## SECTION II: GENERAL ABSTRACTING INSTRUCTIONS

## SECTION II: GENERAL ABSTRACTING INSTRUCTIONS

It is the responsibility of every abstractor working in the state of Florida (including contract abstractors) to know the full content of the latest *FCDS Data Acquisition Manual (FCDS DAM)* and to update it upon receipt of any change from FCDS. Should you need training in cancer registry data collection, please visit the FLccSC Learning Management System and consider taking the FCDS Abstracting Basics Course to gain a better understanding of the skills and training required to meet FCDS abstracting requirements and the national standards used when abstracting and coding cancer cases. Note: This course is being updated.

This manual is intended to explain in detail each data item required for Florida Cancer Data System (FCDS) case reporting. It should be used as the primary information resource for any data item that must be coded and documented in accordance with Florida cancer reporting rules and statutes. Descriptions are only intended to provide sufficient detail to achieve consensus in submitting the required data. In no way does this manual imply any restriction on the type or degree of detail information collected, classified or studied within any healthcare facility-based cancer registry. Special Use Fields are available as needed.

**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 essentially be comparable in content, rules, instructions, and examples provided to ensure consistent coding across programs.

2) Always submit a separate abstract for each reportable primary neoplasm identified.

3) Text is required to adequately justify ALL coded values 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 Details of Treatment 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 within text in each section 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 a format widely accepted outside of the registry setting. The format is 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 own systems. Only valid portions of any date are to be transmitted.

3) 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 these new requirements beginning 8/1/2019. All Treatment (surgery, radiation, chemo, etc.) also requires a valid date consistent with the Date of Diagnosis so the edits can validate the treatment is indeed 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

| NAACCR Item Number | Item Name |
|---|---|
| 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 (NACCR 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 is not the same as 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 (NACCR 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 in which 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 "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.

When a patient is deleted from the database, **do not re-use the accession number** for another patient.

Multiple primary reportable malignant neoplasms in one patient are designated by successive sequence numbers. Therefore, when submitting abstracts for multiple primary neoplasms for one patient at the same time, 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 entire lifetime of the person, regardless of where they were diagnosed or treated.

The Reporting Facility (NACCR 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 diagnosis and/or treatment of the tumor. 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 diagnosis and/or treatment of the tumor, whether as an inpatient or an outpatient for 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 that was 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 as well as for the Date of Diagnosis.

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

Date of 1st Contact is one of several data items that can be used to measure 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 Date of First Contact to allow registries to revise the date to the date when the patient's case became 'analytic' for the facility. FCDS does not receive or allow Modify or Update Records – so, 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 judgement to try and 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 (it can be 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) or you may enter any facility identification number or. billing number that will be helpful in locating 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). Unknown date is not acceptable in this field.

**To CoC accredited facilities: Please do not submit incomplete Rapid Cancer Reporting System (RCRS) abstracts to FCDS.** Please wait until ALL first course therapy has been completed. FCDS continues to monitor patient/cancer to ensure first course therapy is consistent with stage of disease and specific biomolecular and genetic tumor markers for targeted therapies. Do not send cases too early. For cases not yet completed by the June 30th deadline, you may code the treatment as recommended, unknow 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 ABSTRACTOR CODE) NAACCR ITEM #570

Enter the three-digit FCDS Abstractor Code of the person abstracting this case. Each abstractor that submits cases to FCDS must have her/his own unique FCDS Abstractor Code.All abstracts submitted must have an approved and valid (current) FCDS Abstractor Code in this field. Validation of the FCDS Abstractor 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.

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 being prepared for an analytic cancer case at a facility accredited by the Commission on Cancer (CoC). The flag may be assigned manually or can be defaulted by the registry's software.

CoC-accredited facilities are required to collect certain data items including TNM staging. The flag is a means of incorporating the accredited status into abstracts at the time of abstraction by someone who has knowledge of the status. The flag thus simplifies validating that required items have been abstracted by CoC-accredited facilities.

**Codes**

| | |
|---|---|
| 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 | • Hospital inpatient ; Includes outpatient services of HMOs and large multi-specialty physician group practices with unit record.<br>• Offices/facilities with unit record<br>• HMO physician office or group | 1 |

| Code | Label | Source Documents | Priority |
|---|---|---|---|
| | | • HMO affiliated free-standing laboratory, surgery, radiation or oncology clinic | |
| **2** | Radiation Treatment Centers or Medical Oncology Centers (hospital-affiliated or independent) | • Facilities with serial record (not a unit record)<br>• Radiation treatment centers<br>• Medical oncology centers (hospital affiliated or independent)<br>There were no source documents from code 1. | 2 |
| **3** | Laboratory Only (hospital-affiliated or independent | • Laboratory with serial record (not a unit record)<br>There were no source documents from codes 1, 2, 8, or 4. | 5 |
| **4** | Physician's Office/Private Medical Practitioner | • Physician's office that is NOT an HMO or large multi-specialty physician group practice.<br>There were no source documents from codes 1, 2 or 8 | 4 |
| **5** | Nursing/Convalescent Home/Hospice | • Nursing or convalescent home or a hospice.<br>There were no source documents from codes 1, 2, 8, 4, or 3. | 6 |
| **6** | Autopsy Only | • Autopsy<br>The cancer was first diagnosed on autopsy.<br>There are no source documents from codes 1, 2, 8, 4,<br>3 or 5. | 7 |
| **7** | Death Certificate Only | 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 | |
| **8** | Other hospital outpatient units/surgery centers | • Other hospital outpatient units/surgery centers. Includes, but not limited to, outpatient surgery and nuclear medicine services.<br>There are no source documents from codes 1 or 2. | 3 |

## PATIENT DEMOGRAPHICS

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

**Data Items Included in this Section (CONFIDENTIAL):**

| NAACCR Item Number | Item Name |
|---|---|
| 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 from a previously submitted neoplasm, contact your Field Coordinator to correct any Demographic EDITS including Name EDITS prior to submission.

**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 Name-Maiden field.

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

This is a new data item 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 not known 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 person with Medicare has been assigned an MBI. The MBI is confidential like the SSN 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 not available, the patient is a non-Medicare patient, or the number is unknown.

**SOCIAL SECURITY NUMBER (SSN)** **NAACCR ITEM #2320**

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

**Please Reference APPENDIX Q - FLORIDA DEPARTMENT OF HEALTH LETTER Regarding Patient Social Security Number – A Florida Mandated Data Item** printed on Florida DOH Letterhead.

Enter the patient's complete nine-digit Social Security Number.

The Social Security Number is entered without dashes and without a letter suffix.

If the patient's Social Security Number is unknown, not applicable or incomplete, enter 999999999.

Do not use computer-generated hospital-specific billing numbers in this field.

Do not enter a partial Social Security Number with a valid last 4-digits. This is not a valid number.

Sequential numbers such as 123456789 and other contrived numbers will not be accepted as valid.

If you are unable to 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. For *in utero* diagnosis and treatment, record the actual date of birth.
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 both 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.

If the patient has multiple primaries, the state of birth is the same for each tumor.

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 in which 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** |

Refer to the **Race Coding Instructions** Supplement and to Appendix D **(Race and Nationality Descriptions from the 2000 Census and Bureau of Vital Statistics)** for guidance.

| 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) |
| **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 be different for each primary. If a patient is younger than 15 years of age, 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 record or physician office record.

**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://manuelsweb.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 record or physician office record.
**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 a weight of less than 100 pounds should be recorded with a leading 0.

## TOBACCO USE SMOKING STATUS NAACCR ITEM #344

Record the patient's past or current use of tobacco (cigarette, cigar and/or pipe). Tobaccos smoking history can be obtained from sections such as the Nursing Interview Guide, Flow Chart, Vital Stats or Nursing Assessment section, or other available source from the patient's hospital medical record or physician office record.

Cigarette smoking is the leading preventable cause of death in the US and a major risk factor for cancer.

