the years. Please use the most current version of the ICD-O-3.2 Excel File and the Solid Tumor Manual or Hematopoietic Database to CONFIRM the current preferred behavior code for any given histologic type. Some Histology codes are compatible with more than 1 behavior code. Always check the biopsy/resection path.

Use behavior code 3 if any invasion is present, no matter how limited.

- Code 3 if any *malignant* invasion is present, no matter how limited.
- Code 3 if any *malignant* metastasis to nodes or tissue beyond the primary is present.

For example Intraductal carcinoma (8500/2) with focal areas of invasion code behavior of 3.

Please note that behavior codes for some neoplasms have changed over time. Some neoplasms have changed from non-malignant to malignant, from invasive to non-invasive, and from not reportable to reportable. Always use the most current version of ICD-O to ensure the histology and the behavior code are current. See the ICD-O-3 Updates in Appendix R.

Use the most current version of the Solid Tumor Rules (<https://seer.cancer.gov/tools/solidtumor/>) when coding the histology for all reportable solid tumors.

Use the Hematopoietic and Lymphoid Neoplasm Case Reportability and Coding Manual and the hematopoietic and Lymphoid Neoplasms Database (Hematopoietic DB) for histology 9590-9993.

Code	Label	Description
0	Benign	Benign (Reportable for intracranial and CNS sites only)
1	Borderline	Uncertain whether benign or malignant Borderline malignancy Low malignant potential Uncertain malignant potential (Reportable for intracranial and CNS sites only)
2	Insitu and/or carcinoma insitu	Carcinoma in situ;

Code	Label	Description
		Intraepithelial; Noninfiltrating; Noninvasive
2	Synonymous with In situ; adopted from the SEER Program Coding and Staging Manual	AIN III (C211) Behavior code '2' Bowen disease (not reportable for C440-C449) Clark level I for melanoma (limited to epithelium) Confined to epithelium Hutchinson melanotic freckle, NOS (C44_) Intracystic, non-infiltrating Intraductal Intraepidermal, NOS Intraepithelial, NOS Involvement up to, but not including the basement membrane Lentigo maligna (C44_) Noninfiltrating Noninvasive No stromal invasion/involvement Papillary, noninfiltrating or intraductal Precancerous melanosis (C44_) Queyrat erythroplasia (C60_) Stage 0 (except Paget's disease (8540/3) of breast and colon or rectal tumors confined to the lamina propria) VAIN III (C529) VIN III (C51_)
3	Invasive	Malignant, primary site (invasive) or Microinvasive

INTRODUCTION TO CODING GRADE

Solid tumors diagnosed 2018 and forward, grade will be collected in four data items, Grade Clinical, Grade Pathological, Grade PostTherapy Clin (yc) and Grade Post Therapy Path (yp). The codes and coding instructions will depend on the type of cancer.

Please use the Grade Coding Manual and the Grade Tables to ensure you are using the proper rules and instructions for coding grade for each specific neoplasm abstracted.

Please use the manuals as designed to ensure the proper code is assigned for invasive and for non-invasive cancers. Some codes can only be used for in-situ cancers. Some only for malignant cancers. All must be histologically proven grade.

The revised grade codes are based on the recommended grading systems specified in the relevant chapters of the AJCC Cancer Staging Manual, 8th and 9th edition and/or the CAP cancer protocols.

Use the most current version of the Grade Coding Manual, v3.1 and the Grade Tables at <https://apps.naaccr.org/ssdi/list/> for coding instructions and site-specific coding rules for all grades.

- The codes for each cancer-specific grading system are to be used in hierarchy from top to bottom.
- The cancer-specific grading will always appear at the top of the grading hierarchy for that cancer site.
- The terms high/low grade are generally used only for non-invasive/in-situ cancers – but, can be used when this is the best information you have.
- The terms well differentiated, moderately differentiated, poorly differentiated and undifferentiated generally fall at the bottom of the selection list for all cancer-specific grading systems and are to be used when this is the only grade information provided on the pathology report.
- Never convert terminology based on old grade tables. Assign them literally from the text.
- Only code the grade from the primary site. Do not code grade from a metastatic site.
- Grade from imaging reports is used to code Clinical Grade for brain tumors without biopsy/resection
- If the patient has a biopsy before the resection of the primary site, then clinical grade = biopsy grade (first grade identified).
- If the patient has a biopsy and does not have a resection of the primary site, then clinical grade = biopsy grade (first grade identified) and the pathological grade = 9.
- If the patient does not have a biopsy but does have a resection of the primary, then clinical grade = 9 and the pathological grade = resection of the primary site grade.
- If the patient does not have a biopsy but does have a resection of primary site, then the clinical grade = 9 and the pathologic grade = resection of primary site grade.
- If the patient has a biopsy assign the biopsy grade, and a resection assign the pathologic grade.
- If the biopsy/clinical grade is higher than the resection/pathological grade – assign the pathological grade to both the clinical and pathological grade. (IMPORTANT: BUT – don't do the reverse of this and recode the clinical grade to a higher code when the pathological grade is higher.)

Code	Grade Description
1	Site-specific grade system category
2	Site-specific grade system category
3	Site-specific grade system category
4	Site-specific grade system category
5	Site-specific grade system category
8	Not applicable (Hematopoietic neoplasms only)
9	Grade cannot be assessed, Unknown
A	Well differentiated
B	Moderately differentiated
C	Poorly differentiated

D	Undifferentiated and anaplastic
E	Site-specific grade system category
H	High grade
L	Low grade
M	Site-specific grade system category
s	Site-specific grade system category
Blank	(Post therapy only)

Codes 1-5, H, L, M, S, and 9 all represent AJCC recommended grading systems.

Categories L and H are applicable for the AJCC recommended grading systems of “low grade” and “high grade” for those cancers for which these are used (e.g. urinary cancers with urothelial histologies). It also includes **M for intermediate grade to be used with L and H for breast in situ cancers.**

S is utilized for sarcomatous overgrowth in corpus uteri adenosarcoma, an AJCC registry data collection variable.

Codes A-E are the generic grade categories (definitions) that have been used by the cancer surveillance community for many years. Codes A-E are not available for all cancers since although many AJCC chapters continue to use the traditional grade terms, many of the chapters now use a three-grade system, instead of the four-grade system.

Your software will include mapping to the correct grade coding system based on your selection of primary site (topography) and histology/behavior and on occasion other factor(s). However, it is important to understand the concepts used to develop the 30+ Grade Coding Tables used in software.

GRADE CLINICAL

NAACCR ITEM #3843

Record the grade of a solid primary tumor before any treatment(surgical resection, systemic therapy, radiation therapy, or neoadjuvant therapy). All surgical procedures are not treatment, e.g. TURB and endoscopic biopsies. Clinical Grade is coded from a biopsy specimen not a tumor resection. One exception to the biopsy rule is for brain and CNS tumors; you may code Clinical Grade from Imaging without biopsy.

For cases diagnosed January 1, 2018 and later, this data item, along with Grade Clinical and Grade Post-Neoadjuvant, replaces NAACCR Data Item Grade (#440) as well as SSF's for cancer sites with alternative grading systems (e.g., breast [Bloom-Richardson], prostate [Gleason]).

GRADE PATHOLOGICAL

NAACCR ITEM #3844

Record the grade of a solid primary tumor that has been resected and for which no neoadjuvant therapy was administered. If AJCC pathological 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, as all information from diagnosis (clinical staging) through the surgical resection is used for pathological staging.

For cases diagnosed January 1, 2018 and later, this data item, along with Grade Clinical and Grade Post-Neoadjuvant, replaces NAACCR Data Item Grade (#440) as well as SSF's for cancer sites with alternative grading systems (e.g., breast [Bloom-Richardson], prostate [Gleason]).

Please reference the most current version of the Grade Coding Manual and Grade Tables at <https://apps.naaccr.org/ssdi/list/> version 3.1 for detailed coding instructions and site-specific coding rules.

GRADE POST THERAPY CLIN (YC)

NAACCR ITEM #1068

Record the grade of a solid primary tumor that has been biopsied following neoadjuvant therapy. If AJCC pathological staging is being assigned. Record the highest grade documented from the surgical treatment resection specimen of the primary site following neoadjuvant therapy.

Please reference the most current version of the Grade Coding Manual and Grade Tables at <https://apps.naaccr.org/ssdi/list/> version 3.1 for detailed coding instructions and site-specific coding rules.

GRADE POST THERAPY PATH (YP)

NAACCR ITEM #3845

Record the highest grade documented from the surgical treatment resection specimen of the primary site following neoadjuvant therapy. If AJCC post-therapy staging is being assigned, the tumor must have met the surgical resection requirements in the AJCC manual. Neoadjuvant therapy must meet guidelines or standards, and not be that given for variable or unconventional reasons as noted in the AJCC manual.

TUMOR SIZE SUMMARY

NAACCR ITEM #756

Record the most accurate measurement in millimeters of a solid primary tumor, usually measured on the surgical resection specimen. Tumor Size Summary replaces CS Tumor Size.

Tumor size is one indication of the extent of disease the time of diagnosis. It is used frequently by both clinicians and researchers to assess cancer screening efforts and initial treatment options and variations. Tumor size that is independent of stage is also useful for quality assurance efforts.

Coding Instructions:

1. All measurements should be in millimeters (mm).
2. Size measured on the surgical resection specimen, when surgery is administered as the first definitive treatment, i.e., no pre-surgical treatment administered.
 - a. If there is a discrepancy among tumor size measurements in the various sections of the pathology report, code the size from the synoptic report (also known as CAP protocol or pathology report checklist).
 - b. If only a text report is available, use: final diagnosis, microscopic, or gross examination, in that order.
3. If neoadjuvant (preoperative) therapy followed by surgery, do not record the size of the pathologic specimen. Code the largest size of tumor prior to neoadjuvant (preoperative) treatment; if unknown code size as 999.

Example: Patient has a 2.2 cm mass in the oropharynx; find needle aspiration of mass confirms squamous cell carcinoma. Patient receives a course of neoadjuvant combination chemotherapy. Pathologic size after total resection is 2.8 cm. Record tumor size as 022 (22 mm).

4. If no surgical resection, then largest measurement of the tumor from the imaging, physical exam, or other diagnostic procedures in this order of priority prior to any other form of treatment.
5. If #2, 3, and 4 do not apply, the largest size from all information available within four months of the date of diagnosis, in the absence of disease progression.
6. Tumor size is the diameter of the tumor, not the depth or thickness of the tumor.
7. Multifocal/multicentric tumors: If the tumor is multi-focal or if multiple tumors are reported as a single primary, code the size of the largest invasive tumor or if all of the tumors are in situ, code the size of the largest in situ tumor.
8. Record tumor size stated less than or greater than as follows
 - a. If tumor size is reported as less than x mm or less than x cm, the reported tumor size should be 1 mm less. Examples: Tumor size is stated as: < 1 cm, code as 009; < 2 cm, code as 019; < 3 cm, code as 029; < 4 cm, code as 039; < 5 cm is coded as 049. If stated as less than 1 mm, use code 001.
 - b. If tumor size is reported as more than or greater than x mm or more than x cm, code size as 1 mm more. Examples: Tumor size is stated as: >10 mm or >1 cm, code as 011; > 2 cm, code as 021; > 3 cm, code as 031; > 4 cm, code as 041; > 5 cm, code as 051. If described as anything greater than 989 mm (98.9 cm), code as 989.
 - c. If tumor size is reported to be between two sizes, record tumor size as the midpoint between the two: i.e., add the two sizes together and then divide by two. Examples: Tumor size is between 2 and 3 cm, code as 025. Code size as 025 since $2 + 3 = 5$ divided by 2 = 2.5 cm (or 025 mm).
9. Record the higher tumor size when stated as a range. Example: Tumor size is 8-10 mm or tumor size is 8 to 10 mm. Code size as 010 since 10 mm is the higher of the values in the range.
10. Round the tumor size only if it is described in fractions of millimeters
 - a. When tumor size is greater than 1 millimeter, round tenths of millimeters in the 1-4 range down to the nearest whole millimeter and round tenths of millimeters in the 5-9 range up to the nearest whole millimeter. See Exception for breast cancer.
 - b. Do not round tumor size expressed in centimeters to the nearest whole centimeter; rather, convert the measurement to millimeters by moving the decimal point one space to the right.

Note 1: Record tumor size as 001 (do not round down to 000) when the largest dimension of a tumor is less than 1 millimeter (between 0.1 and 0.9 mm).

Note 2: Code 001 when tumor size is 1 mm.

Exception to rounding rules for BREAST primaries:

Round tumor sizes greater than 1.0 mm and up to 2.4 mm to 2 mm (002). The purpose of this exception is so that the size recorded in the Tumor Size Summary data item will derive the correct AJCC TNM Primary Tumor (T) category for breast primaries. Do not apply this instruction to any other site.

Examples: Breast cancer described as 6.5 millimeters in size. Round up to 7 mm and code as 007.

Breast cancer described as 1.3 mm in size. Round up to 2 mm and code as 002.

2.3 millimeters cancer in a polyp. Round down to 2 mm and code 002.

Hypopharynx: Focus of cancer described as 1.4 mm in size. Round down to 1 mm and code as 001.

5.2 cm breast cancer. Convert to millimeters and code 052.

2.5 cm rectal cancer. Do not round, record as 025 millimeters.

11. If no surgical resection, then largest measurement of the tumor from physical exam, imaging, or other diagnostic procedures prior to any other form of treatment.
12. Priority of imaging/radiographic techniques: Information on size from imaging/radiographic techniques can be used to code size when there is no more specific size information from a pathology or operative report, but it should be taken as low priority, over a physical exam.
13. Tumor size discrepancies among imaging and radiographic reports: If there is a difference in reported tumor size among imaging and radiographic techniques, unless the physician specifies which imaging is most accurate, record the largest size in the record, regardless of which imaging technique reports.
14. Record the size of the invasive component, if given.
15. Record the largest dimension or diameter of tumor, whether it is from an excisional biopsy specimen or the complete resection of the primary tumor.
16. Record the size as stated for purely in situ lesions.
17. Disregard microscopic residual or positive surgical margins when coding tumor size.
18. Code the size of the primary tumor, not the size of the polyp, ulcer, cyst, or distant metastasis. However, if the tumor is described as a “cystic mass” and only the size of the entire mass is given, code the size of the entire mass, since the cysts are part of the tumor itself.
20. Assign code 999 when
 - a. Size is unknown and for the following sites and schemas/schema IDs
 - i. Any case coded to primary site C420, C421, C423, C424, C770-C779, or C809
 - ii. HemeRetc 00830
 1. Excluding Spleen (C422)
 - iii. Kaposi Sarcoma 00458
 - iv. Lymphoma 00790
 - v. Lymphoma-CLL/SLL 00795
 - vi. Melanoma Choroid and Ciliary Body 00672
 - vii. Melanoma Iris 00671
 - viii. Plasma Cell Disorders 00822
 - ix. Plasma Cell Myeloma 00821

b. The only measurement describes pieces or chips in a pathology report. Do not add the size of pieces or chips together to create a whole; they may not be from the same location, or they may represent only a very small portion of a large tumor. However, when the pathologist states an aggregate or composite size (determined by fitting the tumor pieces together and measuring the total size), record that size.

c. The only measurement is for calcifications that span given distance or a cluster of microcalcifications. Do not record the size of calcifications as tumor size. If there is no measurement of the mass or tumor, record 999.

d. Neoadjuvant therapy has been administered and resection was performed. Do not use a post-neoadjuvant size to code pathologic tumor size; however, you may use the clinical tumor size if available.

19. Document the information to support coded tumor size in the appropriate text field of the abstract.

Code	Description
000	No mass/tumor found
001	1 mm or described as less than 1 mm
002-988	Exact size in millimeters (2mm-988mm)
989	989 millimeters or larger
990	Microscopic focus or foci only and no size of focus is given
998	SITE-SPECIFIC CODES Alternate descriptions of tumor size for specific sites: Familial/multiple polyposis: Colon (C18.0, C18.2-C18.9) and/or Rectosigmoid and Rectum (C19.9, C20.9) If no size is documented: Circumferential: Esophagus (C15.0 C15.5, C15.8 C15.9) Diffuse; widespread: 3/4s or more; linitis plastica: Stomach and Esophagus GE Junction (C16.0 C16.6, C16.8 C16.9) Diffuse, entire lung or NOS: Lung and main stem bronchus (C34.0 C34.3, C34.8 C34.9) Diffuse: Breast (C50.0 C50.6, C50.8 C50.9)
999	Unknown; size not stated; Not documented in patient record; Size of tumor cannot be assessed; Not applicable

REGIONAL LYMPH NODES POSITIVE

NAACCR ITEM #820

Record the exact number of regional nodes examined by the pathologist and found to contain metastases. This data item is necessary for pathologic staging, and it serves as a quality measure for pathology reports and the extent of the surgical evaluation and treatment of the patient. When only Isolated Tumor Cells are identified by immunohistochemistry test within lymph node the lymph node is not counted as positive. There are not enough cancer cells in the node to treat as positive node.

Do not automatically code Nodes Positive=99 and Nodes Examined=99.

The 99/99 combination is restricted to lymphoma, leukemia, brain tumors and unknown primary.

When an FNA or Core Biopsy of a Regional Lymph Node is performed you must code Regional Lymph Nodes Examined = 95, regardless of whether the node biopsied was positive or negative. However, you may code Lymph Nodes Positive = 95 or 00 depending upon the result of the FNA/Core.

FNA/Core Biopsy of a Regional Lymph Node with Scope of Regional Lymph Node Surgery is no longer considered 'treatment' and is not to be used when considering whether or not treatment was given or in the sequence of surgery to radiation therapy or systemic therapy in the Treatment Status Fields.

Code	Description
00	All nodes examined are negative
01-89	1-89 nodes are positive (code exact number of nodes positive)
90	90 or more nodes are positive
95	Positive aspiration of lymph node(s) was performed
97	Positive nodes are documented, but the number is unspecified
98	No nodes were examined
99	It is unknown whether nodes are positive; not applicable; not stated in patient record

REGIONAL LYMPH NODES EXAMINED

NAACCR ITEM #830

Record the total number of regional lymph nodes that were removed and examined by the pathologist. This data item serves as a quality measure of the pathologic and surgical evaluation and treatment of the patient.

Do not automatically code Nodes Positive=99 and Nodes Examined=99. The 99/99 combination is restricted to lymphoma, leukemia, brain tumors and unknown primary.

When an FNA or Core Biopsy of a Regional Lymph Node is performed, code Regional Lymph Nodes Examined = 95, regardless of whether the node biopsied was positive or negative. However, you may code Lymph Nodes Positive = 95 or 00 depending upon the result of the FNA/Core.

FNA/Core Biopsy of a Regional Lymph Node with Scope of Regional Lymph Node Surgery is no longer considered 'treatment' and is not to be used when considering whether or not treatment was given or in the sequence of surgery to radiation therapy or systemic therapy in the Treatment Status Fields. You do not code FNA/Core Biopsy of a Regional Lymph Node or Sentinel Lymph Node Biopsy as a Diagnostic/Staging Procedure. It still must be coded under the treatment data item RX SUMM – Scope Reg LN Surgery = 1 or = 2. You may not have to enter the date, and it is no longer 'counted' as treatment for the patient.

