Site-Specific Data Item (SSDI) Manual

Effective with Cases Diagnosed 1/1/2018 and Forward

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Editors: Jennifer Ruhl, MSHCA, RHIT, CCS, ODS-C, NCI SEER
Jim Hofferkamp, ODS-C, NAACCR

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- Jennifer Ruhl, MSHCA, RHIT, CCS, ODS-C (NCI SEER) (Co-chair)
- Donna M. Hansen, ODS-C (California Cancer Registry) (Co-chair)
- Aleisha Williams, MBA, ODS-C (AJCC)
- Cheryl Radin-Norman, LPN, RHIT, ODS-C (NPCR)
- Cindy Traylor-Richards, ODS-C (CoC)
- Claudia Byrd RN, ODS-C (CoC)
- Delores Akin, ODS-C (CoC)
- Donna Gress, RHIT, ODS-C (AJCC)
- Heather Donahue, ODS-C (Registry Partners)
- Donna Gress, RHIT, ODS-C (AJCC)
- Janine Smith, BS, ODS-C (California Cancer Registry)
- Jim Hofferkamp, ODS-C (NAACCR)
- Mary Brant, BS, ODS-C (California Cancer Registry)
- Nicola Schussler, BS (IMS)
- Richard Moldwin, M.D., Ph.D (College of American Pathologists)
- Sheila Fukumura, ODS-C (Manitoba Cancer Registry)

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The following individuals contributed to document support and web development.

- Suzanne Adams, BS, ODS-C (IMS)
- Michael Coffey, BS (IMS)
- Kathy Conklin, MSCS, Manager of IT, AJCC
- Dustin Dennison, M.MIS (Information Technology Administrator, NAACCR)
- Chuck May, BS (IMS)
- Daniel Oluwadare, Programmer, AJCC
- Nicola Schussler, BS (IMS)

This manual is effective for all cases diagnosed 1/1/2018 and after.

- Once a new version is released, that version can be used for all cases diagnosed 2018+.
- Schemas and SSDIs continue to be introduced based on the rolling updates of AJCC Version 9. These will be clearly marked and will be restricted to the years for which they are applicable.

Send questions, suggestions and corrections to:

Forums - CAnswer Forum: **Choose Site Specific Data Items/Grade**

Table of Contents

Organization of the SSDI Manual and Suggestions for How to Use it

The Site-Specific Data Item (SSDI) manual is the primary resource for documentation and coding instructions for site-specific data items introduced in 2018. Information in the SSDI Manual is similar to that provided in the Collaborative Stage v2 (CSv2) Manual Part I, Section II for Site Specific Factors (SSF).

Before using the Manual as an information resource for specific data items, it is important to review the introductory materials and general instructions carefully. Although the majority of data items that are collected as SSDIs were previously collected as SSFs, the format of the data items and allowable values have changed substantially, particularly for laboratory values.

Information about the SSDIs has been organized using primary site groupings and presented in the order used in the AJCC Manuals, a format that is familiar and useful to registrars and most others using the SSDI Manual. However, we have also provided an alphabetical index for the SSDIs with the corresponding page number in the last 2 pages of the Manual for those who may want to search it for a specific SSDI by data item name. The Table of Contents for the Manual contains hyperlinks so that clicking anywhere on the line where an SSDI and page number are listed will take you directly to that page in the Manual.

An important new concept introduced in 2018 is the use of a Schema ID to define the applicable SSDIs and grade table for a particular tumor, based on primary site, histology, and in some cases, additional information. The appropriate Schema ID will be defined by registry software and will not have to be assigned by the registrar. However, a Schema ID Table defining the Schema ID number, description and associated SSDIs is provided in the SSDI Manual for reference purposes. The Schema ID Table will also be useful for registrars abstracting cases before their software is available. In addition to Schema IDs, the Schema ID Table also provides the applicable SSDIs with a hyperlink to the page on which the description of the relevant SSDIs begins. A hyperlink at the end of the information on each SSDI can be used to return to the Schema ID Table.

For each SSDI, the SSDI Manual includes:

- NAACCR Data Item Name
- Item Length
- NAACCR Item #
- NAACCR Alternative Name
- Schema ID(s)
- Description
    - The description is a brief summary used to define the data item in the NAACCR data dictionary
- Rationale
    - The rationale describes the reason why the data item is collected, such as required for staging or recommended for registry data collection by AJCC. If the data item was collected in CSv2, the primary site and SSF# is included in the rationale

- Definition
    - The definition provides additional background on the data item and its clinical importance. This information was previously included in the CSv2 Manual, Part I, Section II
- Additional Information
    - This section may include source documents, other names, normal reference ranges and any other information deemed relevant for a particular SSDI. This information was previously included in the CSv2 Manual, Part I, Section II
- Coding instructions and Codes
    - Coding instructions are provided as numbered notes. Codes are provided in a table. Codes and coding instructions are usually provided in registry software.

Appendix A

Appendix A, presented in Schema ID order, provides detailed information on the sites, histologies and behavior codes included in each schema, along with the applicable SSDIs, grade table, EOD Schema Name, Summary Stage 2018 Chapter and the current AJCC Staging System. This information is used in registry software development and may also be useful to researchers and others interested in understanding schema definitions.

Appendix B

Appendix B is an excel spreadsheet which lists all of the CSv2 site specific factors by CS Schema, their current status (based on CoC), primary site, and (where applicable), the NAACCR v18 Data Item # and Name. This appendix is not updated based on new SSDIs.

Appendix C

Appendix C is a WORD document which lists all the SSDIs in numerical order, the applicable Schema ID(s) and the start and end year.

Introduction

In 2018, Collaborative Stage (CS) Site-Specific Factors (SSFs) were discontinued, and Site-Specific Data Items (SSDIs) are used for collection of site-specific information. SSDIs will have unique names and NAACCR data item numbers and can be applied to as many sites as needed. Unlike SSFs, field length is not limited to 3 digits, decimals are allowed, and different coding conventions are used to record actual values, percentages, and ranges. NAACCR is the custodian of the SSDIs and the SSDI TF is responsible for their development and updates.

The NAACCR Site-Specific Data Item Taskforce

In October 2016, the NAACCR Site-Specific Data Item (SSDI) Taskforce was formed to determine how to collect information recorded in the site-specific factors (SSFs) which are part of the Collaborative Stage software (CS DLL). The taskforce evaluated the structure of the CS SSFs and made recommendations on how the information should be collected and then updated/revised the format, codes, and coding instructions as needed.

Task force members evaluated several different ways of collecting the information. The final decision was to discontinue the CS SSF approach and create new individual site-specific data items (SSDIs) for data collection beginning with cases diagnosed in 2018. There are several reasons for this decision.

- More flexibility
- No longer will all site-specific data items be three characters in length. Some are shorter, others are longer
- Also, registrars can record lab values with the decimal point as part of the code.
- Meaningful names
- Each new data item has been given a name that will be displayed in registry software.
    - For *example*, the software displays ER instead of Breast, SSF1
- It is easier for registrars and researchers to retrieve data.
    - For *example*, query the database for PSA instead of remembering that SSF1 is PSA in Prostate
- Reduced duplication
- CS SSFs which were collected for multiple sites/chapters/schema under different SSF numbers are now one data item when possible

What is a SSDI?

A "SSDI'" is a site-specific data item. "Site" in this instance is based on the primary site, the AJCC Staging System, Summary Stage chapter and the EOD schema. SSDIs were preceded by CS SSFs, which were first introduced in 2004 with CSv1, and went through major revisions in 2010 with **Collaborative Stage v2 (CSv2)**. 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/systems /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.

Unless otherwise noted, all SSDIs start collection in 2018. For those that have a collection start date later than 2018, a note has been added to instruct registrars when it should be collected.

How SSDIs are associated with relevant site/histologies and schemas

In **Collaborative Stage v2 (CSv2),** 153 Schemas were defined based on site/histology and used to assign applicable site-specific factors (SSFs) and staging algorithms. For 2018, Schema ID [3800] is used to link all combinations of sites and histologies (using additional information from schema discriminators if needed) with the appropriate stage data collection systems and SSDIs. AJCC ID [995] is used to link AJCC staging eligible sites/histologies (using additional information from schema discriminators if needed) with the appropriate AJCC Staging System and staging algorithm. Schema ID and AJCC ID will be derived by registry software based on site and histology codes entered by the registrar. Refer to **Appendix A** for a complete listing of schemas IDs and other schema information.

Process of Developing the SSDIs

Development of the SSDIs began with reviewing the CS SSFs. Due to the number of CS SSFs, and the fact that many of them were discontinued in CSv0204, a priority order was established.

- First: schema discriminators. These are data items needed to determine the correct SSDIs, AJCC Staging System, EOD schema, or Summary Stage schema
- Second: data items required to assign stage
- Third: data items currently required by at least one standard setter and listed as registry collection data items in at least one AJCC Staging System
- Last: certain data items required by standard setters and not necessarily associated with staging. These comprise a small percentage of the data items

CS SSFs discontinued in CSv0204 were not reviewed for 2018 data collection. New registry data collection items listed in the AJCC Staging System was not reviewed unless they are required for staging.

Number of SSDIs compared to CS SSFs

- Approximately 260 unique CS SSFs in CSv0205
- 101 discontinued
- 12 obsolete
- 147 required
- Of these, 27 are not required for 1/1/2018+
- 120 SSDIs added to the NAACCR v18 layout

CS SSF data will be retained for cases diagnosed 2004-2017. CS SSF data will not be mapped to the SSDIs.

- Collection of CS SSFs or the new SSDIs is based strictly on the date of diagnosis. For cases diagnosed 2004-2017, CS SSFs will continue to be collected according to the appropriate standard setter. For cases diagnosed 2018 or later, the SSDIs will be collected according to the appropriate standard setter

Example: A case diagnosed in 2017 is abstracted in 2018. Code the applicable/required CS SSFs for that case, not the SSDIs.

For a complete listing of site-specific factors from CSv0205 and the corresponding SSDI (if any) for 2018, see **Appendix B.**

Timing for collection of SSDIs

The SSDIs are to be collected during the initial diagnosis, work up and first course of treatment. Some SSDIs have specific instructions as to when the SSDIs are collected (e.g., CEA is to be collected prior to polypectomy, or PSA is to be collected prior to needle core biopsy).

Note: Active surveillance is first course of treatment.

Consult Reports

If a report is sent out for consult and the results are different than the original report, record the results from the consult.

Note: *Recent discussions with the SSDI WG and the standards setters also confirms that if a facility re-reads the slides, and provides an updated report, when a patient comes to their facility for treatment, that this also qualifies as a consult.*

Example 1: Patient had biopsy done at a facility with a Gleason Score of 4+4=8. Slides were sent out for consult and their review showed Gleason Score 4+3=7.

- Record the Gleason score of 4+3=7 based on the consult.

Example 2**:** Original pathology report states ER and PR positive. Slides were sent out for consult and their review showed ER and PR negative.

- Record ER and PR as negative

Example 3**:** Breast pathology report states Grade 3, ER 95% strong on outside pathology. Patient presents at facility for treatment and the slides from the outside facility are reviewed and a new report is provided, with the results of Grade 2, ER 80% intermediate.

- Record Grade 2 and ER 80% intermediate

Example 4: Patient diagnosed at facility A with prostate cancer. Pathology reports shows a 3+4 Gleason pattern. Patient presents to facility B for treatment. Facility's policy is to review all outside pathology reports and slides prior to treating the patient. The slide review and report at facility B shows adenocarcinoma 3+3. Urologist recommended active surveillance because of the G1 assessment on slide review.

- Record Gleason pattern 3+3 (based on facility B review)
- Record Gleason score 6 (based on facility B review)
- Record Grade Clinical 1 (based on facility B review)

General Definitions and Format of SSDI Codes

Not applicable: This code is to be used ONLY when the data item is relevant for the case and the standard setter does not require the data item. Not applicable codes ALWAYS end in an 8 but will differ depending on the length of the data item.

Note: "Not applicable" is not available for schema discriminators or data items which are required for staging.

Examples:

- Perineural Invasion. This is a 1-digit field. "Not applicable" is **8**
- FIGO Stage (for all GYN cases). This is a 2-digit field. "Not applicable" is **98**
- Creatinine Pretreatment Lab Value. This is a 4-digit field including the decimal point. "Not applicable" is **XX.8**
- AFP (Alpha Fetoprotein) Pre-Orchiectomy Lab Value. This is a 7-digit field including the decimal point. "Not applicable" is **XXXXX.8**

It is important to review each data item carefully to determine how the "not applicable" code is formatted.

Unknown: Previous codes from CS for test not done (998) and unknown (999) have been combined. Unknown codes ALWAYS end in a 9 but will differ depending on the length of the data item. The unknown code includes

- Test/evaluation/assessment **not** done or UNKNOWN if done

Examples:

- Perineural Invasion. This is a 1-digit field. "Not applicable" is **9**
- FIGO Stage (for all GYN cases). This is a 2-digit field. "Not applicable" is **99**
- Creatinine Pretreatment Lab Value. This is a 4-digit field including the decimal point. "Not applicable" is **XX.9**
- AFP (Alpha Fetoprotein) Pre-Orchiectomy Lab Value. This is a 7-digit field including the decimal point. "Not applicable" is **XXXXX.9**

"Cannot be determined" on the pathology report. For some data items, this is a selection box on the College of American Pathologists (CAP) protocol. "Cannot be determined" is primarily used when a tissue specimen is not adequate for testing.

- If the pathology report includes "cannot be determined," code unknown

"Not identified." For some data items, this is a selection box on the CAP protocol. This means that the pathologist has looked for it and it is not present. This is not the same thing as looking for it in the medical record and not finding it (this would be "not documented in the medical record.")

- For some SSDIs, "not identified," may be a specific code description
- If the pathologist stated, "not identified," and the SSDI does not include a specific code for not identified, code to negative

Death Certificate Only (DCOs) cases

For DCOs, the applicable SSDIs (except for applicable Schema Discriminators) may be blank.

- *Note*: This instruction is for central registries only.

Source Documents

Source documents are suggested for some data items as the most likely sources of information.

- If no source document is suggested, use any information provided in the medical record
- If a pathology report is suggested that document includes
    - Addenda or revisions to the report
    - Gross or microscopic description
    - Synoptic reports
    - CAP protocol, or cancer checklist information provided by the pathologist

It is important to review each data item carefully to determine where the information can be found. For some data items, the information is based on imaging or some other type of clinical exam. Other data items are based on pathological findings from a surgical resection.

General Rules for Entering Laboratory Values and Other Measurements

Lab values and other measurements that are not integers (whole numbers) and are reported as continuous variables (not categories or ranges) will be recorded to a single decimal place with an explicit decimal point.

There must always be a numeral or the letter 'X' immediately before the decimal point and a numeral after the decimal point, which will be in the next-to-last character position in the field. The entered value must be right justified in the field and padded with spaces to the left if necessary to fill the field.

Users' software will usually justify and pad the value automatically for the registrar.

In addition to the actual values, codes are defined for situations such as value unknown; test done but results not in chart; and other special cases. Sometimes codes will be provided for when a value is expressed as "at least" some value.

- These may be needed, for *example*, in the measurement of tumor size or thickness when the tumor has been transected and the actual size cannot be determined. These codes will begin with one or more 'X's.

When a value in the medical record does not provide the expected decimal digit, i.e., it is expressed as a whole number, then enter the value followed by a decimal point and a zero.

Examples for a 6-Character Lab Value

Value in Record	Data Item Coded as
0.0	0.0
0	0.0
.1	0.1
11.0	11.0
11.1	11.1
11	11.0
111.1	111.1
1111.1	1111.1

Rounding Rules

SSDIs follow the standard definitions for rounding. These general rules can be followed for most SSDIs where lab values or percentages are recorded. All SSDIs that have lab values, percentages or measurements are set up to record in the 10ths (one digit after the decimal point). If a lab value, percentage, or measurement is recorded in 100ths (two digits after the decimal point), then the last digit must be rounded.

The general rounding rules are:

- If digit is 0-4, round down
- If digit is 5-9, round up

  Note: Currently (2018+), the only SSDIs that have exceptions to the general rounding rules are:

  - HER2 ISH Single Probe Copy Number (2018-2020 only)
  - HER2 ISH Dual Probe Copy Number (2018-2020 only)
  - HER2 ISH Dual Probe Ratio (2018-2020 only)

Examples

- Breslow's measurement 4.32 mm
  - Since the last digit is 2, round down and record 4.3
- CEA lab value 18.35
  - Since the last digit is 5, round up and record 18.4
- *Note*: ER (and PR) percent positive do not have decimal points in the data items, so anything with a decimal point will have to be rounded.
  - ***Example***: 78.6. Since the last digit is 6, round up and record 079 (79%)
  - *Note*: For ER and PR percent positive, if a value is documented as 99.5% to 99.9%, round up to 100% (code 100)

Recording values when “less than,” “greater than,” and “or least” are used

Record the value as **one less** than stated when a value is reported as “less than X,” and as **one more** than stated when a value is reported as “more than X” or “at least.” **One less** or **one more** may refer to a whole number (1), or a decimal (0.1), depending on the code structure of the field.

SSDIs with decimals in their code structures

Example 1: PSA stated as < (less than) 5. Record 4.9

Example 2: hCG lab value resulting findings of < (less than) 1. Record 0.9

Example 3: Ki-67 reported as > (greater than) 20%. Record 20.1 (Breast schema only)

- *Note*: for the NET schemas, > (greater than) 20% would be coded as XXX.6 since there is a specific code for that.

Example 4: CEA reported as at least 30. Record 30.1

SSDIs without decimals in their code structure:

Example 1: ER Percent Positive stated as < (less than) 60%. Record 059 (59%)

Example 2: PR Percent Positive stated as > (greater than) 75%. Record 076 (76%)

Example 3: ER Percent Positive < (less than) 50%. Record 049 (49%)

Example 4: PR Percent Positive reported as at least 55. Record 056 (56%)

Rules for Recording Laboratory Values

Laboratory values refer to any tests that are based on blood, urine, ascites, or spinal fluid. Most of these are based on blood.

Do not apply these rules to SSDIs that are based on tissue; see Rules for Recording Tests Based on Solid Tissue .

Follow the below guidelines for recording laboratory values:

- All laboratory values must be done no earlier than approximately three months before diagnosis
    - ***Notes: Rules for recording PSA have changed in Version 3.3 of the SSDI manual. This rule no longer applies to PSA. Please review the specific rules in the PSA SSDI (Prostate Schema). The updated rule can be applied for cases 2018+.***
- Only record test results obtained before any cancer-directed treatment is given (neoadjuvant therapy or surgical), unless instructions for a specific laboratory test state otherwise
- Record the highest laboratory value if multiple laboratory tests results are available, unless instructions for a specific laboratory test state otherwise

The following SSDIs record laboratory values. If the SSDI specific coding rules column is yes, then check the SSDI for additional coding instructions

Schema	SSDI#	SSDI	SSDI Specific Coding Rules
Colon and Rectum	3820	CEA Pretreatment Lab Value	Yes
Colon and Rectum	3819	CEA Pretreatment Interpretation	Yes
Liver	3810	AFP Pretreatment Lab Value	
Liver	3809	AFP Pretreatment Interpretation	
Liver	3813	Bilirubin Pretreatment Total Lab Value	
Liver	3814	Bilirubin Pretreatment Unit of Measure	
Liver	3820	Creatinine Pretreatment Total Lab Value	
Liver	3825	Creatinine Pretreatment Unit of Measure	
Liver	3860	International Normalized Ratio for Prothrombin Time	
Lymphoma	3859	HIV	
Lymphoma (CLL/SLL)	3811	Anemia	
Lymphoma (CLL/SLL)	3933	Thrombocytopenia	
Mycosis Fungoides	3910	Peripheral Blood Involvement	
Ovary, Fallopian Tube, Primary Peritoneal Carcinoma	3818	CA-125 Pretreatment Interpretation	
Melanoma Skin	3932	LDH Lab Value	Yes
Melanoma Skin	3869	LDH Level	Yes
Melanoma Skin	3870	LDH Upper Limits of Normal	Yes
Pancreas	3942	CA 19-9 PreTx Lab Value	
Plasma Cell Myeloma	3930	Serum Albumin Pretreatment Level	
Plasma Cell Myeloma	3931	Serum Beta-2 Microglobulin Pretreatment Level	
Plasma Cell Myeloma	3932	LDH Lab Value	
Prostate	3920	PSA Lab Value (See SSDI specific instructions)	Yes
Testis	3807	AFP Pre-Orchiectomy Lab Value	Yes
Testis	3808	AFP Pre-Orchiectomy Range	Yes
Testis	3805	AFP Post-Orchiectomy Lab Value	Yes

Schema	SSDI#	SSDI	SSDI Specific Coding Rules
Testis	3806	AFP Post-Orchiectomy Range	Yes
Testis	3848	hCG Pre-Orchiectomy Lab Value	Yes
Testis	3849	hCG Pre-Orchiectomy Range	Yes
Testis	3846	hCG Post-Orchiectomy Lab Value	Yes
Testis	3847	hCG Post-Orchiectomy Range	Yes
Testis	3868	LDH Pre-Orchiectomy Range	Yes
Testis	3867	LDH Post-Orchiectomy Range	Yes

If the only test or tests performed do not meet these criteria, code "test not done" or "unknown if test performed."

The results of laboratory values vary according to the laboratory conducting the test. The normal reference range is included in the tumor marker comments as background information only. Some data items ask for a laboratory value, others ask for the “interpretation” of the laboratory test (normal, elevated, and so forth).

When the data item asks for the interpretation of a laboratory test, code the clinician’s/pathologist’s interpretation, if available, as first priority. This would include statements of “abnormal”, “elevated”, “normal”, “equivocal”, “present”, “absent”, and so forth. In addition, the physician's statement of a T, N, or M value or stage group for the case could be an implied interpretation of a lab value used to determine the TNM classification.

- ***Example 1:*** Physician summarizes breast cancer workup by saying "HER2 IHC was positive at 3+.” Registrar would code interpretation as positive
- ***Note:*** If the pathologist uses the term "indeterminate," code as borderline; undetermined if positive or negative if that code exists in the data item. If a code for borderline or undetermined does not exist, code as unknown

In the absence of a physician’s interpretation of the test, if the reference range for the lab is listed on the test report, the registrar may use that information to assign the appropriate code.

- ***Example 2:*** Medical record laboratory report shows ovarian cancer patient's CA-125 as 69 (normal range < 35 U/ml). Registrar may infer that CA-125 is elevated

When there is no clinician/pathologist interpretation of the lab test and no description of the reference range in the medical record the registrar should code unknown. Do not code the lab value interpretation based on background information provided in this manual for the data item.

Note: There will be some cases where an interpretation may be inferred from the background information in this manual because the lab result is extremely abnormal. In such cases, common sense would dictate that the case should be coded as elevated rather than unknown.

- ***Example 3:*** Physician reports that Alpha Fetoprotein (AFP) collected in the office for a patient suspected to have primary liver cancer was 750 but does not interpret this value. Background information in the manual indicates a high normal would be > 500 but hepatocellular carcinoma values are > 1000. Registrar should code AFP Interpretation as unknown

- ***Example 4:*** Physician reports a CEA of 450 for a colon cancer without interpreting it. Background information in the manual indicates a high normal would be 5 ng/ml. Registrar may code CEA as elevated

What does SI mean? SI is the French abbreviation for International System (*Systeme Internationale)*, standard units of measure (meter, kilogram, second). Most SI values are based on the kilogram and the liter. A nanogram (ng) is one-thousandth of a microgram (µg). A milliliter (ml) is one-thousandth of a liter. Therefore, a lab value expressed in mg/L is equivalent to the same value expressed in ng/ml. Some lab values, such as hormone levels, are recorded in International Units per Liter (IU/L). This is equivalent to mIU/mL. The equivalence of mIU to ng varies according to what is measured.

Note that instructions for entering many lab values state that the registrars should not convert the values. For those where conversion is allowed, one measurement conversion website is:

https://www.amamanualofstyle.com/page/si-conversion-calculator

SI Conversion: 1 mg/L = 1 ng/ml.

- For *example*, 1 ng of AFP is approximately equal to 1 mIU.

Note*:* Micrograms (µg) per liter may be printed as ug/L.

Prefixes and abbreviations. Units of measure can be described and written in various ways in the medical record. In some circumstances, the unit of measure may be dependent on the printer used for the report.

- For *example*, the prefix "micron" (one millionth of a unit) is represented in scientific notation by the Greek letter **mu** (m), but not all printers have the capability to print Greek symbols. As a result, micro- may be printed as a lower-case **u** or as the abbreviation mc.
- Do not confuse the abbreviation for micro- (u) with the abbreviation for Unit (an international system measurement, U).

Tables I-2-1a – I-2-1c below show abbreviations for units of measurement and the abbreviations for fractions or multiples of those units.

Table I-2-1a. Measurement Prefixes

Number	Prefix	Written
1,000,000	Mega-	M
1000	Kilo-	k
10	Deka-	da
1 (baseline)		
1/10	Deci-	d
1/100	Centi-	c
1/1000	Milli-	m
One millionth	Micro-	m, u, or mc
One billionth	Nano-	n
One trillionth	Pico-	p
One quadrillionth	Femto	f

Table I-2-1b. Unit Abbreviations

Unit	Abbrev.
Liter	L
Unit	U
Meter	m
Unit-of-substance	mole, mol
Gram	g, gr
milli-Equivalent	mEq, meq

Table I-2-1c. ***Examples***

Unit	Abbrev.
Femtomole	fmol
Microgram	ugr, mcg, mgr
Milliliter	ml

Rules for Recording Tests Based on Solid Tissue

Priority Order for SSDIs that are tissue based

- Addendums or amendments (corrections that are not incorporated into the initial synoptic report, including CAP Cancer Protocol)
- Synoptic report (including CAP Cancer Protocol)
- Pathology report: final diagnosis
- Physician statement

For these SSDIs, a microscopic evaluation (tissue examination) is required.

- If no microscopic evaluation (biopsy, surgical resection), code the SSDI to the unknown value.
- Liquid biopsies cannot be used to code SSDIs.