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

In addition, 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.

This single data item replaces the 4 smoking data items previously collected from 2013-2021. FCDS has collected some form of smoking status since 1981. However, the definitions during 3 specific time periods (1981-2012, 2013-2021, and 2022>) do not allow any direct conversion from 1 field to 4 fields and then back to 1 field. Generalized conversions can be made on the self-reported smoking status data items. However, over the years FCDS has recognized that self-reported smoking status is not a reliable indicator for risk of development of smoking-related cancers primarily due to self-reported nature of the data from a medical record source. Furthermore, the new smoking status item does not capture e-cigs.

In addition to describing tobacco use patterns and trends in patients diagnosed with cancer, the collection of cigarette smoking history can enable researchers to better understand the association of cigarette smoking to cancer outcomes. Cigarette use data at diagnosis may help health professionals better understand how tobacco use impacts cancer prognosis, including how smoking is related to effectiveness of treatment and survival. In addition, this information is important to target and assess tobacco control efforts to cancer survivors and their families.

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

## ADDR 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.

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 it is not acceptable in the standard address fields.

This field may also be used to record if the patient is homeless, a transient patient, or a foreign resident.

**ADDR 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 be different 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.

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

For non-analytic cases, the address at diagnosis may not be the patient's current address. Review of 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 place the patient was staying 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 residents of the facility.

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.

**ADDR at DX – CITY** **NAACCR ITEM #70**

Enter the name of the city or town in which 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 be different 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 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 residents of the facility.

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.

## ADDR 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 in which the patient resides at the time the reportable tumor is diagnosed.

If the patient has multiple primaries, the state of residence may be different for each tumor.

**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 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 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 |

**ADDR at DX – COUNTRY** **NAACCR ITEM #102**

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

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

**Refer to Appendix B for specific ISO Country Codes.**

**ADDR at DX – POSTAL CODE** **NAACCR ITEM #100**

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 also available on the Internet, including http://www.usps.com/ncsc/lookups/lookup_zip+4.html.

**COUNTY at DX** **NAACCR ITEM #90**

Code for the county of the patient's residence at the time 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, the county codes may be different for each tumor.

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 |

**ADDR 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 be different 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 residents of the facility.

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.

**ADDR 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 residents of the facility.

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.

## ADDR CURRENT – STATE NAACCR ITEM #1820

USPS abbreviation for the state, territory, commonwealth, U.S. possession, or Canada Post abbreviation for the Canadian province/territory of the patient's current usual 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 |

## ADDR CURRENT – COUNTRY NAACCR ITEM #1832

Enter the three-character International Organization for Standardization (ISO) Country Code abbreviation (Appendix B) for the country in which the patient was living 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.**

## ADDR 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 not available, 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 also available on the Internet, including http://www.usps.com/ncsc/lookups/lookup_zip+4.html.

## COUNTY – CURRENT NAACCR ITEM #1840

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. If any residence is out of Florida, the county 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)

999 COUNTY UNKNOWN

Use code 998 for Canadian residents.

**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 that corresponds to the patient's primary method of payment 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 the type 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] |
| **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 persons who are uninsured 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 persons who are uninsured, 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.<br>Federal government insurance for persons who are retired or disabled. |

| Code | Label | Description |
|---|---|---|
| **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 who has responsibility for the patient at the reporting facility. Generally, each facility assigns their own coding scheme to physicians on staff. If the physician is no longer on staff, enter the FCDS facility number or enter the physician's last name. Use leading zeros when necessary to right justify.

## NPI – MANAGING PHYSICIAN NAACCR ITEM #2465

Identifies the physician who is responsible for the overall management of the patient 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
• Record the 10-digit NPI for the physician responsible for managing the patient's care.
• 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.
• NPI should be recorded as available.
• NPI may be left blank.

Blanks are allowed in this field when data are not available. 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. However, FCDS recognizes these items may not be available or may not be applicable to all cases.

| 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
• Record the 10-digit NPI for the physician currently responsible for the patient's medical care.
• 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.
• NPI should be recorded as available.
• 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**
• Record the 10-digit NPI for the physician who performed the most definitive surgical procedure.
• 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.
• NPI should be recorded as available for all cases diagnosed January 1, 2008, and later.
• 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**
• Record the 10-digit NPI for the physician.
• 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.
• NPI should be recorded as available.
• 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**
- Record the 10-digit NPI for the physician.
- 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.
- NPI should be recorded as available.
- 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

Enter sufficient text to document the patient's usual occupation, also known as the type of job or kind of work performed during most of the patient's working life before diagnosis of cancer. Occupation is the type of job the patient was engaged in for the longest time prior to a cancer diagnosis. It is not necessarily the highest paid job nor is it the job considered the most prestigious, but 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.

Do enter "Unknown" when no information is available.

If the patient has never worked, record "never worked" as the Usual Occupation.

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 name of the employer 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 the set of 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

| NAACCR Item Number | Item Name |
|---|---|
| 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 |

Reference: 2023 SEER Coding and Staging Manual – Appendix C: Site Specific Coding Modules
https://seer.cancer.gov/tools/codingmanuals/index.html

## 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.

**UNKNOWN DATE OF INITIAL DIAGNOSIS IS NO LONGER ACCEPTED BY FCDS.**

**DO NOT USE THE DATE OF ADMISSION AS A PROXY FOR DATE OF DIAGNOSIS.**

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

Positive Tumor Markers alone are NEVER diagnostic of cancer. Diagnostic Confirmation = 5 is not allowed.

Use the date of clinical diagnosis, positive imaging, or positive histologic/cytological confirmation as the date of diagnosis – never the date of a positive tumor marker. No tumor marker alone is specific enough to diagnose cancer.

**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).

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 new requirement.

Note: 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 Instructions 22 & 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.

**DO NOT USE THE DATE OF ADMISSION AS A PROXY FOR DATE OF DIAGNOSIS.**

Often, the History and Physical or a Consultation Report will provide clues to aid in estimating a date of diagnosis. Key words and phrases such as recently, a few months ago, or in the distant past can provide hints to when a patient was diagnosed without providing an exact year or date. However, registrars can use these key words and phrases to guide them when determining an estimated date of diagnosis. Some medical record histories provide no clues 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 this primary reportable neoplasm is recognized by a medical practitioner. 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.**

**The initial diagnosis date may be from a clinical diagnosis or other 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 at a later date 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 or when an acceptable imaging study, laboratory or genetic test is allowed to be used as a confirmation of a cancer diagnosis.
2. When diagnostic imaging or other test confirms a diagnosis (including when the diagnosis uses one of the "Ambiguous Terms" defined in Section I), the date of diagnosis is the date of the first diagnosis from positive imaging, allowable confirmatory diagnostic testing, or biopsy/resection.
3. **2019 Clarification for Use of Breast Imaging Dates:** Breast Imaging includes 2D/3D Mammography, MRI or other imaging technique with a diagnosis of BIRADS Category 4 (suspicious for cancer) or BIRADS Category 5 (positive for cancer). This is an "exception" to Instruction 4.
   a. A positive/suspicious mammogram alone should never be used to code the date of diagnosis.
   b. A positive/suspicious mammogram date should be used as the date of diagnosis ONLY when the patient goes on to subsequently have a positive biopsy and/or resection that confirms the suspicious abnormality is in fact a malignancy.
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 supercedes 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. DO NOT CODE the Date of First Admission as Dx Date
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. This would include sputum smears, bronchial brushings, bronchial washings, prostatic secretions, breast secretions, gastric fluids, spinal fluid, peritoneal fluid, urinary sediment, and cervical and vaginal smears. This does not include FNA.

Use the date of clinical, histologic, or positive cytologic confirmation as the date of diagnosis.