Code	Description
00	No nodes were examined
01-89	1-89 nodes were examined (code the exact number of regional lymph nodes examined)

90	90 or more nodes were examined
95	No regional nodes were removed, but aspiration of regional nodes was performed
96	Regional lymph node removal was documented as a sampling, and the number of nodes is unknown/not stated
97	Regional lymph node removal was documented as a dissection, and the number of nodes is unknown/not stated
98	Regional lymph nodes were surgically removed, but the number of lymph nodes is unknown/not stated and not documented as a sampling or dissection; nodes were examined, but the number is unknown
99	It is unknown whether nodes were examined; not applicable or negative; not stated in patient record

LYMPH-VASCULAR INVASION**NAACCR ITEM #1182**

Lymph-vascular invasion (LVI) indicates the presence or absence of tumor cells in lymphatic channels (not lymph nodes) or blood vessels within the primary tumor as noted microscopically by the pathologist. LVI includes lymphatic invasion, vascular invasion, and lymphovascular invasion.

Presence or absence of cancer cells in the lymphatic ducts or blood vessels is useful for prognosis. CAP Protocols for some disease sites will be expanded to distinguish between lymphatic and small vessel invasion only, venous (large vessel) invasion only, and BOTH lymphatic and small vessel AND venous (large vessel) invasion. This data item is primarily used with the AJCC Cancer Staging Manual and CAP.

Code	Label
0	Lymphovascular Invasion stated as Not Present
1	Lymphovascular Invasion Present/Identified (NOT used for thyroid and adrenal)
2	Lymphatic and small vessel invasion only (L) OR Lymphatic invasion only (thyroid/adrenal only)
3	Venous (large vessel) invasion only (V) OR Angioinvasion (thyroid and adrenal only)
4	BOTH lymphatic and small vessel AND venous (large vessel) invasion OR BOTH lymphatic AND angioinvasion (thyroid and adrenal only)
8	Not Applicable
9	Unknown/Indeterminate/not mentioned in path report

Coding Instructions:

1. Use code 0 when the pathology report indicates that there is no lymphovascular invasion. This includes cases of purely in situ carcinoma, which biologically have no access to lymphatic or vascular channels below the basement membrane.
2. Use code 1 when the pathology report or a physician's statement indicates that lymphovascular invasion (or one of its synonyms) is present in the specimen.
3. **Lymphovascular invasion must be coded 0, 1, 2, 3, 4, or 9 for the schema ids in the following list:**

AMPULLA VATER	00270
APPENDIX	09190
BILE DUCTS DISTAL	00260
BILE DUCTS INTRAHEPATIC	00230
BILE DUCTS PERIHILAR	00250
BLADDER	00620
BUCCAL MUCOSA	00076
CERVIX	09520
CERVIX SARCOMA	00528
COLON AND RECTUM	00200
CORPUS ADENOSARCOMA	00542
CORPUS CARCINOMA	00530
CORPUS SARCOMA	00541
ESOPHAGUS (INCL GE JUNCT)(EXCL SQUAMOUS)	00169
ESOPHAGUS (INCL GE JUNCTION) SQUAMOUS	00161
FLOOR OF MOUTH	00074
GUM	00073
HYPOPHARYNX	00112
LARYNX GLOTTIC	00132
LARYNX OTHER	00130
LARYNX SUBGLOTTIC	00133
LARYNX SUPRAGLOTTIC	00131
LIP	00071
LUNG	09360
MAJOR SALIVARY GLANDS	00080
MAXILLARY SINUS	00121
MELANOMA SKIN	00470
MERKEL CELL SKIN	00460
MOUTH OTHER	00077
NASAL CAVITY AND ETHMOID SINUS	00122
NET AMPULLA OF VATER	09302
NET APPENDIX	09320
NET COLON AND RECTUM	09330
NET DUODENUM	09301
NET PANCREAS	09340
NET STOMACH	09290
OROPHARYNX (P16-)	00111
OROPHARYNX (P16+)	00100
PALATE HARD	00075
PANCREAS	00280
PENIS	00570
PLACENTA	00560
SMALL INTESTINE	00180
STOMACH	00170
TESTIS	00590
THYMUS	09350
TONGUE ANTERIOR	00072
VAGINA	00510
VULVA	09500

4. Lymphovascular invasion must be coded 0, 2, 3, 4, or 9 for the schema ids in the following list:

ADRENAL GLAND	00760
THYROID	00730

THYROID MEDULLARY	00740
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5. Lymphovascular invasion may use any code (0, 1, 2, 3, 4, 8, or 9) for the remaining schema ids:

ADNEXA UTERINE OTHER	00760
ANUS	09210
BILIARY OTHER	00278
BONE APPENDICULAR SKELETON	00381
BONE PELVIS 00383	
BONE SPINE	00382
BRAIN	09721
BREAST (INVASIVE)	00480
CERVICAL LNS, OCCULT HEAD & NECK	00060
CNS OTHER	09722
CONJUNCTIVA	00650
CUTANEOUS CARCINOMA HEAD AND NECK	00150
CYSTIC DUCT	00242
DIGESTIVE OTHER	00288
ENDOCRINE OTHER	00778
EYE OTHER	00718
FALLOPIAN TUBE	00553
GALLBLADDER	00241
GENITAL FEMALE OTHER	00559
GENITAL MALE OTHER	00598
GIST (2018-2020)	00430
HEART, MEDIASTINUM, AND PLEURA	00422
ILL-DEFINED OTHER	99999
INTRACRANIAL GLAND	09723
KAPOSI SARCOMA	00458
KIDNEY PARENCHYMA	00600
KIDNEY RENAL PELVIS	00610
LACRIMAL GLAND	00690
LACRIMAL SAC	00698
LIVER	00220
MEDULLOBLASTOMA	09724
MELANOMA CHOROID AND CILIARY BODY	00672
MELANOMA CONJUNCTIVA	00660
MELANOMA HEAD AND NECK	00140
MELANOMA IRIS	00671
MIDDLE EAR	00119
NASOPHARYNX	09090
NET ADRENAL GLAND	00770
NET JEJUNUM AND ILEUM	09310
ORBITAL SARCOMA	00700
OVARY	00551
PARATHYROID	00750
PHARYNX OTHER	00118
PLEURAL MESOTHELIOMA	09370
PRIMARY PERITONEAL CARCINOMA	00552
PROSTATE	00580

RESPIRATORY OTHER	00378
RETINOBLASTOMA	00680
RETROPERITONEUM	00440
SINUS OTHER	00128
SKIN EYELID	00640
SKIN OTHER	00478
SOFT TISSUE ABDOMEN AND THORAX	00421
SOFT TISSUE HEAD AND NECK	00400
SOFT TISSUE OTHER	00450
SOFT TISSUE TRUNK AND EXTREMITIES	00410
TRACHEA	00358
URETHRA	00631
URETHRA-PROSTATIC	00633
URINARY OTHER	00638

6. Lymphovascular invasion must be coded 8 (not applicable) for all other schema ids:

GIST 2021+	00430
HEMERETIC	00830
LYMPHOMA	00790
LYMPHOMA (CLL/SLL)	00795
LYMPHOMA OCULAR ADNEXA	00710
MYCOSIS FUNGOIDES	00811
PLASMA CELL DISORDER	00822
PLASMA CELL MYELOMA	00821
PRIMARY CUTANEOUS LYMPHOMA NON-MF	00812

7. Use code 9 when:

- There is no microscopic examination of a primary tissue specimen
- The primary site specimen is cytology only or a fine needle aspiration
- The biopsy is only a very small tissue sample
- It is not possible to determine whether lymphovascular invasion is present
- The pathologist indicates the specimen is insufficient to determine lymphovascular invasion
- Lymphovascular invasion is not mentioned in the pathology report
- Primary site is unknown

8. Clarification between codes 8 and 9:

- Code 8 should only be used when the standard-setter does not require this item.
- For cases with no information from the pathology report or other sources, code 9.

CANCER STAGING INFORMATION AND REQUIREMENTS BY DATE OF DIAGNOSIS

FCDS Cancer Staging Requirements follow the NPCR Staging Requirements by Year

State and national cancer staging requirements have evolved over time. The focus of state and national cancer programs is monitoring cancer incidence over time. To support standardization and consistency in reporting the stage of cancer at the time of diagnosis, state and national cancer surveillance programs have often utilized a “summary staging” approach with stable anatomic staging criteria, which includes both clinical data from imaging reports and medical procedures, combined with pathological data obtained from surgical resection of the primary tumor and regional lymph nodes. This is known as SEER Summary Stage. SEER Summary Stage has undergone two revisions since it was instituted in the mid-1970s. The latest edition is Summary Stage 2018 or SS2018. Summary Stage has been required for all cases since 1981.

Continuity of staging requirements is essential for longitudinal cancer studies; however, our programs acknowledge that changes in anatomic staging criteria have been and continue to be modified over time. Moreover, biomolecular and genetic tests to help classify stage subgroups are being utilized more frequently, with tests providing greater detail for staging than ever before. To begin capturing these new tumor markers and other cancer-specific testing or prognostic-related laboratory tests, the United States created the Collaborative Stage Data Collection System, which includes Site-Specific Factors to house these cancer-specific test results and other clinical care and research-oriented data items to enhance staging.

The Collaborative Stage Data Collection System was implemented for cases diagnosed 1/1/2004-12/31/2015 and provided algorithmic solutions to deriving standardized stage groupings based in multiple cancer staging systems including SS1977, SS2000, AJCC TNM 6th ed and AJCC TNM 7th ed.

The combined system of staging parameters was decommissioned and replaced by the original staging systems being directly coded for SS2000 and AJCC TNM 7th ed. in 2016, with another update in 2018 to provide revised anatomic and prognostic staging data items to meet current and future research needs.

SUMMARY STAGE 2018 (SS2018): Direct-Assignment of SEER Summary Stage using the SEER Summary Stage 2018 Manual is required for all cases diagnosed and reported to FCDS 1/1/2018 forward. The most current version of the SEER Summary Stage 2018 is version 3.1 <https://seer.cancer.gov/tools/ssm/>.

Site-Specific Data Items (SSDI): An “SSDI” is a site-specific data item. “Site” in this instance is based on the primary site, the histologic type or histology of the tumor, the AJCC Chapter, Summary Stage Chapter and the EOD Schema. SSDIs were preceded by Collaborative Stage Data Collection System Site-Specific Factors or SSFs, which were first introduced in 2004 with CSv1, and went through major revisions in 2010 with Collaborative Stage v2 (CSv2). The CS SSFs were discontinued as of 12/31/2017. FCDS only requires a limited number of SSDI’s be reported. See the table further in this section for details. The most current version of the SSDI manual is version 3.1 <https://apps.naaccr.org/ssdi/list/>.

SEER*RSA (Registrar Staging Assistant) Website is a Tremendous Resource to assist Registrars in understanding, coding, testing and learning about Cancer Staging, Staging Schema Criteria, Site Specific Data Items, SEER Extent of Disease Coding (EOD), Collaborative Stage Data Collection System and the Collaborative Stage Site Specific Factors. This is a wonderful resource highly recommended by FCDS to assist registrars in understanding how to associate staging criteria and codes to specific cancer types, histologic types, staging and grading schema, and site-specific requirements. <https://seer.cancer.gov/tools/staging/rsa.html>

HISTORICAL STAGING SYSTEMS REFERENCE BY DIAGNOSIS YEAR

SEER SUMMARY STAGE 1977: Direct-Assignment of SEER Summary Stage using the SEER Summary Stage 1977 Manual was required for all cases abstracted and reported to FCDS before 1/1/2000.

SEER SUMMARY STAGE 2000: Direct-Assignment of SEER Summary Stage using the SEER Summary Stage 2000 Manual is required for all cases abstracted and reported to FCDS before 1/1/2018

SEER SUMMARY STAGE 2018: Direct Assignment of SEER Summary Stage using the SEER Summary Stage 2018 Manual (most current version September 2020) is required for all cases abstracted and reported to FCDS on or after 1/1/2018.

AJCC TNM CANCER STAGING - FCDS does not require AJCC TNM for any cases. Registrars may decide to include AJCC TNM staging in their section of the abstract used to document Staging Information to help support the Summary Stage assignment. However, text documentation for Summary Staging is also required.

COLLABORATIVE STAGING (CSv2): Direct-Assignment of Core CS Data Items was required for all cases diagnosed 1/1/2004 and 12/31/2015 and seen at the facility for continuation of initial course of treatment or with evidence of recurrence or progression of cancer not previously reported to FCDS. This includes “non-analytic” cases with evidence of cancer. Some cases may still require the abstractor to use Collaborative Staging.

NOTE: Minimal Historical Cases (historical cancers with no evidence of the historical cancer – but having a new primary cancer diagnosis or undergoing treatment for a different primary cancer) are not required to have the Core CS Data Items coded. However, the minimal historical case will be required to have a SEER Summary Stage 2000 assigned and entered in the “historical grid” that is sent to FCDS.

Required Core CS Data Items (Cancers diagnosed 1/1/2004 thru 12/31/2015)

- *CS Tumor Size* (NAACCR Item #2800)
- *CS Extension* (NAACCR Item #2810)
- *CS Tumor Size/Ext Eval* (NAACCR Item #2820)
- *CS Lymph Nodes* (NAACCR Item #2830)
- *CS Reg Lymph Nodes Eval* (NAACCR Item #2840)
- *Regional Lymph Nodes Examined* (NAACCR Item #830)
- *Regional Lymph Nodes Positive* (NAACCR Item #820)
- *CS Mets at DX* (NAACCR Item #2850)
- *CS Mets Eval* (NAACCR Item #2860)

CS SITE-SPECIFIC FACTORS: CS Site-Specific Factors 1-25 were required for all cancers with an exception made for Minimal Historical Cases.

Site-Specific Data Items (SSDI): An “SSDI” is a site-specific data item. “Site” in this instance is based on the primary site, the histologic type or histology of the tumor, the AJCC Chapter, Summary Stage Chapter and the EOD Schema. SSDIs were preceded by Collaborative Stage Data Collection System Site-Specific Factors or SSFs, which were first introduced in 2004 with CSv1, and went through major revisions in 2010 with Collaborative Stage v2 (CSv2). The CS SSFs were discontinued as of 12/31/2017.

SSDIs have their own data item name and number and can be collected for as many sites/chapters/schemas as needed. Each Site-Specific Data Item (SSDI) applies only to selected schemas. SSDI fields should be

blank for schemas where they do not apply. Please refer to the SSDI Manual for SSDI definitions, rationale, and coding instructions. Comparison of SSDI to SSF is not advised due to differences in coding over time.

The most current version 3.1 of the SSDI and Grade Coding Manuals and Tools are available on the NAACCR Website <https://apps.naacr.org/ssdi/list/3.1>

FCDS requires only a subset of the SSDIs documented in the SSDI Manual. FCDS requires all SSDIs that are ‘required for staging’ or ‘prognostically significant’ according to AJCC, NPCR, and SEER reviews. Commission on Cancer-accredited cancer programs require all the SSDIs documented in the SSDI Manual. FCDS only requires those SSDIs required by the CDC/NPCR and are listed in the table below, also listed in Appendix G. New additions to SSDI Required are highlighted in yellow with red printing. Please note that HER2 Overall Summary is now required for 2021+ for esophagus and stomach, and breast cancers.

FCDS Requires the Following SSDIs for Cases Diagnosed/Treated 2018 and Forward:

Core/Derived	Item #	Item Name	Length	Start Date
C	1068	Grade Post Therapy Clin (yc)	2	2021
D	3800	Schema ID	5	2018
C	1172	Post Transplant Lymphoproliferative Disorder (PTLD)	1	2025
C	1174	PD-L1	5	2025
C	3816	Brain Molecular Markers	2	2018
C	3817	Breslow Tumor Thickness	4	2018
C	3827	Estrogen Receptor Summary	1	2018
C	3829	Esophagus and EGJ Tumor Epicenter	1	2022
C	3835	Fibrosis Score	1	2018
C	3838	Gleason Patterns Clinical	2	2021
C	3839	Gleason Patterns Pathological	2	2021
C	3840	Gleason Score Clinical	2	2021
C	3841	Gleason Score Pathological	2	2021
C	3842	Gleason Tertiary Pattern	2	2021
C	3843	Grade Clinical	1	2018
C	3844	Grade Pathological	1	2018
C	3845	Grade Post Therapy Path (yp)	1	2018
C	3855	HER2 Overall Summary (breast)	1	2018
C	3890	Microsatellite Instability (MSI)	1	2018
C	3915	Progesterone Receptor Summary	1	2018
C	3920	PSA (Prostatic Specific Antigen) Lab Value	5	2018
C	3932	LDH Pretreatment Lab Value	7	2018
C	3956	P16 (cervix, anus, vulva)	2	2024
C	3960	Histologic Subtype (appendix)	1	2023
C	3964	Brain Primary Tumor Location	1	2024

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SEER*RSA - GO TO: <https://seer.cancer.gov/tools/staging/rsa.html>

SEER SUMMARY STAGE 2018 General Coding Instructions – Required for ALL Cancers

Refer to the most current version of the *SEER Summary Stage 2018 General Coding Instructions* for site-specific coding instructions. **Always use the latest version.** This manual is online at https://seer.cancer.gov/manuals/2024/SPCSM_2024_MainDoc.pdf

SEER Summary Stage is based on a combination of imaging, pathologic, operative and clinical assessments. Gross observations at surgery are particularly important when all malignant tissue is not removed. In the event of a discrepancy between pathology and operative reports concerning excised tissue, priority is given to the pathology report.

SEER Summary Stage 2018 is based on all information available through completion of surgery(ies) the first course of treatment or within four months of diagnosis in the absence of disease progression, whichever is longer. This includes clinical, imaging, diagnostic, pathological, operative, and other information.

Enter the SEER Summary Stage 2018 at the Time of Initial Diagnosis of the reportable tumor using the most current version of the *SEER Summary Staging Manual 2018* published October 2023.

CODES	DEFINITIONS
0	<i>in situ</i>
1	Local
2	Regional/Direct Extension
3	Regional/Nodes Only
4	Regional/Direct Extension & Nodes
7*	Distant/Systemic Disease
8**	Benign/Borderline Brain Tumor
9***	Unknown, Unstaged, Not Applicable, NED, Unknown Primary

*The following malignancies must have summary stage at diagnosis = 7.

- Leukemia
- Plasma Cell Myeloma
- Reticuloendotheliosis
- Letterer-Siwe Disease
- Myelodysplastic Syndrome

** all benign/borderline brain and central nervous system tumors stage = 8

***all unknown primaries (C80.9) must have summary stage at diagnosis = 9.

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TREATMENT INFORMATION

The Treatment Information section includes the data items used to describe how the cancer or tumor was treated. FCDS only collects the **First Course of Treatment**. Treatment must be fully documented, whether given at your facility or any other facility, or per history. This provides FCDS with a more complete picture of the patient's entire cancer treatment experience from the time of first diagnosis through recurrence/progression until death.

Cancers can be treated using many different means, including surgery, radiation therapy, chemotherapy, hormones, biological response modifiers, and even unconventional or unproven methods. Within these broad categories of treatments are many finer designations of specific treatment types. This section helps to categorize cancer-directed therapies by type and specific method. Please document any and all treatment given throughout the patient's course of disease. Only code the First Course of Treatment.