General Rules versus SSDI specific rules

- Unless instructions for a specific tissue test state otherwise, record the highest value (positive versus negative, or actual numerical value) obtained from any tissue-based examination (biopsy, surgical resection, bone marrow biopsy).
- If the SSDI specific coding rules column is yes, then check the SSDI for additional coding instructions

Schema	SSDI#	SSDI	SSDI Specific Coding Rules
Bile Ducts Intrahepatic	3935	Tumor Growth Pattern	
Bile Ducts Intrahepatic Liver	3835	Fibrosis Score	
Bile Ducts Intrahepatic, Bile Ducts Perihilar	3917	Primary Sclerosing Cholangitis	
Bone	3908	Percent Necrosis Post Neoadjuvant	Yes
Brain, CNS	3816	Brain Molecular Markers	
Brain, CNS	3801	Chromosome 1p: Loss of Heterozygosity	
Brain, CNS	3802	Chromosome 19q: Loss of Heterozygosity	
Brain, CNS	3889	Methylation of O6-Methylguanine-Methyltransferase (MGMT)	
Breast	3827	Estrogen Receptor Summary	Yes
Breast	3826	Estrogen Receptor Percent Positive or Range	Yes
Breast	3828	Estrogen Receptor Total Allred Score	Yes
Breast	3882	LN Positive Axillary Level I-II	Yes
Breast	3915	Progesterone Receptor Summary	Yes
Breast	3914	Progesterone Receptor Percent Positive or Range	Yes
Breast	3916	Progesterone Receptor Total Allred Score	Yes
Breast	3855	HER2 Overall Summary	Yes
Breast	3903	Oncotype Dx Recurrence Score-DCIS	
Breast	3905	Oncotype Dx Risk Level-DCIS	
Breast	3904	Oncotype Dx Recurrence Score-Invasive	
Breast	3906	Oncotype Dx Risk Level Invasive	
Breast	3863	Ki-67	Yes
Breast	1178	Residual Cancer Burden (RCB)	Yes
Breast	1179	RCB Class	Yes
Colon and Rectum	3823	Circumferential Resection Margin	Yes
Colon and Rectum	3866	KRAS	

Schema	SSDI#	SSDI	SSDI Specific Coding Rules
Colon and Rectum	3890	Microsatellite Instability (MSI)	
Colon and Rectum	3909	Perineural Invasion	Yes
Colon and Rectum	3934	Tumor Deposits	Yes
Colon and Rectum	3940	BRAF Mutational Analysis	
Colon and Rectum	3941	NRAS Mutational Analysis	
Cutaneous Carcinoma Skin	3858	High Risk Histologic Features	
Cutaneous Carcinoma Skin	3909	Perineural Invasion	Yes
Esophagus (both schemas)	3855	HER2 Overall Summary	
GIST	3865	KIT Gene Immunochemistry	
HemeRetic	3862	JAK2	
Kidney	3864	Invasion Beyond Capsule	Yes
Kidney	3886	Major Vein Involvement	Yes
Kidney	3861	Ipsilateral Adrenal Gland Involvement	Yes
Kidney	3925	Sarcomatoid Features	
Lacrimal Gland	3803	Adenoid Cystic Basaloid Pattern	
Lacrimal Gland	3909	Perineural Invasion	Yes
Lung	3938	ALK Rearrangement	
Lung	3939	EGFR Mutational Analysis	
Lung	3937	Visceral and Parietal Pleural Invasion	
Lung	1176	Lung STAS	
Melanoma Choroid and Ciliary Body; Iris	3821	Chromosome 3 status	
Melanoma Choroid and Ciliary Body; Iris	3822	Chromosome 8q status	
Melanoma Choroid and Ciliary Body; Iris	3834	Extravascular Matrix Patterns	
Melanoma Choroid and Ciliary Body; Iris	3887	Measured Basal Diameter	
Melanoma Choroid and Ciliary Body; Iris	3888	Measured Thickness	
Melanoma Choroid and Ciliary Body; Iris	3891	Microvascular Density	
Melanoma Choroid and Ciliary Body; Iris	3892	Mitotic Count Uveal Melanoma	
Melanoma Skin	3817	Breslow Tumor Thickness	Yes
Melanoma Skin	3936	Ulceration	Yes
Melanoma Skin	3893	Mitotic Rate Melanoma	
NET Schemas	3863	Ki-67	Yes
Plasma Cell Myeloma	3857	High Risk Cytogenetics	
Prostate	3838	Gleason Patterns Clinical	Yes
Prostate	3840	Gleason Score Clinical	Yes
Prostate	3839	Gleason Patterns Pathological	Yes
Prostate	3841	Gleason Score Pathological	Yes
Prostate	3898	Number of Cores Positive	Yes
Prostate	3897	Number of Cores Examined	Yes
Retinoblastoma	3856	Heritable Trait	
Stomach	3855	HER2 Overall Summary	

Rules for Recording Ranges

When a result is documented in a range, code the next highest number based on the lower value. Depending on the SSDI, this may be a whole number, or a decimal.

Note: For some data items, there are specific instructions on how to code ranges. If there are no notes on how to code the ranges, use the general instruction stated here.

Example 1: Melanoma mitotic rate is documented as Mitoses 5-10/mm2

- Code Mitotic Rate Melanoma to 06

Example 2: CRM is documented as 2-3 cm

- Code CRM to 2.1 (Since this SSDI has a decimal point, you code one above the lower value by 0.1 instead of 1)

Histologic Examination

Histologic examination is the assessment of a tissue specimen. Aspiration of fluid (cells) is a cytologic examination. Some data items require analysis of tissue, whereas others can be performed on any specimen (tissue or fluid). Pathological examination can refer to either histological or cytological examination.

Also referred to as “microscopic confirmation.”

Schema Discriminators

Introduced in Collaborative Stage version 2 (CSv2), schema discriminators are used when primary site and/or histology are not sufficient to identify the correct AJCC staging algorithm. Due to the complexity of some of the AJCC Staging System, more than one schema discriminator may be needed to define the correct schema. Three SSDIs (Data Item #'s 3926, 3927 and 3928) are available to collect the information needed to define schema, although most systems that require a schema discriminator need only one.

Schema discriminators are used to define both Schema ID, used to link all combinations of sites and histologies, with the appropriate stage data collection systems and SSDIs, and AJCC ID, used to link AJCC staging eligible sites/histologies with the appropriate AJCC Staging System and staging algorithm.

Schema discriminators do not have a "not applicable" code. If the schema discriminator is needed for some sites or histologies within the schema but not for all, it should be left blank where it is not necessary.

3926: Schema Discriminator 1

Item Length: 1
NAACCR Item #: 3926
XML Parent-NAACCR ID: Tumor-schemaDiscriminator1
NAACCR Alternate Name: None
Active years: 2018+

Description

Captures additional information needed to generate AJCC ID and Schema ID for some anatomic sites. Discriminators can be based on sub site, histology or other features which affect prognosis.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Summary Stage and EOD data collection system.

Codes (The information recorded in Schema Discriminator differs for each anatomic site. See the SSDI manual for most current version of the site-specific codes and coding structures.)

The following are Schema Discriminator 1

3927: Schema Discriminator 2

Item Length: 1
NAACCR Item #: 3927
XML Parent-NAACCR ID: Tumor-schemaDiscriminator2
NAACCR Alternate Name: None
Active years: 2018+

Description

Captures additional information needed to generate AJCC ID and Schema ID for some anatomic sites. Discriminators can be based on sub site, histology or other features which affect prognosis.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Summary Stage and EOD data collection system.

Codes (The information recorded in Schema Discriminator differs for each anatomic site. See the SSDI manual for most current version of the site-specific codes and coding structures.)

The following are Schema Discriminator 2

- 3927: Schema Discriminator 2: Histology Discriminator for 8020/3
- 3927: Schema Discriminator 2: Oropharyngeal p16
- 3927: Schema Discriminator 2: Soft Tissue Sarcoma (C473, C475, C493-C495)

3928: Schema Discriminator 3

Item Length: 1
NAACCR Item #: 3928
XML Parent-NAACCR ID: Tumor-schemaDiscriminator3
NAACCR Alternate Name: None
Active years: 2018+

Description

Captures additional information needed to generate AJCC ID and Schema ID for some anatomic sites. Discriminators can be based on sub site, histology or other features which affect prognosis.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Summary Stage and EOD data collection system.

There are currently no defined Schema Discriminators 3s.

SSDIs Required for Stage

In addition to AJCC T, N, M or EOD fields (primary tumor, regional nodes, and mets), there are SSDIs that are needed to either assign an AJCC stage or derive the EOD Derived Stage Group.

- ***Note***: Required for stage data items do not have a "not applicable" code. These data items must be coded for all applicable cases. If the information is not available, code the appropriate "unknown" value.

For further information on these data items, see the individual data items.

SSDI#/Description	Schema ID#/Description
3829: Esophagus and EGJ Tumor Epicenter	00161: Esophagus (including GE junction) Squamous
3827: Estrogen Receptor Summary	00480: Breast
3915: Progesterone Receptor Summary	00480: Breast
3855: HER2 Overall Summary	00480: Breast
3904: Oncotype Dx Recurrence Score-Invasive	00480: Breast
3837: Gestational Trophoblastic Prognostic Scoring Index	00560: Placenta
3920: PSA (Prostatic Specific Antigen) Lab Value	00580: Prostate
3838: Gleason Patterns Clinical	00580: Prostate
3839: Gleason Patterns Pathological	00580: Prostate
3840: Gleason Score Clinical	00580: Prostate
3841: Gleason Score Pathological	00580: Prostate
3923: S Category Clinical	00590: Testis
3924: S Category Pathological	00590: Testis
3856: Heritable Trait	00680: Retinoblastoma
3804: Adenopathy	00795: Lymphoma (CLL/SLL)
3811: Anemia	00795: Lymphoma (CLL/SLL)
3885: Lymphocytosis	00795: Lymphoma (CLL/SLL)
3907: Organomegaly	00795: Lymphoma (CLL/SLL)
3933: Thrombocytopenia	00795: Lymphoma (CLL/SLL)
3910: Peripheral Blood Involvement	00811: Mycosis Fungoides
3857: High Risk Cytogenetics	00821: Plasma Cell Myeloma
3869: LDH Level	00821: Plasma Cell Myeloma
3930: Serum Albumin Pretreatment Level	00821: Plasma Cell Myeloma
3931: Serum Beta-2 Microglobulin Pretreatment Level	00821: Plasma Cell Myeloma

SSDIs used for EOD Derived Stage Group

In addition to the SSDIs required for AJCC stage, the following SSDIs are used for the EOD Derived Stage group. These SSDIs are only required for those registries that are collecting EOD but may be collected by others.

SSDI#/Description	Schema ID#/Description
3883: LN Size	00100: Oropharynx HPV-Associated 09100: Oropharynx HPV-Associated
3913: Pleural Effusion	00370: Pleura Mesothelioma 09370: Pleural Mesothelioma
3817: Breslow's Depth	00470: Melanoma Skin
3936: Ulceration	00470: Melanoma Skin
3869: LDH Level	00470: Melanoma Skin
3882: LN Positive Axillary Level I-II	00480: Breast
3911: Peritoneal Cytology	00528: Cervix Sarcoma
3911: Peritoneal Cytology	00530: Corpus Carcinoma and Carcinosarcoma
3911: Peritoneal Cytology	00541: Corpus Sarcoma
3911: Peritoneal Cytology	00542: Corpus Adenosarcoma
3887: Measured Basal Diameter	00672: Melanoma Choroid and Ciliary Body
3888: Measured Thickness	00672: Melanoma Choroid and Ciliary Body

3800: Schema ID (2018+)

Item Length: 5
NAACCR Item #: 3800
XML Parent-NAACCR ID: Tumor-schemaID
NAACCR Alternate Name: None
Active years: 2018+

Description

The derived values in this data item link Site-Specific Data Items (including grade data items) with the appropriate site/histology grouping and account for every combination of primary site and histology. The values for this data item are derived based on primary site, histology, and schema discriminator fields (when required). The derived values link Site-Specific Data Items with the appropriate site/histology grouping.

- For *example*, the Schema ID for an adenocarcinoma of the lung is 00360. This value links the Site-Specific Data Items associated with adenocarcinoma of the lung: Separate Tumor Nodules [3929], Visceral and Parietal Pleural Invasion [3937], and Pleural Effusion [3913].

The Schema ID would also link to the appropriate grade data items an adenocarcinoma of the lung. The AJCC ID [995] code for Lung is 36. The AJCC ID [995] would link to the AJCC TNM Data items (Clin T, Clin N, Etc.) specific to Lung. AJCC ID [995] will not be assigned when a site/histology combination is not eligible for TNM staging.

Rationale

The purpose of the derived Schema ID is to link the appropriate Site-Specific Data Items with the patient's primary site/histology. This data item is similar to AJCC ID [995] but includes additional site/histologies that may not be eligible for TNM staging using the current AJCC Staging Manual. AJCC ID [995] is left blank if a case is not eligible for TNM Staging using the current AJCC Staging Manual. Separating AJCC ID [995] and the Schema ID allows coding of Site-Specific Data Items for site/histology combinations that are not eligible for an AJCC Stage but are eligible for Summary Stage. This data item will also be used to develop edits and could potentially be used for analysis. Codes: See the NAACCR Site-Specific Data Item webpage for codes. Each Site-Specific Data Item (SSDI) applies only to selected primary sites, histologies, and years of diagnosis.

Definition

In **Collaborative Stage v2 (CSv2),** 153 Schemas were defined based on site/histology and used to assign applicable site-specific factors (SSFs) and staging algorithms. Beginning on January 1, 2018, SSFs are replaced with SSDIs, and site-specific grading systems are used and Schema ID [3800] is used to link all combinations of sites and histologies (using additional information from schema discriminators if needed) with the appropriate SSDIs and site-specific grading system. A separate data item, AJCC ID [995], is used to link AJCC staging eligible sites/histologies (using additional information from schema discriminators if needed) with the appropriate AJCC Staging System and staging algorithm. Schema ID and AJCC ID will be derived by registry software based on site and histology codes entered by the registrar.

[Schema ID Table]

Schema ID#/Description	SSDI #/Description	Years Applicable
00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)	**3926:** Schema Discriminator 1: Occult Head and Neck Lymph Nodes (primary site C760)	**2018+**
	3831: Extranodal Extension Head and Neck Clinical	**2018+**
	3832: Extranodal Extension Head and Neck Pathological	**2018+**
	3876: LN Head and Neck Levels I-III	**2018+**
	3877: LN Head and Neck Levels IV-V	**2018+**
	3878: LN Head and Neck Levels VI-VII	**2018+**
	3879: LN Head and Neck Other	**2018+**
	3883: LN Size	**2018+**
00071: Lip (2018+) **00072: Tongue Anterior (2018+)** **00073: Gum (2018+)** **00074: Floor of Mouth (2018+)** **00075: Palate Hard (2018+)** **00076: Buccal Mucosa (2018+)** **00077: Mouth Other (2018+)**	**3831**: Extranodal Extension Head and Neck Clinical	**2018+**
	3832: Extranodal Extension Head and Neck Pathological	**2018+**
	3883: LN Size	**2018+**
00080: Major Salivary Glands (2018-2025) **09081: Major Salivary Glands (2026+)**	**3831**: Extranodal Extension Head and Neck Clinical	**2018+**
	3832: Extranodal Extension Head and Neck Pathological	**2018+**
	3883: LN Size	**2018+**
00090: Nasopharynx (2018-2024) **09090: Nasopharynx (2025+)**	**3926**: Schema Discriminator 1: Nasopharynx/PharyngealTonsil	**2018-2024**
	3831: Extranodal Extension Head and Neck Clinical	**2018+**
	3832: Extranodal Extension Head and Neck Pathological	**2018+**
	3883: LN Size	**2018+**
00100: Oropharynx HPV-Associated (2018-2025) **09100: Oropharynx HPV-Associated (2026+)** **00111: Oropharynx-Independent (2018+)**	**3926**: Schema Discriminator 1: Nasopharynx/PharyngealTonsil	**2018-2024**
	3927: Schema Discriminator 2: Oropharyngeal p16	**2018+**
	3831: Extranodal Extension Head and Neck Clinical	**2018+**
	3832: Extranodal Extension Head and Neck Pathological	**2018+**
	3883: LN Size	**2018+**
00112: Hypopharynx (2018+)	**3831**: Extranodal Extension Head and Neck Clinical	**2018+**
	3832: Extranodal Extension Head and Neck Pathological	**2018+**
	3883: LN Size	**2018+**

Schema ID#/Description	SSDI #/Description	Years Applicable
00118: Pharynx Other (2018+)	No SSDIs defined for this Schema ID	**NA**
00119: Middle Ear (2018+)	No SSDIs defined for this Schema ID	**NA**
00121: Maxillary Sinus (2018+) **00122: Nasal Cavity and Ethmoid Sinuses (2018+)**	**3831**: Extranodal Extension Head and Neck Clinical **3832**: Extranodal Extension Head and Neck Pathological **3883**: LN Size	**2018+** **2018+** **2018+**
00128: Sinus Other (2018+)	No SSDIs defined for this Schema ID	**NA**
00130: Larynx Other (2018+) **00131: Larynx Supraglottic (2018+)** **00132: Larynx Glottic (2018+)** **00133: Larynx SubGlottic (2018+)**	**3831**: Extranodal Extension Head and Neck Clinical **3832**: Extranodal Extension Head and Neck Pathological **3883**: LN Size	**2018+** **2018+** **2018+**
00140: Mucosal Melanoma of the Head and Neck (2018+)	**3831**: Extranodal Extension Head and Neck Clinical **3832**: Extranodal Extension Head and Neck Pathological **3876**: LN Head and Neck Levels I-III **3877**: LN Head and Neck Levels IV-V **3878**: LN Head and Neck Levels VI-VII **3879**: LN Head and Neck Other **3883**: LN Size	**2018+** **2018+** **2018+** **2018+** **2018+** **2018+** **2018+**
00150: Cutaneous Carcinoma of the Head and Neck (2018+)	**3858**: High Risk Histologic Features **3883**: LN Size **3909**: Perineural Invasion	**2018+** **2018+** **2018+**
00161: Esophagus (including GE junction) Squamous (2018+)	**3926**: Schema Discriminator 1: EsophagusGE Junction (EGJ)/Stomach) (primary site C160) **3927**: Schema Discriminator 2: Histology Discriminator for 8020/3 **3829**: Esophagus and EGJ Tumor Epicenter **3855:** HER2 Overall Summary	**2018+** **2018+** **2018+** **2021+**
00169: Esophagus (including GE junction) (excluding Squamous) (2018+)	**3926**: Schema Discriminator 1: EsophagusGE Junction (EGJ)/Stomach) (primary site C160) **3927**: Schema Discriminator 2: Histology Discriminator for 8020/3 **3855:** HER2 Overall Summary	**2018+** **2018+** **2021+**
00170: Stomach (2018+)	**3926**: Schema Discriminator 1: EsophagusGE Junction (EGJ)/Stomach) (primary site C160) **3855:** HER2 Overall Summary	**2018+** **2021+**
00180: Small Intestine (2018+)	No SSDIs defined for this Schema ID	**NA**
00190: Appendix (2018-2022) **09190: Appendix (2023+)**	**3819**: CEA Pretreatment Interpretation **3820**: CEA Pretreatment Lab Value	**2018-2022** **2018-2022**

Schema ID#/Description	SSDI #/Description	Years Applicable
00200: Colon and Rectum (2018+)	**3819**: CEA Pretreatment Interpretation	**2018+**
	3820: CEA Pretreatment Lab Value	**2018+**
	3823: Circumferential Resection Margin (CRM)	**2018+**
	3866: KRAS	**2018+**
	3890: Microsatellite Instability (MSI)	**2018+**
	3909: Perineural Invasion	**2018+**
	3934: Tumor Deposits	**2018+**
	3940: BRAF Mutational Analysis	**2021+**
	3941: NRAS Mutational Analysis	**2021+**
00210: Anus (2018-2022) **09210: Anus (2023+)**	No SSDIs defined for this Schema ID	**NA**
00220: Liver (2018+)	**3809**: AFP Pretreatment Interpretation	**2018+**
	3810: AFP Pretreatment Lab Value	**2018+**
	3813: Bilirubin Pretreatment Total Lab Value	**2018+**
	3814: Bilirubin Pretreatment Unit of Measure	**2018+**
	3824: Creatinine Pretreatment Lab Value	**2018+**
	3825: Creatinine Pretreatment Unit of Measure	**2018+**
	3835: Fibrosis Score	**2018+**
	3860: International Normalized Ratio	**2018+**
00230: Bile Ducts Intrahepatic (2018+)	**3835**: Fibrosis Score	**2018+**
	3917: Primary Sclerosing Cholangitis	**2018+**
	3935: Tumor Growth Pattern	**2018+**
00241: Gallbladder	No SSDIs defined for this Schema ID	**NA**
00242: Cystic Duct (2018+)	**3926**: Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct	**2018+**
00250: Bile Ducts Perihilar (2018+)	**3926**: Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct	**2018+**
	3917: Primary Sclerosing Cholangitis	**2018+**
00260: Bile Duct Distal (2018+)	**3926**: Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct	**2018+**
00270: Ampulla of Vater (2018+)	No SSDIs defined for this Schema ID	**NA**
00278: Biliary Other (2018+)	No SSDIs defined for this Schema ID	**NA**
00280: Pancreas (2018+)	**3942:** CA 19-9 PreTx Lab Value	**2021+**
00288: Digestive Other (2018+)	No SSDIs defined for this Schema ID	**NA**
00290: NET Stomach (2018-2023) **09290: NET Stomach (2024+)**	**3863:** Ki-67	**2021-2023, 2024+**

Schema ID#/Description	SSDI #/Description	Years Applicable
00301: NET Duodenum (2018-2023) **09301: NET Duodenum (2024+)** **00302: NET Ampulla of Vater (2018-2023)** **09302: NET Ampulla of Vater (2024+)**	**3863:** Ki-67	**2021-2023, 2024+**
00310: NET Jejunum and Ileum (2018-2023) **09310: NET Jejunum and Ileum (2024+)**	**3863:** Ki-67	**2021-2023, 2024+**
00320: NET Appendix (2018-2023) **09320: NET Appendix (2024+)**	**3863:** Ki-67	**2021-2023, 2024+**
00330: NET Colon and Rectum (2018-2023) **09330: NET Colon and Rectum (2024+)**	**3863:** Ki-67	**2021-2023, 2024+**
00340: NET Pancreas (2018-2023) **09340: NET Pancreas (2024+)**	**3863:** Ki-67	**2021-2023, 2024+**
00350: Thymus (2018-2024) **09350: Thymus (2025+)**	No SSDIs defined for this Schema ID	**NA**
00358: Trachea	No SSDIs defined for this Schema ID	**NA**
00360: Lung (2018-2024) **09360: Lung (2025+)**	**3929**: Separate Tumor Nodules **3937**: Visceral and Parietal Pleural Invasion **3938:** ALK Rearrangement **3939:** EGFR Mutational Analysis **1174:** PD-L1 **1176:** Lung STAS	**2018-2024** **2018-2024** **2018-2024** **2018-2024** **2025+** **2026+**
00370: Pleura Mesothelioma (2018-2024) **09370: Pleura Mesothelioma (2025+)**	**3913**: Pleural Effusion	**2018-2024, 2025+**
00378: Respiratory Other (2018+)	No SSDIs defined for this Schema ID	**NA**
00381: Bone Appendicular Skeleton (2018+) **00382: Bone Spine (2018+)** **00383: Bone Pelvis (2018+)**	**3908**: Percent Necrosis Post Neoadjuvant	**2018+**
00400: Soft Tissue Head and Neck (2018+)	**3815**: Bone Invasion	**2018+**
00410: Soft Tissue Trunk and Extremities (2018+)	**3815**: Bone Invasion **3927:** Schema Discriminator 2: Soft Tissue Trunk and Extremities/ Soft Tissue Abdomen and Thoracic	**2018+** **2018+**

Schema ID#/Description	SSDI #/Description	Years Applicable
00421: Soft Tissue Abdomen and Thoracic (2018+)	**3815**: Bone Invasion **3927:** Schema Discriminator 2: Soft Tissue Trunk and Extremities/ Soft Tissue Abdomen and Thoracic	**2018+** **2018+**
00422: Heart, Mediastinum and Pleura (2018+)	**3815**: Bone Invasion	**2018+**
00430: GIST (2018+)	**3926**: Schema Discriminator 1: Primary Peritoneum Tumor **3865**: KIT Gene Immunohistochemistry	**2018+** **2018+**
00440: Retroperitoneum (2018+)	**3815**: Bone Invasion	**2018+**
00450: Soft Tissue Rare (2018+)	**3815**: Bone Invasion	**2018+**
00459: Soft Tissue Other (2018+)	**3815**: Bone Invasion **3926:** Schema Discriminator 1: Occult Head and Neck Lymph Nodes (primary site C760) **3927:** Schema Discriminator 2: Soft Tissue Sarcoma	**2018+** **2018+** **2018+**
00458: Kaposi Sarcoma	No SSDIs defined for this Schema ID	**NA**
00460: Merkel Cell Carcinoma (2018+)	**3830**: Extranodal Extension Clin (non-Head & Neck) **3833**: Extranodal Extension Path (non-Head & Neck) **3880**: LN Isolated Tumor Cells (ITC) **3918**: Profound Immune Suppression	**2018+** **2018+** **2018+** **2018+**
00470: Melanoma Skin (2018+)	**3817**: Breslow Tumor Thickness **3936**: Ulceration **3893**: Mitotic Rate Melanoma **3932**: LDH Lab Value **3869**: LDH Level **3870**: LDH Upper Limits of Normal **3961:** Clinical Margin Width	**2018+** **2018+** **2018+** **2018+** **2018+** **2018+** **2023+**
00478: Skin Other (2018+)	No SSDIs defined for this Schema ID	**NA**

Schema ID#/Description	SSDI #/Description	Years Applicable
00480: Breast (2018+)	**3826**: Estrogen Receptor Percent Positive or Range	**2018+**
	3827: Estrogen Receptor Summary	**2018+**
	3914: Progesterone Receptor Percent Positive or Range	**2018+**
	3915: Progesterone Receptor Summary	**2018+**
	3855: HER2 Overall Summary	**2018+**
	3903: Oncotype Dx Recurrence Score-DCIS	**2018+**
	3904: Oncotype Dx Recurrence Score-Invasive	**2018+**
	3905: Oncotype Dx Risk Level-DCIS	**2018+**
	3906: Oncotype Dx Risk Level-Invasive	**2018+**
	3863: Ki-67	**2018+**
	3882: LN Positive Axillary Level I-II	**2018+**
	3922: Response to Neoadjuvant Therapy	**2018+**
	1178: Residual Cancer Burden	**2026+**
	1179: RCB Class	**2026+**
	***3828**: Estrogen Receptor Total Allred Score*	***2018-2022***
	***3916**: Progesterone Total Allred Score*	***2018-2022***
	***3850**: HER2 IHC Summary*	***2018-2020***
	***3851**: HER2 ISH Dual Probe Copy Number*	***2018-2020***
	***3852**: HER2 ISH Dual Probe Ratio*	***2018-2020***
	***3853**: HER2 ISH Single Probe Copy Number*	***2018-2020***
	***3854**: HER2 ISH Summary*	***2018-2020***
	3894: Multigene Signature Method	***2018-2025***
	3895: Multigene Signature Results	***2018-2025***
00500: Vulva (2018-2023) **09500: Vulva (2024+)**	**3836**: FIGO Stage (Vulva)	**2018+**
	3959: LN Status: Femoral-Inguinal	**2018+**
	3871: LN Assessment Method Femoral-Inguinal	**2018+**
	3957: LN Status: Pelvic	**2018+**
	3873: LN Assessment Method Pelvic	**2018+**
	3881: LN Laterality	**2018+**
	3956: p16	**2024+**
00510: Vagina (2018+)	**3836**: FIGO Stage (Vagina)	**2018+**
	3959: LN Status: Femoral-Inguinal	**2018+**
	3871: LN Assessment Method Femoral-Inguinal	**2018+**
	3958: LN Status: Para-aortic	**2018+**
	3872: LN Assessment Method Para-aortic	**2018+**
	3957: LN Status: Pelvic	**2018+**
	3873: LN Assessment Method Pelvic	**2018+**
	3874: LN Distant Assessment Method	**2018+**
	3875: LN Distant: Mediastinal, Scalene	**2018+**