11. **Positive tumor marker alone is never diagnostic of cancer.** There may be rare exceptions that may use a combination of clinical and laboratory tests to confirm a diagnosis – but not a lab test or tumor marker, alone. The combination of a positive digital rectal exam or DRE plus an elevated PSA can be used as a clinical diagnosis of prostate cancer. These are rare exceptions. In most cases, you will still use the date of imaging, histologic, or positive cytologic confirmation as the date of diagnosis.
12. 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.
13. 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.
14. Treatment dates may not be coded to unknown.
15. 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.
16. 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.
17. 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.
18. 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.
19. Use the actual date of diagnosis for an in utero diagnosis (For cases diagnosed before January 1, 2009, assign the date of birth).
20. 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.
21. **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.**
22. If a registrar wants to estimate month and day – they can decide whichever dates best suit the case.

23. **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 taking into account 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

| 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** | |
|---|---|
| ***Initial diagnosis at reporting facility*** | |
| **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 *Class of Case* 10 |
| **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 |

| ***Initial diagnosis elsewhere*** | |
|---|---|
| **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**

| ***Patient appears in person at reporting facility*** | |
|---|---|
| **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 |
| *Patient does not appear in person at reporting facility* | |
| **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 |
| *Patient appears in person at reporting facility* | |
| **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 M9590-9992)**

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. DO NOT USE Code 5 (diagnosis based on laboratory tests or marker studies).T**here is not a single laboratory test that can be used to confirm a diagnosis of any type of solid tumor or histology. Code 5 should never be used for solid tumors.**

6. 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.

7. Code 7 is used when the diagnosis is based only on an imaging report finding of primary tumor and/or metastatic tumor on imaging study.

8. Code 8 when the case was diagnosed by any clinical method that cannot be coded as 6 or 7.

9. 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 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 or a fluid suspension or 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). |
| **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<br>Note: DO NOT USE THIS CODE | 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<br>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). |

**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.

   1. **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

   2. **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)?

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:

a. Confirms the neoplasm OR
b. 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."
c. Peripheral blood smear followed by flow cytometry (most commonly done with CLL/SLL, 9823/3)
   Note: Flow cytometry studies are normally 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. To date there is not a single laboratory test that can be used to confirm any patient has evidence of cancer without diagnostic imaging and/or biopsy to support the diagnosis. The Hematopoietic Manual suggests the test for Bence Jones Protein in Urine and possibly in Serum may be a lab test that fits the definition for use of Code 5. However, proteinemia can be cause by other than cancer and must be ruled out for other causes. Plasma Cell Neoplasms usually have a bone marrow or bone biopsy plus or minus imaging as better Dx Confirmation. Therefore, Code 5 should be used sparingly if at all…only for Plasma Cell Myeloma

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 when the case was diagnosed by any clinical method that cannot be coded as 6 or 7.

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 EVEN ON HISTORICAL CASES**

11. Some 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.

**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<br>• Positive immunophenotyping AND/OR<br>• Positive genetic studies<br>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.<br>(9861/3) Genetic testing shows AML with inv(16)(p13.1q22)<br>(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. |
| **5** | Positive laboratory test/marker study<br>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<br>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. The ONLY C76.* series code you should ever use is code C76.0 for node positive head and neck cancer without evidence of a primary site. This is the one code that FCDS allows in the C76.* series.

4. Topography codes are indicated by a "C" preceding the three-digit code number. Do not record the decimal point. You can still use the ICD-O-3 purple book for Topography (Primary Site) Coding...none of the Topography Codes have changed.

5. 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.

6. Try not to assign unknown/ill-defined site topography codes; they are general terms/vague anatomy. Unknown/Ill-Defined Sites Include:069,189, 260-269, 328-329, 390-399, 409, 419, 479, 499, 559, 579, 639, 760-769, 809

7. Follow the instructions in *Hematopoietic and Lymphoid Neoplasm Case Reportability and Coding Manual* and the Hematopoietic and Lymphoid Neoplasms Database (Hematopoietic DB) – 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.

8. Use subcategory 8 for single tumors that overlap the boundaries of two or more sub-sites and the point of origin is not known.

9. Use subcategory 9 for multiple tumors that originate in different subsites of one organ.

### *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. The ONLY C76.* series code you should ever use is C76.0 for node positive head and neck cancer without evidence of a primary site. This is the one code FCDS allows in the C76.* series.

4. 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;<br>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<br>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/type is biologically impossible, i.e., the particular form of cancer does not arise in the specified site.

It is helpful to check medical references or discuss problem cases with the registry's medical advisors. The suggestions below are a starting point for analyzing an impossible site/morphology 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 identifies 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 areas of 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. 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.

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 addressed in this edit which site should be used instead of an ill-defined site in the range C76.0-C76.8.
(See 2007 Multiple Primary and Histology Coding Rules)

**IMPOSSIBLE PRIMARY SITE/HISTOLOGY COMBINATIONS**

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

**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 on 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. Where the right and left sides of paired sites (for C441--C447, C700, C710-C714, and C722-C725 ONLY) are contiguous (come into contact) and the lesion is at the point of contact of the right and left sides, use code 5, midline. Most paired sites cannot develop midline tumors. For example, skin of the trunk can have a midline tumor, but the breasts can not.
5. Non-paired sites may be coded right or left, if appropriate. Otherwise, code non-paired sites 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.<br>A bilateral laterality (4) should be assigned when there are multiple nodules in both lungs |
| **5** | Paired site: midline tumor ONLY for C441-C447, C700, C710-C714, and C722-C725 |
| **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 |
| C09.0 | Tonsillar fossa |
| C09.1 | Tonsillar pillar |
| C09.8 | Overlapping lesion of tonsil |
| C09.9 | Tonsil, NOS |
| C30.0 | Nasal cavity (excluding nasal cartilage and nasal septum) |
| C30.1 | Middle ear |
| C31.0 | Maxillary sinus |
| C31.2 | Frontal sinus |
| C34.0 | Main bronchus (excluding carina) |
| C34.1 – C34.9 | Lung |
| C38.4 | Pleura |

| ICD-O-3 | SITES |
|---|---|
| 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 |
| C41.3 | Rib and clavicle (excluding sternum) |
| C41.4 | Pelvic bones ("excluding" not in the sacrum, coccyx and symphysis pubis) |
| 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 automatic 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 Required - SEE APPENDIX R and all reference resources to code histology.**

| | |
|---|---|
| **International Classification of Diseases for Oncology, 3rd ed. Geneva, World Health Organization: 2000** | The World Health Organization<br>WHO Publications Center USA;<br>49 Sheridan Avenue;<br>Albany, NY 12210<br>ISBN 9241545348 Order Number 11503350<br>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), 2022 | https://seer.cancer.gov/seertools/hemelymph/ |
| **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<br>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)

**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. There are specific changes in this area for 2021 – 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<br>Borderline malignancy<br>Low malignant potential<br>Uncertain malignant potential (Reportable for intracranial and CNS sites only) |
| 2 | Insitu and/or carcinoma insitu | Carcinoma in situ;<br>Intraepithelial;<br>Noninfiltrating;<br>Noninvasive |
| 2 | Synonymous with Insitu<br>adopted from the SEER Program Coding and Staging Manual | AIN III (C211)<br>Behavior code '2'<br>Bowen disease (not reportable for C440-C449)<br>Clark level I for melanoma (limited to epithelium)<br>Confined to epithelium<br>Hutchinson melanotic freckle, NOS (C44_)<br>Intracystic, non-infiltrating<br>Intraductal<br>Intraepidermal, NOS<br>Intraepithelial, NOS<br>Involvement up to, but not including the basement membrane<br>Lentigo maligna (C44_)<br>Lobular, noninfiltrating (C50_)<br>Noninfiltrating<br>Noninvasive<br>No stromal invasion/involvement<br>Papillary, noninfiltrating or intraductal<br>Precancerous melanosis (C44_)<br>Queyrat erythroplasia (C60_)<br>Stage 0 (except Paget's disease (8540/3) of breast and colon or rectal tumors confined to the lamina propria)<br>VAIN III (C529)<br>VIN III (C51_) |
| 3 | Invasive | Malignant, primary site (invasive) or<br>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.