The SEER Site-Specific Coding Modules are an excellent resource for registrars. The 2024 SEER Coding and Staging Manual includes the Site-Specific Coding Modules, Appendix C of the manual. Download SEER Appendix C at <https://seer.cancer.gov/manuals/2024/appendixc.html>

Data Items Included In This Section:

<u>NAACCR Item Number</u>	<u>Item Name</u>
1290	Rx Summ – Surg Prim Site 03-22
1291	Rx Summ – Surg 2023
1292	Rx Summ – Scope Regional Lymph Node Surgery
1294	Rx Summ – Surgery of Oth Reg/Dis
1200	Date of First Surgical Procedure
3170	Rx Date – Date of Most Definitive Surgical Procedure
1340	Reason for No Surgery
1380	Rx Summ – Surg/Rad Seq
1506	Phase I Radiation Treatment Modality
1210	Rx Date – Radiation
1430	Reason for No Radiation
2620	Rx Text – Radiation (Beam)
2630	Rx Text – Radiation Other
1639	Rx Summ – Systemic Surg Seq
1390	Rx Summ – Chemo
1220	Rx Date – Chemo
2640	Rx Text – Chemo
1400	Rx Summ – Hormone
1230	Rx Date – Hormone
2650	Rx Text – Hormone
1410	Rx Summ – BRM/Immunotherapy
1240	Rx Date – BRM/Immunotherapy
2660	Rx Text – BRM
1420	Rx Summ – Other
1250	Rx Date – Other
2670	Rx Text – Other
3250	Rx Summ – Transplnt/Endocr
1285	Rx Summ--Treatment Status

DEFINITION OF FIRST COURSE OF TREATMENT

The first course of treatment includes all methods of treatment recorded in the treatment plan and administered to the patient before disease progression or recurrence.

Active surveillance is a form of planned treatment for some patients; its use is coded in the RX Summ – Treatment Status item. Active Surveillance is often used with low grade, slow growing, early stage cancers that may not need to be treated immediately. The cases are monitored over time to see if they progress. If progression is noted, treatment is started. But, the first course of therapy is surveillance. Active Surveillance involves actively monitoring the course of disease with the expectation to intervene with curative intent if the cancer progresses. Life expectancy is a key determinant when deciding on ‘active surveillance’ as the primary treatment plan. These would be younger patients with life expectancy greater than 10 years and with very low-risk disease. Some patients with intermediate-risk disease and a life expectancy greater than 10 years may also opt for ‘active surveillance’. The intent is to begin treatment to cure the patient once the cancer begins to show signs of progression.

A patient in Active Surveillance will have frequent PSA (at least once every 6 months), DRE (at least once a year), repeat biopsy at least once a year, repeat imaging at least once a year, etc. There is a schedule to the activities used to surveil or keep an active eye on the cancer for signs of progression. This is a decision to delay curative treatment.

Note: Active Surveillance may also be called Watchful Waiting.

However, **Watchful Waiting is actually different than Active Surveillance.** In Watchful Waiting the patient is being followed for signs and symptoms of progression of disease or clinical progression. These are more often late stage cancers that may not be treated until they become symptomatic.

Watchful Waiting is just Observation. Observation or No Treatment is the treatment of choice when a patient has a life expectancy less than 10 years and has low to very high risk of disease progression or already has regional or metastatic prostate cancer and a life expectancy less than 5 years. Treatment of any kind is postponed until the patient becomes symptomatic. Once the patient becomes symptomatic, he may qualify for definitive therapy or for palliative care depending on the progression and re-stage of disease and patient choice to treat or not to treat. But, the patient with a shorter life expectancy can avoid the possible side effects of unnecessary confirmatory testing and definitive therapy when he undergoes a true ‘watch and wait’ plan to treat only once symptoms occur.

Observation can be either Active Surveillance or Watchful Waiting depending upon the intent.

No therapy is also different than Active Surveillance. No Therapy or No Treatment is a treatment option that occurs if the patient refuses treatment, the family or guardian refuses treatment, the patient dies before treatment starts, or the physician recommends no treatment be given. No Treatment may be the best option for very advanced and rapidly progressive neoplasms or patients with untreatable cancer. These patients are often referred directly to Hospice with no anti-neoplastic therapy recommended. If the patient refuses all treatment, code “patient refused” (Code 7 or 87) for all treatment modalities.

Maintenance therapy given as part of the first course of planned therapy (example: maintenance chemo for leukemia) is part of the planned first course treatment. **Patients receiveing maintenance therapy are analytic cases for the state and for facility and are reportable.**

Treatment Plan

A treatment plan describes the type(s) of therapies intended to modify, control, remove, or destroy proliferating cancer cells. The documentation confirming a treatment plan may be found in several different sources; for example, medical or clinic records, consultation reports, and outpatient records.

- A discharge plan must be part of the patient record in a JCAHO-accredited hospital and may contain all or only part of the full treatment plan for any given patient.
- All therapies specified in the physician(s) treatment plan(s) are a part of the first course of treatment if they are actually administered to the patient.
- An established protocol or accepted treatment management guideline for the type of cancer an individual is receiving treatment may also be used as a treatment plan when available. These may also be referred to as treatment guidelines. Treatment guidelines may be local to your institution, protocol-specific, or may be published national guidelines such as the NCCN Treatment Guidelines.
- If there is no treatment plan, established treatment protocol, or treatment management guidelines (local or national), and a consultation with a physician advisor is not possible, use the principle: “initial treatment must begin within four months of the date of initial diagnosis.”
- If the first course of treatment plan changes due to an improvement in the tumor burden, the added treatment would still be considered first course. An example is palliative chemotherapy/radiation is recommended and administered per the first course treatment plan. Initially resection of primary tumor was contraindicated due to tumor size and location. Follow up imaging shows an improvement in tumor burden and treatment plan changed since tumor is now resectable to include surgery. Even though the primary tumor resection was not noted in the first course of treatment plan, the resection would be captured as first course of treatment since there was no progression of tumor.

DEFINITION OF NON-CANCER DIRECTED THERAPY

Palliative treatment: The World Health Organization describes palliative care as treatment that improves the quality of life by preventing or relieving suffering. Note: Palliative therapy is part of the first course of therapy only when it destroys or modifies cancer tissue.

Patients receiving treatment for supportive care (non-curative treatment) and/or palliative care ARE also required to be reported to FCDS. They still have active cancer – they are just not being treated for it. Patients receiving supportive/palliative care enter a facility with clear evidence of cancer (evidence of disease on admission). While the treatment given in hospice or for palliative care is not designed to cure the patient, the patient does have evidence of cancer and may be given cancer-directed treatment, but with the intent of alleviating symptoms and/or pain control, but there is no intent to cure the patient.

Anti-neoplastic therapy used to treat symptoms is still recorded in the abstract as ‘treatment’.

Pain control with narcotics or other methods can be recorded in the abstract; however, it is not coded.

These non-cancer-directed therapies are designed to prolong a patient’s life, alleviate pain, or make the patient comfortable. They are not meant to cure the cancer, destroy the tumor, control the tumor, or delay the spread of disease. These treatments include diagnostic tests, palliative care, and supportive care.

The term “palliative” may be used in different context: (a) as meaning non-curative and (b) as meaning the alleviation of symptoms. Thus, some treatments termed palliative fall within the definition of cancer directed treatment and some treat the patient but not the cancer. For example, radiation therapy to bony metastases is considered cancer directed treatment because in addition to alleviating pain, the radiation also kills cancer cells in the bone.

Palliative care description: This treatment qualifies the patient as analytic if it is given as part of the planned first course of treatment.

Time period for First Course of Treatment (in order of precedence)

1. If there is a documented, planned first course of treatment, first course ends at the completion of this treatment plan, regardless of the duration of the treatment plan.
2. If the patient is treated according to a facility or published national standard of practice, first course ends at the completion of the treatment.
3. If there is no documentation of a planned first course of treatment or standard of practice, first course of treatment includes all treatment received before disease progression or treatment failure. If it is undocumented whether there is disease progression/treatment failure and the treatment in question begins more than one year after diagnosis, assume that the treatment is not part of first course.
4. If a patient refuses all treatment modalities and does not change his/her mind within a reasonable time frame, or if the physician opts not to treat the patient, record that there was no treatment in the first course.
5. When a patient only receives palliative care as the first course of therapy, please code it as such. Do not exclude palliative therapy as treatment unless palliative care is for pain management.

TREATMENT DEFINITIONS

Active Surveillance – See Watchful Waiting – It is different than a decision not to treat – No Treatment.

Surgery: First course surgery items describe the most definitive type of surgical treatment the patient received from any facility, when it was performed, and its efficacy. When no surgical treatment is given, the reason is recorded. Please be sure to attribute where each procedure was performed, whether it was at your facility or at another facility and if at another facility, note where if known. Multiple surgical treatment data items exist to describe the extent of surgical resection directed at the primary tumor, regional lymphatics, and/or other distant locations from the primary tumor. It is also important to record when no surgery is performed, when other treatments preceded surgery (neoadjuvant) and what, where, and when each surgical procedure is performed – to the best of your ability.

Surgical Procedure: Any surgical procedure coded in the fields Surgery of Primary Site, Scope of Regional Lymph Node Surgery, or Surgery of Other Regional or Distant Sites.

Ablation of the primary tumor: Ablation is the treatment of and removal of a part of biological tissue (primary tumor), traditionally by surgery but more recently using a wide variety of techniques, the newest of which is to use a catheter to target the tumor for ablation which improves outcome and reduces effects on surrounding tissues. These techniques provide minimally invasive treatment to a primary tumor for early stage disease or can be used for local control of metastatic tumor that might bleed or cause other symptoms in patients with advanced disease and can be used for a wide variety of cancers in many locations.

Electrocautery was the first type of ablation used to vaporize tumors in the bladder for example when TURBT was performed – it is still used today. But, today they call it radiofrequency ablation rather than electrocautery when it is the technique used to destroy tumor.

Thermal techniques are generally classified as “ablative” and include radiofrequency, laser, microwave, cryotherapy, and high intensity focused ultrasound.

Ablative techniques do not effect a lot of the surrounding tissue and can be an alternative to surgery for more and more types of cancers. Typical tumors where ablation is a viable option include lung, bladder, kidney, liver, and skin cancers.

RFA or radiofrequency ablation is one of the ablative techniques that is coded under ‘surgery of primary site’ as long as it is ablation of the primary tumor and not a metastatic tumor.

When any type of ablative technique is used to treat a metastatic tumor(s) the procedure should be coded.

Most tumors treated with ablation are small (<3cm) and accessible to the probes needed to reach the tumor. Two major factors in deciding on this treatment type.

All forms of Thermal Tumor Ablation (cold and heat) are coded in the Surgery of Primary Site data item using Code Range 10-19.

Liver ablation is probably the most often ablation technique used and reported as ‘ablation’ alone. Some cancers have cautery thermal ablation as part of another procedure such as TURBT, TURP.

There is also tumor ablation for bladder, lung, skin, liver, pancreas, kidney, and even some sarcomas.

There is ‘no specimen is sent to pathology’ but there is ‘local tumor destruction’ – most use heat from some source...but the source varies.

There are other forms of thermal ablation that are a part of the ‘ablation’ group:

- Radiofrequency ablation (RFA) – high frequency electrical current ablation – can be monopolar or multipolar,
- Traditional electrocautery,
- Laser ablation,
- Microwave ablation,
- High-intensity focused ultrasound (HIFU) ablation,
- Cryoablation (cold not heat),
- Surface ablation (skin),
- Photodynamic therapy (lung and bladder),
- Percutaneous ethanol injection,
- Acetic acid injection,
- Irreversible electroporation (IRE) (electrical pulse but not considered thermal ablation)

Tumor Embolization (of primary tumor and/or metastasis)

The term *embolization* refers to the intentional blocking of an artery or vein. The mechanism and the reason for embolization determine how and whether it is to be recorded. “Embolization” is a procedure performed to create an embolus, a blocked or hardened blood vessel, and is used to shut down blood flow and blood supply to the primary tumor or to metastasis. Embolization can include injection of a chemical like alcohol or a chemo agent to sclerose or harden key blood vessel(s) and may even trap chemo behind the embolus; or can be performed by injecting a foreign material or substance like coils or radioactive beads to block the artery and prevent any blood flow to the tumor.

Embolization may follow tumor ablation using RFA or other techniques to further treat the tumor or metastases. Ccode both if this is the case.

Types of Embolization Include:

- Chemo-Embolization – Uses Chemotherapy Agent(s) – TACE (transcatheter arterial chemoembolization) is an image-guided, minimally invasive procedure for the delivery of chemotherapeutic drugs directly to the tumor. Code as chemotherapy when the embolizing agent(s) is a chemotherapeutic drug(s). Use SEER*RX to determine whether the drugs used are classified as chemotherapeutic agents. Do Not Code the method of delivery.
- Alcohol-Embolization – Uses Alcohol
- Radioactive Beads/Spheres
- Artificial Embolus – plastic or metal coils, foam, other plugs
- Treatment Code Will Depend on Type of Embolization

Chemoembolization is a procedure in which the blood supply to the tumor is blocked surgically or mechanically and anticancer drugs are administered directly into the tumor. This permits a higher concentration of drug to be in contact with the tumor for a longer period of time.

Code chemoembolization as Chemotherapy when the embolizing agent(s) is a chemotherapeutic drug(s) or when the term chemoembolization is used with no reference to the agent.

Use SEER*Rx Interactive Drug Database (<http://seer.cancer.gov/>) to determine whether the drugs used are classified as chemotherapeutic agents.

Also code as Chemotherapy when the patient has primary or metastatic cancer in the liver and the only information about embolization is a statement that the patient had chemoembolization, tumor embolization or embolization of the tumor in the liver.

If alcohol is specified as the embolizing agent, even in the liver, code the treatment as Other Therapy.

Radioembolization is embolization combined with injection of small radioactive beads or coils into an organ or tumor.

Assign Radiation Modality to code 13 Radioisotopes for radioembolization procedures (e.g. intravascular Yttrium90) for cases diagnosed January 1, 2018, or later. For cases diagnosed prior to January 1, 2018, use code 07 Brachytherapy, NOS. See STORE for more info.

Embolization is coded as Other Therapy (code 1) if the embolizing agent is alcohol, or if the embolized site is other than the liver and the only information in the record is that the patient was given “embolization” with no reference to the agent.

Do not code pre-surgical embolization of hypervascular tumors with particles, coils or alcohol. These presurgical embolizations are typically performed to make the resection of the primary tumor easier. Examples where pre-surgical embolization is used include meningiomas, hemangioblastomas, paragangliomas, and renal cell metastases in the brain.

Systemic Therapy: Systemic therapy encompasses the treatment modalities captured by the data items chemotherapy, hormone therapy, and immunotherapy. These may be given alone or in combination and may include bone marrow or stem cell transplant procedure following completion of systemic treatments. Systemic therapies are often delivered in treatment cycles, either alone or in combination with other agents. If a patient has an adverse reaction to one or more of the agents, the physician may decide to change one or more of the agents to better accommodate the clinical status of the patient. When this occurs and the replacement agent is in the same treatment category as the original agent, there is no change in the original treatment plan and all therapy should be coded. However, if the agent changes class of drugs or the entire protocol is changed, or if the patient exhibits progression of disease while being treated with the initial agent(s), any new agent(s) would not be included as part of the first course of treatment but should be documented in the abstract as subsequent therapy. Systemic agents may be administered via a variety of routes including IV administration, oral administration, intrathecal administration (directly into the cerebrospinal canal), intraperitoneal/intraleural/intrapericardial agents are injected into the peritoneal space, pleural space, or pericardial space, and using other means.

Radiation Therapy: Radiation therapy uses high-energy radiation to shrink tumors and kill cancer cells. X-rays, gamma rays, and charged particles are types of radiation used for cancer treatment. The radiation may be delivered by a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near cancer cells (internal radiation therapy, also called brachytherapy). Systemic radiation therapy uses radioactive substances, such as radioactive iodine, that travel in the blood to kill cancer cells. Radiation therapy is sometimes given with curative intent (that is, with the hope that the treatment will cure a cancer, either by eliminating a tumor, preventing cancer recurrence, or both). In such cases, radiation therapy may be used alone or in combination with surgery, chemotherapy, or both. Radiation therapy may also be given with palliative intent. Palliative treatments are not intended to cure. Instead, they relieve symptoms and reduce the suffering caused by cancer.

Neoadjuvant Therapy: Neoadjuvant Therapy is Treatment given as a first step to shrink a tumor before the main treatment, which is usually surgery, is given. Examples of neoadjuvant therapy include radiation therapy, and systemic therapies such as chemotherapy, biological therapies, and hormone therapy. It is a type of induction therapy. Neoadjuvant therapies have become a mainstay for a number of common cancer types and under certain pre-surgical conditions to improve patient outcomes. Cancer Sites often receiving neoadjuvant therapy include but are not limited to: breast, rectum, lung, brain, stomach, etc.

Adjuvant Therapy: Adjuvant therapies are therapies delivered after the primary treatment of a cancer, usually surgery, and may include radiation, chemotherapy, biological therapy, immunotherapy, hormonal therapy, targeted therapy or any combination of these treatments. Adjuvant therapy usually refers to surgery followed by chemo- or radiotherapy to help decrease the risk of the cancer recurrence/progression

Palliative Care: Palliative care is provided to prolong the patient's life by controlling symptoms, to alleviate persistent pain, or to make the patient comfortable. Palliative care provided to relieve symptoms may include surgery, radiation therapy, Systemic therapy (chemotherapy, hormonal therapy, or other systemic agents), and/or other pain management therapy. Patients receiving palliative care are reportable to FCDS. This treatment may or may not be coded as part of first course of therapy.

Treatment Failure: The treatment modalities did not destroy or modify the cancer cells. The tumor either became larger (disease progression) or stayed the same size after treatment.

Recurrence: The patient must have had a disease-free interval or remission (the cancer was not clinically evident). Following a disease-free interval, there is documentation that the initial/original tumor gave rise to the later tumor.

Progression: Tumor Progression is characterised by increased growth speed and invasiveness of the tumor cells. As a result of the progression, phenotypical changes occur and the tumor becomes more aggressive and acquires greater malignant potential.

Watchful Waiting: A treatment option for patients with slow, indolent diseases, such as prostate cancer and chronic lymphocytic leukemia (CLL). The physician closely monitors the patient and delays treatment until the patient becomes symptomatic or there are other signs of disease progression, such as rising PSA. If treatment is given for symptoms/disease progression after a period of “watchful waiting,” this treatment is not considered part of first course. For example, if a physician and patient choose a “wait and watch” approach to prostate cancer or chronic lymphocytic leukemia and the patient becomes symptomatic, consider the symptoms to be an indication that the disease has progressed and that any further treatment is not part of first course. This is different than a decision not to treat – No Treatment.

Coding Instructions:

1. When physician decides to do watchful waiting for a patient who has prostate cancer, the first course of therapy is no treatment. Code all of the treatment fields to 00, not done. When the disease progresses and the patient is symptomatic; any prescribed treatment is second course.
2. When the patient refuses treatment the first course of therapy is no treatment. Code the treatment fields to refused. If the patient later changes his/her mind and decides to have the prescribed treatment code:
 - a. Code the treatment as first course of therapy if it has been less than one year since the cancer was diagnosed and there has been no documented disease progression.
 - b. Code the treatment as second course of therapy if it has been more than one year since the original cancer was diagnosed or if there has been documented disease progression.
 - c. Code all treatment that was started and administered.