Schema ID#/Description	SSDI #/Description	Years Applicable
00520: Cervix (2018-2020) **09520: Cervix (2021+)**	**3836**: FIGO Stage (Cervix)	**2018-2020**
	3958: LN Status: Para-aortic	**2018-2020**
	3872: LN Assessment Method Para-aortic	**2018-2020**
	3957: LN Status: Pelvic	**2018-2020**
	3873: LN Assessment Method Pelvic	**2018-2020**
	3875: LN Distant: Mediastinal, Scalene	**2018-2020**
	3874: LN Distant Assessment Method	**2018-2020**
	3956: p16	**2021+**
00528: Cervix Sarcoma	**3836**: FIGO Stage (Cervix Sarcoma)	**2021+**
	3899: Number of Examined Para-Aortic Nodes	**2021+**
	3900: Number of Examined Pelvic Nodes	**2021+**
	3901: Number of Positive Para-Aortic Nodes	**2021+**
	3902: Number of Positive Pelvic Nodes	**2021+**
	3911: Peritoneal Cytology	**2021+**
00530: Corpus Carcinoma and Carcinosarcoma (2018+)	**3836**: FIGO Stage (Corpus Carcinoma and Carcinosarcoma)	**2018+**
	3890: Microsatellite Instability	**2026+**
	3899: Number of Examined Para-Aortic Nodes	**2018+**
	3900: Number of Examined Pelvic Nodes	**2018+**
	3901: Number of Positive Para-Aortic Nodes	**2018+**
	3902: Number of Positive Pelvic Nodes	**2018+**
	3911: Peritoneal Cytology	**2018+**
00541: Corpus Sarcoma (2018+)	**3836**: FIGO Stage (Corpus Sarcoma)	**2018+**
	3899: Number of Examined Para-Aortic Nodes	**2018+**
	3900: Number of Examined Pelvic Nodes	**2018+**
	3901: Number of Positive Para-Aortic Nodes	**2018+**
	3902: Number of Positive Pelvic Nodes	**2018+**
	3911: Peritoneal Cytology	**2018+**
00542: Corpus Adenosarcoma (2018+)	**3836**: FIGO Stage (Corpus Adenosarcoma)	**2018+**
	3899: Number of Examined Para-Aortic Nodes	**2018+**
	3900: Number of Examined Pelvic Nodes	**2018+**
	3901: Number of Positive Para-Aortic Nodes	**2018+**
	3902: Number of Positive Pelvic Nodes	**2018+**
	3911: Peritoneal Cytology	**2018+**
00551: Ovary (2018+)	**3818**: CA-125 Pretreatment Interpretation	**2018+**
00552: Primary Peritoneal Carcinoma (2018+)	**3836:** FIGO Stage (Ovary, Fallopian Tube and Primary Peritoneal Carcinomas)	**2018+**
00553: Fallopian Tube (2018+)	**3921**: Residual Tumor Volume Post Cytoreduction	**2018+**
00558: Adnexa Uterine Other (2018+)	No SSDIs defined for this Schema ID	**NA**
00559: Genital Female Other (2018+)	No SSDIs defined for this Schema ID	**NA**

Schema ID#/Description	SSDI #/Description	Years Applicable
00560: Placenta (2018+)	**3836**: FIGO Stage (Gestational Trophoblastic Tumors)	**2018+**
	3837: Gestational Trophoblastic Prognostic Scoring Index	**2018+**
00570: Penis (2018+)	**3830:** Extranodal Extension Clin (non-Head and Neck)	**2018+**
	3833: Extranodal Extension Path (non-Head and Neck)	**2018+**
00580: Prostate (2018+)	**3838:** Gleason Patterns Clinical	**2018+**
	3839: Gleason Patterns Pathological	**2018+**
	3840: Gleason Score Clinical	**2018+**
	3841: Gleason Score Pathological	**2018+**
	3842: Gleason Tertiary Pattern	**2018+**
	3897: Number of Cores Examined	**2018+**
	3898: Number of Cores Positive	**2018+**
	3920: PSA (Prostatic Specific Antigen) Lab Value	**2018+**
00590: Testis (2018+)	**3805**: AFP Post-Orchiectomy Lab Value	**2018+**
	3806: AFP Post-Orchiectomy Range	**2018+**
	3807: AFP Pre-Orchiectomy Lab Value	**2018+**
	3808: AFP Pre-Orchiectomy Range	**2018+**
	3846: hCG Post-Orchiectomy Lab Value	**2018+**
	3847: hCG Post-Orchiectomy Range	**2018+**
	3848: hCG Pre-Orchiectomy Lab Value	**2018+**
	3849: hCG Pre-Orchiectomy Range	**2018+**
	3867: LDH Post-Orchiectomy Range	**2018+**
	3868: LDH Pre-Orchiectomy Range	**2018+**
	3923: S Category Clinical	**2018+**
	3924: S Category Pathological	**2018+**
00598: Genital Male Other (2018+)	No SSDIs defined for this Schema ID	**NA**
00600: Kidney Parenchyma (2018+)	**3861**: Ipsilateral Adrenal Gland Involvement	**2018+**
	3864: Invasion Beyond Capsule	**2018+**
	3886: Major Vein Involvement	**2018+**
	3925: Sarcomatoid Features	**2018+**
00610: Kidney Renal Pelvis (2018+)	No SSDIs defined for this Schema ID	**NA**
00620: Bladder (2018+)	No SSDIs defined for this Schema ID	**NA**
00631: Urethra (2018+) **00633: Urethra-Prostatic (2018+)**	**3926**: Schema Discriminator 1 (Urethra/Prostatic Urethra)	**2018+**
00638: Urinary Other (2018+)	No SSDIs defined for this Schema ID	**NA**
00640: Skin Eyelid (2018+)	**3909**: Perineural Invasion	**2018+**
00650: Conjunctiva (2018+)	No SSDIs defined for this Schema ID	**NA**

Schema ID#/Description	SSDI #/Description	Years Applicable
00660: Melanoma Conjunctiva (2018+)	**3888**: Measured Thickness	**2018+**
00671: Melanoma Iris (2018+) **00672: Melanoma Choroid and Ciliary Body (2018+)**	**3926:** Schema Discriminator 1 (Melanoma Ciliary Body/Melanoma Iris) **3821**: Chromosome 3 Status **3822**: Chromosome 8q Status **3834**: Extravascular Matrix Patterns **3887**: Measured Basal Diameter **3888**: Measured Thickness **3891**: Microvascular Density **3892**: Mitotic Count Uveal Melanoma	**2018+** **2018+** **2018+** **2018+** **2018+** **2018+** **2018+** **2018+**
00680: Retinoblastoma (2018+)	**3856:** Heritable Trait	**2018+**
00690: Lacrimal Gland (2018+)	**3926:** Schema Discriminator 1 (Lacrimal Gland/Lacrimal Sac) **3803**: Adenoid Cystic Basaloid Pattern **3909**: Perineural Invasion	**2018+** **2018+** **2018+**
00698: Lacrimal Sac (2018+)	**3926:** Schema Discriminator 1 (Lacrimal Gland/Lacrimal Sac)	**2018+**
00700: Orbital Sarcoma (2018+)	No SSDIs defined for this Schema ID	**NA**
00710: Lymphoma Ocular Adnexa (2018+)	No SSDIs defined for this Schema ID	**NA**
00718: Eye Other (2018+)	No SSDIs defined for this Schema ID	**NA**
00721: Brain (2018-2022) **09721: Brain (2023+)**	**3801**: Chromosome 1p: Loss of Heterozygosity (LOH) **3802**: Chromosome 19q: Loss of Heterozygosity (LOH) **3816**: Brain Molecular Markers **3889**: Methylation of O6-Methylguanine-Methyltransferase **3964:** Brain Primary Tumor Location	**2018-2022** **2018-2022** **2018-2022** **2018-2022** **2018-2022** **2024+**
00722: CNS Other (2018-2022) **09722: CNS Other (2023+)**	**3801**: Chromosome 1p: Loss of Heterozygosity (LOH) **3802**: Chromosome 19q: Loss of Heterozygosity (LOH) **3816**: Brain Molecular Markers **3889**: Methylation of O6-Methylguanine-Methyltransferase	**2018-2022; 2023+** **2018-2022; 2023+** **2018-2022; 2023+** **2018-2022; 2023+**
00723: Intracranial Other (2018-2022) **09723: Intracranial Other (2023+)**	No SSDIs defined for this Schema ID	**NA**
09724: Medulloblastoma (2023+)	**3816**: Brain Molecular Markers	**2023+**

Schema ID#/Description	SSDI #/Description	Years Applicable
00730: Thyroid (2018+)	**3926**: Schema Discriminator 1 (Thyroid Gland/Thyroglossal Duct)	**2018+**
00740: Thyroid Medullary (2018+)	**3926**: Schema Discriminator 1 (Thyroid Gland/Thyroglossal Duct)	**2018+**
00750: Parathyroid (2018+)	No SSDIs defined for this Schema ID	**NA**
00760: Adrenal Gland (2018+)	No SSDIs defined for this Schema ID	
00770: NET Adrenal Gland (2018+)	No SSDIs defined for this Schema ID	
00778: Endocrine Other (2018+)	No SSDIs defined for this Schema ID	
00790: Lymphoma (excluding CLL/SLL) (2018+)	**3926**: Schema Discriminator 1 (Histology Discriminator for 9591/3) **3812**: B Symptoms **3859**: HIV Status **3896**: NCCN International Prognostic Index (IPI) **1172**: PTLD	**2018+** **2018+** **2018+** **2018+** **2025+**
00795: Lymphoma-CLL/SLL (2018+)	**3812**: B Symptoms **3859**: HIV Status **3896**: NCCN International Prognostic Index (IPI) **3804:** Adenopathy **3811:** Anemia **3885:** Lymphocytosis **3907:** Organomegaly **3933:** Thrombocytopenia **3955:** Derived Rai Stage **1172**: PTLD	**2018+** **2018+** **2018+** **2018+** **2018+** **2018+** **2018+** **2018+** **2018+** **2025+**
00811: Mycosis Fungoides (2018+)	**3910:** Peripheral Blood Involvement	**2018+**
00812: Primary Cutaneous Lymphomas (excluding Mycosis Fungoides) (2018+)	**1172**: PTLD	**2025+**
00821: Plasma Cell Myeloma (2018+)	**3926**: Schema Discriminator 1 (Multiple Myeloma Terminology) **3857**: High Risk Cytogenetics **3869**: LDH Level **3930**: Serum Albumin Pretreatment Level **3931**: Serum Beta-2 Microglobulin Pretreatment Level **1172**: PTLD	**2018+** **2018+** **2018+** **2018+** **2018+** **2025+**

Schema ID#/Description	SSDI #/Description	Years Applicable
00822: Plasma Cell Disorders (2018+)	**1172**: PTLD	**2025+**
00830: HemeRetic (2018+)	**3926**: Schema Discriminator 1 (Histology Discriminator for 9591/3) **3862**: JAK2	**2018+** **2018+**
99999: ILL-DEFINED OTHER (2018+)	**3926:** Schema Discriminator 1 (Occult Head and Neck Lymph Nodes) **(Primary site C760 only)**	**2018+**

00060: Cervical Lymph Nodes and Unknown Primary

3926: Schema Discriminator 1

Item Length: 1
NAACCR Item #: 3926
XML Parent-NAACCR ID: Tumor-schemaDiscriminator1
NAACCR Alternate Name: Schema Discriminator 1: Occult Head and Neck Lymph Nodes
Active years: 2018+
Schema(s):

- 00060: Cervical Lymph Nodes and Unknown Primary
- 00459: Soft Tissue Other
- 99999: Ill-Defined Other

Description

In AJCC 8th edition, a new chapter was introduced for situations when there are positive cervical nodes (head and neck nodes for Levels I-VII, and other group), however, the primary tumor is not evident (occult tumor), and the primary tumor is suspected to be from the head and neck region (primary sites C00-C14, C30-32).

- If the differential diagnosis includes non-head and neck sites, the primary site should be coded to C809
    - ***Example***: path report states metastasis to the cervical lymph node could be from a head and neck primary, lung primary, or gynecologic primary
- If there is no indication that the cervical lymph node is from a head and neck site, then the primary site should be coded to C809
- If the tumor is found to be EBV+ or p16+. See Coding Guidelines below.
- If the tumor is suspected to be from a head and neck site, or a potential head and neck site is indicated by the physician, see Coding Guidelines below.

To develop a software algorithm that can be used to send the registrar to the right chapter/schema, this schema discriminator was developed.
To get to this schema discriminator, the registrar will code C760 (head and neck, NOS) when there is a suspected head and neck tumor, yet the primary site is not known, and/or the primary tumor was not identified. The schema discriminator will then be brought up.

- **Note**: If the physician "suspects" or "assigns" a specific head and neck subsite, the registrar is still to assign C760 so that the correct staging information can be abstracted.
    - ***Example***: FNA of cervical lymph node metastases shows squamous cell carcinoma, p16 negative. Workup shows no evidence of primary tumor, although physician states this may be a laryngeal primary based on "best guess".

- Even though the primary site is suspected to be larynx, primary site would still be coded to C760. For all head and neck sites, except for Oropharynx HPV-Associated and Nasopharynx EBV positive, no evidence of primary tumor (T0) does not exist in the individual AJCC chapters or EOD schemas. These cases are collected as unknown head and neck primary (C760), which will have no evidence of primary tumor. This Schema ID was designed specifically to group together these cases of an occult primary, a tumor that is not identified on physical exam or imaging techniques.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Summary Stage and EOD data collection system.

Additional Information

Source documents: imaging, pathology report, p16 results, EBV results

Notes

Note: Schema Discriminator for C760

- This schema discriminator is used to discriminate between head and neck tumors with unknown primary site coded as C760.
- **00060: Cervical Lymph Nodes and Unknown Primary** Occult head and neck tumor with cervical metastasis in Levels I-VII, and other group lymph nodes without a p16 immunostaining or with negative results and without an Epstein-Barr virus (EBV) encoded small RNAs (EBER) by in situ hybridization performed or with negative results are staged using the AJCC Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck Staging System. **Assign primary site C760; code the schema discriminator accordingly.**
- **00090: Nasopharynx 8th (2018-2024) and 09090: Nasopharynx V9 (2025+)** Occult head and neck tumors with cervical metastasis in Levels I-VII, and other group lymph nodes that is positive for Epstein-Barr virus (EBV+) (regardless of p16 status) encoded small RNAs (EBER) identified by in situ hybridization are staged using the AJCC Nasopharynx Staging System. **Assign primary site C119; do NOT code this discriminator**
- **00100: Oropharynx HPV-Associated 8th (2018-2025) and 09100: Oropharynx HPV-Associated V9 (2026+)** Occult head and neck tumors with cervical metastasis in Levels I-VII, and other group lymph nodes, p16 positive with histology consistent with HPV-associated oropharyngeal carcinoma (OPC), are staged using the AJCC Oropharynx HPV-Associated Staging System. **Assign primary site C109; do NOT code this discriminator**

- **99999: Ill-Defined Other**
  If the tumor is not occult or does not have cervical metastasis in Levels I-VII, and other group lymph nodes, it is not included in the AJCC Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck Staging System and will be classified as Ill-Defined Other for Summary Staging

Coding Guidelines

1) Code 0: Not occult

- Primary tumor is evident in the head and neck region; however, a specific primary site cannot be identified.
- If overlapping lesions are evident and the primary site cannot be determined, this would not be a C760, but C148 (overlapping lesions) (Schema ID 00118: Pharynx Other)
- For tumors in this category, C760 should be used sparingly. If C760 is assigned, this would be collected in the following schemas: Schema ID 99999: Ill-Defined Other OR Schema ID 00450: Soft Tissue Other (if specified sarcoma)
  - ***Examples include*** Cases with limited information, historical case

2) Code 1: Occult, Negative cervical nodes (regional head and neck nodes)

- No evidence of primary tumor or positive cervical lymph nodes (head and neck regional lymph nodes), suspected head and neck primary.
- This type of situation would be rare but would probably be diagnosed based on metastatic disease, including distant lymph nodes (Mediastinal [excluding superior mediastinal node(s)])
- This case would be collected in the **Ill-Defined Other** schema, or **Soft Tissue Other** (if specified sarcoma).

3) Code 2: Not tested for EBV or p16 in head and neck regional nodes (EBV and p16 both unknown)

- There is no documentation in the record regarding p16 or EBV.

4) Code 3: Unknown EBV, p16 negative in head and neck regional nodes

- p16 is done and reported as negative. No documentation in the medical record regarding EBV.

5) Code 4: Unknown p16, EBV negative in head and neck regional nodes

- EBV done and reported as negative. No documentation in the medical record regarding p16.

6) Code 5: Negative for both EBV and p16 in head and neck regional nodes

- Both EBV and p16 done and reported as negative

Code	Description	Schema ID #/Description
0	Not Occult	99999: Ill Defined Other 00459: Soft Tissue Other (8941/3 only)
1	Occult, Negative cervical nodes (regional head and neck nodes)	99999: Ill Defined Other 00459: Soft Tissue Other (8941/3 only)
2	Not tested for EBV or p16 in head and neck regional nodes (EBV and p16 both unknown)	00060: Cervical Lymph Nodes and Unknown Primary
3	Unknown EBV, p16 negative in head and neck regional nodes	00060: Cervical Lymph Nodes and Unknown Primary
4	Unknown p16, EBV negative in head and neck regional nodes	00060: Cervical Lymph Nodes and Unknown Primary
5	Negative for both EBV and p16 in head and neck regional nodes	00060: Cervical Lymph Nodes and Unknown Primary
<Blank>	Not C760, discriminator does not apply Positive p16 in head and neck regional nodes, EBV unknown or negative Assign primary site C109 Positive EBV in head and neck regional nodes, p16 positive, negative, or unknown Assign primary site C119	Various 00100: Oropharynx HPV-Associated 8th (2018-2025) 09100: Oropharynx HPV-Associated V9 (2026+) 00090: Nasopharynx 8th (2018-2024) 09090: Nasopharynx V9 (2025+)

00060: Cervical Lymph Nodes and Unknown Primary

3831: Extranodal Extension Head and Neck Clinical

Item Length: 1
NAACCR Item #: 3831
XML Parent-NAACCR ID: Tumor-extranodalExtensionHeadNeckClin
NAACCR Alternate Name: Extranodal Extension Head and Neck Clinical
Active years: 2018+
Schema(s):

- 00060: Cervical Lymph Nodes and Unknown Primary
- 00071: Lip
- 00072: Tongue Anterior
- 00073: Gum
- 00074: Floor of Mouth
- 00075: Palate Hard
- 00076: Buccal Mucosa
- 00077: Mouth Other
- 00080: Major Salivary Glands [8th: 2018-2025]
- 09081: Major Salivary Glands [V9: 2026+]
- 00090: Nasopharynx [8th: 2018-2024]
- 09090: Nasopharynx [V9: 2025+]
- 00100: Oropharynx HPV-Associated [8th: 2018-2025]
- 09100: Oropharynx HPV-Associated [V9: 2026+]
- 00111: Oropharynx HPV-Independent
- 00112: Hypopharynx
- 00121: Maxillary Sinus
- 00122: Nasal Cavity and Ethmoid Sinus
- 00130: Larynx Other
- 00131: Larynx Supraglottic
- 00132: Larynx Glottic
- 00133: Larynx Subglottic
- 00140: Melanoma Head and Neck

Description

Extranodal extension is defined as “the extension of a nodal metastasis through the lymph node capsule into adjacent tissue” and is a prognostic factor for most head and neck tumors. This data item pertains to extranodal extension detected radiologically or by physical examination and may not correlate with pathological extranodal extension.

ENE on physical examination (clinical ENE, cENE) is described in the AJCC Head and Neck Staging System as “unambiguous evidence of gross ENE on clinical examination (e.g., invasion of skin,

infiltration of musculature, tethering to adjacent structures, or cranial nerve, brachial plexus, sympathetic trunk, or phrenic nerve invasion with dysfunction)"

Imaging-detected extranodal extension (iENE) refers to unequivocal radiological signs of tumor invasion through the capsule of a lymph node into either perinodal fat or adjacent tissues (e.g. skin, muscle, or neurovascular structures) or a coalescent nodal mass (a coalescent nodal mass comprises ≥ 2 adjacent lymph nodes that have lost their intervening tissue planes and capsules to merge into a single indivisible structure).

Rationale

Extranodal Extension Head and Neck Clinical is a Registry Data Collection Variable in AJCC. It was previously collected as Head and Neck SSF #8 (Common SSF). Since the introduction of iENE in AJCC Version 9, both clinical ENE and imaging-detected ENE should be considered in this data item.

Additional Information

Source documents: imaging reports, physical exam

Other names include Extracapsular extension (ECE), extranodal spread (ENS), or extracapsular spread (ECS)

- **Note**: ENE is the preferred terminology, and includes
    - **cENE** for clinical ENE
    - **iENE** for imaging-detected ENE
    - **pENE** for pathological ENE

For further information, refer to the **Head and Neck** cancer protocols published by the College of American Pathologist for the AJCC Staging Systems for *Head and Neck*.

Notes

Note 1: Physician Statement

- Physician statement indicating the presence or absence of extranodal extension (ENE) can be used to code this data item when no other information is available
- Physical exam alone is sufficient to determine Clinical ENE

Note 2: Clinical assessment criteria

- The assessment of ENE must be based on evidence acquired prior to definitive surgery of the primary site, chemotherapy, radiation, or other type of treatment, i.e., the clinical timeframe for staging.
- The assessment for ENE may **include imaging and/or physical examination.**

  - Biopsy of the regional lymph node or surrounding tissue can be used to confirm the presence of metastatic carcinoma and thus verify the clinical assessment, but cannot be used in isolation to determine ENE during clinical staging

- Fixed nodes are clinical indications of cENE
- Matted nodes are indications of iENE
- iENE is identified exclusively on imaging
- ENE during clinical staging is considered present when cENE and/or iENE are present
- Note that the rules for coding ENE for head and neck sites compared to non-head and neck sites are different

Coding Guidelines

1) Code 0 when lymph nodes are determined to be **clinically positive** and there is **no clinical evidence of ENE** based on physical examination.

2) Code 1 when there is **definitive (unquestionable) evidence of ENE** as determined by physical examination

3) Code 2 when there is **definitive (unquestionable) evidence of ENE** as determined by physical examination and/or imaging **and** nodal involvement is microscopically confirmed by biopsy

4) Code 4 when there is **definitive (unquestionable) evidence of ENE**, but the means of identification is not known

5) Code 7 when nodes are clinically negative (cN0)

6) Code 9 when

- No information in the medical record
- Positive nodes clinically, not evaluated (assessed) for ENE
- Positive nodes clinically, unknown if evaluated (assessed) for ENE
- Lymph nodes not evaluated (assessed) clinically
- Unknown if lymph nodes evaluated (assessed) clinically

Code	Description
0	Regional lymph node(s) involved, ENE not present/not identified during diagnostic workup
1	Regional lymph node(s) involved, ENE present/identified during diagnostic workup, based on physical exam and/or imaging
2	Regional lymph node(s) involved, ENE present/identified during diagnostic workup, based on microscopic confirmation
4	Regional lymph nodes involved, ENE present/identified, unknown how identified
7	No lymph node involvement during diagnostic workup (cN0)
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit)
9	Not documented in medical record ENE not assessed during diagnostic workup, or unknown if assessed Clinical assessment of lymph node(s) not done, or unknown if done

00060: Cervical Lymph Nodes and Unknown Primary

3832: Extranodal Extension Head and Neck Pathological

Item Length: 3
NAACCR Item #: 3832
XML Parent-NAACCR ID: Tumor-extranodalExtensionHeadNeckPath
NAACCR Alternate Name: Extranodal Extension Head and Neck Pathological
Active years: 2018+
Schema(s):

- 00060: Cervical Lymph Nodes and Unknown Primary
- 00071: Lip
- 00072: Tongue Anterior
- 00073: Gum
- 00074: Floor of Mouth
- 00075: Palate Hard
- 00076: Buccal Mucosa
- 00077: Mouth Other
- 00080: Major Salivary Glands [8th: 2018-2025]
- 09081: Major Salivary Glands [V9: 2026+]
- 00090: Nasopharynx [8th: 2018-2024]
- 09090: Nasopharynx [V9: 2025+]
- 00100: Oropharynx HPV-Associated [8th: 2018-2025]
- 09100: Oropharynx HPV-Associated [V9: 2026+]
- 00111: Oropharynx HPV-Independent
- 00112: Hypopharynx
- 00121: Maxillary Sinus
- 00122: Nasal Cavity and Ethmoid Sinus
- 00130: Larynx Other
- 00131: Larynx Supraglottic
- 00132: Larynx Glottic
- 00133: Larynx Subglottic
- 00140: Melanoma Head and Neck

Description

Extranodal extension (ENE) is defined as “the extension of a nodal metastasis through the lymph node capsule into adjacent tissue” and is a prognostic factor for most head and neck tumors. This data item pertains to pathological staging extension.

The presence of extranodal extension (ENE) from regional lymph nodes is an important prognostic factor in some cancers because these patients are rarely cured without some type of systemic chemotherapy or radiation. Extranodal extension is defined as metastatic tumor

growing from within the lymph node outward through the lymph node capsule and into surrounding connective tissues.

- "A regional node extending into a distant structure or organ is categorized as ENE and is not recorded as distant metastatic disease."

This data item is for ENE that is detected pathologically for head and neck primaries.

Rationale

Extranodal Extension Head and Neck Pathological is a Registry Data Collection Variable in AJCC. It was previously collected as Head and Neck SSF #9 (Common SSF).

Additional Information

Source documents: imaging reports, physical exam

Other names include Extracapsular extension (ECE), extranodal spread (ENS), or extracapsular spread (ECS)

- **Note**: ENE is the preferred terminology, and includes
    - **cENE** for clinical ENE
    - **iENE** for imaging-detected ENE
    - **pENE** for pathological ENE

For further information, refer to the **Head and Neck** cancer protocols published by the College of American Pathologist for the AJCC Staging Systems for *Head and Neck*.

Notes

Note 1: Physician Statement

- Physician statement of extranodal extension (ENE) pathologically during a lymph node dissection or physician pathological stage indicating the absence or presence of ENE can be used to code this data item when no other information is available.

Note 2: Pathological assessment criteria

- Code the status of ENE assessed on histopathologic examination of **surgically resected** involved regional lymph node(s)
    - Includes presence of ENE in a sentinel lymph node.
- Do not code ENE from a lymph node biopsy (FNA, core, incisional), or the absence of ENE from a sentinel

Note 3: Regional vs. distant lymph nodes

- Do not code ENE for any distant lymph nodes

Note 4: Minor and Major ENE

- Minor ENE is defined as less than or equal to 2 mm
- Major ENE is defined as greater than 2 mm
    - Matted lymph nodes and soft tissue metastasis are considered major ENE

Coding Guidelines

1) Code 0.0 when there are positive nodes pathologically, but ENE not identified/not present.

- **Absence of ENE**, positive lymph nodes assessed by lymph node dissection (1292: Scope of Regional Lymph Node Surgery must be 3-7)

2) Code the actual size of the ENE in the range 0.1-9.9 mm

3) Code X.1 when actual size of the ENE is 10 mm or greater

4) Code X.2 when stated to be microscopic [ENE (mi)]

5) Code X.3 when stated to be major [ENE (ma)]

6) Code X.4 when size not documented, unknown whether microscopic (mi) or major (ma)

7) Codes 0.1-9.9, X.1, X.2, X.3, X.4 as appropriate for

- Presence of ENE assessed by Sentinel Lymph Node biopsy
- Presence of ENE assessed by lymph node biopsy
- If codes 0.1-0.9, X.1-X.7 are used, this indicates that the lymph nodes were surgically resected, or a Sentinel Lymph Node biopsy was done and Scope of Regional Lymph Node Surgery [NAACCR Data Item: 1292] must be 2-7

8) Code X.7 when nodes are surgically resected, and they are negative (pN0)

- Lymph nodes negative for cancer assessed by Sentinel lymph node biopsy or lymph node dissection
- 1292: Scope of Regional Lymph Node Surgery must be 2-7

9) Code X.9 when

- Absence of ENE, positive lymph nodes assessed by Sentinel Lymph Nodes Biopsy
- Positive nodes pathologically, not evaluated (assessed) for ENE
- Positive nodes pathologically, unknown if evaluated (assessed) for ENE

- Lymph nodes not evaluated (assessed) pathologically (no surgical resection of lymph nodes)
- Unknown if lymph nodes evaluated pathologically (assessed)

Code	Description
0.0	Lymph nodes positive for cancer but ENE not identified or negative
0.1-9.9	ENE 0.1 to 9.9 mm
X.1	ENE 10 mm or greater
X.2	ENE minor, size unknown Stated as ENE (mi)
X.3	ENE major, size unknown Stated as ENE (ma)
X.4	ENE present, minor or major unknown, size unknown
X.7	Surgically resected regional lymph node(s) negative for cancer (pN0)
X.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X.8 may result in an edit error)
X.9	Not documented in medical record No surgical resection of regional lymph node(s) ENE not assessed pathologically, or unknown if assessed Pathological assessment of lymph node(s) not done, or unknown if done

00060: Cervical Lymph Nodes and Unknown Primary

3883: LN Size

Item Length: 4
NAACCR Item #: 3883
XML Parent-NAACCR ID: Tumor-lnSize
NAACCR Alternate Name: LN Size
Active years: 2018+
Schema(s):

- 00060: Cervical Lymph Nodes and Unknown Primary
- 00071: Lip
- 00072: Tongue Anterior
- 00073: Gum
- 00074: Floor of Mouth
- 00075: Palate Hard
- 00076: Buccal Mucosa
- 00077: Mouth Other
- 00080: Major Salivary Glands [8th: 2018-2025]
- 09081: Major Salivary Glands [V9: 2026+]
- 00090: Nasopharynx [8th: 2018-2024]
- 09090: Nasopharynx [V9: 2025+]
- 00100: Oropharynx HPV-Associated [8th: 2018-2025]
- 09100: Oropharynx HPV-Associated [V9: 2026+]
- 00111: Oropharynx HPV-Independent
- 00112: Hypopharynx
- 00121: Maxillary Sinus
- 00122: Nasal Cavity and Ethmoid Sinus
- 00130: Larynx Other
- 00131: Larynx Supraglottic
- 00132: Larynx Glottic
- 00133: Larynx Subglottic
- 00140: Melanoma Head and Neck
- 00150: Cutaneous Carcinoma of Head and Neck

Description

Lymph Node Size records the largest diameter of any involved regional lymph node(s). Pathological measurement takes precedence over a clinical measurement for the same node.