DO NOT RELY ON VENDOR PULL DOWN MENU SELECTIONS and GUESS.

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, v3.0** and the Grade Tables at https://apps.naaccr.org/ssdi/list/2.1 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 (Hematopoeitic 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 themost current version of the Grade Coding Manual and Grade Tables at https://apps.naaccr.org/ssdi/list/3.0 for detailed coding instructions and site-specific coding rules..

## GRADE POST THERAPY CLIN (YC) - NEW 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/2.1 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.

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.

4. 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.

5. 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.

6. 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.

7. Record the size of the invasive component, if given.

8. Record the largest dimension or diameter of tumor, whether it is from an excisional biopsy specimen or the complete resection of the primary tumor.

9. Record the size as stated for purely in situ lesions.

10. Disregard microscopic residual or positive surgical margins when coding tumor size.

11. Do not add the size of pieces or chips together to create a whole. NEW - The only exception to this instruction is when the pathologist aggregates the size and provides a definite aggregate size in the pathology report final diagnosis. The registrar should never add the size of the specimen, themselves.

12. 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.

13. 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<br>Alternate descriptions of tumor size for specific sites: |

| | |
|---|---|
| | Familial/multiple polyposis:<br>Colon (C18.0, C18.2-C18.9) and/or Rectosigmoid and Rectum (C19.9, C20.9)<br>**If no size is documented:**<br>Circumferential:<br>Esophagus (C15.0 C15.5, C15.8 C15.9)<br>Diffuse; widespread: 3/4s or more; linitis plastica:<br>Stomach and Esophagus GE Junction (C16.0 C16.6, C16.8 C16.9)<br>Diffuse, entire lung or NOS:<br>Lung and main stem bronchus (C34.0 C34.3, C34.8 C34.9)<br>Diffuse:<br>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.**

**NEW:** 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.

**NEW:** 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 – 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. 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 Variable 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 – BUT YOU STILL MUST CODE THESE PROCEDURES in the right field.

**Codes**

| 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 - UPDATED 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<br>BOTH lymphatic AND angioinvasion (thyroid and adrenal only) |
| 8 | Not Applicable |
| 9 | Unknown/Indeterminate/not mentioned in path report |

Use of codes.

A. 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.

B. 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.

C. **Lymphovascular invasion must be coded 0, 1, 2, 3, 4, or 9 for the schema ids in the following list:**

| | |
|---|---|
| 00071 | Lip |
| 00072 | Tongue anterior |
| 00073 | Gum |
| 00074 | Floor of mouth |
| 00075 | Palate hard |
| 00076 | Buccal mucosa |
| 00077 | Mouth other |
| 00080 | Major salivary glands |
| 00100 | Oropharynx (p16+) |
| 00111 | Oropharynx (p16-) |
| 00112 | Hypopharynx |
| 00121 | Maxillary sinus |
| 00122 | Nasal cavity and ethmoid sinus |
| 00130 | Larynx other |
| 00131 | Larynx supraglottic |
| 00132 | Larynx glottic |
| 00133 | Larynx subglottic |
| 00161 | Esophagus (incl ge junction) squamous |
| 00169 | Esophagus (incl ge junction) (excl squamous) |
| 00170 | Stomach |
| 00180 | Small intestine |
| 00190 | Appendix |
| 00200 | Colon and rectum |
| 00230 | Epatic |
| 00250 | Bile ducts perihilar |
| 00260 | Bile ducts distal |
| 00270 | Ampulla vater |
| 00280 | Pancreas |
| 00290 | Net stomach |
| 00301 | Net duodenum |
| 00302 | Net ampulla of vater |
| 00320 | Net appendix |
| 00330 | Net colon and rectum |
| 00340 | Net pancreas |
| 00350 | Thymus |
| 00360 | Lung |
| 00460 | Merkel cell skin |
| 00470 | Melanoma skin |

| | |
|---|---|
| 00500 | Vulva |
| 00510 | Vagina |
| 00520 | Cervix |
| 00530 | Corpus carcinoma |
| 00541 | Corpus sarcoma |
| 00542 | Corpus adenosarcoma |
| 00560 | Placenta |
| 00570 | Penis |
| 00590 | Testis |
| 00620 | Bladder |

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

| | |
|---|---|
| 00730 | Thyroid |
| 00740 | Thyroid medullary |
| 00760 | Adrenal gland |

**E. Lymphovascular invasion may use any code (0, 1, 2, 3, 4, 8, or 9) for the remaining schema ids**

| | |
|---|---|
| 00060 | Cervical lymph nodes, occult head and neck |
| 00090 | Nasopharynx |
| 00118 | Pharynx other |
| 00119 | Middle ear |
| 00128 | Sinus other |
| 00140 | Melanoma head and neck |
| 00150 | Cutaneous carcinoma head and neck |
| 00210 | Anus |
| 00220 | Liver |
| 00241 | Gallbladder |
| 00242 | Cystic duct |
| 00278 | Biliary other |
| 00288 | Digestive other |
| 00310 | Net jejunum and ileum |
| 00358 | Trachea |
| 00370 | Pleural mesothelioma |
| 00378 | Respiratory other |
| 00381 | Bone appendicular skeleton |
| 00382 | Bone spine |
| 00383 | Bone pelvis |
| 00400 | Soft tissue head and neck |
| 00410 | Soft tissue trunk and extremities |
| 00421 | Soft tissue abdomen and thorax |
| 00422 | Heart, mediastinum, and pleura |
| 00430 | Gist (2018-2020) |
| 00440 | Retroperitoneum |
| 00450 | Soft tissue other |
| 00458 | Kaposi sarcoma |
| 00478 | Skin other |
| 00480 | Breast (invasive) |
| 00551 | Ovary |

| | |
|---|---|
| 00552 | Primary peritoneal carcinoma |
| 00553 | Fallopian tube |
| 00558 | Adnexa uterine other |
| 00559 | Genital female other |
| 00580 | Prostate |
| 00598 | Genital male other |
| 00600 | Kidney parenchyma |
| 00610 | Kidney renal pelvis |
| 00631 | Urethra |
| 00633 | Urethra-prostatic |
| 00638 | Urinary other |
| 00640 | Skin eyelid |
| 00650 | Conjunctiva |
| 00660 | Melanoma conjunctiva |
| 00671 | Melanoma iris |
| 00672 | Melanoma choroid and ciliary body |
| 00680 | Retinoblastoma |
| 00690 | Lacrimal gland |
| 00698 | Lacrimal sac |
| 00700 | Orbital sarcoma |
| 00718 | Eye other |
| 00721 | Brain |
| 00722 | Cns other |
| 00723 | Intracranial gland |
| 00750 | Parathyroid |
| 00770 | Net adrenal gland |
| 00778 | Endocrine other |
| 99999 | Ill-defined other |

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

| | |
|---|---|
| 00430 | Gist (2021+) |
| 00710 | Lymphoma ocular adnexa |
| 00790 | Lymphoma |
| 00795 | Lymphoma (cll/sll) |
| 00811 | Mycosis fungoides |
| 00812 | Primary cutaneous lymphoma non mf |
| 00821 | Plasma cell myeloma |
| 00822 | Plasma cell disorder |
| 00830 | Hemeretic |

G. Use code 9 when:

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

H. 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 Stage Requirements by Year

State and National cancer staging requirements have changed over time. The focus of State and National cancer programs is monitoring cancer incidence over time. In order to support standardization and consistency in reporting stage of cancer at time of diagnosis, state and national cancer surveillance programs have often utilized a "summary staging" approach with stable anatomic staging criteria that includes both clinical data from imaging reports and medical procedures combined with pathological data gleaned from surgical resection of the primary tumor and regional lymph nodes. This is known as SEER Summary Stage. SEER Summary Stage has gone through 2 revisions since it was instituted back in the mid 1970s. The latest edition is Summary Stage 2018 or SS2018. Summary Stage is required for all cases since 1981.