Example: The patient completed only the first dose of a planned 30 day chemotherapy regimen. Code chemotherapy as administered.

3. If a patient has multiple primaries and the treatment given for one primary also affects/treats the other primary, code the treatment for both primary sites.

Example 1: The patient had prostate and bladder cancer. The bladder cancer was treated with a TURB. The prostate cancer was treated with radiation to the prostate and pelvis. The pelvic radiation includes the regional lymph nodes for the bladder. Code the radiation as treatment for both the bladder and prostate cases.

Example 2: The patient had a hysterectomy for ovarian cancer. The pathology report reveals a previously unsuspected microinvasive cancer of the cervix. Code the hysterectomy as surgical treatment for both the ovarian and cervix primaries.

4. If a patient has multiple primaries and the treatment given affects only one of the primaries, code the treatments only on the site that is affected.

Example: The patient has colon and tonsil primaries. The colon cancer is treated with a hemicolectomy and the tonsil primary is treated with radiation to the tonsil and regional nodes. Do not code the radiation for the colon. Do not code the hemicolectomy for the tonsil.

5. If a patient is diagnosed with an unknown primary, code the treatment given as first course even if the correct primary is identified later.

Example: The patient is diagnosed with metastatic carcinoma, unknown primary site. After a full course of chemotherapy, the primary site is identified as prostate. Hormonal treatment is started. Code the chemotherapy as first course of treatment. The hormone therapy is second course.

6. **Treatment Codes 99 or 00:** Treatment was either performed, not performed, recommended or refused. You may not know recommended/refused. It should never be coded as 99 unknown if performed. Do not guess if treatment was performed or not. Do not presume treatment should have been recommended based on published Treatment Guidelines. Treatment Recommended or Refused MUST be documented in the medical record AND it must be coded in the required treatment data item. These instructions are for analytic or non-analytic cases. You can look on the H&P to identify surgery or other treatment performed for a patient with recurrence or progression of their disease.

7. You code only First Course Treatment. You document Subsequent Treatment(s). If you do not know if a treatment was recommended, refused, performed or not performed – then you assign treatment code = 00 not done. In other words - Code any treatment performed, recommended and refused regardless of where it was done or how complete your information is. Below is a bulleted list to help when coding treatment of any type.

- First Course Treatment Must Be Coded
- Subsequent Treatment Must Be Documented
- If you do not know if a treatment was performed, recommended or refused – code 00 (no treatment)
- Treatment ‘99’ is not a placeholder for treatment that *might have been* done, recommended or refused
- Do not guess if treatment was done, recommended or refused.
- Do not code treatment recommended based on registrar’s interpretation of treatment guidelines.
- Treatment performed, recommended or refused must be stated in the medical record by a physician or by evidence of treatment in the record.
- You should both document and code any treatment given/recommended/refused – and where it was done if you know.
- There are NOS codes for any type of treatment performed, but you must have a statement that treatment was performed.
- If a treatment was performed – per history at another facility or at your facility – you code it – even if you have to code xyz treatment, NOS.
- There are treatment-recommended codes for all types of treatment, albeit in different fields in some cases, such as Surgery and Radiation.
- There are treatment-refused codes for all treatments, albeit in different fields in some cases, such as Surgery and Radiation.

DEFINITIONS OF FIRST COURSE OF TREATMENT Leukemias And Hematopoietic Diseases

LEUKEMIAS

The first course of treatment includes all therapies planned and administered by the physician(s) during the first diagnosis of leukemia. Record all remission-inducing or remission-maintaining therapy as the first course of treatment. Treatment regimens often include multiple modes of therapy. The administration of these therapies can span up to a year or longer.

A patient may relapse after achieving a first remission. All therapy administered after a relapse is not counted as first course of treatment. It is referred to as secondary or subsequent therapy.

Leukemia is grouped or typed by how quickly the disease develops and gets worse. Chronic leukemia gets worse slowly. Acute leukemia gets worse quickly.

Leukemia is also grouped by the type of white blood cell that is affected. The groupings are: lymphoid leukemia and myeloid leukemia.

Definitions

Induction: Initial intensive course of chemotherapy.

Consolidation: Repetitive cycles of chemotherapy are given immediately after the remission.

Maintenance: Chemotherapy is given for months or years to maintain remission.

“Maintenance treatment given as part of the first course of planned treatment (for example, for leukemia) is first course treatment, and cases receiving that treatment are analytic.”

Remission: The bone marrow is normocellular with less than 5% blasts, there are no signs or symptoms of the disease, no signs or symptoms of central nervous system leukemia or other extramedullary infiltration, and all of the following laboratory values are within normal limits: white blood cell count and differential, hematocrit/hemoglobin level, and platelet count.

Treatment for leukemia is divided into three phases:

1. Remission induction (chemotherapy and/or biologic response modifiers)
2. CNS prophylaxis or consolidation (irradiation to brain, chemotherapy)
3. Remission continuation or maintenance (chemotherapy or bone marrow transplants).

Coding First Course of Therapy for Leukemia and Hematopoietic Diseases:

When precise information permits, the first course of definitive treatment will be related to the first “remission” as follows. If a patient has a partial or complete remission during the first course of therapy:

- Code all therapy that is “remission-inducing” as first course. All definitive therapy is considered as “remission-inducing” for the first remission.
- Code all therapy that is “consolidation” as first course.
- Code all therapy that is “remission-maintaining” as first course.

All definitive therapy considered as “remission-maintaining” for the first remission, i.e., maintenance chemotherapy, or irradiation to the central nervous system.

Note: Do not record treatment given after the patient relapses (is no longer in remission).

Some patients do not have a remission.

A change in the treatment plan indicates a failure to induce remission. If the patient does not have a remission:

- Record the treatment given in an attempt to induce remission.
- Do not record treatment administered after the change in treatment plan.

RX SUMM – SURG PRIM SITE 03-22

NAACCR ITEM #1290

Record surgery of the primary site for all cases diagnosed prior to 2023 using the Site-Specific Surgery Codes found in Appendix F. You must use the correct year-specific set of Surgery of Primary Site Codes based on the Date of Diagnosis. **Site-specific surgical codes for this data item are found in Appendix F.**

Surgery to remove regional tissue or organs is coded in this field only if the tissue or organs are removed with the primary site in an en bloc resection. An en bloc resection is the removal of organs in one piece at one time. **DO NOT DOUBLE-CODE ANY SURGERY** in more than one treatment field. For example; do not code debulking under both Surgery of Primary Site and Surgery/Other/Reg/Distant. It is only one procedure – and the code under Surgery of Primary Site includes the other sites debulked.

Code the most **invasive, extensive, or definitive** surgery if the patient has multiple surgical procedures of the primary site even if there is no tumor found in the pathologic specimen.

1. Rx Summ – Surg of Primary Site 03-22 (Item 1290) is for all cases diagnosed prior to 1/1/2023.
2. Rx Summ - Surg 2023 is for cases diagnosed 2023 forward. The first character of the code is either an “A” or a “B” followed by 3 numbers. “B” indicates new codes. “A” indicates new format for the old code until it is reviewed – then the A’s become B’s with new codes and definitions. In 2023 only Skin Site Specific Surgery Codes were updated to B codes. In 2024, pancreas, thyroid, colon, lung, and breast were updated to B codes.
3. BOTH Items (1290 and 1291) are included in the Appendix F - Site-Specific Surgery Codes.
4. Once it is determined that cancer-directed surgery was performed, use the **entire operative report** as the primary source document to determine the best surgery of primary site code. The body of the

operative report will designate the surgeon's planned procedure as well as a description of the procedure that was actually performed. **The pathology report may be used to complement the information appearing in the operative report, but the operative report takes precedence.**

5. If a surgical procedure removes the remaining portion of an organ, which had been partially resected previously for any condition, code as total removal of the organ.
6. A date field is also included to document the first date of any surgery performed.
7. If there is no indication anywhere in the patient's medical record that surgery was either planned or performed enter Surgery Rx Summary as 00 or A000/B000 – No Surgical Procedure.
8. There is no need to code any non-cancer-directed surgery performed (i.e., the patient had only a biopsy, exploratory or bypass surgery without resection of the primary or metastatic tumor).
9. If multiple primaries are excised at the same time, code the appropriate surgery for each site.

Example:

1. If a total abdominal hysterectomy was done for a patient with two primaries, one of the cervix and one of the endometrium, code each as having had a total abdominal hysterectomy.
2. If a total colectomy was done for a patient with multiple primaries in several segments of the colon, code total colectomy for each of the primary segments. Ignore the surgical approach when coding procedures. Ignore the surgical margins when coding procedures. Ignore the use of laser if used only for the initial incision.
3. Surgical procedures performed solely for the purpose of establishing a diagnosis/stage or for the relief of symptoms, and procedures such as brushings, washings, and aspiration of cells as well as hematologic findings (peripheral blood smears) are not considered cancer therapy.
4. Surgery for extranodal lymphomas should be coded using the schema for the extranodal site.

Example: A lymphoma of the stomach is to be coded using the schema for stomach.

Record the most invasive, extensive surgical procedure performed during the first course of therapy (whether or not it was performed at your facility).

Note: Surgery for extranodal lymphomas should be coded using the schema for the extranodal site. Surgeries for all other primary cancers not listed above should be coded using the general surgery code schema for All Other Sites at the end of Appendix F.

RX SUMM – SURG 2023

NAACCR ITEM #1291

Rx Summ – Surg 2023, effective for cases diagnosed 01/01/2023 forward, describes a surgical procedure that removes and/or destroys tissue of the primary site that is performed as part of the initial diagnostic and staging work-up or first course of therapy.

All 2024 site-specific surgery codes begin with a letter A except for the primary sites listed below, which start with a letter B indicating a significant change in coding. The year following the primary site is the year the change in the surgical code was implemented for that specific primary site. Site-specific surgical codes for this data item are found in Appendix F for cases diagnosed in 2023 and 2024 forward.

- C44.0-C44.9 Skin (2023)
- C18.0-C18.9 Colon (2024)
- C25.0-C25.9 Pancreas (2024)

- C34.0-C34.9 Lung (2024)
- C50.0-C50.9 Breast (2024)
- C73.9 Thyroid (2024)

For diagnosis years prior to 2023 code data item RX Summ-Surg Prime Site 03-22 [NAACCR #1290].
Site-specific surgical codes for this data item are found in Appendix F.

General Coding Structure

Code	Description
A000	None; no surgical procedure of primary site; diagnosed at autopsy only
A100-A190	Site-specific codes. Tumor destruction; no pathologic specimen or unknown whether there is a pathologic specimen
A200-A800	Site-specific codes. Resection; pathologic specimen
A900	Surgery, NOS. A surgical procedure to the primary site was done, but no information on the type of surgical procedure is provided.
A980	Special codes for hematopoietic neoplasms; ill-defined sites; and unknown primaries (See site-specific codes for the sites and histologies), except death certificate only
A990	Unknown if surgery performed- DO NOT USE THIS CODE

Use the **entire operative report** as the primary source document to determine the best surgery of primary site code. The body of the operative report will designate the surgeon's planned procedure as well as a description of the procedure that was actually performed. The pathology report may be used to complement the information appearing in the operative report, but **the operative report takes precedence**.

Coding Instructions:

- Code **A000** or **B000** when
 - No surgery was performed on the primary site, OR
 - First course of treatment was active surveillance/watchful waiting, OR
 - Case was diagnosed at autopsy

Note: Codes A000 and B000 exclude all sites and histologies that would be coded as A980. (See Coding Instruction 10 below.)
- Use the site-specific coding scheme corresponding to the primary site or histology.
- Code the most invasive, extensive, or definitive surgery if the patient has multiple surgical procedures of the primary site even if there is no residual tumor found in the pathologic specimen from the more extensive surgery.

Example: Patient has a needle biopsy of prostate that is positive for adenocarcinoma. The patient chooses to have a radical prostatectomy. The pathologic examination of the prostatectomy specimen shows no residual tumor. Code the radical prostatectomy.
- Code an excisional biopsy, even when documented as incisional, when

- a. All disease is removed (margins free), OR
- b. All gross disease is removed and there is only microscopic residual at the margin

Note 1: Do not code an incisional biopsy as an excisional biopsy when there is macroscopic residual disease.

Note 2: Shave or punch biopsies are most often diagnostic. Code as a surgical procedure only when the entire tumor is removed and margins meet the criteria in either 4.a or 4.b above.

Example: Shave biopsy performed for a suspicious lesion on the skin of the right arm that has been changing in size and color. The shave biopsy pathology report showed malignant melanoma with only microscopically positive margins. Code the shave biopsy as an excisional biopsy.

- 5. Code total removal of the primary site when a previous procedure resected a portion of the site and the current surgery removed the rest of the organ. The previous procedure may have been cancer directed or non-cancer directed surgery.

Example: Left thyroidectomy for suspicious nodules. Path showed papillary carcinoma. Completion thyroidectomy was performed. Code surgery of primary site as total thyroidectomy (A500).

- 6. Assign the code that reflects the cumulative effect of all surgeries to the primary site.
 - a. When a previous surgical procedure to remove a portion of the primary site is followed by surgery to remove the remainder of the primary site, code the total or final results. Do not rely on registry software to perform this task.

Example: The patient underwent a partial mastectomy and sentinel lymph node biopsy, followed by an axillary lymph node dissection for the first right breast primary in 2011. The separate 2020 right breast primary was treated with a total mastectomy and removal of one involved axillary lymph node. The operative report only refers to this as a non-sentinel lymph node, with no mention of other axillary findings. Cumulatively, this patient has undergone a modified radical mastectomy since there were likely no remaining axillary lymph nodes. For the 2020 primary, code the cumulative effect of the surgery done in 2011 plus the surgery performed in 2020. Use text fields on both abstracts to record the details.

- 7. Code the removal of regional or distant tissue/organs when they are resected in continuity with the primary site (en bloc) and that regional organ/tissue is listed in the Surgery of Primary Site 2023 codes. Specimens from an en bloc resection may be submitted to pathology separately.

Example: Code an en bloc removal when the patient has a hysterectomy and an omentectomy.

- 8. Code surgery for extra-lymphatic lymphoma using the site-specific surgery coding scheme for the primary site. Do not use the lymph node scheme.

- 9. Assign the surgery code(s) that best represents the extent of the surgical procedure that was actually carried out when surgery is aborted. If the procedure was aborted before anything took place, assign code A000. See 1.a. above.

- 10. Code A800, B800, A900, or B900 only when there is no specific information.

- 11. Code A980 for the following primary sites unless the case is death certificate only (see #13 below).

- a. Any case coded to C420, C421, C423, C424, C760-C768, or C809

12. When Surgery of Primary Site 2023 is coded A980

a. Code Reason for No Surgery of Primary Site (#1340) to 1

13. Code A990 or B990 for death certificate only (DCO) cases or if patient record does not state whether a surgical procedure of the primary site was performed (i.e., is unknown). **DO NOT USE THIS CODE.**

RX SUMM – SCOPE REG LN SUR

NAACCR ITEM #1292

This field describes the removal, biopsy, or aspiration of regional lymph node(s) at the time of surgery of the primary site or during a separate surgical event. Regional lymph node(s) are defined in numerous manuals. Please do not code distant lymph nodes removed in this data item. Also, please do not double-code lymph node surgery in both this field and the field Surgery Other Regional Distant Sites.

The following instructions should be applied to all surgically treated cases for all types of cancers. The treatment of breast and skin cancer is where the distinction between sentinel lymph node biopsies (SLNBx) and more extensive dissection of regional lymph nodes is most frequently encountered. For all other sites, non-sentinel regional node dissections are typical, and codes 2, 6 and 7 are infrequently used.

Assign Code = 1 when only an FNA or Core Biopsy of a Regional Lymph Node has been performed. This is not treated as ‘therapy’ any longer. So, when you code the Treatment Status Items, do not include Scope = 1 as ‘treatment given’ or consider Scope = 1 when determining sequence of Surgery with radiation therapy or systemic therapy (before or after surgery, etc). CoC finally recognized Scope = 1 is not a treatment, it is just an FNA or Core biopsy and has no anti-neoplastic effect on the cancer.

Code	Label	General Instructions Applying to ALL Sites	Additional Notes Specific for Breast (C50.x)
0	No regional lymph node surgery	No regional lymph node surgery.	
1	Biopsy or aspiration of regional lymph node(s)	Review the operative report of to confirm whether an excisional biopsy or aspiration of regional lymph nodes was actually performed. If additional procedures were performed on the lymph nodes, use the appropriate code 2-7.	Excisional biopsy or aspiration of regional lymph nodes for breast cancer is uncommon. Review the operative report of to confirm whether an excisional biopsy or aspiration of regional lymph nodes was actually performed; it is highly possible that the procedure is a SLNBx (code 2) instead. If additional procedures were performed on the lymph nodes, such as axillary lymph node dissection, use the appropriate code 2-7.
2	Sentinel Lymph Node Biopsy	<ul style="list-style-type: none"> The operative report states that a SLNBx was performed. Code 2 SLNBx when the operative report describes a procedure using injection of a dye, radio label, or combination to identify a lymph node (possibly more than one) for 	<ul style="list-style-type: none"> If a relatively large number of lymph nodes, more than 5, are pathologically examined, review the operative report to confirm the procedure was limited to a SLNBx and did not include an axillary lymph node dissection (ALND).