This data item is used to code the size of involved lymph nodes and is recorded in millimeters.

Rationale

Lymph Nodes Size is a Registry Data Collection Variable in AJCC for several chapters. It was previously collected in the Head and Neck chapters as Size of Lymph Nodes, SSF #1.

Additional Information

Source documents: pathology report, imaging reports, physical exam

Other names include ENE, extracapsular extension, ECE

For further information, refer to the **Head and Neck** cancer protocols published by the College of American Pathologist for the AJCC Staging Systems for *Head and Neck*.

Notes

Note 1: Physician Statement

- Physician statement of Lymph Nodes Size can be used to code this data item when no other information is available.

Note 2: Criteria for coding LN size

- The metric is the **size of the largest tumor deposit** in the lymph node, not the size of the overall lymph node that is involved.
- For larger nodes however, the size of the deposit becomes essentially the size of the overall lymph node as the nodes become almost entirely overtaken with tumor.
- Code the size of the largest deposit if pathology reports separately list the size of a deposit and the size of the overall lymph node that the deposit is involving.

Note 3: Clinical vs Pathological size

- Code the **clinical node size** when the largest involved node is not examined pathologically.
- Code the **pathological node size** when the largest involved node (or same level) is examined clinically and pathologically, even if the pathological size is smaller.
- Code the **size of the largest deposit** when the pathology report separately lists the size of a deposit and the size of the overall lymph node that the deposit is involving.
    - ***Example:*** Clinical evaluation shows 1.5 cm (15 mm) Level II lymph node, pathological examination shows positive Level II node 1.3 cm (13 mm), with size of largest nodal deposit 1.3 mm
        - Code 13.0.

Note 4: Regional vs. distant nodes

- Do not code the size of any distant nodes.

Coding Guidelines

1) Code the largest size in millimeters of any involved regional lymph nodes for head and neck (cervical lymph nodes). The measurement can be pathological, if available, or clinical. **See note 3.**

- Record size in millimeters

2) Code 0.0 when no regional lymph nodes are involved

3) Code XX.1 for 100 millimeters (10 cm) or greater

4) Code XX.2 for microscopic focus or foci only and no size of focus given

5) Code XX.3 for lymph node met less than 1 cm (10 mm)

- Lymph node described as "subcentimeter"

6) Code XX.9 when

- Positive lymph nodes but size not stated
- No information about regional lymph nodes
- Lymph nodes not assessed or unknown if assessed

7) In order to align with the CAP guidelines, additional codes have been added for "at least" categories which are used in the CAP protocols. Only use these codes when the pathologist has used this terminology to indicate the lymph node size.

- **XX.4:** Describes a lymph node size at least 2 cm (20 mm)
- **XX.5:** Described a lymph node size at least 3 cm (30 mm)
- **XX.6:** Describes a lymph node size at least 4 cm (40 mm)
- **XX.7:** Describes a lymph node size 5 cm (50 mm) or greater

Code	Description
0.0	No regional lymph node involvement Non-invasive neoplasm (behavior /2)
0.1-99.9	0.1 - 99.9 millimeters (mm) (Exact size of lymph node to nearest tenth of a mm)
XX.1	100 millimeters (mm) or greater

Code	Description
XX.2	Microscopic focus or foci only and no size of focus given
XX.3	Described as “less than 1 centimeter (cm)” or “subcentimeter”
XX.4	Described as “at least” 2 cm
XX.5	Described as “at least” 3 cm
XX.6	Described as “at least” 4 cm
XX.7	Described as greater than 5 cm
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error)
XX.9	Not documented in medical record Regional lymph node(s) involved, size not stated Lymph Nodes Size not assessed, or unknown if assessed

00060: Cervical Lymph Nodes and Unknown Primary

3876: LN Head and Neck Levels I-III

Item Length: 1
NAACCR Item #: 3876
XML Parent-NAACCR ID: Tumor-lnHeadAndNeckLevels1To3
NAACCR Alternate Name: Lymph Nodes Head and Neck Levels I-III
Active years: 2018+
Schema(s):

- 00060: Cervical Lymph Nodes and Unknown Primary
- 00140: Melanoma Head and Neck

Description

Lymph Nodes for Head and Neck, Levels I-III records the involvement of Levels I-III lymph nodes.

This data item is used to code the presence or absence of lymph node involvement in head and neck levels I-III. The definitions of the levels are the same for all applicable head and neck sites.

- **Note:** This data item was previously collected for all head and neck sites. It is now only clinically relevant for unknown head and neck primaries with positive cervical (head and neck) lymph nodes and mucosal melanomas of the head and neck.

Level I is subdivided into levels IA and IB, which contain the submental and submandibular triangles bounded by the anterior and posterior bellies of the digastric muscle, the hyoid bone inferiorly, and the body of the mandible superiorly. Lymph node chains at this level:

- Submental (Level IA), submandibular (Level IB), submaxillary (Level IB)

Level II is subdivided into levels IIA and IIB, which contain the upper jugular lymph nodes and extend from the level of the skull base superiorly to the hyoid bone inferiorly. A vertical plane defined by the spinal accessory nerve is the boundary between level IIA (anterior to spinal accessory nerve) and IIB (posterior to spinal accessory nerve). Lymph node chains at this level:

- Jugulodigastric (subdigastric), upper deep cervical, upper jugular

Level III contains the middle jugular lymph nodes from the hyoid bone superiorly to the level of the lower border of the cricoid cartilage inferiorly. Lymph node chains at this level:

- Middle deep cervical, mid-jugular

Rationale

Level of nodal involvement is a Registry Data Collection Variable in AJCC for several head and neck chapters. This data item was previously collected as Head and Neck SSF #3 (common SSF).

Additional Information

Source documents: pathology report, imaging

For more information on **Head and Neck levels**, see AJCC 8th edition, Chapter 5: Staging Head and Neck Cancers, Table 5.1.

Notes

Note 1: Physician Statement

- Physician statement of Levels I-III lymph node involvement can be used to code this data item when no other information is available.

Note 2: Related data items

- 3876: LN Head and Neck Levels I-III
- 3877: LN Head and Neck Levels IV-V
- 3878: LN Head and Neck Levels VI-VII
- 3879: LN Head and Neck Other

Note 3: Priority order

- Pathological information takes priority over clinical.

Coding Guidelines

1) Code all applicable levels that are involved

- ***Example:*** A carcinoma of the base of tongue involves bilateral submandibular nodes and left upper, mid-, and lower jugular nodes, the largest measuring 4 cm. There is no extracapsular extension. These are level I, II, III, and IV lymph nodes according to AJCC definitions.
    - Levels I-III: Code 7 (Levels I, II and III lymph nodes involved) to show that levels I, II, and III are involved
    - Levels IV-V: Code 1 to show that level IV is involved
    - Levels VI-VII: Code 0 for no other nodes involved
    - Head and Neck, Other: Code 0 for no other nodes involved

2) If information is available on some nodes, but the others are unknown, code what is known.

- ***Example:*** Multiple lymph nodes involved, level II documented, but the other levels not mentioned. Code 2 to indicate level II involvement.

3) If a lymph node is described as involving two levels, or documented as a range, code both levels.

- ***Example:*** Physical examination for a floor of mouth cancer describes a large lymph node mass low in level II stretching into Level III. Code 6 for Levels II-III because both Level II and Level III are mentioned.

4) Code 9 when the only information available is "Regional nodes, NOS" or "Cervical nodes, NOS" or "Internal jugular nodes, NOS" or "Lymph nodes, NOS". In other words, if regional nodes are known to be positive but the level(s) of nodes involved is unknown, code 9.

- ***Example:*** Patient diagnosed elsewhere with carcinoma of oropharynx with cervical lymph node involvement. No other information available. All Head and Neck Level data items are coded to 9 since there is no specific information about the levels.
    - Levels I-III: Code 9
    - Levels IV-V: Code 9
    - Levels VI-VII: Code 9
    - Head and Neck, Other: Code 9

Code	Description
0	No involvement in Levels I, II, or III lymph nodes Non-invasive neoplasm (behavior /2)
1	Level I lymph node(s) involved
2	Level II lymph node(s) involved
3	Level III lymph node(s) involved
4	Levels I and II lymph nodes involved
5	Levels I and III lymph nodes involved
6	Levels II and III lymph nodes involved
7	Levels I, II and III lymph nodes involved
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error)
9	Not documented in medical record Positive nodes, but level of positive node(s) unknown Lymph node levels I-III not assessed, or unknown if assessed

00060: Cervical Lymph Nodes and Unknown Primary

3877: LN Head and Neck Levels IV-V

Item Length: 1
NAACCR Item #: 3877
XML Parent-NAACCR ID: Tumor-lnHeadAndNeckLevels4To5
NAACCR Alternate Name: Lymph Nodes Head and Neck Levels IV-V
Active years: 2018+
Schema(s):

- 00060: Cervical Lymph Nodes and Unknown Primary
- 00140: Melanoma Head and Neck

Description

Lymph Nodes for Head and Neck, Levels IV-V records the involvement of Levels IV-V lymph nodes.

This data item is used to code the presence or absence of lymph node involvement in head and neck levels I-III. The definitions of the levels are the same for all applicable head and neck sites.

- Note: This data item was previously collected for all head and neck sites. It is now only clinically relevant for unknown head and neck primaries with positive cervical (head and neck) lymph nodes and mucosal melanomas of the head and neck.

Level IV contains the lower jugular lymph nodes from the level of the cricoid cartilage superiorly to the clavicle inferiorly. Lymph node chains at this level:

- Jugulo-omohyoid (supraomohyoid), lower deep cervical, lower jugular

Level V is subdivided into levels VA and VB, which contain the lymph nodes in the posterior triangle bounded by the anterior border of the trapezius muscle posteriorly, the posterior border of the sternocleidomastoid muscle anteriorly, and the clavicle inferiorly. For descriptive purposes, Level V may be further subdivided into upper (VA) and lower (VB) levels corresponding to a plane defined by the inferior border of the cricoid cartilage. Lymph node chains at this level:

- Posterior cervical, posterior triangle (spinal accessory, transverse cervical [upper, middle, and lower, corresponding to the levels that define upper, middle, and lower jugular nodes]), supraclavicular

Rationale

Level of nodal involvement is a Registry Data Collection Variable in AJCC. This data item was previously collected as Head and Neck SSF #4 (common SSF).

Additional Information

Source documents: pathology report, imaging

For more information on **Head and Neck levels**, see AJCC 8th edition, Chapter 5: Staging Head and Neck Cancers, Table 5.1.

Notes

Note 1: Physician Statement

- Physician statement of Levels IV-V lymph node involvement can be used to code this data item when no other information is available.

Note 2: Related data items

- 3876: LN Head and Neck Levels I-III
- 3877: LN Head and Neck Levels IV-V
- 3878: LN Head and Neck Levels VI-VII
- 3879: LN Head and Neck Other

Note 3: Priority order

- Pathological information takes priority over clinical.

Note 4: Supraclavicular nodes

- If lymph nodes are described only as "supraclavicular," try to determine if they are in Level IV (deep to the sternocleidomastoid muscle, in the lower jugular chain) or Level V (in the posterior triangle, inferior to the transverse cervical artery) and code appropriately.
    - If the specific level cannot be determined, or is documented as supraclavicular with no further information, code them as Level V nodes

Note 5: Priority order

- Pathological information takes priority over clinical.

Coding Guidelines

1) Code all applicable levels that are involved

- ***Example:*** A carcinoma of the base of tongue involves bilateral submandibular nodes and left upper, mid-, and lower jugular nodes, the largest measuring 4 cm. There is no extracapsular extension. These are level I, II, III, and IV lymph nodes according to AJCC definitions.

- Levels I-III: Code 7 (Levels I, II and III lymph nodes involved) to show that levels I, II, and III are involved
- Levels IV-V: Code 1 to show that level IV is involved
- Levels VI-VII: Code 0 for no other nodes involved
- Head and Neck, Other: Code 0 for no other nodes involved

2) If information is available on some nodes, but the others are unknown, code what is known.

- ***Example:*** Multiple lymph nodes involved, level II documented, but the other levels not mentioned. Code 2 to indicate level II involvement.

3) If a lymph node is described as involving two levels, or documented as a range, code both levels.

- ***Example:*** Physical examination for a floor of mouth cancer describes a large lymph node mass low in level II stretching into Level III. Code 6 for Levels II-III because both Level II and Level III are mentioned.

4) Code 9 when the only information available is "Regional nodes, NOS" or "Cervical nodes, NOS" or "Internal jugular nodes, NOS" or "Lymph nodes, NOS". In other words, if regional nodes are known to be positive but the level(s) of nodes involved is unknown, code 9.

- ***Example:*** Patient diagnosed elsewhere with carcinoma of oropharynx with cervical lymph node involvement. No other information available. All Head and Neck Level data items are coded to 9 since there is no specific information about the levels.
  - Levels I-III: Code 9
  - Levels IV-V: Code 9
  - Levels VI-VII: Code 9
  - Head and Neck, Other: Code 9

Code	Description
0	No involvement in Levels I, II, or III lymph nodes Non-invasive neoplasm (behavior /2)
1	Level IV lymph node(s) involved
2	Level V lymph node(s) involved
3	Levels IV and V lymph node(s) involved

Code	Description
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error)
9	Not documented in medical record Positive nodes, but level of positive node(s) unknown Lymph node levels IV-V not assessed, or unknown if assessed

00060: Cervical Lymph Nodes and Unknown Primary

3878: LN Head and Neck Levels VI-VII

Item Length: 1
NAACCR Item #: 3878
XML Parent-NAACCR ID: Tumor-lnHeadAndNeckLevels6To7
NAACCR Alternate Name: Lymph Nodes Head and Neck Levels VI-VII
Active years: 2018+
Schema(s):

- 00060: Cervical Lymph Nodes and Unknown Primary
- 00140: Melanoma Head and Neck

Description

Lymph Nodes for Head and Neck, Levels VI-VII records the involvement of Levels VI-VII lymph nodes.

This data item is used to code the presence or absence of lymph node involvement in head and neck levels I-III. The definitions of the levels are the same for all applicable head and neck sites.

Level VI contains the lymph nodes of the anterior central compartment from the hyoid bone superiorly to the suprasternal notch inferiorly. On each side, the lateral boundary is formed by the medial border of the carotid sheath. Lymph node chains at this level:

- Laterotracheal, Paralaryngeal, paratracheal (above suprasternal notch), perithyroidal, Precricoid (Delphian), Prelaryngeal, recurrent laryngeal)

Level VII contains the lymph nodes inferior to the suprasternal notch in the superior mediastinum. Lymph node chains at this level:

- Esophageal groove, paratracheal (below suprasternal notch), Pretracheal (below suprasternal notch)

Rationale

Level of nodal involvement is a Registry Data Collection Variable in AJCC. This data item was previously collected as Head and Neck SSF #5 (common SSF).

Additional Information

Source documents: pathology report, imaging

For more information on **Head and Neck levels**, see AJCC 8th edition, Chapter 5: Staging Head and Neck Cancers, Table 5.1.

Notes

Note 1: Physician Statement

- Physician statement of Levels IV-V lymph node involvement can be used to code this data item when no other information is available.

Note 2: Related data items

- 3876: LN Head and Neck Levels I-III
- 3877: LN Head and Neck Levels IV-V
- 3878: LN Head and Neck Levels VI-VII
- 3879: LN Head and Neck Other

Note 3: Priority order

- Pathological information takes priority over clinical.

Coding Guidelines

1) Code all applicable levels that are involved

- ***Example:*** A carcinoma of the base of tongue involves bilateral submandibular nodes and left upper, mid-, and lower jugular nodes, the largest measuring 4 cm. There is no extracapsular extension. These are level I, II, III, and IV lymph nodes according to AJCC definitions.
    - Levels I-III: Code 7 (Levels I, II and III lymph nodes involved) to show that levels I, II, and III are involved
    - Levels IV-V: Code 1 to show that level IV is involved
    - Levels VI-VII: Code 0 for no other nodes involved
    - Head and Neck, Other: Code 0 for no other nodes involved

2) If information is available on some nodes, but the others are unknown, code what is known.

- ***Example:*** Multiple lymph nodes involved, level II documented, but the other levels not mentioned. Code 2 to indicate level II involvement.

3) If a lymph node is described as involving two levels, or documented as a range, code both levels.

- ***Example:*** Physical examination for a floor of mouth cancer describes a large lymph node mass low in level II stretching into Level III. Code 6 for Levels II-III because both Level II and Level III are mentioned.

4) Code 9 when the only information available is "Regional nodes, NOS" or "Cervical nodes, NOS" or "Internal jugular nodes, NOS" or "Lymph nodes, NOS". In other words, if regional nodes are known to be positive but the level(s) of nodes involved is unknown, code 9.

- ***Example:*** Patient diagnosed elsewhere with carcinoma of oropharynx with cervical lymph node involvement. No other information available. All Head and Neck Level data items are coded to 9 since there is no specific information about the levels.
    - Levels I-III: Code 9
    - Levels IV-V: Code 9
    - Levels VI-VII: Code 9
    - Head and Neck, Other: Code 9

Code	Description
0	No involvement in Levels VI or VII lymph nodes Non-invasive neoplasm (behavior /2)
1	Level VI lymph node(s) involved
2	Level VII lymph node(s) involved
3	Levels VI and VII lymph node(s) involved
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error)
9	Not documented in medical record Positive nodes, but level of positive node(s) unknown Lymph nodes levels VI-VII not assessed, or unknown if assessed

00060: Cervical Lymph Nodes and Unknown Primary

3879: LN Head and Neck Other

Item Length: 1
NAACCR Item #: 3879
XML Parent-NAACCR ID: Tumor-lnHeadAndNeckOther
NAACCR Alternate Name: Lymph Nodes Head and Neck Other
Active years: 2018+
Schema(s):

- 00060: Cervical Lymph Nodes and Unknown Primary
- 00140: Melanoma Head and Neck

Description

Lymph Nodes for Head and Neck, Other records the involvement of lymph nodes other than Levels I-III, IV-V, and VI-VII.

This data item is used to code the presence or absence of lymph node involvement in head and neck levels I-III. The definitions of the levels are the same for all applicable head and neck sites.

Other head and neck lymph nodes:

- Cervical, NOS; deep cervical (NOS), facial, buccinator (buccal), infraauricular, internal jugular (NOS), intraparotid, mandibular, nasolabial, parapharyngeal, parotid, periparotid, preauricular, retroauricular (mastoid), retropharyngeal, suboccipital

Rationale

Level of nodal involvement is a Registry Data Collection Variable in AJCC. This data item was previously collected as Head and Neck SSF #6 (common SSF).

Additional Information

Source documents: pathology report, imaging

For more information on **Head and Neck levels**, see AJCC 8th edition, Chapter 5: Staging Head and Neck Cancers, Table 5.1.

Notes

Note 1: Physician Statement

- Physician statement of other head and neck lymph node involvement can be used to code this data item when no other information is available.

Note 2: Related data items

- 3876: LN Head and Neck Levels I-III
- 3877: LN Head and Neck Levels IV-V

- 3878: LN Head and Neck Levels VI-VII
- 3879: LN Head and Neck Other

Note 3: Priority order

- Pathological information takes priority over clinical.

Coding Guidelines

1) Code all applicable levels that are involved

- ***Example 1:*** A carcinoma of the base of tongue involves bilateral submandibular nodes and left upper, mid-, and lower jugular nodes, the largest measuring 4 cm. There is no extracapsular extension. These are level I, II, III, and IV lymph nodes according to AJCC definitions.
    - Levels I-III: Code 7 (Levels I, II and III lymph nodes involved) to show that levels I, II, and III are involved
    - Levels IV-V: Code 1 to show that level IV is involved
    - Levels VI-VII: Code 0 for no other nodes involved
    - Head and Neck, Other: Code 0 for no other nodes involved

2) If information is available on some nodes, but the others are unknown, code what is known.

- ***Example:*** Multiple lymph nodes involved, level II documented, but the other levels not mentioned. Code 2 to indicate level II involvement.

3) If a lymph node is described as involving two levels, or documented as a range, code both levels.

- ***Example:*** Physical examination for a floor of mouth cancer describes a large lymph node mass low in level II stretching into Level III. Code 6 for Levels II-III because both Level II and Level III are mentioned.

4) Code 9 when the only information available is “Regional nodes, NOS” or “Cervical nodes, NOS” or “Internal jugular nodes, NOS” or “Lymph nodes, NOS”. In other words, if regional nodes are known to be positive but the level(s) of nodes involved is unknown, code 9.

- ***Example:*** Patient diagnosed elsewhere with carcinoma of oropharynx with cervical lymph node involvement. No other information available. All Head and Neck Level data items are coded to 9 since there is no specific information about the levels.
    - Levels I-III: Code 9
    - Levels IV-V: Code 9

- Levels VI-VII: Code 9
- Head and Neck, Other: Code 9

Code	Description
0	No involvement in other head and neck lymph node regions Non-invasive neoplasm (behavior /2)
1	Buccinator (facial) lymph node(s) involved
2	Parapharyngeal lymph node(s) involved
3	Periparotid and intraparotid lymph node(s) involved
4	Preauricular lymph node(s) involved
5	Retropharyngeal lymph node(s) involved
6	Suboccipital/retroauricular lymph node(s) involved
7	Any combination of codes 1-6
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Positive nodes, but level of positive node(s) unknown Other Head and Neck lymph nodes not assessed, or unknown if assessed

00071: Lip

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00072: Tongue Anterior

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00073: Gum

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00074: Floor of Mouth

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00075: Palate Hard

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00076: Buccal Mucosa

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00077: Mouth Other

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00080: Major Salivary Glands [8th: 2018-2025]

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

09081: Major Salivary Glands [V9: 2026+]

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00090: Nasopharynx [8th: 2018-2024]

3926: Schema Discriminator 1

Item Length: 1
NAACCR Item #: 3926
XML Parent-NAACCR ID: Tumor-schemaDiscriminator1
NAACCR Alternate Name: Schema Discriminator 1: Nasopharynx/PharyngealTonsil
Active years: 2018+
Schema(s):

- 00090: Nasopharynx [8th: 2018-2024]
- 00100: Oropharynx HPV-Associated [8th: 2018-2025]
- 00111: Oropharynx HPV-Independent

Description

Nasopharynx and pharyngeal tonsil have the same ICD-O topography code (C111). However, for purposes of stage grouping AJCC 8th edition, nasopharynx and pharyngeal tonsil are staged in different chapters. A schema discriminator is necessary to distinguish between these primary sites so that the appropriate chapter/schema is used.

Note: This schema discriminator is only needed for diagnosis years 2018-2024. It should be left blank for diagnosis years 2025 and after.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Summary Stage and EOD data collection system.

Additional Information

Source documents: pathology report, imaging, clinician's statement

For further information, refer to the **Pharynx** cancer protocol published by the College of American Pathologist for the AJCC Staging Systems *Nasopharynx, Oropharynx (p16-) and Oropharynx HPV-mediated (p16+)*.

Notes

Note: Schema discriminator for C111

- A schema discriminator is used to discriminate for primary site C111: Posterior wall of nasopharynx. Code the specific site in which the tumor arose.
- **This schema discriminator is only needed for diagnosis years 2018-2024. It should be left blank for diagnosis years 2025 and after.**

- **00090: Nasopharynx (see code 1)**
  Used to stage for the following primary site description: posterior wall of nasopharynx (NOS)

- **00100 (Oropharyngeal HPV-Associated) or 00111 (Oropharyngeal HPV-Independent) (see code 2)**
  Oropharynx Staging Systems are used for the following primary site descriptions. An additional schema discriminator will be used to distinguish between the AJCC HPV-Mediated (p16+) Oropharyngeal Cancer and Oropharynx (p16-) and Hypopharynx Staging System.
    - Adenoid
    - Pharyngeal tonsil

Code	Description	Schema ID #/Description
1	Posterior wall of nasopharynx, NOS	00090: Nasopharynx 8th (2018-2024)
2	Adenoid Pharyngeal tonsil	3927: Schema discriminator 2: Oropharyngeal p16
<Blank>	Primary Site is NOT C111, Discriminator is not necessary Year of Diagnosis is 2025 or later, Discriminator is not necessary	

09090: Nasopharynx [V9: 2025+]

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00100: Oropharynx HPV-Associated [8th: 2018-2025]

3927: Schema Discriminator 2

Item Length: 1
NAACCR Item #: 3927
XML Parent-NAACCR ID: Tumor-schemaDiscriminator2
NAACCR Alternate Name: Schema Discriminator 2: Oropharyngeal p16
Active years: 2018+
Schema(s):

- 00100: Oropharynx HPV-Associated [8th: 2018-2025]
- 09100: Oropharynx HPV-Associated [V9: 2026+]
- 00111: Oropharynx HPV-Independent

Description

Staging for oropharyngeal cancers changed in the AJCC 8th edition. Oropharynx was divided into **Oropharynx HPV-Associated (p16+)** and **Oropharynx HPV-Independent (p16-).** A schema discriminator is necessary to determine the HPV status so that the appropriate protocol/schema is used.

There are several methods for determination of HPV status. The most frequent, and preferred test is IHC for p16 expression, which is a surrogate marker for transcriptionally active high-risk HPV.

- Other tests that may be used for this data item **in addition to p16 or when p16 is not available** include (but are not limited to)
    - High-risk HPV RNA ISH
    - High-risk HPV DNA ISH
- Other tests that may be used for this data item **in addition to p16 include** but are not limited to
    - High-risk HPV DNA PCR

High-risk HPV types include: 16, 18, 26, 31, 33, 34, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 70, 73, and 82.

Low-risk (cannot be used to determine HPV status) HPV types include: 6, 11, 42, 43, and 44.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Grade, Summary Stage and EOD data collection system.

Additional Information

Source documents: pathology report, clinician's statement

For further information, refer to the **HPV-associated Squamous Cell Carcinoma of the Oropharynx** or the **HPV-independent Oropharynx and Hypopharynx** cancer protocols published by the College of American Pathologist for the AJCC Staging Systems *Oropharynx-Associated* and *Oropharynx-Independent*.

Notes

Note 1: Schema discriminator for Oropharynx

- A schema discriminator is used to discriminate between oropharyngeal tumors that are p16 positive and oropharyngeal tumors that are p16 negative OR p16 status unknown.