Continuity of staging requirements is essential for longitudinal cancer studies, but our programs recognize that changes in anatomic staging criteria have and continue to be modified over time. Furthermore, biomolecular and genetic tests to help qualify stage subgroups are being used more frequently with tests offering greater details for staging than ever before. In order 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 including Site-Specific Factors to house these cancer-specific tests results and other clinical care and research oriented data items to expand '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 originating staging systems being directly coded for SS2000 and AJCC TNM 7th ed. in 2016 and again updated in 2018 to provide updated anatomic and prognostic staging data items to meet current and future research needs.

**SUMMARY STAGE 2018 (SS2018):** Direct-Assignment of SEER Summlary 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 Summary Stage 2018 is version 3 – found on SEER website.**

**2018 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 **Site-Specific Data Items is currently in version 3 – found on the NAACCR Website.**

**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.

**SEER*RSA - GO TO:** 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. There have been multiple versions of SS2018 published.

**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 STAGE DATA COLLECTION SYSTEM (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 Stage – please use the on-screen help to assign.

**NOTE:** Minimal Historical Cases (historical cancers with no evidence of the historical cancer – but having a new primary cancer diagnosis or undergiong 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 1/1/20014 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.

**2018 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 (2023 – version 3) SSDI and Grade Coding Manuals and Tools are available on the NAACCR Website @ https://apps.naaccr.org/ssdi/list/**

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 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 in addition to 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 | 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 Lab Value | 7 | 2018 |
| C | 3956 | P16 (cervix, anus) | 1 | 2023 |
| C | 3960 | Histologic Subtype (appendix) | 1 | 2023 |

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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 Summary Stage 2018 General Coding Instructions* for site-specific coding instructions. The most current version was published September 2020. **Always use the latest version.** This manual is online at https://seer.cancer.gov/tools/ssm/.

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 info.

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* version 3 published October 2022.

| CODES | DEFINITIONS |
|---|---|
| **0** | *in situ* |
| **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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GO TO: https://seer.cancer.gov/tools/staging/rsa.html

# TREATMENT INFORMATION

The Treatment Information section includes the set of data items used to describe how the cancer or tumor was treated. FCDS only collects the "**First Course of Treatment**." This concept is described and reinforced throughout the chapter. 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 each of 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 2023 SEER Coding and Staging Manual includes the Site-Specific Coding Moduleas as Appendix C of the manual. Download SEER Appendix C at** https://seer.cancer.gov/manuals/2021/appendixc.html

This Appendix brings together the site-specific instructions needed to abstract a case, facilitating efficiency and accuracy. The site-specific coding modules include SEER coding guidelines; equivalent terms, definitions, tables, charts and illustrations; multiple primary rules; histology coding rules; stage coding instructions and surgery of primary site codes. .

Data Items Included In This Section:

| NAACCR Item Number | Item Name |
|---|---|
| 1290 | Rx Summ – Surg Prim Site (03-22) |
| 1291 | Rx Summ – Surg Prim Site (2023) - NEW |
| 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 |

# ***NO TREATMENT IS DIFFERENT THAN ACTIVE SURVEILLANCE***
# ***NO TREATMENT IS DIFFERENT THAN WATCH AND WAIT***
# ***ACTIVE SURVEILLANCE IS DIFFERENT THAN WATCH AND WAIT***

## Active Surveillance or Watchful Waiting
## Is there a difference? YES

Cancer Registries started recording the data item "Treatment Status" back in 2010. This was the first time we were given an opportunity or a place to record 'active surveillance/watchful waiting' for prostate cancers. It had been nearly 20 years since the PSA became a 'first-line screening test' for prostate cancer. Population-Based Screening Guidelines were developed and promoted as the way to find prostate cancer early and to treat it definitively when found. These screening guidelines were adopted far and wide resulting in improved survival and mortality. PSA Screening was a huge success.

During the years 1990-2010 many thousands of men were screened for prostate cancer with the combination of PSA and DRE (digital rectal examination). And, many thousands of prostate cancers were identified and treated with prostatectomy and/or radiation therapy.

PSA Screening resulted in the identification of many cancers (early and late stage), treatment of many cancers (early and late stage), and these in turn helped to improve survival and mortality for prostate cancers across the board. But, at the same time we were improving survival and mortality from prostate cancer, we were also learning more about the risk versus benefit of finding and treating early cancers based on an elevated PSA.

By the early 2010s, population-based PSA screening was being called into question because of concerns that the benefits of screening may not justify the risks of overdiagnosis and overtreatment of potentially harmless prostate cancers. Were we really improving and extending the lives of all men diagnosed and treated for their prostate cancer? Or, were we finding and treating far more prostate cancers than needed treatment for their disease (overdiagnosis and overtreatment)? And, was that a negative risk?

So, our research began to focus on trying to find a balance between the benefits of treatment for early diagnosis and the potential harms of overtreatment (providing treatment when it would not truly benefit the patient by extending his life or improving his life – only treat the cancer). This was accomplished by identifying strategic 'risk groups' for treatment stratification. And then modifying screening guidelines based on the best treatment options available for these strategic risk groupings.

The current Prostate Cancer Risk Groups are based on a combination of the PSA prior to biopsy, the Gleason Score and Grade, and the expected lifetime of the patient. Treatment has become more individualized and 'very early' prostate cancer patients are now given the option of receiving treatment or not receiving treatment based on the overall profile of their cancer. This all depends on the risk group they fall into. Additionally, screening guidelines changed multiple times between 1990-2020.

So now we have a group of individuals who may be prescribed a 'watch and wait' approach or an 'active surveillance' approach to treatment. Both approaches delay treatment of the cancer. But the differences are somewhat nuanced. Unfortunately, cancer registrars only have 1 code under Treatment to document both 'watch and wait' and 'active surveillance' – but, the two approaches are different.

"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 opt for 'active surveillance' as well. 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 surveille or keep an active eye on the cancer for signs of progression. This is a decision to delay curative treatment.

"Watch and Wait" on the other hand 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.

"No therapy" is 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.

## TREATMENT INFORMATION – DO NOT USE CODE 99 FOR ANY TREATMENT

**TREATMENT – 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 – read the history – do not guess.

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 that should help anybody 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 – registrar does not recommend treatment.
- 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 statement that treatment was actually 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 types of treatment…same as above – in different fields in some cases such as Surgery and Radiation.

# 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 right away. 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'.

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.

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

"No therapy" is 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.

Question: Patient was initiated on FOLFOX and after 5 cycles was discontinued due to intolerance. The patient was then switched to FOLFIRI. Since this added a different drug, would this be considered a change from the initial treatment plan and considered subsequent treatment?

Answer: The reference you are looking for is in the SEER Program Coding and Staging Manual (SEER is the originator of SEER*Rx). You will not find a reference in the STORE or in any other reference manual – so hang on to this reference – we will try to remember to put it into the 2023 FCDS DAM so we have it in our documentation, also. See Section VII: First Course of Therapy on pages 210 and 211 of the 2022 SEER Program Coding and Staging Manual – and you also must reference SEER*Rx to identify the Subcategory of the Chemotherapy for Oxaliplatin and Irinotecan to confirm answer.

Oxaliplatin is Subcategory Platinum Analog and Irinotecan is Subcategory Topoisomerase Inhibitor. The change in the Subcategory of chemotherapy (found in SEER*Rx) indicates they do not belong in the same 'group' or 'subcategory'. So, when they changed from FOLFOX to FOLFIRI – they swapped out 1 drug in 1 subcategory for a different drug in a different subcategory. Therefore, the First Course of Therapy ended when they started the FOLFIRI and the Irinotecan…even when the reason for the switch is because the patient cannot tolerate the original agent. It doesn't matter how many cycles of FOLFOX the patient got. Once they switched to FOLFIRI – they changed the

## 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."

## DEFINITION OF NON-CANCER DIRECTED THERAPY

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 test, 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 first course of therapy – please code the palliative therapy as first course of therapy. Do not exclude palliative therapy as treatment. It is treatment.