		<p>removal/examination.</p> <ul style="list-style-type: none"> When a SLNBx is performed, additional non-sentinel nodes can be taken during the same operative procedure. These additional non-sentinel nodes may be discovered by the pathologist or selectively removed (or harvested) as part of the SLNBx procedure by the surgeon. Code this as a SLNBx (code 2). If review of the operative report confirms that a regional lymph node dissection followed the SLNBx, code these cases as 6. 	<ul style="list-style-type: none"> Infrequently, a SLNBx is attempted and the patient fails to map (i.e. no sentinel lymph nodes are identified by the dye and/or radio label injection) and no sentinel nodes are removed. Review the operative report to confirm that an axillary incision was made and a node exploration was conducted. Patients undergoing SLNBx who fail to map will often undergo ALND. Code these cases as 2 if no ALND was performed, or 6 when ALND was performed during the same operative event. Enter the appropriate number of nodes examined and positive in the data items <i>Regional Lymph Nodes Examined</i> (NAACCR Item #830) and <i>Regional Lymph Nodes Positive</i> (NAACCR Item #820).
3	Number of regional lymph nodes removed unknown or not stated; regional lymph nodes removed, NOS	<ul style="list-style-type: none"> The operative report states that a regional lymph node dissection was performed (a SLNBx was not done during this procedure or in a prior procedure). Code 3 (Number of regional lymph nodes removed unknown, not stated; regional lymph nodes removed, NOS). Check the operative report to ensure this procedure is not a SLNBx only (code 2), or a SLNBx with a regional lymph node dissection (code 6 or 7). Code 4 (1-3 regional lymph nodes removed) should be used infrequently. Review the operative report to ensure the procedure was not a SLNBx only. Code 5 (4 or more regional lymph nodes removed). If a relatively small number of nodes was examined pathologically, review the operative report to confirm the procedure was not a SLNBx only (code 2). If a relatively large number of nodes was examined pathologically, review the operative report to confirm that there was not a SLNBx in addition to a more extensive regional lymph node dissection during the same, or separate, procedure (code 6 or 7). Infrequently, a SNLBx is attempted and the patient. 	<p>Generally, ALND removes at least 7~9 nodes. However, it is possible for these procedures to remove or harvest fewer nodes. Review the operative report to confirm that there was not a SLNBx in addition to a more extensive regional lymph node dissection during the same procedure (code 6 or 7).</p>
4	1-3 regional lymph nodes removed		
5	4 or more regional lymph nodes removed		
6	Sentinel node biopsy and code 3, 4, or 5 at same time,	<ul style="list-style-type: none"> SNLBx and regional lymph node dissection (code 3, 4, or 5) during the same surgical event, or timing not known Generally, SLNBx followed by a 	<ul style="list-style-type: none"> Generally, SLNBx followed by ALND will yield a minimum of 7-9 nodes. However it is possible for these procedures to harvest fewer (or more) nodes.

	or timing not stated	<p>regional lymph node completion will yield a relatively large number of nodes. However it is possible for these procedures to harvest only a few nodes.</p> <ul style="list-style-type: none"> • If relatively few nodes are pathologically examined, review the operative report to confirm whether the procedure was limited to a SLNBx only. • Infrequently, a SNLBx is attempted and the patient fails to map (i.e. no sentinel lymph nodes are identified by the dye and/or radio label injection.) When mapping fails, the surgeon usually performs a more extensive dissection of regional lymph nodes. Code these cases as 6. 	<ul style="list-style-type: none"> • If relatively few nodes are pathologically examined, review the operative report to confirm whether the procedure was limited to a SLNBx, or whether a SLNBx plus an ALND was performed.
7	Sentinel node biopsy and code 3,4, or 5 at different times	<ul style="list-style-type: none"> • SNLBx and regional lymph node dissection (code 3, 4, or 5) in separate surgical events. • Generally, SLNBx followed by regional lymph node completion will yield a relatively large number of nodes. However, it is possible for these procedures to harvest only a few nodes. • If relatively few nodes are pathologically examined, review the operative report to confirm whether the procedure was limited to a SLNBx only. 	
9	9 Unknown or not	<ul style="list-style-type: none"> • The status of regional lymph node evaluation should be known for surgically-treated cases (i.e., cases coded 19-90 in the applicable data item <i>Surgery of Primary Site</i> [NAACCR Item #1290]). Review surgically treated cases coded 9 in <i>Scope of Regional/Lymph Node Surgery</i> to confirm the code. 	

General Instructions:

Use the operative report as the primary sources document to determine whether the operative procedure was a sentinel lymph node biopsy (SLNBx), or a more extensive dissection of regional lymph nodes, or a combination of both SNLBx and regional lymph node dissection. The operative report will designate the surgeon's planned procedure as well as a description of the procedure that was actually performed. The pathology report may be used to complement the information appearing in the operative report, but the operative report takes precedence when attempting to distinguish between SLNBx and regional lymph node dissection or a combination of these 2 procedures. Do not use the number of lymph nodes removed and pathologically examined as the sole means of distinguishing between a SLNBx and a regional lymph node dissection.

Coding Instructions:

1. Do not double-code surgical procedures in more than one surgery field. This field is for regional lymph node procedures, only. Do not code surgical procedures on distant lymph nodes in this field.
2. Code 0 when regional lymph node removal procedure was not performed.

3. Code 0 if there is no indication anywhere in the patient's medical record that regional lymph node surgery was either planned or performed.
4. Codes 1-7 are hierarchical. Code the procedure that is numerically higher.
5. The regional lymph node surgical procedure(s) may be done to diagnose cancer, stage the disease, or as part of the initial treatment. Record all surgical procedures that remove, biopsy, or aspirate regional lymph node(s) whether or not there were any surgical procedures of the primary site.
Example: Patient has a sentinel node biopsy of a single lymph node. Assign code 2 (Sentinel lymph node biopsy [only]).
6. The Scope of Regional Lymph Node field is cumulative; add the number of all of the lymph nodes removed during each surgical procedure performed as part of the first course of treatment.
Example: Patient has a positive cervical node biopsy. The pathology report from a subsequent node dissection identifies three cervical nodes. Assign code 5 (4 or more regional lymph nodes removed).
7. If the operative report lists a lymph node dissection, but no nodes were found by the pathologist, code the Scope of Regional Lymph Node Surgery to 0 (No lymph nodes removed)
8. If the patient has two primaries with common regional lymph nodes, code the removal of regional nodes for both primaries.
Example: Patient has a cystoprostatectomy and pelvic lymph node dissection for bladder cancer. Pathology identifies prostate cancer as well as the bladder cancer and 4/21 nodes positive for metastatic adenocarcinoma. Code Scope of Regional Lymph Node Surgery to 5 (4 or more regional lymph nodes removed) for both primaries.
7. Code Scope **9** for:
 - a. Primary sites
 - Brain (C700-C709) OR
 - Spinal cord (C710-C719) OR
 - Cranial nerves and other parts of the central nervous system (C720-C729)
 - Endocrine glands and related structures (C751-C753)
 - b. Lymphoma with primary site in lymph nodes (C770-C779) AND histology:
Histologies: 9590-9726, 9728-9732, 9734-9740, 9750-9762, 9811-9831, 9940, 9948 and 9971
 - c. Hematopoietic, reticuloendothelial, immunoproliferative, or myeloproliferative disease
 - Primary sites: C420, C421, C423, or C424 AND
 - Histologies: 9727, 9733, 9741-9742, 9764-9809, 9832, 9840-9931, 9945-9946, 9950-9967, and 9975-9993
 - Unknown or ill-defined sites (C761-C768, C809)

RX SUMM – SURG OTH REG/DIS

NAACCR ITEM #1294

Enter the surgical removal of distant lymph nodes or other tissue(s)/organ(s) beyond the primary site. This field is for all procedures that do not meet the definitions of Surgery of Primary Site. The removal of non-primary tissue documents the extent of surgical treatment and is useful in evaluating the extent of metastatic involvement.

Do not double-code surgical procedures in more than one surgery field. This field is for other than primary site resection procedures and/or regional lymph node procedures. Often adjacent regional structures and organs are removed incidentally or as part of a standard routine operative procedure. Do not include removal of these organs as Surgery Other/Regional/Distant Sites. The removal of the incidental organs are generally included in the Surgery of Primary Site Code or as a Debulking Procedure Code under Surgery of Primary Site. Do Not Double-Code Resected Tissues.

Code 0 if there is no indication in the patient's medical record that surgical resection of distant lymph node(s) and/or regional/distant tissue or organs was planned or performed.

Code the highest numerical code that describes the surgical resection of distant lymph node(s) and/or regional/distant tissue or organs.

Example: A patient has an excisional biopsy of a hard palate lesion that is removed from the roof of the mouth and a resection of a metastatic lung nodule during the same surgical event. Code the resection of the lung nodule as **3** (distant site).

Code the removal of non-primary tissue that was removed because the surgeon suspected it was involved with the malignancy even if the pathology is negative.

Do not code the incidental removal of tissue. Incidental is defined as tissue removed for reason other than the malignancy.

Example: During a colon resection, the surgeon noted that the patient had cholelithiasis and removed the gall bladder. Do not code removal of the gall bladder.

Code	Label	Description
0	None	No surgical procedure of nonprimary site was performed. Diagnosed as autopsy.
1	Nonprimary surgical procedure performed	Nonprimary surgical resection to other site(s), unknown if whether the site(s) is regional or distant.
2	Nonprimary surgical procedure to other regional sites	Resection of regional site.
3	Nonprimary surgical procedure to distant lymph node(s)	Resection of <i>distant lymph node(s)</i>
4	Nonprimary surgical procedure to distant site	Resection of distant site.
5	Combination of codes 2 , 3 , or 4	Any combination of surgical procedures 2 , 3 , or 4 .
9	Unknown	It is unknown whether any surgical procedure of a nonprimary site was performed. ONLY USE FOR DEATH CERTIFICATE CASES

RX DATE OF FIRST SURGICAL PROCEDURE

NAACCR ITEM #1200

Records the earliest date on which any first course surgical procedure was performed. This could be the date of first biopsy (FNA, core, incisional or excisional) or date of resection if not preceded by biopsy.

Coding Instructions:

Record the date of the first surgical procedure of the types coded as *RX Summ—Surg Prim Site 03-22* (NAACCR Item #1290) or *RX Summ-Surg 2023* (NAACCR Item #1291), *Scope of Regional Lymph Node Surgery* (NAACCR Item #1292) (excluding code 1) or *Surgical Procedure/Other Site* (NAACCR Item #1294) performed at this or any facility.

The date in this item may be the same as that in *Date of Most Definitive Surgical Resection of the Primary Site* (NAACCR Item #3170), if the patient received only one surgical procedure and it was a resection of the primary site.

DATE MOST DEFINITIVE SURG RESECTION**NAACCR ITEM #3170**

Records the date of the most definitive (most extensive) surgical procedure of the primary site that was performed as part of the first course of treatment.

This item is used to measure the lag time between diagnosis and the most definitive surgery of the primary site and to evaluate treatment efficacy.

Coding Instructions:

- Record the date on which the surgery described by surgical procedure of primary site (NAACCR Item #1290) or (NAACCR ITEM #1291), was performed at this or any facility.

The date in this item may be the same as that in *Date of First Surgical Procedure* (NAACCR Item #1200), if the patient received only one surgical procedure and it was a resection of the primary site.

REASON FOR NO SURGERY**NAACCR ITEM #1340**

This data item records the reason that surgery of the primary site was not part of the first course of treatment.

Code	Description
0	Surgery of the primary site was performed.
1	Surgery of the primary site was not performed because it was not part of the planned first-course treatment.
2	Surgery of the primary site was not recommended/performed because it was contraindicated due to patient risk factors (comorbid conditions, advanced age, etc.)
5	Surgery of the primary site was not performed because the patient died prior to planned or recommended surgery.
6	Surgery of the primary site was not performed; it was recommended by the patient's physician, but was not performed as part of the first-course of therapy. No reason was noted in patient record.
7	Surgery of the primary site was not performed; it was recommended by the patient's physician, but this treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in patient record.
8	Surgery of the primary site was recommended, but it is unknown if it was performed. Further follow-up is recommended.
9	It is unknown whether surgery of the primary site was performed. Diagnosed at autopsy or death certificate only. ONLY FOR DEATH CERTIFICATE CASES

Coding Instructions:

1. Assign code 0 when surgery of the primary site was performed (Surgery of Primary Site is coded in the range of 10-90 or coded in the range of A100-A900 or B100-B900 (the patient did have surgery of primary site).
2. Assign a code in the range of 1-8 if Surgery of Primary Site is coded 00 or 98, or Surgery of Primary Site 2023 is coded A000 or B000.
3. Assign code 1
 - a. Primary site is C420, C421, C423, C424, C760-C768, or C809
Note: Surgery is not standard treatment for these cases.
 - b. There is no information in the patient's medical record about surgery AND It is known that surgery is not usually performed for this type and/or stage of cancer OR There is no reason to suspect that the patient would have had surgery of primary site.
 - c. If the treatment plan offered multiple treatment options and the patient selected treatment that did not include surgery of the primary site. Patient elects to pursue no treatment following the discussion of radiation treatment. Discussion does not equal a recommendation.
 - d. Active Surveillance or Watchful waiting (prostate)
 - e. Patient diagnosed at autopsy
4. Assign code 6
 - a. When it is known that surgery was recommended AND
 - b. It is known that surgery was not performed AND
 - c. There is no documentation explaining why surgery was not done.
5. Assign code 7 if the patient **refused** recommended surgery, or made a blanket statement that he/she refused all treatment.
6. Assign code 8 if the treatment plan offered/recommended surgery, but it is **unknown** if the patient actually had the surgery.
Note: Referral to a surgeon is equivalent to a recommendation for surgery.
Example: There is documentation in the medical record that the primary care physician referred the patient to a surgical oncologist. Follow-back to the surgical oncologist and primary care physician yields no further information. Assign code 8, it is known that surgery was recommended but there is no information on whether or not the patient actually had the surgical procedure.
7. Assign code 9
 - a. When there is no documentation that surgery was recommended or performed.
 - b. Death certificate only.
 - c. Autopsy only.

RX TEXT – SURGERY

NAACCR ITEM #2610

Enter information describing the surgical procedure(s) performed as part of first course of therapy. Include dates and chronology of care. See Appendix L.

PHASE I RADIATION TREATMENT MODALITY**NAACCR ITEM # 1506**

Identifies the radiation modality administered during the first phase of radiation treatment delivered during the first course of treatment. Radiation modality reflects whether a treatment was external beam, brachytherapy, a radioisotope as well as their major subtypes, or a combination of modalities. This data item should be used to indicate the radiation modality administered during the first phase of radiation.

Historically, the Regional Treatment Modality data item [1570] utilized codes that were not mutually exclusive. Rather, it included codes describing a mix of modalities, treatment planning techniques, and delivery techniques that are commonly utilized by radiation oncologists. The goal of the 2018 implementation of separate phase-specific data items for the recording of radiation modality and radiation treatment planning techniques is to clarify this information and implement mutually exclusive categories.

Many new devices, methods and descriptions for some radiation therapy approaches are referenced by brand name, methodology name, or other descriptive terminology. Below are some helpful definitions and a website that is helpful in learning what these the radiation therapy methods or devices or approaches do and how they should be understood. This is to help with terminology. It is up to the registrar to learn whether dosing is high-dose or low-dose based on the application device. When a device is removed after the administration of a dose of radiation, the dose is usually high-dose. When the application device or method remains in place when the patient goes home, the dose is usually low-dose.

EBRT – external beam radiation therapy

IMRT – intensity modulated radiation therapy

IGRT – image-guided radiation therapy

Particle Therapy – proton therapy/carbon ion therapy

SRS – stereotactic radiosurgery

SBRT – stereotactic body radiation therapy

SABR – stereotactic ablative radiation therapy

Brachytherapy LDR/HDR – low dose/high dose brachytherapy and devices used to deliver LDR/HDR

Assign Radiation Modality to code 13 Radioisotopes for radioembolization procedures (e.g. intravascular Yttrium90) for cases diagnosed January 1, 2018, or later. For cases diagnosed prior to January 1, 2018, use code 07 Brachytherapy, NOS. See STORE for more info.

<https://www.targetingcancer.com.au/radiation-therapy/ebrt/>

Phase I Radiation Treatment Modality Codes:

00	No radiation treatment
01	External beam, NOS
02	External beam, photons
03	External beam, protons
04	External beam, electrons
05	External beam, neutrons
06	External beam, carbon ions
07	Brachytherapy, NOS
08	Brachytherapy, intracavitary, LDR
09	Brachytherapy, intracavitary, HDR

10	Brachytherapy, Interstitial, LDR
11	Brachytherapy, Interstitial, HDR
12	Brachytherapy, electronic
13	Radioisotopes, NOS
14	Radioisotopes, Radium-232
15	Radioisotopes, Strontium-89
16	Radioisotopes, Strontium-90
98	Radiation treatment administered; modality unknown
99	Unknown if radiation treatment administered – ONLY FOR DEATH CERTIFICATE CASES

RX DATE RADIATION**NAACCR ITEM #1210**

Records the date on which radiation therapy began at any facility that is part of the first course of treatment.

Coding Instructions:

1. If you know that radiation therapy was performed as a part of the first course of therapy, but do not know the exact date the therapy was initiated, estimate the date therapy was initiated.
2. The date when treatment started will typically be found in the radiation oncologist's summary letter for the first course of treatment.

REASON FOR NO RADIATION**NAACCR ITEM #1430**

Reason for No Radiation identifies why radiation therapy was not provided to the patient and distinguishes a physician's not recommending this therapy due to contraindicating conditions from a patient's refusal of a recommended treatment plan.

Coding Instructions:

- If Regional Treatment Modality (NAACCR Item #1570) is coded 00, then record the reason based on documentation in patient record.
- Code 1 if the treatment plan offered multiple options and the patient selected treatment that did not include radiation therapy.
- Code 7 if the patient refused recommended radiation therapy, made a blanket refusal of all recommended.
- treatment, or refused all treatment before any was recommended.
- Code 8 if it is known that a physician recommended radiation treatment, but no further documentation is available yet to confirm its administration.
- Code 8 to indicate referral to a radiation oncologist was made and the registry should follow to determine.
- whether radiation was administered. If follow-up to the specialist or facility determines the patient was never there and no other documentation can be found, code 1.
- Cases coded 8 should be followed and updated to a more definitive code as appropriate.
- Code 9 if the treatment plan offered multiple options, but it is unknown which treatment, if any, was provided.

Code	Definition
0	Radiation therapy was administered.
1	Radiation therapy was not administered because it was not part of the planned first course treatment.
2	Radiation therapy was not recommended/administered because it was contraindicated due to other patient risk factors (comorbid conditions, advanced age, progression of tumor prior to planned radiation etc.).
5	Radiation therapy was not administered because the patient died prior to planned or recommended therapy.
6	Radiation therapy was not administered; it was recommended by the patient's physician, but was not administered as part of first course treatment. No reason was noted in patient record.
7	Radiation therapy was not administered; it was recommended by the patient's physician, but this treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in patient record.
Code	Definition
8	Radiation therapy was recommended, but it is unknown whether it was administered.
9	It is unknown if radiation therapy was recommended or administered. Death certificate and autopsy cases only.

RX TEXT—RADIATION (BEAM)**NAACCR ITEM #2620**

Enter the types of beam radiation administered to the patient as part of first course of therapy. Include dates and chronology of care. See Appendix L

Suggestion for text:

- Date when radiation treatment began
- Where treatment was given, e.g., at this facility, at another facility
- Other treatment information, e.g., patient discontinued after 5 treatments; unknown if radiation was given

RX TEXT--RADIATION OTHER**NAACCR ITEM #2630**

Enter the types of non-beam radiation administered to the patient as part of first course of therapy. Include dates and chronology of care. See Appendix L

Suggestion for text:

- Date treatment was started
- Where treatment was given, e.g., at this facility, at another facility
- Other treatment information, e.g., unknown if radiation was given

RX SUMM--SURG/RAD SEQ**NAACCR ITEM #1380**

Codes for the sequencing of radiation and surgery given as part of the first course of treatment.

Coding Instructions:

1. Surgical procedures include RX Summ—Surg Prim Site 03-22 (NAACCR Item #1290) or Surgery of Primary Site 2023 (codes A100-A900 or B100-B900); Scope of Regional Lymph Node Surgery

(NAACCR Item #1292) (excluding code 1); Surgical Procedure/Other Site (NAACCR Item #1294). If all of these procedures are coded 0, then this item should be coded 0.

2. If the patient received both radiation therapy and any one or a combination of the following surgical procedures: RX Summ—Surg Prim Site, Regional Lymph Node Surgery (excluding code 1), or Surgical Procedure/Other Site, then code this item 2-9, as appropriate.