Note 2: p16 testing

- p16 testing will guide classification of most patients but some will have HPV-specific testing that should be used in conjunction for classification when the pathologist performs it.
- **00100: Oropharynx HPV-Associated (p16+) (see code 2)**
    - p16 positive and it is the only test performed
    - p16 positive when subsequent high-risk HPV-specific testing is performed and is positive
    - p16 equivocal (50-70% staining) when subsequent high-risk HPV-specific testing is performed and is positive
    - p16 not performed but when high-risk HPV-specific testing is positive (High-risk HPV RNA ISH or high-risk HPV DNA ISH when performed alone).
        - High-risk HPV DNA PCR testing if used alone is not reliable to assign HPV status.
    - Stated as **HPV-associated** or **High-risk HPV**
- **00111: Oropharynx HPV-Independent (p16-) (see code 1)**
    - p16 negative and it is the only test performed
    - p16 expression of limited (<50%) distribution only
    - p16 positive but when subsequent reliable high-risk HPV-specific testing is performed and is negative (reliable high-risk HPV-specific tests include high-risk HPV RNA ISH and high-risk HPV DNA PCR)
    - Stated as **Oropharynx-Independent**

- **HPV testing not done or unknown if done (see code 9)**
    - Cases coded as unknown will be included with the Oropharynx HPV-Independent (p16-) schema
    - Stated as **HPV positive** and no indication if it's p16, low risk or high risk
    - Stated as **low risk HPV**

Code	Description	Schema ID #/Description
1	p16 Negative; Nonreactive	00111: Oropharynx HPV-Independent
2	p16 positive with extensive (>70%) moderate to strong reactivity WITH or WITHOUT positive high-risk HPV-specific testing Or in rare instances, high-risk HPV specific testing positive alone	00100: Oropharynx HPV-Associated 8th (2018-2025) 09100: Oropharynx HPV-Associated V9 (2026+)
9	Not tested for p16; Unknown	00111: Oropharynx HPV-Independent

09100: Oropharynx HPV-Associated [V9: 2026+]

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3927: Schema Discriminator 2
- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00111: Oropharynx HPV-Independent

See **00090: Nasopharynx [8th: 2018-2024]**

- 3926: Schema Discriminator 1

See **00100: Oropharynx HPV-Associated [8th: 2018-2025]**

- 3927: Schema Discriminator 2

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00112: Hypopharynx

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00121: Maxillary Sinus

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00122: Nasal Cavity and Ethmoid Sinus

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00130: Larynx Other

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00131: Larynx Supraglottic

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00132: Larynx Glottic

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00133: Larynx Subglottic

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size

00140: Melanoma Head and Neck

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3831: Extranodal Extension Head and Neck Clinical
- 3832: Extranodal Extension Head and Neck Pathological
- 3883: LN Size
- 3876: LN Head and Neck Levels I-III
- 3877: LN Head and Neck Levels IV-V
- 3878: LN Head and Neck Levels VI-VII
- 3879: LN Head and Neck Other

00150: Cutaneous Carcinoma of Head and Neck

3909: Perineural Invasion

Item Length: 1
NAACCR Item #: 3909
XML Parent-NAACCR ID: Tumor-perineuralInvasion
NAACCR Alternate Name: Perineural Invasion
Active years: 2018+
Schema(s):

- 00150: Cutaneous Carcinoma of Head and Neck

Description

Perineural Invasion, within or adjacent to the primary tumor, is a negative prognostic factor for cutaneous squamous cell carcinomas of the head and neck and carcinomas of the colon and rectum, eyelid, and lacrimal gland.

Perineural invasion is infiltration of nerves in the area of the lesion by tumor cells or spread of tumor along the nerve pathway. The presence of perineural invasion has been shown in several studies to be an indicator of poor patient prognosis. If perineural invasion is not mentioned in the pathology report, do not assume that there is no perineural invasion.

Rationale

Perineural Invasion is a Registry Data Collection Variable in AJCC. It was previously collected as Skin, SSF #11.

Additional Information

Source documents: pathology report

Other names include PNI, neurotropism

For further information, refer to the **Cutaneous Carcinoma of Head and Neck** cancer protocols published by the College of American Pathologist for the AJCC Staging Systems for *Cutaneous Carcinoma of Head and Neck*.

Notes

Note 1: Physician Statement

- Physician statement of microscopically confirmed perineural invasion can be used to code this data item when no other information is available.

Note 2: Pathology report from a biopsy or surgical resection

- Information on **presence** of perineural invasion **must be from a pathology report** (biopsy or surgical resection)

- Absence of perineural invasion **can only be taken from a surgical resection pathology report**

Note 3: Perineural Invasion not documented on pathology report

- Code 9 if surgical resection of the primary site is performed and there is no mention of perineural invasion.
- Do not assume that there is no perineural invasion

Code	Description
0	Perineural invasion not identified/not present Non-invasive neoplasm (behavior /2)
1	Perineural invasion identified/present
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Pathology report does not mention perineural invasion Cannot be determined by the pathologist Perineural invasion not assessed or unknown if assessed

00150: Cutaneous Carcinoma of Head and Neck

3858: High Risk Features

Item Length: 1
NAACCR Item #: 3858
XML Parent-NAACCR ID: Tumor-highRiskHistologicFeatures
NAACCR Alternate Name: High Risk Histologic Features
Active years: 2018+
Schema(s):

- 00150: Cutaneous Carcinoma of Head and Neck

Description

High Risk Histologic Features are defined in AJCC 8 Chapter 15 to include the terms "poor differentiation, desmoplasia, sarcomatoid differentiation, undifferentiated." High risk histologic features are a prognostic factor for cutaneous cell carcinomas of the head and neck.

In addition to the tumor size (diameter, not depth), the presence of certain specific high risk features is of prognostic significance for skin cancers of the head and neck.

Rationale

High Risk Histologic Features is a Registry Data Collection Variable in AJCC. It was previously collected as Skin, CS SSF # 12.

Additional Information

Source documents pathology report, consultation report, other statements in the medical record

Other names include high risk histologic features, high risk tumor features

For further information, refer to the **Cutaneous Carcinoma of Head and Neck** cancer protocols published by the College of American Pathologist for the AJCC Staging Systems for *Cutaneous Carcinoma of Head and Neck*.

Notes

Note 1: Physician Statement

- Physician statement of high risk histologic features can be used to code this data item when no other information is available.

Note 2: High risk histologic features include

- Desmoplasia
- Poor differentiation (grade 3)
- Sarcomatoid differentiation (features)

- Undifferentiated (grade 4)

Coding Guidelines

1) Code the presence or absence of high risk histologic features as documented in the pathology report.

2) Code 1 for desmoplasia

3) Code 2 for poor differentiation (grade 3)

4) Code 3 for sarcomatoid differentiation (features)

5) Code 4 for undifferentiated (grade 4)

6) Code 5 when more than one high risk feature is present

7) Code 6 when high risk features are present, but it is not specified which one

8) Code 9 when

- Not documented in medical record
- High risk features not evaluated (assessed)
- Unknown if high risk features evaluated (assessed)

Code	Description
0	No high risk histologic features Non-invasive neoplasm (behavior /2)
1	Desmoplasia
2	Poor differentiation (grade 3)
3	Sarcomatoid differentiation
4	Undifferentiated (grade 4)
5	Multiple high risk histologic features
6	Histologic features, NOS (type of high risk histologic feature not specified)
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error)
9	Not documented in medical record High risk histologic features not assessed or unknown if assessed

GASTROINTESTINAL TRACT (UPPER AND LOWER)

00161: Esophagus (including GE junction) Squamous

3926: Schema Discriminator 1

Item Length: 1
NAACCR Item #: 3926
XML Parent-NAACCR ID: Tumor-schemaDiscriminator1
NAACCR Alternate Name: Schema Discriminator 1: EsophagusGEJunction (EGJ)/Stomach
Active years: 2018+
Schema(s):

- 00161: Esophagus (including GE junction) Squamous
- 00169: Esophagus (including GE junction) (excluding Squamous)
- 00170: Stomach

Description

The esophagus chapter of the AJCC Cancer Staging Manual 8th edition includes the esophagogastric junction (also called the cardia or gastroesophageal junction) and the proximal 2 cm of the stomach. The cardia is defined as the opening or junction between the esophagus and the stomach, and it is between 0.1 and 0.4 cm in length. This 2-cm boundary measurement is based on the Siewert classification of gastroesophageal cancers, which defines an area 2 cm above and 2 cm below the cardia or esophagogastric junction. Both of these areas are coded to primary site C160, so a discriminator is needed to get to the correct chapter.

To determine whether a cancer of the cardia should be coded according to the esophagus schema or the stomach system, it is necessary to identify the midpoint or epicenter of the tumor. If the midpoint is at or above the cardia, the tumor is esophageal. If the midpoint of the tumor is within 2 cm distal to the gastroesophageal junction (GEJ) and the lesion extends to or across the GEJ, the case should be coded with the esophagus system. If the midpoint of the tumor is within 2 cm distal to the GEJ and the lesion does not extend to the GEJ, the case should be coded with the stomach schema. Any tumor with a midpoint more distal than 2 cm from the GEJ is coded with the stomach schema.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Grade, Summary Stage and EOD data collection system.

Additional Information

Source documents: pathology report, imaging, operative report, clinician's statement

For further information, refer to the **Esophagus** cancer protocol published by the College of American Pathologist for the AJCC Staging System *Esophagus (including GE Junction)*.

Notes

Note 1: Schema Discriminator for C160

- Under primary site code C160, there are two different structures that are staged differently.
    - Esophagogastric junction (Esophagus schema)
    - Cardia of the Stomach (Stomach schema)

Note 2: The gastroesophageal junction

- The gastroesophageal junction (GEJ) (primary site C160) is a poorly defined anatomic area that represents the junction between the distal esophagus and the proximal stomach (cardia).
- The true anatomic GEJ corresponds to the most proximal aspect of the gastric folds, which represents an endoscopically apparent transition point in most individuals.

Note 3: The cardia

- The cardia (also assigned primary site C160) is the **first part of the stomach.** It is the region where the stomach meets the end of the esophageal tube.
- This region is also referred to as the Z-line or the esophagogastric junction.

Note 4: Physician's statement

- Physician's statement can be used to code this data item when no other information is available.
    - ***Example:*** Patient diagnosed with tumor involving the cardia. No other information available. Physician stages the patient using the Esophagus Staging System/CAP protocol
        - ***Answer:*** Code 2 based on physician using the Esophagus Staging System

Note 5: Midpoint (epicenter)

- Tumors with their midpoint (epicenter) in the GE Junction are staged as Esophagus, while tumors with their midpoint (epicenter) in the cardia/stomach are staged using the Stomach Staging System.
    - **Note:** The CAP protocol uses "midpoint" instead of "epicenter". This is the pathologist's assessment of the point of tumor origin, regardless of tumor extension into other tissues.

Coding Guidelines

Select the code that best describes the location and extent of the tumor, and the computer algorithm will bring the correct schema to the screen.

Chapter 16: Esophagus and Esophagogastric Junction (see code 2)

1) Code 2 when

- EGJ is documented as involved and the midpoint (epicenter) is within the proximal (above) 2 cm of the cardia
- EGJ is documented as involved and there is no mention of extension into the stomach or stomach involvement
    - ***Example 1:*** MRI: Findings most consistent with metastatic GE junction cancer. Upper EUS: Medium-sized, fungating, polypoid and ulcerated mass with no active bleeding was found in the gastric cardia extending from GEJ to 42 cm from incisors. One malignant-appearing lymph node was visualized in the peripancreatic region.
        - ***Answer:*** Code 2 for involvement of the GE Junction/Cardia and no mention of involvement of the stomach
- EGJ is documented as involved and there is no information on stomach involvement and
    - Esophagus CAP Protocol is used OR
    - Esophagus Staging System is used
    - If the CAP Protocol and AJCC Staging System are different, default to the AJCC Staging System

Chapter 17: Stomach (see codes 0, 3, and 9)

2) Code 0 when only the cardia is documented as involved (no mention of EGJ)

3) Code 3 when

- EGJ is documented as involved and the midpoint (epicenter) is more than 2 cm distal (below) from the EGJ
- EGJ is documented as involved and there is no information on stomach involvement AND
    - Stomach CAP Protocol is used OR
    - Stomach AJCC Staging System is used
    - If the CAP Protocol and AJCC Staging System are different, default to the AJCC Staging System

4) Code 9 when there is no documentation regarding EGJ involvement.

Code	Description	Schema ID #/Description
0	NO involvement of esophagus or gastroesophageal junction AND epicenter at ANY DISTANCE into the proximal stomach (including into the proximal stomach distance unknown)	00170: Stomach
2	INVOLVEMENT of esophagus or esophagogastric junction (EGJ) AND epicenter LESS THAN OR EQUAL TO 2 cm into the proximal stomach OR no stated involvement of or into the stomach	00161, 00169: Esophagus Schemas AND go to Schema Discriminator 2: Histology discriminator for 8020/3
3	INVOLVEMENT of esophagus or esophagogastric junction (EGJ) AND epicenter GREATER THAN 2 cm into the proximal stomach	00170: Stomach
9	UNKNOWN involvement of esophagus or gastroesophageal junction AND epicenter at ANY DISTANCE into the proximal stomach (including into the proximal stomach distance unknown)	00170: Stomach
<Blank>	Primary Site is NOT C160, Discriminator is not necessary	

00161: Esophagus (including GE junction) Squamous

3927: Schema Discriminator 2

Item Length: 1
NAACCR Item #: 3927
XML Parent-NAACCR ID: Tumor-schemaDiscriminator2
NAACCR Alternate Name: Schema Discriminator 2: Histology Discriminator for 8020/3
Active years: 2018+
Schema(s):

- 00161: Esophagus (including GE junction) Squamous
- 00169: Esophagus (including GE junction) (excluding Squamous)

Description

Histology code 8020/3 is defined as "undifferentiated carcinoma". In the AJCC 8th chapter for Esophagus, this histology code is further subdivided into squamous or glandular component, which are staged differently. A schema discriminator is necessary to distinguish between these histologies so that the appropriate stage group table is used.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Grade, Summary Stage and EOD data collection system.

Additional Information

Source documents: pathology report

For further information, refer to the **Esophagus** cancer protocol published by the College of American Pathologist for the AJCC Staging Systems *Esophagus (including GE Junction)*.

Notes

Note: Schema discriminator for 8020/3

- A schema discriminator is used to discriminate for histology 8020/3: Undifferentiated carcinoma to determine which AJCC Stage Group table to use.
- **8020/3: Undifferentiated carcinoma with squamous component (see code 1)**
    - Use the Squamous Cell Carcinoma AJCC Stage Group Table
- **8020/3: Undifferentiated carcinoma with glandular component (see code 2)**
    - Use the Adenocarcinoma AJCC Stage Group Table

- **8020/3: Undifferentiated carcinoma, NOS (no mention of squamous or glandular component) (see code 3)**
    - Use the Squamous Cell Carcinoma AJCC Stage Group Table

Code	Description	Schema ID #/Description
1	Undifferentiated carcinoma with squamous component	00161: Esophagus (including GE junction) Squamous
2	Undifferentiated carcinoma with glandular component	00169: Esophagus (including GE junction) (excluding Squamous)
9	Undifferentiated carcinoma, NOS	00161: Esophagus (including GE junction) Squamous
<Blank>	Histology is NOT 8020, Discriminator is not necessary	

00161: Esophagus (including GE junction) Squamous

3829: Esophagus and EGJ Tumor Epicenter

Item Length: 1
NAACCR Item #: 3829
XML Parent-NAACCR ID: Tumor-esophagusAndEgjTumorEpicenter
NAACCR Alternate Name: Esophagus and EGJ, Squamous Cell (including adenosquamous), Tumor Location
Active years: 2018+
Schema(s):

- 00161: Esophagus (including GE junction) Squamous

Description

Esophagus and Esophagogastric Junction (EGJ), Squamous Cell (including adenosquamous), Tumor Location refers to the position of the epicenter of the tumor in the esophagus.

Required for Staging: The AJCC Esophagus Staging System and EOD, for **Squamous Cell Carcinomas only**.

Rationale

This data item is required for prognostic stage grouping for squamous and adenosquamous carcinoma in AJCC 8th edition, Chapter 16 Esophagus and Esophagogastric Junction. It is a new data item for cases diagnosed 1/1/2018 and forward.

Additional Information

Source documents: pathology report, operative report, imaging, clinician's statement

For further information, refer to the **Esophagus** cancer protocol published by the College of American Pathologist for the AJCC Staging System *Esophagus (including GE Junction) Squamous*.

Notes

Note 1: Pathological Staging

- This data item is used for pathological staging for squamous cell carcinoma of the esophagus and esophagogastric junction. If information is available for clinical staging, record it.

Note 2: Defining the epicenter

- Location is defined by the position of the **epicenter** of the tumor in the esophagus.
    - ***Example***: If the lesion was from 15-21 cm, this is a 6-cm lesion with epicenter at 18 cm. It is the midpoint

Note 3: Priority statements of epicenter

- Clinician or pathologist statement of epicenter being the upper, middle, or lower takes priority over any individual results or measurements
- If no statement of epicenter is provided indicating upper, middle, or lower is provided, the following measurements may be used.
    - 15-24 cm from incisors = upper
    - 25-29 cm from incisors = middle
    - 30-40/45 cm from incisors = lower

Note 4: Epicenter and Primary Site

- The ascertainment of the epicenter of the tumor is for staging purposes and is separate from the assignment of the ICD-O-3 topography code
- If you have an overlapping tumor (C158), do not recode the topography based on the epicenter.

Note 5: Primary Site C159

- If primary site is C159 (Esophagus, NOS), code 9.

Code	Description
0	U: Upper (Cervical/Proximal esophagus to lower border of azygos vein)
1	M: Middle (Lower border of azygos vein to lower border of inferior pulmonary vein)
2	L: Lower (Lower border of inferior pulmonary vein to stomach, including gastroesophageal junction)
9	X: Esophagus, NOS Specific location of epicenter not documented in medical record Specific location of epicenter not assessed or unknown if assessed

00161: Esophagus (including GE junction) Squamous

3855: HER2 Overall Summary

Item Length: 1
NAACCR Item #: 3855
XML Parent-NAACCR ID: Tumor-her2OverallSummary
NAACCR Alternate Name: HER2 Overall Summary
Active years: 2021+
Schema(s):

- 00161: Esophagus (including GE junction) Squamous
- 00169: Esophagus (including GE junction) (excluding Squamous)
- 00170: Stomach

Description

HER2 Overall Summary is a summary of results from HER2 testing.

Rationale

HER2 overall summary will be collected for Esophagus and Esophagogastric Junction and Stomach for cases diagnosed 1/1/21+ because NCCN guidelines recommend HER2 testing at time of diagnosis if patients are documented or suspected of having metastatic disease. HER2 monoclonal antibodies may be added to chemotherapy for patients with HER2 positive disease.

Additional Information

Source documents: pathology report

For further information, refer to the **Gastric HER2 Biomarker reporting** cancer protocol published by the College of American Pathologist.

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2021+
- For cases diagnosed 2018-2020, this SSDI must be blank

Note 2: Physician Statement

- Physician statement of HER2 Overall Summary can be used to code this data item when no other information is available.

Note 3: Applicable histologies

- HER2 may be recorded for all histologies; however, it is primarily performed for adenocarcinomas. If information is not available, code 9

Note 4: Source of tissue

- The result of the HER2 test performed on the primary tissue is to be recorded in this data item.
- Use the highest (positive versus negative) when there are multiple results

Note 5: Neoadjuvant Therapy

- Record the assay from tumor specimens prior to neoadjuvant therapy.
- If neoadjuvant therapy is given and there are no HER2 results from pre-treatment specimens, report the findings from post-treatment specimens.

Code	Description
0	HER2 negative; equivocal
1	HER2 positive
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Cannot be determined (indeterminate) HER2 Overall Summary status not assessed or unknown if assessed
<Blank>	Must be blank if diagnosis year is before 2021

00169: Esophagus (including GE junction) (excluding Squamous)

See **00161: Esophagus (including GE junction) Squamous**

- 3926: Schema Discriminator 1
- 3927: Schema Discriminator 2
- 3855: HER2 Overall Summary

00170: Stomach

See **00161: Esophagus (including GE junction) Squamous**

- 3926: Schema Discriminator 1
- 3855: HER2 Overall Summary

00190: Appendix [8th: 2018-2022]

3820: CEA Pretreatment Lab Value

Item Length: 6
NAACCR Item #: 3820
XML Parent-NAACCR ID: Tumor-ceaPretreatmentLabValue
NAACCR Alternate Name: CEA (Carcinoembryonic Antigen) Pretreatment Lab Value
Active years: 2018+
Schema(s):

- 00190: Appendix [8th: 2018-2022]
- 09190: Appendix [V9: 2023+]
- 00200: Colon and Rectum

Description

CEA (Carcinoembryonic Antigen) Pretreatment Lab Value records the CEA value prior to treatment. CEA is a nonspecific tumor marker that has prognostic significance for colon and rectum cancer.

CEA is

1) A protein molecule found in many different cells of the body but associated with certain tumors and with the developing fetus.

2) CEA is used as a tumor marker especially for gastrointestinal cancers, as colorectal cancer is the most frequent cause for an increased/elevated CEA.

3) CEA is also elevated by biliary obstruction, alcoholic hepatitis, and heavy smoking.

4) CEA level is most frequently tested on blood serum, but it may be tested in body fluids and/or biopsy tissue.

5) An abnormally high CEA level prior to tumor resection is expected to fall following successful removal of the cancer.

6) An increasing value indicates possible recurrence.

There are 2 related data items that record information on CEA for Colon and Rectum.

- 3820: CEA Pretreatment Lab Value
- 3819: CEA Pretreatment Interpretation

Rationale

CEA (Carcinoembryonic Antigen) Pretreatment Lab Value is a Registry Data Collection Variable in AJCC. It was previously collected as Colon and Rectum, CS SSF #3.

Additional Information

Source documents: clinical laboratory report, sometimes pathology or cytology report; H&P, operative report; consultant report; discharge summary

Other names include Carcinoembryonic antigen

Reference ranges

- Nonsmoker: < 2.5 ng/ml (SI: < 2.5 mg/L) SI Conversion: 1 mg/L = 1 ng/ml
- Smoker: < 5 ng/ml (SI: < 5 mg/L) SI Conversion: 1 mg/mL = 1 ng/L

Notes

Note 1: Physician Statement

- Physician statement of CEA (Carcinoembryonic Antigen) Pretreatment Lab Value can be used to code this data item when no other information is available.

Note 2: Pretreatment results only

- Record the interpretation of the highest CEA test result documented in the medical record **prior to treatment or a polypectomy**.

Note 3: Related data item.

- The same laboratory test should be used to record information in the related data item 3819: CEA Pretreatment Interpretation

Coding Guidelines

1) Record the highest value prior to treatment in nanograms per milliliter (ng/ml) in the range 0.1 (1 ng/ml) to 9999.9 (9999 ng/ml) in the Lab Value data item and the

2) Record to the nearest tenth in nanograms/milliliter (ng/ml) the highest CEA lab value documented in the medical record **prior to treatment or polypectomy**. (Code a pretreatment CEA of 7 ng/ml as 7.0).

3) Record 0.1 when the lab results are stated as less than 0.1 ng/ml with no exact value.

Examples of CEA Lab Values

- CEA Lab Value 0 ng/ml - Code 0.0
- CEA Lab Value 23.6 ng/ml- Code 23.6
- CEA Lab Value 11,000-Code XXXX.1
- CEA Lab Value = Test ordered, results not in chart- Code XXXX7

- CEA Lab Value = Not documented in medical record, CEA test not done, unknown if CEA test done - Code XXXX.9

Code	Description
0.0	0.0 nanograms/milliliter (ng/ml) exactly
0.1-9999.9	0.1-9999.9 ng/ml (Exact value to nearest tenth in ng/ml)
XXXX.1	10,000 ng/ml or greater
XXXX.7	Test ordered, results not in chart
XXXX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XXXX.8 may result in an edit error.)
XXXX.9	Not documented in medical record CEA (Carcinoembryonic Antigen) Pretreatment Lab Value not assessed or unknown if assessed

00190: Appendix [8th: 2018-2022]

3819: CEA Pretreatment Interpretation

Item Length: 1
NAACCR Item #: 3819
XML Parent-NAACCR ID: Tumor-ceaPretreatmentInterpretation
NAACCR Alternate Name: CEA (Carcinoembryonic Antigen) Pretreatment Interpretation
Active years: 2018+
Schema(s):

- 00190: Appendix [8th: 2018-2022]
- 09190: Appendix [V9: 2023+]
- 00200: Colon and Rectum

Description

CEA (Carcinoembryonic Antigen) Pretreatment Interpretation refers to the interpretation of the CEA value prior to treatment. CEA is a nonspecific tumor marker that has prognostic significance for colon and rectum cancer.

CEA is

1) A protein molecule found in many different cells of the body but associated with certain tumors and with the developing fetus.

2) CEA is used as a tumor marker especially for gastrointestinal cancers, as colorectal cancer is the most frequent cause for an increased/elevated CEA.

3) CEA is also elevated by biliary obstruction, alcoholic hepatitis, and heavy smoking.

4) CEA level is most frequently tested on blood serum, but it may be tested in body fluids and/or biopsy tissue.

5) An abnormally high CEA level prior to tumor resection is expected to fall following successful removal of the cancer.

6) An increasing value indicates possible recurrence.

There are 2 related data items that record information on CEA for Colon and Rectum.

- 3820: CEA Pretreatment Lab Value
- 3819: CEA Pretreatment Interpretation

Rationale

CEA (Carcinoembryonic Antigen) is a Registry Data Collection Variable for AJCC 8. CEA (Carcinoembryonic Antigen) Pretreatment Interpretation was previously collected as Colon and Rectum, CS SSF #1.

Additional Information

Source documents: clinical laboratory report, sometimes pathology or cytology report; H&P, operative report; consultant report; discharge summary

Other names include Carcinoembryonic antigen

Reference ranges

- Nonsmoker: < 2.5 ng/ml (SI: < 2.5 mg/L) SI Conversion: 1 mg/L = 1 ng/ml
- Smoker: < 5 ng/ml (SI: < 5 mg/L) SI Conversion: 1 mg/mL = 1 ng/L

Notes

Note 1: Physician Statement

- Physician statement of CEA (Carcinoembryonic Antigen) Interpretation can be used to code this data item when no other information is available.

Note 2: Pretreatment results only

- Record the interpretation of the highest CEA test result documented in the medical record **prior to treatment or a polypectomy**.

Note 3: Related data item.

- The same laboratory test should be used to record information in the related data item 3820: CEA Lab Value

Coding Guidelines

1) Record the clinician's interpretation of the highest value **prior to treatment**, based on the reference range used by the lab in the Interpretation data item.

- If the physician's statement is not available, use the **Reference Ranges** included in **Additional Information** for this data item to determine the interpretation

2) Code 3 when a CEA value was documented in the record, but there is no statement that the CEA is positive/elevated, negative/normal, and the normal range (from which you can determine interpretation), is not documented.

Code	Description
0	CEA negative/normal; within normal limits
1	CEA positive/elevated
2	Borderline

Code	Description
3	Undetermined if positive or negative (normal values not available) AND no MD interpretation
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this data item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record CEA (Carcinoembryonic Antigen) Pretreatment Interpretation not assessed or unknown if assessed

09190: Appendix [V9: 2023+]

3960: Histologic Subtype

Item Length: 1
NAACCR Item #: 3960
XML Parent-NAACCR ID: Tumor-histologicSubtype
NAACCR Alternate Name: Histologic Subtype
Active years: 2023+
Schema(s):

- 09190: Appendix [V9: 2023+]

Description

Histology code for appendiceal tumors (8480) is defined as "Mucinous Adenocarcinoma (in situ or invasive)". In addition, there are also low-grade appendiceal mucinous neoplasm (LAMN) and high-grade appendiceal mucinous neoplasm (HAMN) diagnoses that are assigned the same histology.

Rationale

Due to the different natures of these histologies, there is interest in tracking these different types of tumors. With the current histology codes, a distinction cannot be made. A histology subtype data item is needed.