## TREATMENT DEFINITIONS – not in alphabetical order

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

**Surgery:** First course surgery items descdribe 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 preceed 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 is often not coded for some reason – it should be but it is often missed.

Most tumors treated with ablation are small (<3cm) and accessible to the probes needed to reach the tumor – 2 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.

But, we also do see tumor ablation for bladder, lung, skin, liver, pancreas, kidney, and even some sarcomas.

And, 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 – code 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 chemotheraputic drugs directly to the tumor. Code as chemotherapy when the embolizing agent(s) is a chemotheraputic drug(s). Use SEER*RX to determine whether the drugs used are classified as chemotheraputic 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.

Code Radiation Modality as radioisotope when tumor embolization is performed using a radioactive agent or radioactive seeds such as Ytrium 90. This is actually a low-dose or high-dose brachytherapy technique using a radioisotope modality to deliver the radiation dose. 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 ore 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/intrapleural/intrapericardial agents are injected into the periotoneal 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. Palliataive 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.

## DEFINITIONS OF FIRST COURSE OF TREATMENT - Leukemia And Hematopoietic Diseases

### LEUKEMIA

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 given immediately after the remission.

**Maintenance:** Chemotherapy given for a period of 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 is to 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 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.

**OTHER HEMATOPOIETIC**

Record all treatments as described above. The following treatments are coded as "other" in Other Treatment even though they do not "modify, control, remove, or destroy proliferating cancer tissue."

**Aspirin** (also known as ASA, acetylsalicylic acid, or by a brand name) is coded as a treatment for essential thrombocythemia - ONLY. **DO NOT CODE aspirin as "other treatment" for any site EXCEPT Essential Thrombocythemia.**

Only record aspirin therapy for essential thrombocythemia when it is given to thin the blood for symptomatic control. Use the following guidelines to determine whether aspirin is administered for thinning of blood for thrombocythemia rather than for pain control or cardiovascular protection:

- Aspirin treatment for essential thrombocythemia is low dose, approximately 70-100 mg/day
- The dosage for pain control is approximately 325-1000 mg every 3-4 hours.
- Cardiovascular protection starts at about 160 mg/day.

**Phlebotomy** (also known as blood removal, blood letting, or venesection) is coded as treatment for polycythemia vera - ONLY. **DO NOT CODE phlebotomy as "other treatment" for any condition EXCEPT Polycythemia Vera.**

**Transfusions** may include whole blood, RBCs, platelets, plateletphoresis, fresh frozen plasma (FFP), plasmaphoresis, and cryoprecipitate. **DO NOT CODE transfusion as "other treatment" for any site.**

**RX SUMM – SURG PRIM SITE (03-22) NAACCR ITEM #1290**

Record surgery of the primary site for all cases 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 (1981-2022 or 2023>).

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.

Always code the most invasive surgical procedure for the primary site.

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. **FCDS will use Rx Summ – Surg of Primary Site (Item 1290) for all cases DX 1981-2022.**
2. **Item 1291 Rx Summ - Surg of Primary Site (2023) is for cases DX 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 have been revised.**
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 best information in the operative/pathology reports to determine the operative procedure. Do not depend on the name of the procedure since it may be incomplete.
5. If the operative report is unclear regarding what was excised or if there is a discrepancy between the operative and pathology reports, use the pathology report, unless there is a reason to doubt its accuracy.
6. 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.
7. A date field is also included to document the first date of any surgery performed.
8. 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.
9. 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).
10. If multiple primaries are excised at the same time, code the appropriate surgery for each site.

*For 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.

*For 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 PRIM SITE (2023) NAACCR ITEM #1291

Codes starting with A indicate no significant change to the surgery code validation list. Codes starting with B indicates changes to the surgery code(s).

Rx Summ – Surg 2023 [1291] is a site-specific item that describes the most invasive extent of local tumor destruction or surgical resection of the primary site and of surrounding tissues or organs that are removed in continuity with the primary site.

The code ranges and corresponding descriptions for site-specific Surgical Procedure of Primary Site code are grouped according to the general nature of the procedure:

- Codes A100 through A190 are site-specific descriptions of tumor-destruction procedures that do not produce a
pathologic specimen.
-
- Codes A200 through A800 are site-specific descriptions of resection procedures.

- The special code A980 applies to specific tumors that cannot be clearly defined in terms of primary/nonprimary site. Surgical Procedure of Primary Site should be coded A980 for any tumor characterized by the specific sites and/or morphologies identified in the site-specific code instructions for Unknown and Ill-Defined Primary Sites and Hematopoietic/ Reticuloendothelial/ Immunoproliferating/ Myeloproliferative Disease. The item Surgical Procedure/Other Site is used to indicate whether surgery was performed for these tumors.

- Response categories are defined in logical sequence. Within groups of codes, procedures are defined with increasing degrees of descriptive precision. Succeeding groups of codes define progressively more extensive forms of resection.

## 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 sentinel1ymph 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 radiatinon 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 | • The operative report states that a SLNBx was performed.<br>• 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 removal/examination.<br>• 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. | • 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).<br>• 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 *Regional Lymph Nodes Examined* (NAACCR Item #830) and |

| | | | |
|---|---|---|---|
| | | | *Regional Lymph Nodes Positive* (NAACCR Item #820). |
| **3** | Number of regional lymph nodes removed unknown or not stated; regional lymph nodes removed, NOS | • 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).<br>• 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).<br>• 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.<br>• 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).<br>• Infrequently, a SNLBx is attempted and the patient | 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). |
| 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, or timing not stated | • SNLBx and regional lymph node dissection (code 3, 4, or 5) during the same surgical event, or timing not known<br>• Generally, SLNBx followed by a 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.<br>• If relatively few nodes are pathologically examined, review the operative report to confirm whether the procedure was limited to a SLNBx only.<br>• Infrequently, a SNLBx is attempted | • Generally, SLNBx followed by ALND will yield a minimum of7-9 nodes. However it is possible for these procedures to harvest fewer (or more) nodes.<br>• 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. |

| | | | |
|---|---|---|---|
| | | 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. | |
| **7** | Sentinel node biopsy and code 3,4, or 5 at different times | •SNLBx and regional lymph node dissection (code 3, 4, or 5) in separate surgical events.<br>• 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 pathological1y examined, review the operative report to confirm whether the procedure was limited to a SLNBx only. | |
| **9** | 9 Unknown or not | • 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 *Surgery of Primary Site* [NAACCR Item #1290]). Review surgically treated cases coded 9 in *Scope of Regional/ Lymph Node Surgery* 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 (C760-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 resction 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 anywhere in the patient's medical record that surgical resection of distant lymph node(s) and/or regional/distant tissue or organs was either 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 *distant lymph node(s)* |
| **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* (NAACCR Item #1290), *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) 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

Reason for No Surgery code refers to item Rx Summ-Surg Prim Site.

| 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 Primary Site is coded in the range of 10-90 (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.

3. Assign **code 1**

    a. If RX Summ—Surg Prim Site (NAACCR Item #1290) is coded 98.
    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. Only information available is that the patient was referred to a surgeon. Referral does not equal a

recommendation.
e. Active Surveillance or Watchful waiting (prostate)
f. 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** (refused) if the patient refused recommended surgery, or made a blanket statement that he/she refused all treatment.

6. Assign **code 8** (unknown) if the treatment plan offered surgery, but it is unknown if the patient actually had the surgery.

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 'new' 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 tehrapy

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

**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<br>treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in patient record. |
| **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* (NAACCR Item #1290); *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). |

| Code | Label | Definition |
|---|---|---|
| **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 is 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.

5. Code 87 if the patient refused recommended chemotherapy, made a blanket refusal of all recommended treatment, or refused all treatment before any was recommended.