Code	Label	Definition
0	No radiation therapy and/or surgical procedures	No radiation therapy given; and/or no surgery of the primary site; no scope of regional lymph node surgery; no surgery to other regional site(s), distant site(s), or distant lymph node(s); or no reconstructive surgery. Diagnosed at autopsy.
2	Radiation therapy before surgery	Radiation therapy given before surgery to primary site; scope of regional lymph node surgery (excluding code 1), surgery to other regional site(s), distant site(s), or distant lymph node(s).
3	Radiation therapy after surgery	Radiation therapy given after surgery to primary site; scope of regional lymph node surgery (excluding code 1), surgery to other regional site(s), distant site(s), or distant lymph node(s).
4	Radiation therapy both before and after surgery	Radiation therapy given before and after any surgery to primary site; scope of regional lymph node surgery (excluding code 1), surgery to other regional site(s), distant site(s), or distant lymph node(s).
5	Intraoperative radiation therapy	Intraoperative therapy given during surgery to primary site; scope of regional lymph node surgery (excluding code 1), surgery to other regional site(s), distant site(s), or distant lymph node(s).
6	Intraoperative radiation therapy with other therapy administered before or after surgery	Intraoperative radiation therapy given during surgery to primary site; scope of regional lymph node surgery (excluding code 1), surgery to other regional site(s), distant site(s), or distant lymph node(s) with other radiation therapy administered before or after surgery to primary site; scope of regional lymph node surgery, surgery to other regional site(s), distant site(s), or distant lymph node(s).
7	Surgery both before and after surgery	Radiation was administered between two separate surgical procedures to the primary site; regional lymph nodes (excluding code 1); surgery to other regional site(s), distant site(s), or distant lymph node(s).
9	Sequence unknown	Administration of radiation therapy and surgery to primary site, scope of regional lymph node surgery, surgery to other regional site(s), distant site(s), or distant lymph node(s) were performed and the sequence of the treatment is not stated in the patient record. It is unknown if radiation therapy was administered and/or it is unknown if surgery to primary site; scope of regional lymph node surgery, surgery to other regional site(s), distant site(s), or distant lymph node(s) were performed.

RX-SUMM-CHEMO**NAACCR ITEM #1390**

Records the type of chemotherapy administered as first course treatment at this and all other facilities. If chemotherapy was not administered, then this item records the reason it was not administered to the patient.

Always use the SEER*Rx Online Lookup to be sure you are coding the correct type of systemic therapy (chemotherapy, hormonal therapy, biological/targeted therapy, other therapy).
(<https://seer.cancer.gov/tools/seerrx/>).

Chemotherapy consists of a group of anticancer drugs that inhibit the reproduction of cancer cells by interfering with DNA synthesis and mitosis.

Enter the type of chemotherapy administered during the first course of therapy. Enter the name of each agent given to ensure the correct code of single, multiple agents or unknown number agents is correct.

Coding Instructions:

1. Code 00 if there is no indication anywhere in the patient's medical record that chemotherapy was either planned or administered.
2. Code 00 if chemotherapy was not administered to the patient, and it is known that it is not usually administered for this type and stage of cancer.
3. Code 00 if the treatment plan offered multiple options, and the patient selected treatment that did not include chemotherapy.
4. Codes 82, 85, 86, 87 if it is known that chemotherapy is usually administered for this type and stage of cancer, but was not administered to the patient, use code 82, 85, 86, or 87 to record the reason why it was not administered.
 - Assign code 82 when chemotherapy is a customary option for the primary site/histology but it was not administered due to patient risk factors, such as
 - a. Advanced age
 - b. Comorbid condition(s) (heart disease, kidney failure, other cancer, etc.)
 - c. Progression of tumor prior to administration
 - Assign code 87 when
 - a. The patient refused recommended chemotherapy
 - b. The patient made a blanket refusal of all recommended treatment and chemotherapy is a customary option for the primary site/histology
 - c. The patient refused all treatment before any was recommended and chemotherapy is a customary option for the primary site/histology
 - Assign code 88 when the only information available is
 - a. The patient was referred to an oncologist
 - b. Insertion of port-a-cath**
 - c. Code 88 if chemotherapy was planned, but not started at the time of the most recent follow-up.

5. ONLY USE CODE 99 FOR DEATH CERTIFICATE ONLY CASES.

6. Code chemoembolization as 01, 02, or 03 depending on the number of chemotherapeutic agents involved.
7. The physician may change a drug during the first course of therapy because the patient cannot tolerate the original agent
 - a. This is a continuation of the first course of therapy when the chemotherapeutic agent that is substituted belongs to the same group (alkylating, antimetabolites, natural products, targeted therapy, or other miscellaneous)
 - b. Do not code the new agent as first course therapy when the original chemotherapeutic agent is changed to one that is NOT in the same group. Code only the original agent as first course. When the new agent is in a different group, it is second course therapy.
 - c. Use SEER*Rx and compare the subcategory of each chemotherapy agent to determine whether or not they belong to the same group (subcategory). **See “e” below for the groups and their definitions.** Source: SEER Program Coding and Staging Manual 2024, Section VII: First Course of Therapy
8. Code the chemotherapeutic agents whose actions are chemotherapeutic only; do not code the method of administration.
9. Combination chemotherapy containing prednisone (a hormone) should be coded in this field by counting the number of chemotherapy agents in the combination (excluding prednisone).
10. If chemotherapy was provided as a radiosensitizer or radioprotectant DO NOT code as chemotherapy treatment. When chemotherapy is given for radiosensitization or radioprotection it is given in low doses that do not affect the cancer.
11. Refer to the online *SEER*Rx Interactive Drug Database* (<https://seer.cancer.gov/tools/seerrx/>) for a list of chemotherapeutic, hormonal and biological anti-neoplastic agents.

Code	Description
00	None, chemotherapy was not part of the first course of therapy; not customary therapy for this cancer
01	Chemotherapy, NOS
02	Chemotherapy, single agent
03	Chemotherapy, multiple agents (combination regimen)
82	Chemotherapy was not recommended/administered because it was contraindicated due to patient risk factors (comorbid conditions, advanced age, etc.).
85	Chemotherapy was not administered because the patient died prior to planned or recommended therapy.
86	Chemotherapy was not administered; it was recommended by the patient’s physician, but was not administered as part of first-course therapy. No reason was noted in the patient record.

87	Chemotherapy was not administered; the patient's physician recommended it, but this treatment was refused by the patient, the patient's family member, or patient's guardian. The refusal was noted in the patient record.
88	Chemotherapy was recommended, but it is unknown if it was administered
99	Unknown if chemotherapy was recommended or administered because it is not stated in patient medical record; ONLY USE FOR DEATH CERTIFICATE CASES

Chemotherapeutic Agents

Chemotherapeutic agents are chemicals that affect cancer tissue by means other than hormonal manipulation.

Chemotherapeutic agents can be divided into five groups:

1. Alkylating agents
2. Antimetabolites
3. Natural products
4. Targeted therapy
5. Miscellaneous

1. Alkylating Agents

Alkylating agents are not cell-cycle-specific. Although they are toxic to all cells, they are most active in the resting phase of the cell. Alkylating agents directly damage DNA to prevent the cancer cell from reproducing. Alkylating agents are used to treat many different cancers including acute and chronic

leukemia, lymphoma, Hodgkin disease, multiple myeloma, sarcoma, and cancers of the lung, breast, and ovary. Because the drugs damage DNA they can cause long-term damage to the bone marrow and can, in rare cases, lead to acute leukemia. The risk of leukemia from alkylating agents is "dose-dependent."

Examples of alkylating agents include

- Mustard gas derivatives/nitrogen mustards: mechlorethamine, cyclophosphamide, chlorambucil, melphalan, and ifosfamide
- Ethylenimines: thiotepa and hexamethylmelamine
- Alkylsulfonates: busulfan
- Hydrazines and Trizines: altretamine, procarbazine, dacarbazine, and temozolomide
- Nitrosoureas: carmustine, lomustine, streptozocin, and nitrosourea are unique because they can cross the blood-brain barrier and can be used in treating brain tumors
- Metal salts: carboplatin, cisplatin, and oxaliplatin

2. Antimetabolites

Antimetabolites are cell-cycle specific. Antimetabolites are very similar to normal substances within the cell. When the cells incorporate these substances into the cellular metabolism, they are unable to divide. Antimetabolites are classified according to the substances with which they interfere.

- Folic acid antagonist: methotrexate
- Pyrimidine antagonist: 5-fluorouracil, floxuridine, cytarabine, capecitabine, and gemcitabine

- Purine antagonist: 6-mercaptopurine and 6-thioguanine
- Adenosine deaminase inhibitor: ladribine, fludarabine, nelarabine, and pentostatin

3. Natural Products

a. Plant Alkaloids are cell-cycle specific which means they attack the cells during various phase of division. They block cell division by preventing microtubule function. Microtubules are vital for cell division. Without them, division cannot occur. Plant alkaloids, as the name implies, are derived from certain types of plants.

- Vinca alkaloids: vincristine, vinblastine, and vinorelbine
- Taxanes: paclitaxel and docetaxel
- Podophyllotoxins: etoposide and teniposide
- Camptothecan analogs: irinotecan and topotecan

b. Antitumor antibiotics are also cell-cycle specific and act during multiple phases of the cell cycle. They are made from natural products and were first produced by the soil fungus *Streptomyces*. Antitumor antibiotics form free radicals that break DNA strands, stopping the multiplication of cancer cells.

- Anthracyclines: doxorubicin, daunorubicin, epirubicin, mitotane, and idarubicin
- Chromomycins: dactinomycin and plicamycin
- Miscellaneous: mitomycin and bleomycin

c. Topoisomerase inhibitors interfere with the action of topoisomerase enzymes (topoisomerase I and II). They control the manipulation of the structure of DNA necessary for replication.

- Topoisomerase I inhibitors: irinotecan, topotecan
- Topoisomerase II inhibitors: amsacrine, etoposide, etoposide phosphate, teniposide

4. Targeted Therapy

Targeted cancer therapies are drugs or other substances that block the growth and spread of cancer by interfering with specific molecules ("molecular targets") that are involved in the growth, progression, and spread of cancer. Targeted cancer therapies are sometimes called "molecularly targeted drugs," "molecularly targeted therapies," "precision medicines," or similar names. Examples of molecularly targeted therapy are imatinib (Gleevec), lapatinib (Tykerb), erlotinib (Tarceva), sunitinib (Sutent).

5. Miscellaneous

Miscellaneous antineoplastics that are unique

- Ribonucleotide reductase inhibitor: hydroxyurea
- Adrenocortical steroid inhibitor: mitotane
- Enzymes: asparaginase and pegaspargase
- Antimicrotubule agent: estramustine
- Retinoids: bexarotene, isotretinoin, tretinoin (ATRA)

Source: SEER Program Coding and Staging Manual 2024, Section VII: First Course of Therapy

RX DATE – CHEMO**NAACCR ITEM #1220**

Records the date of initiation of chemotherapy that is part of the first course of treatment.

Coding Instructions:

Enter the date chemotherapy was initiated that is part of the first course of treatment.

RX TEXT—CHEMO**NAACCR ITEM #2640**

Enter the documentation regarding chemotherapy treatment of the tumor being reported. Include dates and chronology of care. See Appendix L.

Suggestion for text:

- Date when chemotherapy began
- Where treatment was given, e.g., at this facility, at another facility
- Type of chemotherapy, e.g., name of agent(s) or protocol – NAME EACH AGENT GIVEN
- Other treatment information, e.g., treatment cycle incomplete, unknown if chemotherapy was given

RX SUMM – HORMONE**NAACCR ITEM #1400**

Records the type of hormone therapy administered as first course treatment at this and all other facilities. If hormone therapy was not administered, then this item records the reason it was not administered to the patient.

Always use the SEER*Rx Online Lookup to be sure you are coding the correct type of systemic therapy (chemotherapy, hormonal therapy, biological/targeted therapy, other therapy). (<https://seer.cancer.gov/tools/seerrx/>).

Hormone therapy consists of a group of drugs that may affect the long-term control of a cancer's growth.

It is not usually used as a curative measure. Name each agent given.

Code	Description
00	None, hormone therapy was not part of the planned first course of therapy; not usually administered for this type and/or stage of cancer; diagnosed at autopsy only.
01	Hormone therapy administered as first course therapy.
82	Hormone therapy was not recommended/administered because it was contra indicated due to patient risk factors (comorbid conditions, advanced age, etc.).
85	Hormone therapy was not administered because the patient died prior to planned or recommended therapy.
86	Hormone therapy was not administered. It was recommended by the patient's physician, but was not administered as part of the first course of therapy. No reason was stated in the patient record.

87	Hormone therapy was not administered. It was recommended by the patient's physician, but this treatment was refused by the patient, a patient's family member, or the patient's guardian. The refusal was noted in the patient record.
88	Hormone therapy was recommended, but it is unknown if it was administered.
99	It is unknown whether a hormonal agent(s) was recommended or administered because it is not stated in patient record. ONLY USE FOR DEATH CERTIFICATE CASES

Coding Instructions:

1. Assign code 00 when
 - a) There is no information in the patient's medical record that hormone therapy was either planned or administered
 - b) There is no reason to suspect that the patient would have had hormone therapy
 - c) If the treatment plan offered multiple treatment options and the patient selected treatment that
 - d) did not include hormone therapy
 - e) Patient elects to pursue no treatment following the discussion of hormone therapy treatment.
 - f) Only information available is that the patient was referred to an oncologist. Referral does not
 - g) equal a recommendation.
 - h) Watchful waiting (prostate)
 - i) Patient diagnosed at autopsy

2. ONLY USE CODE 99 FOR DEATH CERTIFICATE CASES.

Refer to the online *SEER*Rx Interactive Drug Database* (<https://seer.cancer.gov/tools/seerrx/>) for a list of chemotherapeutic, hormonal and biological anti-neoplastic agents.

RX DATE – HORMONE

NAACCR ITEM #1230

Records the date of initiation of hormone therapy that is part of the first course of treatment.

Coding Instructions:

Record the first or earliest date on which hormone therapy was administered by any facility. This date corresponds to administration of the agents coded in *RX Summ Hormone* (NAACCR Item #1390).

RX TEXT—HORMONE

NAACCR ITEM #2650

Enter the documentation regarding the hormone treatment of the tumor being reported. Include dates and chronology of care. See Appendix L

Suggestion for text:

- Date treatment was started
- Where treatment was given, e.g., at this facility, at another facility
- Type of hormone or antihormone, e.g., Tamoxifen
- Type of endocrine surgery or radiation, e.g., orchiectomy
- Other treatment information, e.g., treatment cycle incomplete; unknown if hormones were given

RX SUMM – BRM/IMMUNOTHERAPY**NAACCR ITEM #1410**

Records the date of initiation of immunotherapy or a biologic response modifier (BRM) that is part of the first course of treatment. Immunotherapy (biological response modifier) consists of biological or chemical agents that alter the immune system or change the host's response to the tumor cells.

Refer to the online *SEER*Rx Interactive Drug Database* (<https://seer.cancer.gov/tools/seerrx/>) for a list of chemotherapeutic, hormonal and biological anti-neoplastic agents.

Types of immunotherapy

Interferons: Interferons belong to a group of proteins called cytokines. They are produced naturally by the white blood cells in the body. Interferon-alpha is able to slow tumor growth directly as well as activate the immune system. It is used for a number of cancers including multiple myeloma, chronic myelogenous leukemia (CML), hairy cell leukemia, and malignant melanoma.

Cancer Vaccines: Cancer vaccines are still in the experimental phase and are not coded in this data item. They may be coded in the field Other Therapy. Currently clinical trials use cancer vaccines for brain, breast, colon, kidney, lung, melanoma and ovary.

Interleukins (IL-2) are often used to treat kidney cancer and melanoma.

Monoclonal Antibodies: Monoclonal antibodies are produced in a laboratory. The artificial antibodies are injected into the patient to seek out and disrupt cancer cell activities and to enhance the immune response against the cancer. For example, Rituximab (Rituxan) may be used for non-Hodgkin lymphoma, and trastuzumab (Herceptin) may be used for certain breast cancers.

Coding Instructions:

1. Assign code 00
 - a. When there is no information in the patient's medical record that immunotherapy was either planned or administered
 - b. There is no reason to suspect that the patient would have had immunotherapy.
 - c. If the treatment plan offered multiple treatment options and the patient selected treatment that did not include immunotherapy.
 - d. Patient elects to pursue no treatment following the discussion of immunotherapy. Discussion does not equal a recommendation.
 - e. Only information available is that the patient was referred to an oncologist. Referral does not equal a recommendation.
 - f. Watchful waiting (prostate)
 - g. Patient diagnosed at autopsy
2. Assign code 87
 - a. If the patient refused recommended immunotherapy.
 - b. If the patient made a blanket refusal of all recommended treatment.
3. **ONLY USE CODE 99 FOR DEATH CERTIFICATE CASES.**

Refer to the online *SEER*Rx Interactive Drug Database* (<https://seer.cancer.gov/tools/seerrx/>) for a list of chemotherapeutic, hormonal and biological anti-neoplastic agents.

Code	Description
00	None, Immunotherapy was not part of the first course of therapy; not customary therapy for this cancer
01	Immunotherapy
82	Immunotherapy was not recommended/administered because it was contraindicated due to patient risk factors (comorbid conditions, advanced age, etc.)
85	Immunotherapy was not administered because the patient died prior to planned or recommended therapy.
86	Immunotherapy was not administered; it was recommended by the patient's physician, but was not administered as part of first-course therapy. No reason was noted in the patient record.
87	Immunotherapy was not administered; the patient's physician recommended it, but the patient, the patient's family member, or the patient's guardian refused this treatment. The refusal was noted in the patient's records
88	Immunotherapy was recommended, but it is unknown if it was administered
99	It is unknown if Immunotherapy was recommended or administered because it is not stated in patient record; death certificate-only cases. ONLY USED FOR DCO CASES

RX DATE – BRM/IMMUNOTHERAPY**NAACCR ITEM #1240**

Records the date of initiation of immunotherapy or a biologic response modifier (BRM) that is part of the first course of treatment.

Coding Instructions:

Enter the date the biologic response modifier/immunotherapy was initiated that is part of the first course of treatment.

RX TEXT—BRM**NAACCR ITEM #2660**

Enter the documentation regarding the biological response modifiers or immunotherapy treatments of the tumor being reported. Include dates and chronology of care. See Appendix L

Suggestion for text:

- When treatment was given, e.g., at this facility; at another facility
- Type of BRM agent, e.g., Interferon, BCG
- BRM procedures, e.g., bone marrow transplant, stem cell transplant
- Other treatment information, e.g., treatment cycle incomplete; unknown if BRM was given

RX SUMM—SYSTEMIC / SURGERY SEQ**NAACCR ITEM #1639**

Records the sequencing of systemic therapy and surgical procedures given as part of the first course of treatment.

Coding Instructions:

1. Enter the sequencing of systemic therapy (RX Summ-Chemo [1390], RX Summ-Hormone [1400], and RX Summ-Transplnt/Endocr [3250]) and surgical procedures given as part of the first course of treatment.
2. If none of the following surgical procedures was performed: RX Summ- SurgPrim Site (NAACCR Item #1290 or Surgery of Primary Site 2023 (NAACCR Item #1291), RX Summ--Scope Reg LN Sur

(NAACCR Item #1292) (excluding code 1), RX Summ--Surg Oth Reg/Dis (NAACCR Item #1294), then this item should be coded 0.

3. If the patient received both systemic therapy and any one or a combination of the following surgical procedures: RX Summ--Surg Prim Site (NAACCR Item #1290) or Surgery of Primary Site 2023 (NAACCR Item #1291), RX Summ--Scope Reg LN Sur (NAACCR Item #1292) (excluding code 1), or RX Summ--Surg Oth Reg/Dis (NAACCR Item #1294), then code this item 2—9, as appropriate.