Additional Information

Source documents: pathology report, Solid Tumor Rules

For further information, refer to the **Appendix** cancer protocol published by the College of American Pathologist for the AJCC Staging System *Appendix, Version 9*.

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2023+
- For cases diagnosed 2018-2022, this SSDI must be blank

Note 2: Determining histology

- Use the **Solid Tumor Rules** to determine histology prior to coding this SSDI.
- Histology 8480/2 or 8480/3 have multiple definitions that are collected in this histology.
- This data item is used to further identify specific subtypes for histology code 8480/2 or 8480/3.

Coding Guidelines

Examples:

1. Appendix: Disseminated peritoneal adenomucinous/low grade mucinous carcinoma peritonei. Final diagnosis: Low grade appendiceal mucinous neoplasm

- **Code 1**: This is a low grade mucinous (appendiceal) carcinoma (8480/3), which is LAMN. The peritoneal adenomucinous/low grade mucinous carcinoma peritonei is describing metastatic disease and not the histology

2. Appendix: Low grade (well diff) appendiceal adenocarcinoma

- **Code 0**: This is an adenocarcinoma (8140/3), the low grade (well diff) is describing the grade and not the histology

3. Appendix, appendectomy: Low grade appendiceal mucinous neoplasm (LAMN) with focal high grade mucinous neoplasm.

- **Code 1**: Based on the Solid Tumor Rules, the "focal" would be ignored and this would be a LAMN.

4. Appendectomy: Mucinous adenocarcinoma of the appendix

- **Code 3**: Mucinous adenocarcinoma is the preferred terminology for histology code 8480/3. Since there is no mention of "low grade" or "high grade", this would not be LAMN or HAMN

5. Appendix: Mucinous (colloid) adenocarcinoma

- **Code 3**: Colloid adenocarcinoma is an alternate name for 8480/3

Code	Description
0	Histology is NOT 8480
1	Low-grade appendiceal mucinous neoplasm LAMN
2	High-grade appendiceal mucinous neoplasm HAMN
3	Mucinous Adenocarcinoma/carcinoma Mucus Adenocarcinoma/carcinoma Mucoid adenocarcinoma/carcinoma Colloid adenocarcinoma/carcinoma
4	Other terminology coded to 8480
<Blank>	NA-Diagnosis year is prior to 2023

00200: Colon and Rectum

3934: Tumor Deposits

Item Length: 2
NAACCR Item #: 3934
XML Parent-NAACCR ID: Tumor-tumorDeposits
NAACCR Alternate Name: Tumor Deposits
Active years: 2018+
Schema(s):

- 00200: Colon and Rectum

Description

A tumor deposit is defined as a discrete nodule of cancer in pericolic/perirectal fat or in adjacent mesentery (mesocolic or rectal fat) within the lymph drainage area of the primary carcinoma, without identifiable lymph node tissue or identifiable vascular structure.

Tumor deposits are separate nodules or deposits of malignant cells in perirectal or pericolic fat without evidence of residual lymph node tissue. If present, tumor deposits may be found within the primary lymphatic drainage area of the tumor.

They are different from direct extension from the primary tumor and may be the result of lymphovascular invasion with extravascular extension, a totally replaced lymph node, or discontinuous spread. Nodules of tumor outside the primary lymphatic drainage area of the tumor are distant metastasis.

Rationale

The presence of tumor deposits is a Registry Data Collection Variable in AJCC. It was previously collected as Colon and Rectum CS SSF #4.

Additional Information

Source documents: surgical pathology report

Other names include discontinuous extramural extension, malignant tumor foci, malignant peritumoral deposits, satellite nodule

For further information, refer to the **Colon and Rectum** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Colon and Rectum*.

Notes

Note 1: Physician Statement

- Physician statement of Tumor Deposits can be used to code this data item when no other information is available, provided the criteria for evaluation has been met (*see Note 2*).

Note 2: Criteria for evaluating Tumor Deposits

- A **surgical resection** must be done to evaluate tumor deposits
- Do not use any evaluation of Tumor Deposits from imaging (MRI), or biopsy

Note 3: Tumor deposits vs Tumor budding

- **Tumor deposits** are separate nodules or deposits of malignant cells in perirectal or pericolic fat without evidence of residual lymph node tissue
- **Tumor budding**: The presence of single cells or small clusters of less than five cells at the advancing front of the tumor is considered as peritumoral tumor budding. Numerous studies have shown that high tumor budding in adenocarcinoma arising in a polyp is a significant risk factor for nodal involvement
    - Information on tumor budding is not currently collected

Coding Guidelines

Record the number of Tumor Deposits whether or not there are positive lymph nodes.

- Do not count involved lymph nodes in this field, only tumor deposits

1) Code 00 when the pathology report states that there are no tumor deposits.

2) Code 01-99 (for the exact number of tumor deposits reported in the pathology report)

3) Code X1 for 100 or more tumor deposits.

4) Code X2 if tumor deposits are mentioned but a number is not reported.

5) Code X9 when

- Not documented in medical record
- No surgical resection done
- Pathology report not available
- Surgical resection of the primary site is performed and there is no mention of tumor deposits
- Tumor deposits not evaluated (not assessed)
- Unknown if Tumor Deposits evaluated (assessed)

Code	Description
00	No tumor deposits
01-99	1-99 Tumor deposits (TD) (Exact number of TD)
X1	100 or more Tumor Deposits
X2	Tumor Deposits identified, number unknown
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record Cannot be determined by the pathologist Pathology report does not mention tumor deposits No surgical resection done Tumor Deposits not assessed or unknown if assessed

00200: Colon and Rectum

3909: Perineural Invasion

Item Length: 1
NAACCR Item #: 3909
XML Parent-NAACCR ID: Tumor-perineuralInvasion
NAACCR Alternate Name: Perineural Invasion
Active years: 2018+
Schema(s):

- 00200: Colon and Rectum

Description

Perineural Invasion, within or adjacent to the primary tumor, is a negative prognostic factor for cutaneous squamous cell carcinomas of the head and neck and carcinomas of the colon and rectum, eyelid, and lacrimal gland.

Perineural invasion is infiltration of nerves in the area of the lesion by tumor cells or spread of tumor along the nerve pathway. The presence of perineural invasion has been shown in several studies to be an indicator of poor patient prognosis. If perineural invasion is not mentioned in the pathology report, do not assume that there is no perineural invasion.

Rationale

Perineural Invasion is a Registry Data Collection Variable in AJCC. It was previously collected as Colon and Rectum CS SSF #8.

Additional Information

Source documents: pathology report

Other names include PIN, neurotropism

For further information refer to the **Colon and Rectum** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Colon and Rectum*.

Notes

Note 1: Physician Statement

- Physician statement of microscopically confirmed perineural invasion can be used to code this data item when no other information is available.

Note 2: Pathology report from a biopsy or surgical resection

- Information on **presence** of perineural invasion **must be from a pathology report** (biopsy or surgical resection)

- Absence of perineural invasion **can only be taken from a surgical resection pathology report**

Note 3: Perineural Invasion not documented on pathology report

- Code 9 if surgical resection of the primary site is performed and there is no mention of perineural invasion.
- Do not assume that there is no perineural invasion when there is no mention of it on the pathology report

Coding Guidelines

Code 0 when there is an in situ/non-invasive neoplasm (behavior /2)

- By definition, in situ tumors cannot have perineural invasion
- There are no surgical requirements for an in situ tumor

Code	Description
0	Perineural invasion not identified/not present Non-invasive neoplasm (behavior /2)
1	Perineural invasion identified/present
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Pathology report does not mention perineural invasion Cannot be determined by the pathologist Perineural invasion not assessed or unknown if assessed

00200: Colon and Rectum

3823: Circumferential Resection Margin (CRM)

Item Length: 4
NAACCR Item #: 3823
XML Parent-NAACCR ID: Tumor-circumferentialResectionMargin
NAACCR Alternate Name: Circumferential Resection Margin (CRM)
Active years: 2018+
Schema(s):

- 00200: Colon and Rectum

Description

Circumferential or Radial Resection Margin, the distance in millimeters between the leading edge of the tumor and the surgically dissected margin as recorded on the pathology report, is a prognostic indicator for colon and rectal cancer. This may also be referred to as the Radial Resection Margin or surgical clearance.

The CRM, also referred to as the radial margin or the mesenteric resection margin, is the measurement of the distance from the deepest invasion of the tumor to the margin of resection in the retroperitoneum or mesentery. In other words, the CRM is the width of the surgical margin at the deepest part of the tumor in an area of the large intestine or rectum without serosa (non-peritonealized rectum below the peritoneal reflection) or only partly covered by serosa (upper rectum, posterior aspects of ascending and descending colon).

For segments of the colon completely encased by peritoneum, the mesenteric resection margin is the only relevant circumferential margin.

The CRM is not the same as the distance to the proximal and distal margins of the colon specimen. For rectal cancers, the circumferential resection margin is the most important predictor of local-regional recurrence.

Per the AJCC Staging System Colon and Rectum, “the CRM is the distance in millimeters between the deepest point of tumor invasion in the primary cancer and the margin of resection in the retroperitoneum or mesentery”.

Rationale

Circumferential or Radial Resection Margin is a Registry Data Collection Variable in AJCC. It was previously collected as Colon and Rectum CS SSF #6.

Additional Information

Source documents: pathology report

Other names include circumferential radial margin, mesenteric (mesocolon) (mesorectal) margin, mesenteric excision plane, pericolonic resection margin, radial margin, soft tissue margin

For further information refer to the **Colon and Rectum** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Colon and Rectum*.

Notes

Note 1: Physician Statement

- Physician statement of Circumferential or Radial Resection Margin can be used to code this data item when no other information is available, provided the criteria for evaluation has been met *(see Note 2)*.

Note 2: Criteria for evaluating CRM

- A surgical resection must be done to evaluate circumferential resection margin.
- See *Coding Guidelines #3 and #4* for further information

Note 3: Exact measurements versus XX codes

An exact measurement takes precedence over codes 0.0 and those beginning with XX. Exact measurement also takes priority even if the pathologist states the margin is positive.

- ***Example:*** CRM stated as 0.3 mm in Final Diagnosis and Synoptic states: Circumferential (Radial) Margin Interpreted as involved by invasive carcinoma (tumor less than 1mm from margin).
    - Code the 0.3 mm instead of 0.0 (margin involved with tumor).
        - Code 0.0 is for positive margins, or margin is less than 0.1 mm.

Coding Guidelines

The following guidelines were developed for the coding of surgery codes in relation to CRM. These guidelines were confirmed by the CAP Cancer Committee.

1) Record in Millimeters (mm) to the nearest tenth the distance between the leading edge of the tumor and the nearest edge of surgically dissected margin as recorded in the pathology report.

- ***Examples:*** CRM is 2 mm, code 2.0; CRM is 2.78 mm, code 2.8

2) If the value is recorded in Centimeters, multiply by 10 to get the value in Millimeters (mm).

- ***Example:*** CRM recorded as 0.2 cm. Multiply 0.2 x 10 and record 2.0

3) For **Colon** primaries, surgery of primary site must be a surgical resection

- If surgery of primary site is not a surgical resection (i.e. polypectomy, excisional biopsy), then CRM must be coded as XX.7

4) For **Rectal** primaries, surgery of primary site must be coded as excisional biopsy, transanal excision or surgical resection

- For excisional biopsy, or transanal procedures, the tumor must be located in the peritonealized portion of the rectum. Only the peritonealized portion of the rectum is where you can get the CRM from these procedures
    - If the non-peritonealized portion of the rectum is involved or it's unknown if the peritonealized portion of the rectum is involved, code XX.7
    - If surgery of primary site is not an excisional biopsy, transanal excision or surgical resection, code XX.7

5) Code 0.0 If the margin is involved (positive)

6) Code 0.0 if the margin is described as less than 0.1 mm with no more specific measurement

7) Code XX.0 for margins described as greater than 100 mm

8) Codes 0.1-99.9 are for coding the exact measurement in millimeters of the negative margin.

9) Code XX.1 when the margin is stated as clear, but the distance is not available.

10) Code XX.2 when the pathology reports/CAP checklist states that the margin cannot be assessed/evaluated.

11) Codes XX.3-XX.6 are for when the pathology uses "at least" categories.

12) Code XX.7 when there is no surgical resection of the primary site.

13) Code XX.9 when

- Not documented in the medical record
- CRM is not evaluated (assessed)
- Checked "Not applicable: Radial or Mesenteric Margin" on CAP Checklist
- Pathology report describes only distal and proximal margins, or margins, NOS
- Unknown if CRM is evaluated (assessed)

Code	Description
0.0	Circumferential resection margin (CRM) positive Margin IS involved with tumor Described as “less than 0.1 millimeter (mm)”
0.1-99.9	Distance of tumor from margin: 0.1- 99.9 millimeters (mm) (Exact size to nearest tenth of millimeter)
XX.0	100 mm or greater
XX.1	Margins clear, distance from tumor not stated Circumferential or radial resection margin negative, NOS No residual tumor identified on specimen
XX.2	Margins cannot be assessed
XX.3	Described as “at least” 1 mm
XX.4	Described as “at least” 2 mm
XX.5	Described as “at least” 3 mm
XX.6	Described as “greater than” 3 mm
XX.7	No resection of primary site Surgical procedure did not remove enough tissue to measure the circumferential or radial resection margin (Examples include: polypectomy only, endoscopic mucosal resection (EMR), excisional biopsy only, transanal disk excision)
XX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XX.8 may result in an edit error.)
XX.9	Not documented in medical record Non-invasive neoplasm (behavior /2) Circumferential or radial resection margin not assessed or unknown if assessed

00200: Colon and Rectum

3866: KRAS

Item Length: 1
NAACCR Item #: 3866
XML Parent-NAACCR ID: Tumor-kras
NAACCR Alternate Name: KRAS
Active years: 2018+
Schema(s):

- 00200: Colon and Rectum

Description

KRAS is an important signaling intermediate in the growth receptor pathway which controls cell proliferation and survival. KRAS is a protein with production controlled by the K-ras gene. When the K-ras gene is activated through mutation during colorectal carcinogenesis, production of KRAS continuously stimulates cell proliferation and prevents cell deaths. Activating mutations in KRAS are an adverse prognostic factor for colorectal carcinoma and predict a poor response to monoclonal anti-EGFR antibody therapy in advanced colorectal carcinoma.

KRAS is an oncogene (a gene that, when mutated or overexpressed, helps turn a normal cell into a cancer cell). Mutations of KRAS indicate that a patient may not respond to the anti-epidermal growth factor receptor drugs cetuximab (Erbitux) or panitumumab (Vectibix). ASCO recommends that Stage IV colorectal patients be tested for KRAS if anti-EGFR therapy is being considered. There are two types of KRAS genes: normal and mutated. The normal KRAS gene is also called the wild type allele; the mutated gene may be described as abnormal or having an abnormal codon (abnormal DNA sequence).

Rationale

KRAS is a Registry Data Collection Variable in AJCC. It was previously collected as Colon and Rectum CS SSF #9.

Additional Information

Source documents: pathology report, clinical laboratory report

Other names include K-Ras, K-ras, Ki-Ras

For further information, refer to the **Colon and Rectum Biomarker** Reporting cancer protocol published by the College of American Pathologists for the AJCC Staging System *Colon and Rectum*.

Notes

Note 1: Physician Statement

- Physician statement of KRAS can be used to code this data item when no other information is available.

Note 2: Applicable Stages

- KRAS may be recorded for all stages; however, it is primarily performed for patients with metastatic disease. If information is not available, code 9

Note 3: Results from nodal or metastatic tissue

- Results from nodal or metastatic tissue may be used for KRAS.

Note 4: Timing

- Record the results of the KRAS from the initial workup (clinical and pathological workup).

Coding Guidelines

There are 4 KRAS codons that are commonly mutated in colorectal cancers. This SSDI does not record the actual mutation, but instead records the codon or codon group that contains the mutation. If a specific KRAS mutation is reported, its codon may be identified from the following list of common KRAS mutations grouped by codon.

1) Codon 12 (see code 1)

- Gly12Asp (GGT>GAT)
- Gly12Val (GGT>GTT)
- Gly12Cys (GGT>TGT)
- Gly12Ser (GGT>AGT)
- Gly12Ala (GGT>GCT)
- Gly12 Arg (GGT>CGT)
- Codon 12 mutation, not otherwise specified

2) Codon 13 (see code 1)

- Gly13Asp (GGC>GAC)
- Gly13Arg (GGC>CGC)
- Gly13Cys (GGC>TGC)

- Gly13Ala (GGC>GCC)
- Gly13Val (GGC>GTC)
- Codon 13 mutation, not otherwise specified

3) Codon 61 (see code 1)

- Gln61Leu (CAA>CTA)
- Gln61His (CAA>CAC)
- Codon 61 mutation, not otherwise specified

4) Codon 146 (See code 2)

- Ala146Thr (G436A) (GCA>ACA)
- Codon 146 mutation, not otherwise specified

5) Other specified coding (excluding 12, 13, 61, 146) (See code 3)

6) Unknown codon (See code 4)

- KRAS positive, specific codon not mentioned

7) Code 9 when

- Insufficient amount of tissue available to perform test
- No microscopic confirmation of tumor
- Pathology report available and there is no mention of KRAS
- KRAS not ordered or not done, or unknown if ordered or done

Code	Description
0	Normal KRAS negative, KRAS wild type Negative for (somatic) mutations, no alterations, no (somatic) mutations identified, not present, not detected
1	Abnormal (mutated) in codon(s) 12, 13 and/or 61
2	Abnormal (mutated) in codon 146 only
3	Abnormal (mutated), but not in codon(s) 12, 13, 61, or 146
4	Abnormal (mutated), NOS, codon(s) not specified
7	Test ordered, results not in chart

Code	Description
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record KRAS not assessed or unknown if assessed

00200: Colon and Rectum

3890: Microsatellite Instability

Item Length: 1
NAACCR Item #: 3890
XML Parent-NAACCR ID: Tumor-microsatelliteInstability
NAACCR Alternate Name: Microsatellite Instability (MSI)
Active years: 2018+
Schema(s):

- 00200: Colon and Rectum

Description

The microsatellite instability (MSI) test is a genetic test performed on tumor tissue to look for differences in length of certain non-functioning sections of DNA. The differences are caused by problems with the genes that encode proteins that normally repair certain types of DNA damage. Knowing whether cancer is microsatellite instability high may help plan the best treatment

Microsatellites are short, repeated, sequences of DNA. Cancer cells that have large numbers of microsatellites that may have defects in the ability to correct mistakes that occur when DNA is copied in the cell. Microsatellite instability is found most often in colorectal cancer, other types of gastrointestinal cancer, and endometrial cancer. It may also be found in cancers of the breast, prostate, bladder, and thyroid.

High MSI, found in about 15% of colorectal carcinomas, is an adverse prognostic factor for colorectal carcinomas and predicts poor response to 5-FU chemotherapy (although the addition of oxaliplatin in FOLFOX regimens negates the adverse effects). High MSI is a hallmark of hereditary nonpolyposis colorectal carcinoma, also known as Lynch syndrome.

A high proportion of colon cancers arising in patients with hereditary nonpolyposis colorectal cancer (HNPCC) (also known as Lynch syndrome) have high MSI and a smaller percentage of colon cancers not associated with Lynch syndrome have high MSI. Patients with colon cancers with high MSI may be further tested to determine if they have HNPCC. In addition, MSI is a useful prognostic marker in that patients with high MSI colon cancers have better response to surgery and survival.

Rationale

Microsatellite Instability (MSI) is a Registry Data Collection Variable in AJCC. It was previously collected as Colon and Rectum, CS SSF #7.

Additional Information

Source documents: pathology report

Other names include MSI, Mismatch repair, MMR, MSI-H

For further information, refer to the **Colon and Rectum Biomarker** Reporting cancer protocol published by the College of American Pathologists for the AJCC Staging System *Colon and Rectum*.

Notes

Note 1: Physician Statement

- Physician statement of MSI can be used to code this data item when no other information is available.

Note 2: Applicable stages

- MSI may be recorded for all stages; however, it is primarily performed for invasive neoplasms
- For non-invasive neoplasms (behavior /2), code to 9 if no information available.

Note 3: Results from nodal or metastatic tissue

- Results from nodal or metastatic tissue may be used for Microsatellite Instability.

Coding Guidelines

Microsatellite Instability (MSI)

- Testing for MSI may be done by immunology or genetic testing. Only genetic testing results will specify whether the MSI is low or high.
- MSI is looking at instability in informative markers

1) Code 0

- MSS (Code 0)
- Stable (Code 0)
- Negative (Code 0)
- Low probability of MSI-H (Code 0)
- MSS/MSI-L (Code 0)

2) Code 1

- MSI-L (Code 1)

3) Code 2

- Unstable, high (Code 2)
- Unstable, NOS (no designation of high or low) (Code 2)

- MSI-H (Code 2)

4) Code 9

- MSI-I (intermediate) (Code 9)

Mismatch Repair (MMR)

- Testing for Mismatch Repair (MMR) is usually done by immunohistochemistry (IHC).
- Most common markers are MLH1, MSH2, MSH6, PMS2

1) Code 0

- No loss of nuclear expression (code 0)
- Mismatch repair (MMR) intact (code 0)
- MMR proficient (pMMR or MMR-P) (code 0)
- MMR normal (code 0)

2) Code 2

- Loss of nuclear expression (code 2)
- MMR deficient (dMMR or MMR-D) (code 2)
- MMR abnormal (code 2)

MSI and MMR

1) Code 0 If all tests done are negative

2) Code 2 If both tests are done and one or both are positive

Code	Description
0	Microsatellite instability (MSI) stable; microsatellite stable (MSS); negative, NOS AND/OR Mismatch repair (MMR) intact, no loss of nuclear expression of MMR proteins MMR proficient (pMMR or MMR-P)
1	MSI unstable low (MSI-L)
2	MSI unstable high (MSI-H) AND/OR MMR deficient (dMMR or MMR-D) loss of nuclear expression of one or more MMR proteins, MMR protein deficient)

Code	Description
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record MSI-indeterminate MSI-equivocal Microsatellite instability not assessed or unknown if assessed

00200: Colon and Rectum

3940: BRAF Mutational Analysis

Item Length: 1
NAACCR Item #: 3940
XML Parent-NAACCR ID: Tumor-brafMutationalAnalysis
NAACCR Alternate Name: BRAF Mutational Analysis
Active years: 2021+
Schema(s):

- 00200: Colon and Rectum

Description

The BRAF oncoprotein is involved in transmitting cell growth and proliferation signals from KRAS and NRAS. The BRAF V600E mutation is associated with poorer prognosis and predicts lack of response to anti-EGFR therapies.

"BRAF V600E is a specific mutation (change) in the BRAF gene, which makes a protein that is involved in sending signals in cells and in cell growth. This BRAF gene mutation is found in colorectal cancer. It may increase the growth and spread of cancer cells. Checking for this BRAF mutation in tumor tissue may help to plan cancer treatment. BRAF (V600E) kinase inhibitor RO5185426 blocks certain proteins made by the mutated BRAF gene, which may help keep cancer cells from growing." (NCI Dictionary of Cancer Terms)

NRAS is a gene which belongs to a class of genes known as oncogenes. When mutated, oncogenes have the potential to cause normal cells to become cancerous. Studies suggest that NRAS gene mutations are often present in colorectal cancer.

The most common BRAF mutations is BRAF V600E (c.1799T>A) mutation.

Rationale

BRAF mutational analysis is recommended in clinical guidelines for patients with advanced colorectal cancer as a prognostic marker and factor in determining appropriate therapy. It is a new data item for cases diagnosed 1/1/2021+.

Additional Information

Source documents: pathology report, clinical laboratory report

For further information, refer to the **Colon and Rectum Biomarker** Reporting cancer protocol published by the College of American Pathologists for the AJCC Staging System *Colon and Rectum*.

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2021+
- For cases diagnosed 2018-2020, this SSDI must be blank

Note 2: Physician Statement

- Physician statement of BRAF can be used to code this data item when no other information is available.

Note 3: Applicable stages

- BRAF may be recorded for all stages; however, it is primarily performed for patients with metastatic disease. If information is not available, code 9.

Note 4: Results from nodal or metastatic tissue

- Results from nodal or metastatic tissue may be used for BRAF.

Note 5: Neoadjuvant Therapy

- Record the assay from tumor specimens prior to neoadjuvant therapy.
- If neoadjuvant therapy is given and there are no BRAF results from pre-treatment specimens, report the findings from post-treatment specimens.

Coding Guidelines

1) Code 0 when BRAF negative/wild type/not detected

2) Code 1, 2 or 3 when BRAF identified/detected

3) Code 4 for when BRAF identified, mutation not known

4) Code 9 when

- Insufficient amount of tissue available to perform test
- Test done and documented to be equivocal
- No microscopic confirmation of tumor
- BRAF mutational analysis not ordered or not done, or unknown if ordered or done

Code	Description
0	Normal BRAF negative, BRAF wild type Negative for (somatic) mutations, no alterations, no (somatic) mutations identified, not present, not detected
1	Abnormal (mutated)/detected: BRAF V600E (c.1799T>A) mutation
2	Abnormal (mutated)/detected, but not BRAF V600E (c.1799T>A) mutation
3	Abnormal (mutated)/detected, KIAA1549: BRAF gene fusion
4	Abnormal (mutated), BRAF, NOS
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record BRAF not assessed or unknown if assessed
<Blank>	Must be blank if diagnosis year is before 2021

00200: Colon and Rectum

3941: NRAS Mutational Analysis

Item Length: 1
NAACCR Item #: 3941
XML Parent-NAACCR ID: Tumor-nrasMutationalAnalysis
NAACCR Alternate Name: NRAS Mutational Analysis
Active years: 2021+
Schema(s):

- 00200: Colon and Rectum

Description

NRAS is a signaling intermediate in the growth receptor pathway. Certain NRAS mutations predict poor response to anti-EGFR therapy in patients with metastatic colorectal cancer.

KRAS (NAACCR Data Item # 3866) and NRAS are important signaling intermediates in the growth receptor pathway, which controls cell proliferation and survival. Both KRAS and NRAS may be constitutively activated through mutation during colorectal carcinogenesis so that they continuously stimulate cell proliferation and prevent cell death (reference AJCC 8, pg. 266). KRAS and NRAS mutations predict poor response to anti-EGFR therapy in patients with metastatic colon cancer. AJCC 8 estimates that KRAS may be activated in up to 40% and NRAS in about 7% of colorectal carcinomas.

Rationale

NRAS mutational analysis is recommended in clinical guidelines for patients with metastatic colon cancer who are being considered for anti-EGFR therapy. It is a new data item for cases diagnosed 1/1/2021+.

Additional Information

Source documents: pathology report, clinical laboratory report

For further information, refer to the **Colon and Rectum Biomarker** Reporting cancer protocol published by the College of American Pathologists for the AJCC Staging System *Colon and Rectum*.

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2021+
- For cases diagnosed 2018-2020, this SSDI must be blank

Note 2: Physician Statement

- Physician statement of NRAS can be used to code this data item when no other information is available.

Note 3: Applicable stages

- NRAS may be recorded for all stages; however, it is primarily performed for patients with metastatic disease. If information is not available, code 9.

Note 4: Results from nodal or metastatic tissue

- Results from nodal or metastatic tissue may be used for NRAS.

Note 5: Neoadjuvant Therapy

- Record the assay from tumor specimens prior to neoadjuvant therapy.
- If neoadjuvant therapy is given and there are no NRAS results from pre-treatment specimens, report the findings from post-treatment specimens.

Coding Guidelines

There are 3 NRAS codons that are commonly mutated in colorectal cancers. This SSDI does not record the actual mutation, but instead records the codon or codon group that contains the mutation. If a specific NRAS mutation is reported, its codon may be identified from the following list of common NRAS mutations grouped by codon.