6. Code 88 if chemotherapy was planned, but not started at the time of the most recent follow-up.

7. **ONLY USE CODE 99 FOR DEATH CERTIFICATE ONLY CASES**

8. Code chemoembolization as 01, 02, or 03 depending on the number of chemotherapeutic agents involved.

9. If the managing physician changes one of the agents in a combination regimen, and the replacement agent belongs to a different group (chemotherapeutic agents are grouped as alkylating agents, antimetabolites, natural products, or other miscellaneous) than the original agent, the new regimen represents the start of subsequent therapy, and *only the original agent or regimen is recorded as first course therapy*.

10. Only the agent, not the method of administration, is to be considered in coding.

11. Combination chemotherapy containing prednisone (a hormone) should be coded in this field by counting the number of chemotherapy agents in the combination (excluding prednisone).

12. 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.

13. 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 |

## RX DATE – CHEMO NAACCR ITEM #1220

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

**Coding Instructions**

1. 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. DO NOT USE CODE 99 FOR OTHER THAN DEATH CERTIFICATE ONLY CASE. USE 00

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<br>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**

2. 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.

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/).

**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. **ONLY USE CODE 99 FOR DEATH CERTIFICATE CASES**
2. 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
3. Assign code 87
    a. If the patient refused recommended immunotherapy.
    b. If the patient made a blanket refusal of all recommended treatment.
4. 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**
1. 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 / SUR 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), 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), 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 |

| Code | Label | Description |
|---|---|---|
| | | 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.<br>Code only to be used for Primary Sites Breast and/or Prostate |

| Code | Description |
|---|---|
| **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<br>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

Enter any other cancer-directed therapy received by the patient as part of the first course of therapy. Record any other therapy administered at your facility and all other facilities.

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.

Other Treatment is rare. 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 in addition to the warning the errors will need to be corrected prior to submission. Again, WARNINGS cannot be FORCEd.

The following explanations and definitions are quoted from the website for the National Center for Complementary and Alternative Medicine (NCCAM). Complementary and alternative medicine, as defined by NCCAM, is a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine. While some scientific evidence exists regarding some CAM therapies, for most there are key questions that are yet to be answered through well-designed scientific studies--questions such as whether they are safe and whether they work for the diseases or medical conditions for which they are used.

**Complementary** medicine is used **together with** conventional medicine. An example of a complementary therapy is using aromatherapy to help lessen a patient's discomfort following surgery.

**Alternative** medicine is used **in place of** conventional medicine. An example of an alternative therapy is using a special diet to treat cancer instead of undergoing surgery, radiation, or chemotherapy that has been recommended by a conventional doctor.

**Coding Instructions**

1. Assign **Code 0** when
    a. There is no indication anywhere in the patient's medical record that other therapy was either

planned or administered.
   b. There is no reason to suspect that the patient would have had other therapy.
   c. If the treatment plan offered multiple treatment options and the patient selected treatment that did not include other therapy.
   d. Patient elects to pursue no treatment following the discussion of other therapy. Discussion does not equal a recommendation.
   e. Only information available is that the patient was referred for consideration of other therapy. Referral does not equal a recommendation.
   f. Patient diagnosed at autopsy

2. Assign **code 1**
   a. Hematopoietic treatments such as: phlebotomy for polycythemia vera or aspirin for essential thrombocythemia.
   b. Patient had cancer treatment that could not be assigned to the previous treatment fields (surgery, radiation, chemotherapy, immunotherapy, or systemic therapy).

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

4. 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.

5. Assign **code 6** for **unconventional** methods whether they are the single therapy or given in combination with conventional therapy. See below for more details.

6. Assign **code 8** When other therapy was recommended by the physician but there is no information that the treatment was given.

**7. ONLY USE CODE 9 FOR DEATH CERTIFICATE CASES**

**Code 6**

Use code 6 for unconventional methods (for example, laetrile) when they are given alone or in combination 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 |
| Parabenzoquinone | Bioelectromagnetic Applications |
| **ALTERNATIVE AND COMPLEMENTARY THERAPIES** | Blue Light Treatment |
| MANUAL HEALING | Electroacupuncture |
| Acupressure | Magnetoresonance Spectroscopy |
| Biofield Therapeutics | Diet, Nutrition, Lifestyle |

| | |
|---|---|
| Massage Therapy | Changes In Lifestyle |
| Reflexology | Diet |
| Zone Therapy | Gerson Therapy |
| **MIND/BODY CONTROL** | Macrobiotics |
| Biofeedback | Megavitimins |
| 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.<br>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. *Examples:* hyperbaric oxygen (as adjunct to cancer-directed treatment), or hyperthermia, PUVA, arterial block for renal cell carcinoma, and radio-frequency thermal ablation (hyperthermia).<br>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)<br>Includes any experimental or newly developed method or treatment differing 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<br>Patient is involved in a double blind clinical trial. Code the treatment actually administered when the double blind clinical trial code is broken. Do no code ancillary drugs in this field. |
| **6** | Unproven therapy (including laetrile, krebiozen, etc.)<br>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<br>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 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**

- This item may be left blank for cases diagnosed prior to 2010.
- Treatment given after a period of active surveillance is considered subsequent treatment and it not coded in this item.
- Assigncode 0 (No Treatment) when treatment is refused or the physician decides not to treat for any reason such as the presence of comorbidities.
  - Assign code 0 when the patient does not receive any treatment
    - Scope of Regional Lymph Node Surgery may be coded 0, 1-7, or 9
  - 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.

**Please see Appendix L for specific text documentation requirements.**

**NOTE: ALL Stage Items including ALL Site-Specific Factors MUST have Text Documentation.**

**The use of standard abbreviations in documentation and diagnostic text is acceptable. However, FCDS must be able to understand 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.**

***NOTE:*** 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 |

Reference: 2022 SEER Coding and Staging Manual – Appendix C: Site Specific Coding Modules
https://seer.cancer.gov/manuals/2021/appendixc.html

## ADDITIONAL REFERENCES FOR TEXT DOCUMENTATION:

**NCRA Informational Abstracts - NCRA has published a series of Informational Abstracts FREE FOR DOWNLOAD - Providing cancer-site specific guidelines for text in Abstracts**

The NCRA Informational Abstracts can be found at http://www.cancerregistryeducation.org/rr
**(These References were Updated 11.2019 and Includes the Following Cancers/Cancer Sites)**

- **Benign Brain**
- **Bladder**
- **Breast**
- **Cervix**
- **Colon**
- **Endometrial**
- **Kidney**
- **Larynx**
- **Lung**
- **Lymphoma**
- **Malignant Brain**
- **Melanoma**
- **Ovarian**
- **Pancreas**
- **Prostate**
- **Renal Pelvis**
- **Testis**
- **Thyroid**

**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 REGARDLES 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 examination other than cytology or histopathology for the tumor being reported. 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, Immunostaining, 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 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.

**LIQUID BIOPSY and GENETIC TESTING PANELS:** The Food and Drug Administration (FDA) has approved two blood tests, known as liquid biopsies, in August 2020 that can help guide treatment decisions for people with cancer. The tests, Guardant360 CDx and FoundationOne Liquid CDx. The tests are made by different companies and were approved separately. Below is some information about each.

Both tests can be used for two different purposes: as a companion diagnostic test and for general tumor profiling. A test is considered a companion diagnostic if it provides key information about the safe and effective use of a corresponding drug. In this case, the tests determine whether a patient's tumor has a genetic change that is targeted by a specific drug.

(NOTE: The tests are not currently used for lymphoma, leukemia, or plasma cell neoplasms, only for solid tumors. Hematopoietic neoplasms have many individual genetic markers, specific to blood and lymph, but they are quite different and more specialized than the solid tumor genetic mutations or combinations.)