Code	Label	Description
0	No systemic therapy and/or surgical procedures	No systemic therapy was given; and/or no surgical procedure of primary site; no scope of regional lymph node surgery; no surgery to other regional site(s), distant site(s), or distant lymph node(s); or no reconstructive surgery was performed. Diagnosed at autopsy.
2	Systemic therapy before surgery	Systemic therapy was given before surgical procedure of primary site; scope of regional lymph node surgery (excluding code 1); surgery to other regional site(s), distant site(s), or distant lymph node(s) was performed.
3	Systemic therapy after surgery	Systemic therapy was given after surgical procedure of primary site; scope of regional lymph node surgery (excluding code 1); surgery to other regional site(s), distant site(s), or distant lymph node(s) was performed.
4	Systemic therapy both before and after surgery	Systemic therapy was given before and after any surgical procedure of primary site; scope of regional lymph node surgery (excluding code 1); surgery to other regional site(s), distant site(s), or distant lymph node(s) was performed.
5	Intraoperative systemic therapy	Intraoperative systemic therapy was given during surgical procedure of primary site; scope of regional lymph node surgery (excluding code 1); surgery to other regional site(s), distant site(s), or distant lymph node(s).
6	Intraoperative systemic therapy with other systemic therapy administered before or after surgery	Intraoperative systemic therapy was given during surgical procedure of primary site; scope of regional lymph node surgery (excluding code 1); surgery to other regional site(s), distant site(s), or distant lymph node(s) with other systemic therapy administered before or after surgical procedure of primary site; scope of regional lymph node surgery; surgery to other regional site(s), distant site(s), or distant lymph node(s) was performed.
7	Surgery both before and after systemic therapy	Systemic therapy both before and after radiation”, defined as Systemic therapy was administered between two separate surgical procedures to the primary site; regional lymph nodes (excluding code 1); surgery to other regional site(s), distant site(s), or distant lymph node(s).
9	Sequence unknown	Administration of systemic therapy and surgical procedure of primary site; scope of regional lymph node surgery (excluding code 1); surgery to other regional site(s), distant site(s), or distant lymph node(s) were performed and the sequence of the treatment is not stated in the patient record. It is unknown if systemic therapy was administered and/or it is unknown if surgical procedure of primary site; scope of regional lymph node surgery; surgery to other regional site(s), distant site(s), or distant lymph node(s) were performed.

RX SUMM – TRANSPLNT/ENDOCR**NAACCR ITEM #3250**

Identifies systemic therapeutic *procedures* administered as part of the first course of treatment at this and all other facilities. If none of these *procedures* were administered, then this item records the reason they were not performed. These include bone marrow transplants, stem cell harvests, surgical and/or radiation endocrine therapy.

Definitions:

Bone marrow transplant (BMT): Procedure used to restore stem cells that were destroyed by chemotherapy and/or radiation. Replacing the stem cells allows the patient to undergo higher doses of chemotherapy.

BMT Allogeneic: Receives bone marrow or stem cells from a donor.

BMT Autologous: Uses the patient's own bone marrow and/or stem cells. The tumor cells are filtered out, and the purified blood and stem cells are returned to the patient.

Note: Used for breast cancer, lymphoma, leukemia, aplastic anemia, myeloma, germ cell tumors, ovarian cancer, and small cell lung cancer.

Conditioning: High-dose chemotherapy with or without radiation administered prior to transplants such as BMT and stem cell to kill cancer cells. This conditioning also destroys normal bone marrow cells so the normal cells need to be replaced (rescue). The high dose chemotherapy is coded in the Chemotherapy field.

Hematopoietic Growth Factors: A group of substances that support hematopoietic (blood cell) colony formation. The group includes erythropoietin, interleukin-3, and colony-stimulating factors (CSFs). The growth-stimulating substances are ancillary drugs and not coded.

Non-Myeloablative Therapy: Uses immunosuppressive drugs pre- and post-transplant to ablate the bone marrow. These are not recorded as therapeutic agents.

Peripheral Blood Stem Cell Transplantation (PBSCT): Rescue that replaces stem cells after conditioning.

Rescue: Rescue is the actual BMT or stem cell transplant done after conditioning.

Stem Cells: Immature cells found in bone marrow, blood stream and umbilical cords. The stem cells mature into blood cells.

Coding Instructions:

1. Bone marrow transplants should be coded as either autologous (bone marrow originally taken from the patient) or allogeneic (bone marrow donated by a person other than the patient). For cases in which the bone marrow transplant was syngeneic (transplanted marrow from an identical twin), the item is coded as allogeneic.
2. Stem cell harvests involve the collection of immature blood cells from the patient and the reintroduction by transfusion of the harvested cells following chemotherapy or radiation therapy.
3. Endocrine irradiation and/or endocrine surgery are procedures which suppress the naturally occurring hormonal activity of the patient and thus alter or affect the long-term control of the cancer's growth. These procedures must be bilateral to qualify as endocrine surgery or endocrine radiation. If only one gland is intact at the start of treatment, surgery and/or radiation to that remaining gland qualifies as endocrine surgery or endocrine radiation.
4. Code 00 if a transplant or endocrine procedure was not administered to the patient
5. Code 00 if there is no indication anywhere in the patient's medical record that a transplant or endocrine procedure was either planned or administered.
6. Code 00 if the treatment plan offered multiple options, and the patient selected treatment that did not

- include a transplant or endocrine procedure.
7. If it is known that a transplant or endocrine procedure is usually administered for this type and stage of cancer, but was not administered to the patient, use code 82, 85, 86, or 87 to record the reason why it was not administered.
 8. Code 87 if the patient refused a recommended transplant or endocrine procedure, made a blanket refusal of all recommended treatment, or refused all treatment before any was recommended.
 9. Code 88 if it is known that a physician recommended a hematologic transplant or endocrine procedure, but no further documentation is available yet to confirm its administration.
 10. Code 88 to indicate referral to a specialist for hematologic transplant or endocrine procedures and the registry should follow the case. If follow-up to the specified specialist or facility determines the patient was never there, code 00.
 11. Cases coded 88 should be followed to determine whether they were given a hematologic transplant or endocrine procedure or why not.
 12. Code 99 if it is unknown whether a hematologic transplant and/or endocrine surgery/radiation was administered or recommended.

Code	Description
00	None, transplant procedure or endocrine therapy was not part of the first course of therapy; not customary therapy for this cancer
10	Bone marrow transplant, NOS. A bone marrow transplant procedure was administered, but the type was not specified
11	Bone marrow transplant – autologous
12	Bone marrow transplant – allogeneic
20	Stem cell harvest
30	Endocrine surgery and/or endocrine radiation therapy. Code only to be used for Primary Sites Breast and/or Prostate
40	Combination of endocrine surgery and/or radiation with a transplant procedure (combination of codes 30 and 10, 11, 12 or 20).
82	Hematologic transplant and/or endocrine surgery/radiation was not recommended/administered because it was contraindicated due to patient risk factors (i.e., comorbid conditions, advanced age).
85	Hematologic transplant and/or endocrine surgery/radiation was not administered because the patient died prior to planned or recommended therapy.
86	Hematologic transplant and/or endocrine surgery/radiation was not administered. It was recommended by the patient's physician, but was not administered as part of first-course therapy. No reason was stated in the patient record.
87	Hematologic transplant and/or endocrine surgery/radiation was not administered. It was recommended by the patient's physician, but this treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in the patient record.
88	Hematologic transplant and/or endocrine surgery/radiation was recommended, but it is unknown if it was administered If a bone marrow or stem cell harvest was undertaken, but was not followed by a rescue or re-infusion as part of first course treatment
99	It is unknown whether hematologic transplant and/or endocrine surgery/radiation was recommended or administered because it is not stated in patient record. Autopsy only cases. ONLY USE FOR DEATH CERTIFICATE CASES

RX SUMM – OTHER**NAACCR ITEM #1420**

Identifies Other Treatment that cannot be defined as surgery, radiation, or systemic therapy according to the defined data items in this manual.

This data item will always generate an EDIT WARNING when code = 1 or 2. Warnings do not require EDIT Override or FORCE. If the case has other errors besides the warning, then the errors will need to be corrected before submission.

Coding Instructions

1. The principal treatment for certain reportable hematopoietic diseases could be supportive care that does not meet the usual definition of treatment that “modifies, controls, removes, or destroys” proliferating cancer tissue.
2. Supportive care may include phlebotomy, transfusion, or aspirin. In order to report the hematopoietic cases in which the patient received supportive care, SEER and the Commission on Cancer have agreed to record treatments such as phlebotomy, transfusion, or aspirin as “Other Treatment” (Code 1) for certain hematopoietic diseases ONLY. Consult the most recent version of the Hematopoietic and Lymphoid Neoplasm Case Reportability and Coding Manual for instructions for coding care of specific hematopoietic neoplasms in this item.
3. **Assign code 0** when
 - a. There is no information in the patient’s medical record about other therapy AND
 - i. It is known that other therapy is not usually performed for this type and/or stage of cancer
 - OR
 - ii. There is no reason to suspect that the patient would have had other therapy
 - b. The treatment plan offered multiple treatment options and the patient selected treatment that did not include other therapy
 - c. Patient elects to pursue no treatment following the discussion of other therapy. Discussion does not equal a recommendation. Patient's decision not to pursue other therapy is not a refusal of other therapy in this situation.
 - d. First course of treatment was active surveillance/watchful waiting
 - e. Patient diagnosed at autopsy
4. **Assign code 1** for
 - a. Hematopoietic treatments such as: phlebotomy or aspirin (See SEER*Rx and Hematopoietic and Lymphoid Neoplasm Coding Manual and Database for specific guidance on coding)
 Note: Do not code blood transfusion as treatment.
 Rationale: Blood transfusions may be used for any medical condition that causes anemia. It would be virtually impossible for the registrar to differentiate between blood transfusions used for a co-morbidity (i.e., anemia) from those given as prophylactic treatment of a hematopoietic neoplasm.
 - b. PUVA (Psoralen (P) and long-wave ultraviolet radiation (UVA)) in the RARE event that

it is used as treatment for extremely thin melanomas or cutaneous T-cell lymphomas (e.g., mycosis fungoides)

Note: Code UVB phototherapy for mycosis fungoides as photodynamic therapy under Surgery of Primary Site 2023 for skin. Assign code B110 [Photodynamic therapy (PDT)] when there is no pathology specimen.

c. Photophoresis. This treatment is used **ONLY** for thin melanoma or cutaneous T-cell lymphoma (mycosis fungoides).

d. Cancer treatment that could not be assigned to the previous treatment data items (surgery, radiation, chemotherapy, immunotherapy, or systemic therapy)

5. Assign code 2 for any experimental or newly developed treatment, such as a clinical trial, that differs greatly from proven types of cancer therapy

Note: Hyperbaric oxygen has been used to treat cancer in clinical trials, but it is also used to promote tissue healing following head and neck surgeries. Do not code the administration of hyperbaric oxygen to promote healing as an experimental treatment.

6. Assign code 3 when the patient is enrolled in a double blind clinical trial. When the trial is complete and the code is broken, review and recode the therapy.

7. Assign code 6 for

a. Cancer treatment administered by nonmedical personnel

Example: Cannabis oil or medical marijuana that is used for treatment.

b. Unconventional methods whether they are the only therapy or are given in combination with conventional therapy

Example: DC vax given for brain cancer. Assign code 6. DC vax is not an approved treatment for brain cancer and should not be coded in the immunotherapy or any of the other treatment data items.

c. Complementary and Alternative Medicine (CAM) as any medical system, practice, or product that is not thought of as “western medicine” or standard medical care. CAM treatments may include dietary supplements, megadose vitamins, herbal preparations, acupuncture, massage therapy, magnet therapy, spiritual healing, and meditation.

i. Alternative medicine is treatment that is used instead of standard medical treatments. Alternative therapy is when the patient receives no other type of standard treatment.

ii. Complementary medicine. Treatments that are used along with standard medical treatments but are not standard treatments; also called conventional medicine. One example is using acupuncture to help lessen some side effects of cancer treatment in conjunction with standard treatment.

d. Integrative medicine. A total approach to medical care that combines standard medicine with the CAM practices that have shown to be safe and effective. They treat the patient's mind, body, and spirit.

Note: See complete information on complementary and alternative medicine types specific to cancer at NCI Office of Cancer Complementary and Alternative Medicine. For additional information on cancer and other diseases, please visit NIH National Center for Complementary

and Integrative Health.

8. **Assign code 8** when the physician recommended other therapy, but there is no information that the treatment was given

9. **Assign code 9** when there is no documentation that other therapy was recommended or performed
a. For death certificate only (DCO) cases

Code 6

Use code 6 for unconventional methods (for example, laetrile) when given alone or combined with cancer-directed treatment. Use code 6 for alternative and complementary therapies ONLY. If the patient receives no other type of treatment (for example, do not code megavitamins if the patient also received cancer-directed surgery). Code 6 includes but is not limited to:

UNCONVENTIONAL METHODS	ALTERNATIVE AND COMPLEMENTARY THERAPIES
Cancell	ALTERNATIVE SYSTEMS
Carnivora	Acupuncture
Glyoxylide	Ayurveda
Iscador	Environmental Medicine
Koch Synthetic Antitoxins	Homeopathic Medicine
Krebiozen	Natural Products
Laetrile	Native American, Latin American, Or
Malonide	Traditional Oriental Medicine
Parabenzquinone	Bioelectromagnetic Applications
ALTERNATIVE AND COMPLEMENTARY THERAPIES	Blue Light Treatment
MANUAL HEALING	Electroacupuncture
Acupressure	Magnetoiresonance Spectroscopy
Biofield Therapeutics	Diet, Nutrition, Lifestyle
Massage Therapy	Changes In Lifestyle
Reflexology	Diet
Zone Therapy	Gerson Therapy
MIND/BODY CONTROL	Macrobiotics
Biofeedback	Megavitamins
Humor Therapy	Nutritional Supplements
Meditation	Herbal Medicine
Relaxation Techniques	Ginger
Yoga	Ginkgo Biloba Extract
PHARMACOLOGICAL AND BIOLOGICAL TREATMENTS	Ginseng Root
Anti-Oxidizing Agents	
Cell Treatment	

Code	Description
0	No other cancer directed therapy except as coded elsewhere. Patient received no other cancer-directed therapy.
1	Other cancer-directed therapy – Other, Cancer-directed therapy that cannot be appropriately assigned to other specific treatment modalities. <i>Examples:</i> hyperbaric oxygen (as adjunct to

	cancer-directed treatment), or hyperthermia, PUVA, arterial block for renal cell carcinoma, and radio-frequency thermal ablation (hyperthermia). Embolization using alcohol as an embolization agent. Embolization for a site other than the liver where the embolizing agent is unknown.
2	Other experimental cancer-directed therapy (not included elsewhere) This includes any experimental or newly developed method or treatment that differs greatly from proven types of cancer therapy. It may be used for institution-based clinical trials.
3	Other-Double-blind clinical trial, code not yet broken Patient is involved in a double blind clinical trial. Code the treatment actually administered when the double blind clinical trial code is broken. Do not code ancillary drugs in this field.
6	Unproven therapy (including laetrile, krebiozen, etc.) Unconventional treatments given by non-medical personnel.
7	Refusal, the patient or patient's guardian refused treatment that would have been coded as 1, 2, or 3.
8	Recommended; Other cancer-directed therapy recommended, unknown if administered. Physician recommended other cancer-directed therapy but there is no indication in the record that the patient received the treatment.
9	Unknown if other cancer-directed therapy was administered – DEATH CERTIFICATE ONLY

RX DATE – OTHER**NAACCR ITEM #1250**

Records the date on which other treatment began at any facility.

Coding Instructions:

Enter the date any “other” therapy was initiated that is part of the first course of treatment.

RX SUMM – TREATMENT STATUS**NAACCR ITEM #1285**

This data item summarizes whether the patient received any treatment or the tumor was under Active Surveillance or Watchful Waiting.

Instructions for Coding:

1. This item may be left blank for cases diagnosed prior to 2010.
2. Treatment given after a period of active surveillance is considered subsequent treatment and it not coded in this item.
3. Assign code 0 (No Treatment) when treatment is refused or the physician decides not to treat for any reason such as the presence of comorbidities.
4. Assign code 0 when the patient does not receive any treatment
 - o Scope of Regional Lymph Node Surgery may be coded 0, 1-7, or 9
5. Assign code 1 when the patient receives treatment collected in any of the following data items:
 - a. Surgery of Primary Site
 - b. Surgical Procedure of Other Site
 - c. Radiation Treatment Modality, Phase I, II, III
 - d. Chemotherapy
 - e. Hormone Therapy
 - f. Immunotherapy

Code	Description
0	No treatment given
1	Treatment given – this does not include the decision not to treat the patient
2	Active surveillance (watchful waiting)
9	Unknown if treatment was given – ONLY USE FOR DEATH CERTIFICATE CASES

TEXT- REQUIRED

The Text Required section includes the set of data items where documentation must be entered to verify complete and accurate coding. Please read the Introduction to Text Documentation which precedes this section to become familiar with FCDS text requirements. Text requirements are monitored by FCDS QC Review and through FCDS EDITS. See Additional References for Text Documentation on next page. NOTE: ALL Staging Items including all Site-Specific Data Items must have Text Documentation.

Please see Appendix L for specific text documentation requirements and information on the NCRA Informational Abstracts free for download that provide cancer-site specific guidelines for text in abstracts <http://www.cancerregistryeducation.org/rr>

The use of standard abbreviations in documentation and diagnostic text is acceptable. However, FCDS must be able to understand the use of standard abbreviations to clarify and validate coded data.

Refer to Appendix C for the latest list of standard abbreviations.

CAUTION: Use of Non-Standard Abbreviations

- **Non-Standard Abbreviations may have multiple interpretations and should not be used.**
- **Do not customize abbreviations or overuse abbreviations to the point where the information has no meaning or context.**

Vendor insertion of auto text from coded data is NOT sufficient to meet the CDC/NPCR or FCDS requirements for text documentation. Registrars/Abstractors must know which text areas in their abstracting software will be submitted to FCDS. FCDS does not always know how or where vendors map your screen entry text to the FCDS required text fields.