1) Codon 12 (See code 1)

- Gly12Asp (GGT>GAT)
- Gly12Val (GGT>GTT)
- Gly12Cys (GGT>TGT)
- Gly12Ser (GGT>AGT)
- Gly12Ala (GGT>GCT)
- Gly12Arg (GGT>CGT)
- Codon 12 mutation, not otherwise specified

2) Codon 13 (See code 1)

- Codon 13 mutation, not otherwise specified

3) Codon 61 (See code 1)

- Gln61Lys (CAA>AAA)

- Gln61Arg (CAA>CGA)
- Codon 61 mutation, not otherwise specified

4) Other specified codons (excluding 12, 13, 61) (See code 2)

5) Unknown codon (See code 4)

- NRAS positive, specific codon not mentioned

6) Code 9 when

- Insufficient amount of tissue available to perform test
- No microscopic confirmation of tumor
- Pathology report available and there is no mention of NRAS
- NRAS not ordered or not done, or unknown if ordered or done

Code	Description
0	Normal NRAS negative; NRAS wild type Negative for (somatic) mutations, no alterations, no (somatic) mutations identified, not present, not detected
1	Abnormal (mutated)/detected in codon(s) 12, 13, and/or 61
2	Abnormal (mutated)/detected, codon(s) specified but not in codon(s) 12, 13, or 61
4	Abnormal (mutated), NOS, codon(s) not specified
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record NRAS not assessed or unknown if assessed
<Blank>	Must be blank if diagnosis year is before 2021

09210: Anus [V9: 2023+]

3956: p16 Anus

Item Length: 1
NAACCR Item #: 3956
XML Parent-NAACCR ID: Tumor-p16
NAACCR Alternate Name: p16
Active years: 2023+
Schema(s):

- 09210: Anus [V9: 2023+]

Description

The p16 biomarker is overexpressed (produced) in response to HPV. It is therefore a surrogate marker for HPV disease.

p16 is a tumor suppressor protein also known as cyclin-dependent kinase inhibitor 2A.

The p16 biomarker is overexpressed (produced) in response to HPV. It is therefore a surrogate marker for HPV disease.

Rationale

Patients with HPV have a different survival or outcome, so it is important to be able to distinguish this by documenting the p16 results. Testing is performed by immunohistochemistry (IHC) which is inexpensive and has near universal availability. It has an easily standardized interpretation. HPV testing is usually performed through DNA testing which is more expensive and less widely available. HPV testing also has technically more variability with the interpretation.

Additional Information

Source documents: pathology report, physician's statement

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2023+
- For cases diagnosed 2018-2022, this SSDI must be blank

Note 2: p16 Results ONLY

- This data item must be based on testing results for p16 overexpression.
- Testing for HPV by DNA, mRNA, antibody, or other methods should not be coded in this data item

- Do not confuse p16 with HPV, which is a specific strain of virus. A statement of a patient being HPV positive or negative is not enough to code this data item.

Coding Guidelines

Code 0 for p16 expression of weak intensity or limited distribution.

Code	Description
0	p16 Negative; Nonreactive
1	p16 Positive; Diffuse, Strong reactivity
8	Not applicable: Information not collected for this case (If this time is required by your standard setter, use of code 8 will result in an edit error)
9	Not tested for p16; Unknown
<Blank>	Must be blank if diagnosis year is before 2023

HEPATOBILIARY SYSTEM

00220: Liver

3810: AFP Pretreatment Lab Value

Item Length: 6
NAACCR Item #: 3810
XML Parent-NAACCR ID: Tumor-afpPretreatmentLabValue
NAACCR Alternate Name: AFP (Alpha Fetoprotein) Pretreatment Lab Value
Active years: 2018+
Schema(s):

- 00220: Liver

Description

AFP (Alpha Fetoprotein) Pretreatment Lab Value is a nonspecific serum protein that generally is elevated in the setting of hepatocellular carcinoma (HCC). This data item pertains to the pre-treatment lab value.

A protein normally produced by a fetus. Alpha fetoprotein levels are usually undetectable in the blood of healthy adult men or women (who are not pregnant). An elevated level of alpha-fetoprotein suggests the presence of either a primary liver cancer or germ cell tumor.

There are 2 related data items that record information on CEA for Colon and Rectum.

- 3810: AFP Pretreatment Lab Value
- 3809: AFP Pretreatment Interpretation

Rationale

AFP (Alpha Fetoprotein) Pretreatment Lab Value is a Registry Data Collection Variable in AJCC. This data item was previously collected for Liver, CS SSF #3.

Additional Information

Source documents: clinical laboratory report (blood serum radioimmunoassay or enzyme assay (EIA)); sometimes in history and physical or clinical statement in pathology report

Normal Reference Range:

- Adult men and non-pregnant women: 0-15 ng/ml (SI: 0-15 mg/L)

Notes

Note 1: Physician Statement

- Physician statement of AFP (Alpha Fetoprotein) Pretreatment Lab Value can be used to code this data item when no other information is available.

Note 2: Pretreatment results only

- Record the lab value of the highest AFP test result documented in the medical record prior to treatment. The lab value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Related data item

- The same laboratory test should be used to record information in the related data item 3810: AFP Pretreatment Lab Value

Coding Guidelines

1) Record the highest value prior to treatment in nanograms per milliliter (ng/ml) in the range 0.1 (1 ng/ml) to 9999.9 (9999 ng/ml) in the Lab Value data item.

2) A lab value expressed in micrograms per liter (ug/L) is equivalent to the same value expressed in ng/ml.

Examples

- AFP Lab Value 0 ng/ml - Code 0.0
- AFP Lab Value 23.6 ng/ml - Code 23.6
- AFP Lab Value 11,0000 - Code XXXX.1
- AFP Lab Value Test Ordered, results not in chart - Code XXXX.7
- AFP Lab Value Not documented in medical record, AFP test not done, unknown if APF test done - Code XXXX.9

Code	Description
0.0	0.0 nanograms/milliliter (ng/ml); not detected
0.1-9999.9	0.1-9999.9 ng/ml (Exact value to nearest tenth of ng/ml)
XXXX.1	10,000.0 ng/ml or greater
XXXX.7	Test ordered, results not in chart
XXXX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XXXX.8 will result in an edit error.)
XXXX.9	Not documented in medical record AFP (Alpha Fetoprotein) Pretreatment Lab Value not assessed or unknown if assessed

00220: Liver

3809: AFP Pretreatment Interpretation

Item Length: 1
NAACCR Item #: 3809
XML Parent-NAACCR ID: Tumor-afpPretreatmentInterpretation
NAACCR Alternate Name: AFP (Alpha Fetoprotein) Pretreatment Interpretation
Active years: 2018+
Schema(s):

- 00220: Liver

Description

AFP (Alpha Fetoprotein) Pretreatment Interpretation, a nonspecific serum protein that generally is elevated in the setting of hepatocellular carcinoma (HCC), is a prognostic factor for liver cancer. This data item pertains to the pre-treatment interpretation.

There are 2 related data items that record information on CEA for Colon and Rectum.

- 3810: AFP Pretreatment Lab Value
- 3809: AFP Pretreatment Interpretation

Rationale

AFP (Alpha Fetoprotein) Pretreatment Interpretation is a Registry Data Collection Variable in AJCC. This data item was previously collected for Liver, CS SSF #1.

Additional Information

Source documents: clinical laboratory report (blood serum radioimmunoassay or enzyme assay (EIA)); sometimes in history and physical or clinical statement in pathology report

Normal Reference Range:

- Adult men and non-pregnant women: 0-15 ng/ml (SI: 0-15 mg/L)

Notes

Note 1: Physician Statement

- Physician statement of AFP (Alpha Fetoprotein) Pretreatment Lab Value can be used to code this data item when no other information is available.

Note 2: Pretreatment results only

- Record the lab value of the highest AFP test result documented in the medical record prior to treatment. The lab value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Related data item

- The same laboratory test should be used to record information in the related data item 3810: AFP Pretreatment Lab Value.

Coding Guidelines

1) Record the clinician's interpretation of the highest value **prior to treatment**, based on the reference range used by the lab in the Interpretation data item.

- If the physician's statement is not available, use the **Reference Ranges** included in **Additional Information** for this data item to determine the interpretation

Code	Description
0	Negative/normal; within normal limits
1	Positive/elevated
2	Borderline; undetermined if positive or negative
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record AFP pretreatment interpretation not assessed or unknown if assessed

00220: Liver

3813: Bilirubin Pretreatment Total Lab Value

Item Length: 5
NAACCR Item #: 3813
XML Parent-NAACCR ID: Tumor-bilirubinPretxTotalLabValue
NAACCR Alternate Name: Bilirubin Pretreatment Total Lab Value
Active years: 2018+
Schema(s):

- 00220: Liver

Description

Bilirubin Pretreatment Total Lab Value records the bilirubin value prior to treatment. Bilirubin level is an indicator of how effectively the liver excretes bile and is required to calculate the Model for End-Stage Liver Disease (MELD) score used to assign priority for liver transplant.

Bilirubin is produced from the breakdown of hemoglobin (the protein that binds oxygen) in red blood cells. The liver processes bilirubin by excreting it through bile into the intestine. If the liver is damaged, there will be too much bilirubin in the blood, and this can produce jaundice. Elevated bilirubin levels can indicate liver or blood disorders or blockage of bile ducts.

The Model for End-Stage Liver Disease (MELD) is a numerical scale used to determine how urgently a patient with liver disease needs a liver transplant. Results from three routine lab tests are used to calculate the MELD score. Bilirubin, one of the tests, measures how effectively the liver excretes bile. The purpose of this scale was to help prioritize patients for liver transplant by estimating their risk of dying while waiting for transplant.

There are several related data items that are defined to record the MELD score.

- 3813: Bilirubin Pretreatment Total Lab Value
- 3814: Bilirubin Pretreatment Unit of Measure
- 3824: Creatinine Pretreatment Lab Value
- 3825: Creatinine Pretreatment Unit of Measure
- 3860: International Normalized Ratio

Rationale

Bilirubin Pretreatment Total Lab Value is a Registry Data Collection Variable in AJCC. This data item was previously collected as Liver, CS SSF #6.

Additional Information

Source documents: clinical laboratory report (blood serum); value may be part of a metabolic or liver function panel

Other names include TBIL.

Normal Reference Range

- 0.3-1.5 mg/dL (5-20.5 umol/L)
- The normal range may vary slightly from lab to lab.

Notes

Note 1: Physician Statement

- Physician statement of Bilirubin Pretreatment Total Lab Value can be used to code this data item when no other information is available.

Note 2: Total Bilirubin

- Assay of Bilirubin Pretreatment Total Lab Value includes conjugated (direct) and unconjugated (indirect) bilirubin and total bilirubin values
    - Record the **total bilirubin** value to the nearest tenth of mg/dl (or umol/L) for this data item
    - Do not code **individual** conjugate, direct, unconjugated, indirect, or delta values or bilirubin in urine

Note 3: Pretreatment results only

- Record the lab value of the highest Bilirubin test result documented in the medical record prior to treatment. The lab value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.

Note 4: Related data item

- The same laboratory test should be used to record information in the related data item 3814: Bilirubin Pretreatment Unit of Measure.

Coding Guidelines

1) Record the highest value prior to treatment in the range 0.1 mg/ml to 999.9 mg/ml OR 0.1 umol/L to 999.9 umol/L. in the Lab Value data item and the unit of measure for measuring the lab value in the Unit of Measure data item.

Examples

- Bilirubin Lab Value 0.0 mg/ml: Lab Value = 0.0, Unit Measure = 1
- Bilirubin Lab Value 23.6 umol/L: Lab Value = 23.6, Unit Measure = 2
- Bilirubin Lab Value 127.8 mg/ml: Lab Value = 127.8, Unit Measure = 1

- Bilirubin Lab Value 1567 umol/L: Lab Value 1567.0 Unit Measure = 2
- Bilirubin Lab Value 638.4: Lab Value = 638.4 Unit Measure = 9
- Bilirubin Lab Value Test Ordered, results not in chart: Lab Value = XXXX.7, Unit Measure = 7
- Bilirubin Lab Value Not documented in medical record, Bilirubin test not done, unknown if Bilirubin test done, Lab Value = XXXX.9, Unit Measure 9

Code	Description
0.0	0.0 milligram/deciliter (mg/dL) 0.0 micromole/liter (umol/L)
0.1-999.9	0.1-999.9 milligram/deciliter (mg/dL) 0.1-999.9 micromole/liter (umol/L)
XXX.1	1000 milligram/deciliter (mg/dL) or greater 1000 micromole/liter (umol/L) or greater
XXX.7	Test ordered, results not in chart
XXX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XXX.8 will result in an edit error.)
XXX.9	Not documented in medical record Bilirubin Pretreatment Total Lab Value not assessed or unknown if assessed

00220: Liver

3814: Bilirubin Pretreatment Unit of Measure

Item Length: 1
NAACCR Item #: 3814
XML Parent-NAACCR ID: Tumor-bilirubinPretxUnitOfMeasure
NAACCR Alternate Name: Biliribun Pretreatment Unit of Measure
Active years: 2018+
Schema(s):

- 00220: Liver

Description

Bilirubin Pretreatment Unit of Measure identifies the unit of measure for the bilirubin value measured prior to treatment. Bilirubin is commonly measured in units of Milligrams/deciliter (mg/dL) in the United States and Micromoles/liter (umol/L) in Canada and Europe.

There are two methods of describing bilirubin levels in the blood, weight in grams (milligrams per deciliter), usually used in the US, and molecular count in moles (micromoles per liter) in Canada. Conversion: 1 mg/dL = 17.1 umol/L. Code the unit of measure used by the facility laboratory

There are two related data items that record information on Bilirubin

- 3813: Bilirubin Pretreatment Total Lab Value.
- 3814: Bilirubin Pretreatment Unit of Measure.

Rationale

Bilirubin Pretreatment is a Registry Data Collection Variable in AJCC. Bilirubin Pretreatment Unit of Measure is needed to identify the unit in which bilirubin is measured and was previously collected as Liver, CS SSF #7.

Additional Information

Source documents: clinical laboratory report (blood serum); value may be part of a metabolic or liver function panel

Other names include TBIL

Normal Reference Range:

- 0.3-1.5 mg/dL (5-20.5 umol/L)
- The normal range may vary slightly from lab to lab.

Notes

Note 1: Physician Statement

- Physician statement of Bilirubin Pretreatment Unit of Measure can be used to code this data item when no other information is available.

Note 2: Pretreatment results only

- Record this data item based on a blood test performed at diagnosis (pre-treatment). Use the highest value available
- Record the blood or serum creatinine value for this data item
    - Do not use urine results to code this data item.

Note 3: Measurement definitions

- There are two main methods of describing concentrations: by weight, and by molecular count.
- Weights are recorded in grams, and molecular counts are recorded in moles.
- Milligrams/deciliter (mg/dL) is the unit of measure commonly used in the United States.
- Micromoles/liter (umol/L) is the designated Systeme International (SI) unit of measure commonly used in Canada and Europe.
    - 1 mg/dL of bilirubin is 17.1 umol/L.

Note 4: Related data item

- The same laboratory test should be used to record information in the related data item 3813: Bilirubin Pretreatment Total Lab Value.

Code	Description
1	Milligrams per deciliter (mg/dL)
2	Micromoles/liter (umol/L)
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Bilirubin unit of measure not assessed or unknown if assessed

00220: Liver

3824: Creatinine Pretreatment Lab Value

Item Length: 4
NAACCR Item #: 3824
XML Parent-NAACCR ID: Tumor-creatininePretreatmentLabValue
NAACCR Alternate Name: Creatinine Pretreatment Lab Value
Active years: 2018+
Schema(s):

- 00220: Liver

Description

Creatinine Pretreatment Lab Value, an indicator of kidney function, is required to calculate the Model for End-Stage Liver Disease (MELD) score, which is used to assign priority for liver transplant.

Creatinine concentration in blood is a marker of renal function. Elevated levels are associated with severe liver disease. Creatinine can be measured in blood serum or urine, but these data items apply to blood levels only. Do not code urine creatinine or creatinine clearance in this field.

There are two methods of describing creatinine levels in the blood, weight in grams (milligrams per deciliter), usually used in the US, and molecular count in moles (micromoles per liter) in Canada. Conversion: 1 mg/dL = 17.1 umol/L. Code the unit of measure used by the facility laboratory.

The Model for End-Stage Liver Disease (MELD) is a numerical scale used to determine how urgently a patient with liver disease needs a liver transplant. Results from three routine lab tests are used to calculate the MELD score. Bilirubin, one of the tests, measures how effectively the liver excretes bile. The purpose of this scale was to help prioritize patients for liver transplant by estimating their risk of dying while waiting for transplant.

There are several related data items that are defined to record the MELD score.

- 3813: Bilirubin Pretreatment Total Lab Value
- 3814: Bilirubin Pretreatment Unit of Measure
- 3824: Creatinine Pretreatment Lab Value
- 3825: Creatinine Pretreatment Unit of Measure
- 3860: International Normalized Ratio

Rationale

Creatinine Pretreatment Lab Value is a Registry Data Collection Variable in AJCC. This data item was previously collected for Liver, CS SSF #4.

Additional Information

Source documents: clinical laboratory report (blood serum); value may be part of a metabolic or liver function panel

Other names include Serum creatinine, plasma creatinine (PCr), blood creatinine, Creat, Cre

- Do not confuse with creatinine clearance or creatine; these are not the same tests. Do not code urine creatinine or creatinine clearance.

Normal Reference Range

- Women: 0.5-1.0 mg/dL (45-90 umol/L)
- Men: 0.7-1.2 mg/dL (60-110 umol/L). Male values are usually higher due to greater muscle mass.
- Normal value ranges may vary slightly among different laboratories.

Notes

Note 1: Physician Statement

- Physician statement of Creatinine Pretreatment Lab Value can be used to code this data item when no other information is available.

Note 2: Pretreatment results only

- Record this data item based on a blood test performed at diagnosis (pre-treatment). Use the highest value available
- Record the blood or serum creatinine value for this data item
    - Do not use urine results to code this data item.

Note 3: Related data item

- The same laboratory test should be used to record information in the related data item data item 3825: Creatinine Pretreatment Unit of Measure.

Coding Guidelines

1) Record the highest value prior to treatment in the range 0.1 mg/ml to 999.9 mg/ml OR 0.1 umol/L to 999.9 umol/L in the Lab Value data item and the unit of measure for measuring the lab value in the Unit of Measure data item.

Examples

- Creatinine Lab Value 0.0 mg/ml: Lab Value = 0.0, Unit Measure = 1
- Creatinine Lab Value 0.7 umol/L: Lab Value = 0.7 Unit Measure = 2
- Creatinine Lab Value 98.3: Lab Value = 98.3, Unit Measure = 9
- Creatinine Lab Value Test Ordered, results not in chart: Lab Value = XXXX.7, Unit Measure = 7
- Creatinine Lab Value Not documented in medical record, Bilirubin test not done, unknown if Bilirubin test done: Lab Value = XXXX.9, Unit Measure 9

Code	Description
0.0	0.0 milligram/deciliter (mg/dl) 0.0 micromole/liter (umol/L)
0.1-99.9	0.1-99.9 milligram/deciliter (mg/dl) 0.1-99.9 micromole/liter (umol/L) (Exact value to nearest tenth of mg/dl or umol/L)
XX.1	100 mg/dl or greater 100 umol/L or greater
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error.)
XX.9	Not documented in medical record Creatinine Pretreatment Lab Value not assessed or unknown if assessed

00220: Liver

3825: Creatinine Pretreatment Unit of Measure

Item Length: 1
NAACCR Item #: 3825
XML Parent-NAACCR ID: Tumor-creatininePretxUnitOfMeasure
NAACCR Alternate Name: Creatinine Pretreatment Unit of Measure
Active years: 2018+
Schema(s):

- 00220: Liver

Description

Creatinine Pretreatment Unit of Measure identifies the unit of measure for the creatinine value measured in blood or serum prior to treatment. Creatinine is commonly measured in units of Milligrams/deciliter (mg/dL) in the United States and Micromoles/liter (umol/L) in Canada and Europe.

There are two methods of describing creatinine levels in the blood, weight in grams (milligrams per deciliter), usually used in the US, and molecular count in moles (micromoles per liter) in Canada. Conversion: 1 mg/dL = 17.1 mol/L. Code the unit of measure used by the facility laboratory.

There are two related data items that record information on Creatinine.

- 3824: Creatinine Pretreatment Lab Value.
- 3825: Creatinine Pretreatment Unit of Measure

Rationale

Creatinine Pretreatment Unit of Measure identifies the unit of measure for the creatinine value measured in blood or serum prior to treatment. Creatinine is commonly measured in units of Milligrams/deciliter (mg/dL) in the United States and Micromoles/liter (umol/L) in Canada and Europe.

Additional Information

Source documents: clinical laboratory report (blood serum); value may be part of a metabolic or liver function panel

Other names include Serum creatinine, plasma creatinine (PCr), blood creatinine, Creat, Cre

- Do not confuse with creatinine clearance or creatine; these are not the same tests. Do not code urine creatinine or creatinine clearance.

Normal Reference Range

- Women: 0.5-1.0 mg/dL (45-90 umol/L)

- Men: 0.7-1.2 mg/dL (60-110 umol/L). Male values are usually higher due to greater muscle mass.
- Normal value ranges may vary slightly among different laboratories.

Notes

Note 1: Physician Statement

- Physician statement of Creatinine Pretreatment Unit of Measure can be used to code this data item when no other information is available.

Note 2: Pretreatment results only

- Record this data item based on a blood test performed at diagnosis (pre-treatment). Use the highest value available
- Record the blood or serum creatinine value for this data item
    - Do not use urine results to code this data item.

Note 3: Measurement definitions

- There are two main methods of describing concentrations: by weight, and by molecular count.
- Weights are recorded in grams, and molecular counts are recorded in moles.
- Milligrams/deciliter (mg/dL) is the unit of measure commonly used in the United States.
- Micromoles/liter (umol/L) is the designated Systeme International (SI) unit of measure commonly used in Canada and Europe.
    - 1 mg/dL of bilirubin is 17.1 umol/L.

Note 4: Related data item

- The same laboratory test should be used to record information in the related data item data item 3824: Creatinine Pretreatment Lab Value.

Code	Description
1	Milligrams/deciliter (mg/dL)
2	Micromoles/liter (umol/L)
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Creatinine unit of measure not assessed or unknown if assessed

00220: Liver

3860: International Normalized Ratio Prothrombin Time

Item Length: 3
NAACCR Item #: 3860
XML Parent-NAACCR ID: Tumor-iNRProthrombinTime
NAACCR Alternate Name: INR (International Normalized Ratio for Prothrombin Time)
Active years: 2018+
Schema(s):

- 00220: Liver

Description

International Normalized Ratio for Prothrombin Time (INR), an indicator of the liver's ability to make clotting factors, is required to calculate the Model for End-Stage Liver Disease (MELD) score, is used to assign priority for liver transplant.

The prothrombin time is a measure of how quickly the blood clots, which may also indicate liver disease. The international normalized ratio (INR) is a calculation of the patient's prothrombin time divided by the normal mean prothrombin time for the particular thromboplastin reagent used and is expressed as a decimal number. An elevated level indicates the blood is too "thin" and does not clot properly, increasing the risk of bleeding. A value under 1.0 increases the risk of blood clots.

The Model for End-Stage Liver Disease (MELD) is a numerical scale used to determine how urgently a patient with liver disease needs a liver transplant. Results from three routine lab tests are used to calculate the MELD score. International normalized ratio for prothrombin time (INR), one of the tests, measures the liver's ability to make blood clotting factors.

There are several related data items that are defined to record the MELD score.

- 3813: Bilirubin Pretreatment Total Lab Value
- 3814: Bilirubin Pretreatment Unit of Measure
- 3824: Creatinine Pretreatment Lab Value
- 3825: Creatinine Pretreatment Unit of Measure
- 3860: International Normalized Ratio

Rationale

International Normalized Ratio for Prothrombin Time (INR) is a Registry Data Collection Variable in AJCC. This data item was previously collected for Liver, CS SSF #8.

Additional Information

Source documents: clinical laboratory report (blood serum); value may be part of a metabolic or liver function panel; outpatient or ambulatory blood test (finger stick) reported in patient history

Other names include INR

Normal ranges:

- For a healthy person is 0.9-1.3
- A high INR level such as INR=5 indicates that there is a high chance of bleeding.
- A low level such as INR = 0.5 indicates a high chance of abnormal clotting. Normal values may vary from lab to lab.

Notes

Note 1: Physician Statement

- Physician statement of the International Normalized Ratio for Prothrombin Time (INR) can be used to code this data item when no other information is available.

Note 2: Pretreatment results only

- Record the value of the highest INR test results documented in the medical record prior to treatment. The value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.

Coding Guidelines

1) Codes 0.1-9.9 are for coding the highest INR exact value in the blood prior to treatment

2) Code X.1 for an INR of 10.0 or greater.

3) Code X.7 if the test was ordered and the results are not in the medical record.

4) Code X.9 when

- There is no information in the medical record about the INR or prothrombin time
- The test is not done or it's unknown if the test was done

Code	Description
0.0	0.0
0.1	0.1 or less

Code	Description
0.2-9.9	0.2 - 9.9 (Exact ratio to nearest tenth)
X.1	10 or greater
X.7	Test ordered, results not in chart
X.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X.8 may result in an edit error.)
X.9	Not documented in medical record INR (International Normalized Ratio for Prothrombin Time) not assessed or unknown if assessed

00220: Liver

3835: Fibrosis Score

Item Length: 1
NAACCR Item #: 3835
XML Parent-NAACCR ID: Tumor-fibrosisScore
NAACCR Alternate Name: Fibrosis Score
Active years: 2018+
Schema(s):

- 00220: Liver
- 00230: Bile Ducts Intrahepatic

Description

Fibrosis Score (Ishak Score), the degree of fibrosis of the liver based on pathological examination, is a prognostic factor for liver cancer.

The Fibrosis Score is based on degree of parenchymal fibrosis or cirrhosis of the nontumorous liver as defined in the surgical pathology report. Multiple fibrosis scoring systems have been described for use in pathological evaluation of liver disease.

- Ishak system uses a scale of 0-6 with 6 indicating cirrhosis.
    - Recommended by AJCC and CAP
- Batts-Ludwig system uses a score of 0-4, with a score of 3 defined as fibrous septa with architectural distortion but no obvious cirrhosis, and a score of 4 defined as cirrhosis
    - Used most commonly by US pathologists
- METAVIR uses scores of F0-F4
    - Used mostly in Europe

Rationale

Fibrosis Score is a Registry Data Collection Variable in AJCC. This data item was previously collected for Liver, CS SSF #2.

Additional Information

Source documents: pathology report (biopsy or FNA path report), surgical resection

Other names include Nontumoral hepatic parenchymal fibrosis/cirrhosis (Intrahepatic Bile Duct Tumors)

Notes

Note 1: Physician Statement

- Physician statement of fibrosis score can be used to code this data item when no other information is available.
    - Code 7 when the physician statement of fibrosis score is not based on histologic examination of the liver

Note 2: Criteria for collecting

- Record the results based on information collected during the initial work-up through the first course surgery, in the absence of neoadjuvant treatment. If multiple histologic assessments of the liver (biopsies or resections) are taken and have conflicting scores, record the highest score.
    - Information collected after the start of **neoadjuvant treatment** or primary systemic or radiation therapy **may not be used** to code this data item

Note 3: FIB Scoring

- FIB-4 is **NOT** a pathological fibrosis score of 4, it is a scoring method using the patient's age and relevant lab values to calculate a score. The medical record may show something like "FIB-4 = 3.52."
- Do not code FIB-4 values in this data item.

Note 4: Ishak score (classified by AJCC)

- F0: None to moderate fibrosis (Ishak Score 0-4)
- F1: Cirrhosis/severe fibrosis (Ishak Score 5-6)
- **Note:** These are not the same thing as the METAVIR score F0 or F1

Coding Guidelines

1) To use codes 0 and 1, you must have a **histological (microscopic) confirmation** of fibrosis/cirrhosis. Code the absence (code 0) or presence (code 1) of fibrosis as documented in the pathology report.