(NOTE: Cancer Registries do not yet have a way to report results of these multi-gene panel tests in a standardized manner, yet. We do not yet understand what we should be including in data collection for clinical case reporting (ACOS) or for cancer surveillance reporting (SEER/NPCR/FCDS); nor do we have the capacity to capture all of the results. We are working with physicians and geneticists to better understand our role as cancer registrars and population-based cancer surveillance programs at the state and federal level for capturing this information and what is important for cancer reporting. It may take some time for us to figure this all out. In the meantime, when these tests are used in diagnostic workup and to identify treatment options for patients with solid tumors, registrars should use any physician notes describing testing and results from Summary Reports, Consultations, Lab Results, etc…and specific comments made for each case, as the resource from which tests and results are important for any particular case you are abstracting.)

"Doctors have traditionally based treatment decisions on features like the organ in which the cancer started growing, whether the cancer has spread, and whether the patient has other health conditions. Now they often use another feature to guide treatment: genetic changes in the tumor."

"Certain therapies, called targeted therapies and immunotherapies, work best against tumors that have specific genetic changes. The newly approved tests identify genetic changes, including mutations, by scanning DNA that tumors have shed into the blood."

Doctors can then use that information to determine if there is a targeted therapy or immunotherapy that is likely to work for the patient. Analyzing genetic changes in a patient's cancer is called tumor profiling, genomic profiling, or tumor sequencing.

Both Guardant360 CDx and FoundationOne Liquid CDx are approved for people with any solid cancer (e.g., lung, prostate), but not for those with blood cancers. While FDA has approved other blood tests that check for the presence a single gene mutation in tumor DNA, these are the first approved blood tests that check for multiple cancer-related genetic changes.

Liquid biopsies can sometimes be an alternative to a traditional biopsy, in which a sample of a tumor is removed with a needle or during surgery. They are less invasive and quicker than a traditional tissue biopsy"

"Even though the tests have been around for a while, we don't know how useful they're really going to be in the clinical setting," said Ben Ho Park, M.D., Ph.D., of Vanderbilt-Ingram Cancer Center. Many details about how the blood tests may be incorporated into everyday care for people with cancer, including who should get them and whether the cost is covered by private insurance companies, are still being ironed out."

1. **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 List[2]

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* | *C11orf30 (EMSY)* | *CALR* | *CARD11* | *CASP8* | *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* | *CTNNB1* | *CUL3* | *CUL4A* | *CXCR4* | *CYP17A1* | *DAXX* | *DDR1* | *DDR2* |
| *DIS3* | *DNMT3A* | *DOT1L* | *EED* | *EGFR* | *EP300* | *EPHA3* | *EPHB1* | *EPHB4* |
| *ERBB2* | *ERBB3* | *ERBB4* | *ERCC4* | *ERG* | *ERRFI1* | *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* | *FOXL2* | *FUBP1* | *GABRA6* | *GATA3* | *GATA4* |
| *GATA6* | *GID4 (C17orf39)* | *GNA11* | *GNA13* | *GNAQ* | *GNAS* | *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* | *NFKBIA* | *NKX2-1* | *NOTCH1* | *NOTCH2* | *NOTCH3* |
| *NPM1* | *NRAS* | *NT5C2* | *NTRK1* | *NTRK2* | *NTRK3* | *P2RY8* | *PALB2* | *PARK2* |
| *PARP1* | *PARP2* | *PARP3* | *PAX5* | *PBRM1* | *PDCD1 (PD-1)* | *PDCD1LG2 (PD-L2)* | | *PDGFRA* |
| *PDGFRB* | *PDK1* | *PIK3C2B* | *PIK3C2G* | *PIK3CA* | *PIK3CB* | *PIK3R1* | *PIM1* | *PMS2* |
| *POLD1* | *POLE* | *PPARG* | *PPP2R1A* | *PPP2R2A* | *PRDM1* | *PRKAR1A* | *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* | *SOCS1* |
| *SOX2* | *SOX9* | *SPEN* | *SPOP* | *SRC* | *STAG2* | *STAT3* | *STK11* | *SUFU* |
| *SYK* | *TBX3* | *TEK* | *TET2* | *TGFBR2* | *TIPARP* | *TNFAIP3* | *TNFRSF14* | *TP53* |
| *TSC1* | *TSC2* | *TYRO3* | *U2AF1* | *VEGFA* | *VHL* | *WHSC1 (MMSET)* | *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* | *RSPO2* | *SDC4* | *SLC34A2* | *TERC** | *TERT (promoter only)*** | |
| *TMPRSS2* | | | | | | | | |

**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) | *EGFR* exon 19 deletions and *EGFR* exon 21 L858R alterations | Gilotrif® (afatinib), Iressa® (gefitinib), Tagrisso® (osimertinib) or Tarceva® (erlotinib) |
| | *EGFR* exon 20 T790M alterations | Tagrisso® (osimertinib) |
| | *ALK* rearrangements | Alecensa®(alectinib), Xalkori® (crizotinib), or Zykadia® (ceritinib) |
| | *BRAF* V600E | Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib) |
| | *MET* single nucleotide variants (SNVs) and indels that lead to *MET* exon 14 skipping | Tabrecta™ (capmatinib) |
| Melanoma | *BRAF* V600E | Tafinlar® (dabrafenib) or Zelboraf® (vemurafenib) |
| | *BRAF* V600E or V600K | Mekinist® (trametinib) or Cotellic®(cobimetinib), in combination with Zelboraf® (vemurafenib) |
| Breast Cancer | *ERBB2* (HER2) amplification | Herceptin® (trastuzumab), Kadcyla® (ado-trastuzumab-emtansine), or Perjeta® (pertuzumab) |
| | *PIK3CA* alterations | Piqray® (alpelisib) |
| Colorectal Cancer | *KRAS* wild-type (absence of mutations in codons 12 and 13) | Erbitux® (cetuximab) |
| | *KRAS* wild-type (absence of mutations in exons 2, 3 and 4) and *NRAS* wild-type (absence of mutations in exons 2, 3 and 4) | Vectibix® (panitumumab) |
| Ovarian Cancer | *BRCA1/2* alterations | Lynparza® (olaparib) or Rubraca® (rucaparib) |
| Cholangiocarcinoma | *FGFR2* fusions and select rearrangements | Pemazyre™ (pemigatinib) |
| Prostate Cancer | Homologous Recombination Repair *(HRR) gene (BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D and RAD54L)* 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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2. **<u>Guardant360 CDx - Guardant360® CDx</u>** 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) | *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* |
| Indels | *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* |
| Copy Number Amplifications (CNAs) | *ERBB2, MET* |
| Fusions | *ALK, NTRK1, RET, ROS1* |

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

**<u>TEXT – DX PROC – OP</u>** **<u>NAACCR ITEM #2560</u>**

<u>Enter information from operative reports. Do not just restate the procedure performed.</u> 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. <u>Include dates and chronology of care</u>. See Appendix L

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

Enter information from cytology and histopathology reports. 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, metastatic involvement, etc. YOU MUST INCLUDE DATES AND CHRONOLOGY OF CARE – PLEASE INDICATE IF REPORTS ARE MISSING FROM THE MEDICAL RECORD. INCLUDE BIOPSIES, BONE MARROW REPORTS, RESECTIONS, AND GENETIC TESTING INCLUDED IN THE ANATOMIC PATHOLOGY REPORT. See Appendix L

**TEXT – STAGING** **NAACCR ITEM #2600**

DO NOT JUST ENTER TNM – YOU MUST JUSTIFY THE RATIONALE FOR ASSIGNING SS2018. THERE IS NO CROSSWALK FROM TNM TO SS2018. REFER TO THE SS2018 MANUAL. 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. But, do not only include AJCC TNM information. You must include rationale for assignment of Summary Stage. Please always use the Summary Stage Manual to assign Summary Stage and to document rationale for the code assigned. 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

| NAACCR Item Number | Item Name |
|---|---|
| 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. 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

Enter the cancer status 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 cancer |
| **2** | Evidence of this cancer |
| **9** | Unknown, indeterminate whether this cancer present, not stated in patient record |