Data Items Included In This Section:

NAACCR Item Number Item Name

2520	Text – DX Procedures – Physical Exam
2530	Text – DX Procedures – X-Ray/Scans
2540	Text – DX Procedures – Scopes
2550	Text – DX Procedures – Lab Tests
2560	Text – DX Procedures – Operative Report
2570	Text – DX Procedures – Pathology Report
2580	Text – Primary Site Title
2590	Text – Histology Title
2600	Text – Staging
2610	RX Text – Surgery
2620	RX Text – Radiation (Beam)
2630	RX Text – Radiation Other
2640	RX Text – Chemo
2650	RX Text – Hormone
2660	RX Text – BRM
2670	RX Text – Other
2680	Text – Remarks
2690	Text – Place of Diagnosis

TEXT – DX PROC – PE**NAACCR ITEM #2520**

Enter information from history and physical examinations. Information can include duration and type of symptoms, family history, location of tumor, etc. Include dates and chronology of care. THIS SECTION MUST INCLUDE THE REASON WHY THE PATIENT CAME TO YOUR FACILITY REGARDLESS OF CLASS OF CASE OR TREATMENT GIVEN. See Appendix L

TEXT – DX PROC – X-RAY/SCANS**NAACCR ITEM #2530**

Enter information from diagnostic imaging reports, including X-rays, MRI and PET scans, ultrasound and other imaging studies. Both positive and negative exams are important. YOU MUST INCLUDE DATES IN CHRONOLOGICAL ORDER FOR EACH IMAGING STUDY. See Appendix L

TEXT – DX PROC – SCOPES**NAACCR ITEM #2540**

Enter the text information from endoscopic examinations. Information can include visualization of tumor, location of tumor, etc. Include dates and chronology of care. See Appendix L

TEXT – DX PROC – LAB TESTS**NAACCR ITEM #2550**

Enter information from laboratory examinations other than cytology or histopathology for the tumor being reported. This information can include tumor markers, serum and urine electrophoresis, special studies, etc. Include dates and chronology of care.

Tumor markers can be obtained from serum, Immunostained tissue, and other specimens. They may be cancer-specific or more general, involving markers for numerous cancer types. Include dates and chronology of care to ensure tumor markers are consistent with the timeline of care.

Some tumor marker examples include:

Breast Cancer:	Progesterone Receptors Assays (PRA), Estrogen Receptor Assays (ERA), Her2/neu*
Prostate Cancer:	Prostatic Specific Antigen (PSA)
Testicular Cancer:	Human Chorionic Gonadotropin (hCG), Alpha Feto Protein (AFP)
Liver Cancer:	Alpha Feto Protein (AFP)
Ovarian Cancer:	CA-125
Other Markers Include:	Carcinoembryonic antigen – CEA (Colorectal), CA-19-9, BRCA1 and others

Genetic Tests have become commonplace in cancer tissue evaluation. Please include genetic testing results in this text area to further classify the tumor, to be used as a genetic tumor marker to monitor response to treatment, and for additional clarification of tumor analysis conducted at the molecular level.

FoundationOne CDx - FoundationOne CDx is the first FDA-approved tissue-based broad companion diagnostic (CDx) that has been clinically and analytically validated for all solid tumors. Test results include microsatellite instability (MSI) and tumor mutational burden (TMB) to help inform immunotherapy decisions, and loss of heterozygosity (LOH) for ovarian cancer patients.

You can also order PD-L1 immunohistochemistry (IHC) testing as an optional add-on test. The

FoundationOne CDx test detects substitution, insertion and deletion genetic alterations, and genetic copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens.

- FoundationOne CDx (324 DNA genes interrogated from a tissue sample)
- FoundationOne Liquid CDx (324 DNA genes* interrogated from a simple blood draw)
- FoundationOne Heme (406 DNA and 265 RNA genes interrogated from a variety of sample options)

Current Gene List²

Genes with full coding exonic regions included in FoundationOne®CDx for the detection of substitutions, insertion-deletions (indels), and copy-number alterations (CNAs).

ABL1	ACVR1B	AKT1	AKT2	AKT3	ALK	ALOX12B	AMER1 (FAM123B)	APC
AR	ARAF	ARFRP1	ARID1A	ASXL1	ATM	ATR	ATRX	AURKA
AURKB	AXIN1	AXL	BAP1	BARD1	BCL2	BCL2L1	BCL2L2	BCL6
BCOR	BCORL1	BRAF	BRCA1	BRCA2	BRD4	BRIP1	BTG1	BTG2
BTK	CTNFB30 (EMSY)	CALR	CARD11	CASPB	CBFB	CBL	CCND1	CCND2
CCND3	CCNE1	CD22	CD274 (PD-L1)	CD70	CD79A	CD79B	CDC73	CDH1
CDK12	CDK4	CDK6	CDK8	CDKN1A	CDKN1B	CDKN2A	CDKN2B	CDKN2C
CEBPA	CHEK1	CHEK2	CIC	CREBBP	CRKL	CSF1R	CSF3R	CTCF
CTNNA1	CTNNA1	CUL3	CUL4A	CXCR4	CYP17A1	DAXX	DDR1	DDR2
DIS3	DNMT3A	DOT1L	EED	EGFR	EP300	EPHA3	EPHB1	EPHB4
ERBB2	ERBB3	ERBB4	ERCC4	ERG	ERF1	ESR1	EZH2	FAM46C
FANCA	FANCC	FANCG	FANCL	FAS	FBXW7	FGF10	FGF12	FGF14
FGF19	FGF23	FGF3	FGF4	FGF6	FGFR1	FGFR2	FGFR3	FGFR4
FH	FLCN	FLT1	FLT3	FOXO2	FUBP1	GABRA6	GATA3	GATA4
GATA6	GID4 (CT7orf39)	GNAI1	GNAI3	GNAQ	GNA5	GRM3	GSK3B	H3F3A
HDAC1	HGF	HNF1A	HRAS	HSD3B1	ID3	IDH1	IDH2	IGF1R
IKBKE	IKZF1	INPP4B	IRF2	IRF4	IRS2	JAK1	JAK2	JAK3
JUN	KDM5A	KDM5C	KDM6A	KDR	KEAP1	KEL	KIT	KLHL6
KMT2A (MLL)	KMT2D (MLL2)	KRAS	LTK	LYN	MAF	MAP2K1 (MEK1)	MAP2K2 (MEK2)	MAP2K4
MAP3K1	MAP3K13	MAPK1	MCL1	MDM2	MDM4	MED12	MEF2B	MEN1
MERTK	MET	MITF	MKNK1	MLH1	MPL	MRE11A	MSH2	MSH3
MSH6	MST1R	MTAP	MTOR	MUTYH	MYC	MYCL (MYCL1)	MYCN	MYD88
NBN	NF1	NF2	NFE2L2	NFKB1A	NKX2-1	NOTCH1	NOTCH2	NOTCH3
NPM1	NRAS	NTSC2	NTRK1	NTRK2	NTRK3	P2RY8	PALB2	PARK2
PARP1	PARP2	PARP3	PAX5	PBRM1	PDCD1 (PD-1)	PDCD1LG2 (PD-L2)	PDGFRA	PDGFRA
PDGFRB	PIK1	PIK3C2B	PIK3C2G	PIK3CA	PIK3CB	PIK3RI	PIM1	PMS2
POLD1	POLE	PPARG	PPP2R1A	PPP2R2A	PRDM1	PRKARIA	PRKCI	PTCH1
PTEN	PTPN11	PTPRO	QKI	RAC1	RAD21	RAD51	RAD51B	RAD51C
RAD51D	RAD52	RAD54L	RAF1	RARA	RB1	RBM10	REL	RET
RICTOR	RNF43	ROS1	RPTOR	SDHA	SDHB	SDHC	SDHD	SETD2
SF3B1	SGK1	SMAD2	SMAD4	SMARCA4	SMARCB1	SMO	SNCAIP	SOC1
SOX2	SOX9	SPEN	SPOP	SRC	STAG2	STAT3	STK11	SUFU
SYK	TBX3	TEK	TET2	TGFB2	TIPARP	TNFAIP3	TNFRSF14	TP53
TSC1	TSC2	TYRO3	U2AF1	VEGFA	VHL	WHSC1 (HMMSET)	WHSC1L1	WT1
XPO1	XRCC2	ZNF217	ZNF703					

Select Rearrangements^{2,3}

Genes with select intronic regions for the detection of gene rearrangements, one gene with a promoter region and one non-coding RNA gene.

ALK	BCL2	BCR	BRAF	BRCA1	BRCA2	CD74	EGFR	ETV4
ETV5	ETV6	EWSR1	EZR	FGFR1	FGFR2	FGFR3	KIT	KMT2A (MLL)
MSH2	MYB	MYC	NOTCH2	NTRK1	NTRK2	NUTM1	PDGFRA	RAF1
RARA	RET	ROS1	RSP02	SDC4	SLC34A2	TERC*	TERT (promoter only)**	
TMPS2								

*TERC is non-coding RNA gene.

**TERT is gene with promoter region.

Table 1: Companion diagnostic indications

INDICATIONS	BIOMARKER	FDA-APPROVED THERAPY
Non-Small Cell Lung Cancer (NSCLC)	<i>EGFR</i> exon 19 deletions and <i>EGFR</i> exon 21 L858R alterations	Gilotrif® (afatinib), Iressa® (gefitinib), Tagrisso® (osimertinib) or Tarceva® (erlotinib)
	<i>EGFR</i> exon 20 T790M alterations	Tagrisso® (osimertinib)
	<i>ALK</i> rearrangements	Alecensa® (alectinib), Xalkori® (crizotinib), or Zykadia® (ceritinib)
	<i>BRAF</i> V600E	Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib)
	<i>MET</i> single nucleotide variants (SNVs) and indels that lead to <i>MET</i> exon 14 skipping	Tabrecta™ (capmatinib)
Melanoma	<i>BRAF</i> V600E	Tafinlar® (dabrafenib) or Zelboraf® (vemurafenib)
	<i>BRAF</i> V600E or V600K	Mekinist® (trametinib) or Cotellic® (cobimetinib), in combination with Zelboraf® (vemurafenib)
Breast Cancer	<i>ERBB2</i> (HER2) amplification	Herceptin® (trastuzumab), Kadcyla® (ado-trastuzumab-emtansine), or Perjeta® (pertuzumab)
	<i>PIK3CA</i> alterations	Piqray® (alpelisib)
Colorectal Cancer	<i>KRAS</i> wild-type (absence of mutations in codons 12 and 13)	Erbix® (cetuximab)
	<i>KRAS</i> wild-type (absence of mutations in exons 2, 3 and 4) and <i>NRAS</i> wild-type (absence of mutations in exons 2, 3 and 4)	Vectibix® (panitumumab)
Ovarian Cancer	<i>BRCA1/2</i> alterations	Lynparza® (olaparib) or Rubraca® (rucaparib)
Cholangiocarcinoma	<i>FGFR2</i> fusions and select rearrangements	Pemazyre™ (pemigatinib)
Prostate Cancer	Homologous Recombination Repair (<i>HRR</i>) gene (<i>BRCA1</i> , <i>BRCA2</i> , <i>ATM</i> , <i>BARD1</i> , <i>BRIPI</i> , <i>CDK12</i> , <i>CHEK1</i> , <i>CHEK2</i> , <i>FANCL</i> , <i>PALB2</i> , <i>RAD51B</i> , <i>RAD51C</i> , <i>RAD51D</i> and <i>RAD54L</i>) alterations	Lynparza® (olaparib)
Solid tumors	TMB ≥ 10 mutations per megabase	Keytruda® (pembrolizumab)

The test is also used for detection of genomic loss of heterozygosity (LOH) from formalin-fixed, paraffin-embedded (FFPE) ovarian tumor tissue. Positive homologous recombination deficiency (HRD) status (defined as tBRCA-positive and/or LOH high) in ovarian cancer patients is associated with improved progression-free survival (PFS) from Rubraca (rucaparib) maintenance therapy in accordance with the Rubraca product label.

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Guardant360 CDx - Guardant360® CDx is a qualitative next generation sequencing-based in vitro diagnostic test that uses targeted high throughput hybridization-based capture technology for detection of single nucleotide variants (SNVs), insertions and deletions (indels) in 55 genes, copy number amplifications (CNAs) in two (2) genes, and fusions in four (4) genes. Guardant360 CDx utilizes circulating cell-free DNA (cfDNA) from plasma of peripheral whole blood collected in Streck Cell-Free DNA Blood Collection Tubes (BCTs).

Table 3. Genes Containing Alterations Reported by Guardant360 CDx

Alteration Type	Genes
Single Nucleotide Variants (SNVs)	<i>AKT1, ALK, APC, AR, ARAF, ATM*, BRAF, BRCA1**, BRCA2**, CCND1, CDH1, CDK4, CDK6, CDK12*, CDKN2A, CTNNB1, EGFR, ERBB2, ESR1, FGFR1, FGFR2, FGFR3, GATA3, GNA11, GNAQ, HRAS, IDH1, IDH2, KIT, KRAS, MAP2K1, MAP2K2, MET, MLH1, MTOR, MYC, NF1, NFE2L2, NRAS, NTRK1, NTRK3, PDGFRA, PIK3CA, PTEN, RAF1, RET, RHEB, ROS1, SMAD4, SMO, STK11, TERT, TSC1, VHL</i>
Indels	<i>AKT1, ALK, APC, ATM*, BRAF, BRCA1**, BRCA2**, CDH1, CDK12*, CDKN2A, EGFR, ERBB2, ESR1, FGFR2, GATA3, HNF1A, HRAS, KIT, KRAS, MET, MLH1, NF1, PDGFRA, PIK3CA, PTEN, RET, ROS1, STK11, TSC1, VHL</i>
Copy Number Amplifications (CNAs)	<i>ERBB2, MET</i>
Fusions	<i>ALK, NTRK1, RET, ROS1</i>

*Reporting is enabled for pathogenic germline alterations only. Somatic alterations will not be reported.

** Reporting is enabled for both germline and somatic alterations.

TEXT – DX PROC – OP**NAACCR ITEM #2560**

Enter information from operative reports. Do not just restate the procedure performed. Procedure performed is included under the Surgery Text Field in the Treatment Text Section. Information from operative reports can include observations at surgery, tumor size, extent of involvement of primary or metastatic sites not surgically excised or biopsied and other information that may not be documented elsewhere. Include dates and chronology of care. See Appendix L.

TEXT – DX PROC – PATH**NAACCR ITEM #2570**

Enter information from cytology and histopathology reports, including biopsies, bone marrow reports, resections, and genetic testing included in the anatomic pathology report. Information from these reports can include tissue type, tumor size, extent of tumor spread, involvement of resection margins, tumor type, grade, behavior, lymph node status, and metastatic involvement. Include dates and chronology of care. Indicate if the reports are missing from the medical record. See Appendix L.

TEXT – STAGING**NAACCR ITEM #2600**

Enter the information to justify the rationale for assigning SS2018. Do not just enter TNM information. Enter a summary of all staging information. Information can include a summary of all staging tests with overall stage as stated by physician(s), special considerations for staging, etc. You may include AJCC TNM clinical and/or pathological in this section. Please always use the Summary Stage Manual to assign Summary Stage 2018. Include dates and chronology of care. See Appendix L.

RX TEXT – SURGERY**NAACCR ITEM #2610**

Enter information describing the surgical procedure(s) performed as part of first course of therapy. Include dates and chronology of care. These are not the findings from the surgical procedure. Include the actual name and date of the surgical procedure(s) performed in chronological order. See Appendix L.

RX TEXT--RADIATION (BEAM)**NAACCR ITEM #2620**

Enter the types of beam radiation administered to the patient as part of first course of therapy. Include dates and chronology of care. See Appendix L.

Suggestion for text:

- Date when radiation treatment began
- Where treatment was given, e.g., at this facility, at another facility
- Other treatment information, e.g., patient discontinued after 5 treatments; unknown if radiation was given

RX TEXT--RADIATION OTHER**NAACCR ITEM #2630**

Enter the types of non-beam radiation administered to the patient as part of first course of therapy. Include dates and chronology of care. See Appendix L.

Suggestion for text:

- Date treatment was started
- Where treatment was given, e.g., at this facility, at another facility
- Other treatment information, e.g., unknown if radiation was given

RX TEXT—CHEMO**NAACCR ITEM #2640**

Enter the documentation regarding chemotherapy treatment of the tumor being reported. Include dates and chronology of care. See Appendix L.

Suggestion for text:

- Date when chemotherapy began
- Where treatment was given, e.g., at this facility, at another facility
- Type of chemotherapy, e.g., name of agent(s) or protocol
- Other treatment information, e.g., treatment cycle incomplete, unknown if chemotherapy was given

RX TEXT—HORMONE**NAACCR ITEM #2650**

Enter the documentation regarding the hormone treatment of the tumor being reported. Include dates and chronology of care. See Appendix L.

Suggestion for text:

- Date treatment was started
- Where treatment was given, e.g., at this facility, at another facility
- Type of hormone or antihormone, e.g., Tamoxifen
- Type of endocrine surgery or radiation, e.g., orchiectomy
- Other treatment information, e.g., treatment cycle incomplete; unknown if hormones were given

RX TEXT—BRM**NAACCR ITEM #2660**

Enter the documentation regarding the biological response modifiers or immunotherapy treatments of the tumor being reported. Include dates and chronology of care. See Appendix L.

Suggestion for text:

- When treatment was given, e.g., at this facility; at another facility
- Type of BRM agent, e.g., Interferon, BCG
- BRM procedures, e.g., bone marrow transplant, stem cell transplant
- Other treatment information, e.g., treatment cycle incomplete; unknown if BRM was given

RX TEXT--OTHER**NAACCR ITEM #2670**

Enter the document documentation regarding the treatment of the tumor being reported with treatment that cannot be defined as surgery, radiation, or systemic therapy. This includes experimental treatments (when the mechanism of action for a drug is unknown), and blinded clinical trials. If the mechanism of action for the experimental drug is known, code to the appropriate treatment field. Include dates and chronology of care. See Appendix L.

Suggestion for text:

- Date treatment was started
- Where treatment was given, e.g., at this facility, at another facility
- Type of other treatment, e.g., blinded clinical trial, hyperthermia
- Other treatment information, e.g., treatment cycle incomplete; unknown if other treatment was given

TEXT – REMARKS**NAACCR ITEM #2680**

Enter text information not elsewhere provided and for overflow from other text areas. Include dates and chronology of care. See Appendix L

FOLLOW UP

The Follow Up section includes the set of data items used by the FCDS to monitor a facility's last contact with the patient at the time that the abstract was completed. FCDS does not require the collection of most of the data items pertaining to follow up. The FCDS required follow up data items are limited in scope; they mainly assist in performing limited survival analyses.

Data Items Included In This Section:

<u>NAACCR Item Number</u>	<u>Item Name</u>
1750	Date of Last Contact
1760	Vital Status
1770	Cancer Status

DATE OF LAST CONTACT**NAACCR ITEM #1750**

Records the date of last contact with the patient or the date of death.

Coding Instructions:

1. Record the last date on which the patient was known to be alive or the date of death.
2. This data item is associated with the patient, not the cancer, so all records (primary sites) for the same patient will have the same date of last contact; If a patient has multiple primaries, all records should have the same date of last contact.

VITAL STATUS**NAACCR ITEM # 1760**

Enter the patient's Vital Status as of the date entered in date of last contact.

Code	Description
0	Dead
1	Alive

CANCER STATUS**NAACCR ITEM #1770**

Cancer Status records the presence or absence of clinical evidence of the patient's malignant or non-malignant tumor that corresponds to the date of last contact. Cancer status is the absence or presence of cancer. It is coded independently for each primary. If a patient has multiple primaries, each record could have a different cancer status. If a patient has had surgical removal of the primary cancer and all other involved tissue and is felt to be free of cancer, cancer status should be coded 1 – No evidence of this cancer.

Code	Description
1	No evidence of this tumor
2	Evidence of this tumor
9	Unknown, indeterminate whether this tumor is present, not stated in patient record

Coding Instructions:

1. Assign code 1 when there is no indication or evidence of this tumor, for example, the patient is in remission for a hematopoietic disease.
2. Assign code 2 when there is an indication of this tumor, for example, patient died or is continuing treatment for this tumor.