2) If no score is mentioned, descriptive terms may be used to assign codes 0 and 1 – see specific terms in the table below.

3) Code 7 if there is a **clinical diagnosis (no microscopic confirmation)** of severe fibrosis or cirrhosis.

4) Code 9 If a fibrosis score is stated but the scoring system is not recorded, consult with the physician. If no further information is available.

Code	Description
0	Any of the following histologically confirmed No to moderate fibrosis Ishak fibrosis score 0-4 METAVIR score F0-F3 Batt-Ludwig score 0-3
1	Any of the following histologically confirmed Advanced/severe fibrosis Developing cirrhosis Incomplete cirrhosis Transition to cirrhosis Cirrhosis, probable or definite Cirrhosis, NOS Ishak fibrosis score 5-6 METAVIR score F4 Batt-Ludwig score 4
7	Clinical statement of advanced/severe fibrosis or cirrhosis, AND Not histologically confirmed or unknown if histologically confirmed
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Stated in medical record that patient does not have advanced cirrhosis/advanced fibrosis, not histologically confirmed or unknown if histologically confirmed Fibrosis score stated but cannot be assigned to codes 0 or 1 Fibrosis score stated but scoring system not recorded Fibrosis Score not assessed or unknown if assessed

00230: Bile Ducts Intrahepatic

3917: Primary Scleros Cholangitis

Item Length: 1
NAACCR Item #: 3917
XML Parent-NAACCR ID: Tumor-primarySclerosingCholangitis
NAACCR Alternate Name: Primary Sclerosing Cholangitis (PSC)
Active years: 2018+
Schema(s):

- 00230: Bile Ducts Intrahepatic
- 00250: Bile Ducts Perihilar

Description

Primary sclerosing cholangitis denotes a chronic autoimmune inflammation of the bile ducts that leads to scar formation and narrowing of the ducts over time. It is a prognostic factor for intrahepatic bile duct cancer.

Primary sclerosing cholangitis is an idiopathic liver disease characterized by inflammation and fibrosis of the entire biliary tree. The chronic inflammation and injury to ducts may lead to cirrhosis and predispose to cholangiocarcinoma at any site in the biliary tree.

Patients with primary sclerosing cholangitis are advised to receive neoadjuvant chemoradiation and liver transplantation.

Rationale

Primary Sclerosing Cholangitis is a Registry Data Collection Variable in AJCC. This data item was previously collected for Intrahepatic Bile Duct, SSF #11.

Additional Information

Source documents: patient history, pathology report, imaging reports

Other names include PSC, fibrosing cholangitis, chronic obliterative cholangitis, sclerosing cholangitis

Notes

Note: Physician Statement

- Physician statement of Primary Sclerosing Cholangitis (PSC) can be used to code this data item when no other information is available.

Coding Guidelines

1) Code stated diagnosis of PSC either clinically or pathologically as documented in the medical record. This may be by history.

2) Code 0 when primary sclerosing cholangitis is not present

3) Code 1 when primary sclerosing cholangitis is present

4) Code 9 when

- No information in the medical record
- Pathology report is not available
- Primary sclerosing cholangitis is not evaluated (not assessed)
- Unknown if primary sclerosing cholangitis is evaluated (assessed)
- No mention of primary sclerosing cholangitis on the pathology report or in the medical record

Code	Description
0	PSC not identified/not present
1	PSC present
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record PSC not assessed or unknown if assessed

00230: Bile Ducts Intrahepatic

3935: Tumor Growth Pattern

Item Length: 1
NAACCR Item #: 3935
XML Parent-NAACCR ID: Tumor-tumorGrowthPattern
NAACCR Alternate Name: Tumor Growth Pattern
Active years: 2018+
Schema(s):

- 00230: Bile Ducts Intrahepatic

Description

Tumor Growth Pattern refers to the growth pattern of intrahepatic cholangiocarcinoma.

The tumor growth patterns of intrahepatic cholangiocarcinoma include the mass forming type, the periductal infiltrating type, and a mixed type.

- **Periductal infiltrating type** (20%): spreads along the duct in a diffuse manner that may be associated with poorer prognosis. This type of cholangiocarcinoma demonstrates a diffuse longitudinal growth pattern along the bile duct. Limited analyses suggest that the diffuse periductal infiltrating type is associated with a poor prognosis.
- **Mass-forming** (60% of intrahepatic bile duct cases), which grows outward (radially) from the duct and invades the liver parenchyma in a well-defined mass.

Rationale

Tumor Growth Pattern is a Registry Data Collection Variable in AJCC. This data item was previously collected for Intrahepatic Bile Duct, SSF #10.

Additional Information

Source documents: radiology, surgery, or pathology report

Notes

Note: Physician Statement

- Physician statement of tumor growth pattern can be used to code this data item when no other information is available

Coding Guidelines

Record the specific type of tumor growth pattern.

1) Code 1 when documentation describes the tumor as mass-forming only

2) Code 2 when documentation describes the tumor as periductal infiltrating only

3) Code 3 when documentation mentions mixed, mass forming and periductal infiltrating

4) Code 9 when

- Not documented in the medical record
- Tumor growth pattern not evaluated (assessed)
- Unknown if Tumor Growth Pattern evaluated (assessed)

Code	Description
1	Mass-forming
2	Periductal infiltrating
3	Mixed mass-forming and periductal infiltrating
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Radiology and/or pathology report does not mention tumor growth pattern Cannot be determined by the pathologist Tumor growth pattern not assessed or unknown if assessed

00242: Cystic Duct

3926: Schema Discriminator 1

Item Length: 1
NAACCR Item #: 3926
XML Parent-NAACCR ID: Tumor-schemaDiscriminator1
NAACCR Alternate Name: Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct
Active years: 2018+
Schema(s):

- 00242: Cystic Duct
- 00250: Bile Ducts Perihilar
- 00260: Bile Duct Distal

Description

Cystic duct, distal bile ducts, and perihilar bile ducts all have the same ICD-O topography code (C240). However, for purposes of stage grouping in the AJCC 8th edition, they each have different chapters for stage. A schema discriminator is necessary to distinguish between these primary sites so that the appropriate chapter/schema is used.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Summary Stage and EOD data collection system.

Notes

Note: Schema Discriminator for C240

- A schema discriminator is used to discriminate for primary site C240 (extrahepatic bile ducts) for the subsite in which the tumor arose.
- **00242 : Cystic Duct (see code 3)**
  Per the AJCC Gallbladder Staging System, the gallbladder tapers into the cystic duct
- **00250: Bile Ducts Perihilar (see codes 1, 5, 6, 9)**
  Per the AJCC Perihilar Bile Ducts Staging System, perihilar (or proximal) cholangiocarcinomas involve the main biliary confluence of the right and left hepatic ducts and comprise 50-70% of all cases of bile ducts carcinomas
- **00260: Bile Ducts Distal (see codes 4, 7)**
  Per the AJCC Distal Bile Duct Staging System, these tumors have their center located between the confluence of the cystic duct and common hepatic duct and the Ampulla of Vater (excluding ampullary carcinomas.)

Code	Description	Schema ID #/Description
1	Perihilar bile duct(s) Proximal extrahepatic bile duct(s) Hepatic duct(s)	00250: Bile Ducts Perihilar
3	Cystic bile duct; cystic duct	00242: Cystic Duct
4	Distal bile duct Common bile duct Common duct, NOS	00260: Bile Duct Distal
5	Diffuse involvement More than one subsite involved, subsite of origin not stated	00250: Bile Ducts Perihilar
6	Stated as middle extrahepatic bile duct AND treated with combined hepatic and hilar resection	00250: Bile Ducts Perihilar
7	Stated as middle extrahepatic bile duct AND treated with pancreaticoduodenectomy	00260: Bile Duct Distal
9	Extrahepatic bile ducts, NOS	00250: Bile Ducts Perihilar

00250: Bile Ducts Perihilar

See **00242: Cystic Duct**

- 3926: Schema Discriminator 1

See **00230: Bile Ducts Intrahepatic**

- 3917: Primary Scleros Cholangitis

00260: Bile Duct Distal

See **00242: Cystic Duct**

- 3926: Schema Discriminator 1

00280: Pancreas

3942: CA 19-9 PreTx Lab Value

Item Length: 6
NAACCR Item #: 3942
XML Parent-NAACCR ID: Tumor-ca199PretxLabValue
NAACCR Alternate Name: Carbohydrate Antigen 19-9 Pretreatment Lab Value
Active years: 2021+
Schema(s):

- 00280: Pancreas

Description

Carbohydrate Antigen (CA) 19-9 Pretreatment Lab Value records the CA 19-9 value prior to treatment. CA 19-9 is a tumor marker that has prognostic significance for pancreatic cancer.

CA 19-9 is a sialylated Lewis A blood group antigen that is commonly expressed and shed in pancreatic and hepatobiliary disease and in many malignancies, thus is not tumor specific. Preoperative CA 19-9 levels in pancreatic cancer patients correlate both with AJCC staging and resectability [NCCN Guidelines Version 3.2019 Pancreatic Adenocarcinoma].

Rationale

CA 19-9 Pretreatment Lab Value is a strong predictor of resectability in the absence of metastatic disease. It is a new data item for cases diagnosed 1/1/2021+.

Additional Information

Source documents: clinical laboratory report

Other names include Carbohydrate Antigen 19-9, Cancer Antigen-GI, CA-GI, Cancer Antigen 19-9

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2021+
- For cases diagnosed 2018-2020, this SSDI must be blank

Note 2: Physician Statement

- Physician statement of CA 19-9 (Carbohydrate Antigen 19-9) Pretreatment Lab Value can be used to code this data item when no other information is available.

Coding Guidelines

1) Record to the nearest tenth in Units/milliliter (U/ml), the highest CA 19-9 lab value documented in the medical record prior to treatment.

- ***Example 1***: Code a pretreatment CA 19-9 of 7 U/ml as 7.0
- ***Example 2***: Code a pretreatment CA 19-9 of 1672.3 U/ml as 1672.3

2) Record 0.1 when the lab results are stated as less than 0.1 U/ml with no exact value.

3) A known lab value takes priority over codes XXXX.2 and XXXX.3

- The lab value takes priority even if the physician documents the interpretation
    - ***Example:*** Patient noted to have a CA 19-9 of 3,219. Physician notes that the value is elevated
        - Code 3219.0 instead of XXXX.3 (elevated)

Code	Description
0.0	0.0 Units/milliliter (U/ml) exactly
0.1-9999.9	0.1-9999.9 U/ml (Exact value to nearest tenth in U/ml)
XXXX.1	10,000 U/ml or greater
XXXX.2	Lab value not available, physician states CA 19-9 is negative/normal
XXXX.3	Lab value not available, physician states CA 19-9 is positive/elevated/high
XXXX.7	Test ordered, results not in chart
XXXX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XXXX.8 may result in an edit error.)
XXXX.9	Not documented in medical record CA (Carbohydrate Antigen) 19-9 Pretreatment Lab Value not assessed or unknown if assessed
<Blank>	Must be blank if diagnosis year is before 2021

NEUROENDOCRINE TUMORS (NET) SCHEMAS

00290: NET Stomach [8th: 2018-2023]

3863: Ki-67

Item Length: 5
NAACCR Item #: 3863
XML Parent-NAACCR ID: Tumor-ki67
NAACCR Alternate Name: Ki-67
Active years: 2021+
Schema(s):

- 00290: NET Stomach [8th: 2018-2023]
- 09290: NET Stomach [V9: 2024+]
- 00301: NET Duodenum [8th: 2018-2023]
- 09301: NET Duodenum [V9: 2024+]
- 00302: NET Ampulla of Vater [8th: 2018-2023]
- 09302: NET Ampulla of Vater [V9: 2024+]
- 00310: NET Jejunum and Ileum [8th: 2018-2023]
- 09310: NET Jejunum and Ileum [V9: 2024+]
- 00320: NET Appendix [8th: 2018-2023]
- 09320: NET Appendix [V9: 2024+]
- 00330: NET Colon and Rectum [8th: 2018-2023]
- 09330: NET Colon and Rectum [V9: 2024+]
- 00340: NET Pancreas [8th: 2018-2023]
- 09340: NET Pancreas [V9: 2024+]

Description

Ki-67 (MIB-1) (Proliferative Index) is a marker of cell proliferation. A high value indicates a tumor that is proliferating more rapidly. Codes and coding instructions for this data item are site-specific.

Rationale

Ki-67 (MIB-1) (Proliferative Index) is a Registry Data Collection Variable in AJCC. It was a new data item for breast cases diagnosed 1/1/2018+. It will apply to neuroendocrine tumors (NET) of the gastrointestinal tract (AJCC Chapters 29 – 34) for cases diagnosed 1/1/2021+.

High Ki-67 is an adverse prognostic factor and Ki-67 is a component of grade for these tumors. NCCN guidelines recommend that tumor differentiation, mitotic rate and Ki-67 should be recorded in the pathology report for these tumors.

Additional Information

Source documents: pathology report

Other names include Proliferative index, MIB-1

For further information, refer to the **NET (Endocrine)** cancer protocols published by the College of American Pathologists.

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2021+
- For cases diagnosed 2018-2020, this SSDI must be blank

Note 2: Physician Statement

- Physician statement of Ki-67 (MIB-1), also referred to as the "Proliferative Index," can be used to code this data item when no other information is available

Note 3: Priority order

- A specific value (0.0-100.0) takes priority over XXX.4, XXX.5 or XXX.6.
- Code the exact percentage when provided
- When the exact percentage is not given, including ranges or terms such as "less than" or "greater than" use the range value codes XXX.4, XXX.5, XXX.6.
- XXX.4, XXX.5 and XXX.6 were added since they are listed on the CAP protocol

Note 4: Results from nodal or metastatic tissue

- May **not** be used
    - If the only information you have is a Ki-67 from a metastatic site, code to XXX.9

Note 5: Neoadjuvant Therapy

- Record the assay from tumor specimens prior to neoadjuvant therapy.
- If neoadjuvant therapy is given and there are no Ki-67 results from pre-treatment specimens, report the findings from post-treatment specimens.

Coding Guidelines

1) Ki-67 results are reported as the percentage cell nuclei that stain positive. As of early 2017 there are no established standards for interpretation of results or for cutoffs for positive and negative.

Examples:

- Ki-67 reported as 14%. Code 14.0
- Ki-67 reported as 8.6%. Code 8.6

- Ki-67 stated as less than 1%. Code XXX.4
- Ki-67 stated as 5%-10%. Code XXX.5
- Ki-67 stated as greater than 4%. Code XXX.5
- Ki-67 stated as greater than 30%. Code XXX.6

Code	Description
0.0-100.0	0.0 to 100.0 percent positive: enter percent positive
XXX.4	Ki-67 stated as less than 3%
XXX.5	Ki-67 stated as 3%-20%
XXX.6	Ki-67 stated as greater than 20%
XXX.7	Test done; actual percentage not stated
XXX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XXX.8 will result in an edit error.)
XXX.9	Not documented in medical record Ki-67 (MIB-1) not assessed or unknown if assessed
<Blank>	Must be blank if diagnosis year is before 2021

09290: NET Stomach [V9: 2024+]

See **00290: NET Stomach [8th: 2018-2023]**

- 3863: Ki-67

00301: NET Duodenum [8th: 2018-2023]

See **00290: NET Stomach [8th: 2018-2023]**

- 3863: Ki-67

09301: NET Duodenum [V9: 2024+]

See **00290: NET Stomach [8th: 2018-2023]**

- 3863: Ki-67

00302: NET Ampulla of Vater [8th: 2018-2023]

See **00290: NET Stomach [8th: 2018-2023]**

- 3863: Ki-67

09302: NET Ampulla of Vater [V9: 2024+]

See **00290: NET Stomach [8th: 2018-2023]**

- 3863: Ki-67

00310: NET Jejunum and Ileum [8th: 2018-2023]

See **00290: NET Stomach [8th: 2018-2023]**

- 3863: Ki-67

09310: NET Jejunum and Ileum [V9: 2024+]

See **00290: NET Stomach [8th: 2018-2023]**

- 3863: Ki-67

00320: NET Appendix [8th: 2018-2023]

See **00290: NET Stomach [8th: 2018-2023]**

- 3863: Ki-67

09320: NET Appendix [V9: 2024+]

See **00290: NET Stomach [8th: 2018-2023]**

- 3863: Ki-67

00330: NET Colon and Rectum [8th: 2018-2023]

See **00290: NET Stomach [8th: 2018-2023]**

- 3863: Ki-67

09330: NET Colon and Rectum [V9: 2024+]

See **00290: NET Stomach [8th: 2018-2023]**

- 3863: Ki-67

00340: NET Pancreas [8th: 2018-2023]

See **00290: NET Stomach [8th: 2018-2023]**

- 3863: Ki-67

09340: NET Pancreas [V9: 2024+]

See **00290: NET Stomach [8th: 2018-2023]**

- 3863: Ki-67

THORAX

00360: Lung [8th: 2018-2024]

3929: Separate Tumor Nodules

Item Length: 1
NAACCR Item #: 3929
XML Parent-NAACCR ID: Tumor-separateTumorNodules
NAACCR Alternate Name: Separate Tumor Nodules
Active years: 2018+
Schema(s):

- 00360: Lung [8th: 2018-2024]
- 09360: Lung [V9: 2025+]

Description

"Separate tumor nodules" refers to what is conceptually a single tumor with intrapulmonary metastasis in the ipsilateral (same) lung. Their presence in the same or different lobes of lung from the primary tumor affects the T and M categories.

Separate tumor nodules are defined as intrapulmonary metastasis identified in the same lobe or same lung (ipsilateral) originating from a single lung primary at the time of diagnosis. Biopsy of tumors may or may not be performed. So long as there is a strong suspicion the multiple lesions are of the same histological type by imaging, physician judgement, or microscopically, this meets the criteria of separate tumor nodules representing intrapulmonary metastases. The presence of metastases to extrathoracic sites does not change this distinction.

Rationale

This data item was previously collected for Lung, SSF #1 and at least one standard setter is continuing to collect it.

Additional Information

Source documents: imaging reports and pathology reports

For further information, refer to the **Lung** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Lung*.

Notes

Note 1: Physician Statement

- Physician statement of Separate Tumor Nodules in the ipsilateral (same) lung can be used to code this data item when no other information is available. See discussion of terminology in Note 3.
    - Separate tumor nodules in the contralateral lung are not coded in this data item.

Note 2: Intrapulmonary Metastasis

- Code the presence and location of separate tumor nodules with the same histologic type, also known as intrapulmonary metastasis, at the time of diagnosis in this item.
    - Separate tumor nodules can be defined clinically (by imaging) and/or pathologically.
    - They can be in the same or different lobes of the same lung as the primary tumor.
    - In the case of multiple tumor nodules determined to be the same primary, if not all nodules are biopsies, assume they are the same histology

Note 3: Situations NOT coded in this data item

- Other situations that display multiple lesions are NOT coded in this item. Assign code 0 if the multiple lesions belong to one of these other situations. Refer to the AJCC Staging System Lung for standardized and precise definitions of the situations which aren't separate tumor nodules. They are
    - Second primary tumors, also called synchronous primary tumors (not the same histology as the primary tumor)
    - Multifocal lung adenocarcinoma with ground glass/lepidic features
    - Diffuse pneumonic adenocarcinoma

Note 4: Definition of Synchronous

- "Synchronous" describes the appearance in time compared to the primary tumor
- Do not code this item based solely on the word "synchronous".
- If separate nodules are described as "metachronous," the nodules may be evidence of progression of disease in which case they would not be coded here.

Coding Guidelines

Record the presence of separate tumor nodules within the same ipsilateral lobe and/or different lobes of the same lung which are considered a single primary. The histology of the separate tumors must be the same. Histology may be determined clinically (presumed to be the same based on imaging or physician judgement) or microscopically confirmed.

1) Code 0 when

- Non-invasive neoplasm (/2 behavior)
- SINGLE TUMOR nodule only
- Separate tumor nodules present with DIFFERENT HISTOLOGIES

- Relevant imaging or resection is performed and there is no mention of separate tumor nodules
- Multiple histologies with
    - Second primary tumors, also called synchronous primary tumors (not the same histology as the primary tumor)
    - Multifocal lung adenocarcinoma with ground glass/lepidic features
    - Diffuse pneumonic adenocarcinoma

2) Code 1 when

- Separate tumor nodules present in the SAME LOBE with the SAME HISTOLOGY

3) Code 2 when

- Separate tumor nodules present in DIFFERENT LOBES of the SAME LUNG (ipsilateral) with the SAME HISTOLOGY.

4) Code 3 when

- Separate tumor nodules present in SAME LOBE AND DIFFERENT LOBES of the SAME LUNG with the SAME HISTOLOGY.

5) Code 4 when

- Separate tumor nodules present in SAME LUNG with the SAME HISTOLOGY and it's UNKNOWN IF they are in the SAME LOBE OR DIFFERENT LOBES.

6) Code 7 when

- There are multiple tumor nodules or foci and the terminology used is not readily identifiable as one of the situations described in Note 4 and no other information is available (including consulting with physician) is available. (Do not use this information in staging the primary tumor)

7) Code 9 when

- There is no relevant imaging or resection of the primary site

Code	Description
0	No separate tumor nodules; single tumor only Separate tumor nodules of same histologic type not identified/not present Intrapulmonary metastasis not identified/not present Multiple nodules described as multiple foci of adenocarcinoma in situ or minimally invasive adenocarcinoma Non-invasive neoplasm (behavior /2)

Code	Description
1	Separate tumor nodules of same histologic type in ipsilateral lung, same lobe
2	Separate tumor nodules of same histologic type in ipsilateral lung, different lobe
3	Separate tumor nodules of same histologic type in ipsilateral lung, same AND different lobes
4	Separate tumor nodules of same histologic type in ipsilateral lung, unknown if same or different lobe(s)
7	Multiple nodules or foci of tumor present, not classifiable based on Notes 2 and 3
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Separate Tumor Nodules not assessed or unknown if assessed

00360: Lung [8th: 2018-2024]

3937: Visceral and Parietal Pleural Invasion

Item Length: 1
NAACCR Item #: 3937
XML Parent-NAACCR ID: Tumor-visceralParietalPleuralInvasion
NAACCR Alternate Name: Visceral and Parietal Pleural Invasion
Active years: 2018+
Schema(s):

- 00360: Lung [8th: 2018-2024]
- 09360: Lung [V9: 2025+]

Description

Visceral and Parietal Pleural Invasion is defined as invasion beyond the elastic layer or to the surface of the visceral pleura.

Invasion of one or more layers of the pleura covering the lung (visceral pleura), such as invasion beyond the elastic layer of the pleura. The elastic layer may be identified on hematoxylin and eosin (H&E) stains or by special stains looking for the elastic fibers. An elastic stain is not needed in most cases to assess the pleura for invasion, only in those cases where the distinction between PL0 and PL1 is unclear on H&E sections. Elastic stains may also be helpful in cases where the visceral and parietal pleura are adherent, making it difficult to identify the boundary between the visceral pleural surface and the parietal pleura.

VPI is relevant for peripheral lung tumors. The presence of visceral pleural invasion by tumors smaller than 3 cm changes the T category from pT1 to pT2 and increases the stage from IA to IB in patients with no nodal disease or stage IIA to IIB in patients with peribronchial or hilar nodes. Studies have shown that tumors smaller than 3 cm that penetrate beyond the elastic layer of the visceral pleura behave similarly to similar-size tumors that extend to the visceral pleural surface. Visceral pleural invasion should therefore be considered present not only in tumors that extend to the visceral pleural surface, but also in tumors that penetrate beyond the elastic layer of the visceral pleura. Four to six layers of visceral pleura may be described by the pathologist.

Rationale

Visceral and Parietal Pleural Invasion (previously called “pleural/elastic layer invasion (PL)”) is a Registry Data Collection Variable for AJCC. This data item was previously collected for Lung, SSF #2.

Additional Information

Source documents: pathology report

Other names include VPI, PL (number)

For further information, refer to the **Lung** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Lung*.

Notes

Note 1: Physician Statement

- Physician statement of Visceral and Parietal Pleural Invasion can be used to code this data item when no other information is available.

Note 2: Criteria for coding

- A surgical resection **must** be done to determine if the visceral and/or parietal pleural is involved.
    - ***Exception***: In situ tumors (/2) can be coded 0 based on biopsy or surgical resection
- Do not use imaging findings to code this data item

Coding Guidelines

1) Record results of visceral pleural invasion as stated on pathology report.

- Do not code separate pleural tumor foci or nodules in this field (discontinuous pleural metastasis).

2) Code 0 when

- No evidence of visceral and parietal pleural invasion or described as PL0
- Tumor does not penetrate beyond the elastic layer of the visceral pleura
- Extends to the elastic layer
- Non-invasive neoplasm (/2) neoplasms (surgical resection not required)

3) Code 4 when

- Invasion of pleura without specifying visceral or parietal pleura
- Uncertain whether elastic stain has been performed to identify visceral pleura invasion
- Pathology report states PL1 or PL2

4) Code 5 when tumor extends to the parietal pleura (classified as T3) or described as PL3

5) Code 9 when

- No information in the medical record
- Only FNA performed (A FNA is not adequate to assess pleural layer invasion)

- Surgical resection of the primary site is performed and there is no mention of visceral and/or parietal pleural invasion
- Surgical pathology report is not available

Code	Description
0	No evidence of visceral pleural invasion identified Tumor does not completely traverse the elastic layer of the pleura Stated as PL0 Primary tumor is in situ Non-invasive neoplasm (behavior /2) No evidence of primary tumor
4	Invasion of visceral pleura present, NOS Stated as PL1 or PL2
5	Tumor invades into or through the parietal pleura OR chest wall Stated as PL3
6	Tumor extends to pleura, NOS; not stated if visceral or parietal
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record No surgical resection of primary site is performed Visceral Pleural Invasion not assessed or unknown if assessed or cannot be determined

00360: Lung [8th: 2018-2024]

3938: ALK Rearrangement

Item Length: 1
NAACCR Item #: 3938
XML Parent-NAACCR ID: Tumor-alkRearrangement
NAACCR Alternate Name: ALK Rearrangement
Active years: 2021+
Schema(s):

- 00360: Lung [8th: 2018-2024]
- 09360: Lung [V9: 2025+]

Description

Testing for ALK rearrangement is performed for patients with advanced non-small cell lung cancer (NSCLC) to identify tumors which are sensitive to small-molecule ALK kinase inhibitors.

“ALK positive cancer describes cancer cells that have a change in the structure of the anaplastic lymphoma kinase (ALK) gene or a higher-than-normal amount of ALK protein on their surface. In normal cells, ALK helps control cell growth. When cancer cells have the changed ALK gene or make too much ALK protein, the cancer cells may grow more quickly. Knowing whether a cancer is ALK positive may help plan treatment for advanced non-small cell cancers in the lung.” (NCI Dictionary of Cancer Terms Definition of EGFR - NCI Dictionary of Cancer Terms - NCI)

The absence or presence of ALK protein expression determines if the tumor will respond to treatment with a targeted inhibitor. ALK protein expression predicts the ALK rearrangement gene, which are more likely to respond to the targeted inhibitor treatment. The most common ALK rearrangements are.

- EML4-ALK
- KIF5B-ALK
- TFG-ALK
- KLC1-ALK

Rationale

ALK rearrangement is recommended by treatment guidelines for patients with advanced lung cancer to as a prognostic marker and factor in determining appropriate therapy. It is a new data item for cases diagnosed 1/1/2021+.

Additional Information

Source documents: pathology report or clinical laboratory report, molecular report, immunohistochemistry report

Other names include ALK tyrosine kinase receptor, anaplastic lymphoma kinase, anaplastic lymphoma receptor tyrosine kinase, CD246, CD246 antigen, NBLST3

For further information, refer to the **Lung Biomarker Reporting** cancer protocol published by the College of American Pathologists.

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2021+
- For cases diagnosed 2018-2020, this SSDI must be blank

Note 2: Physician Statement

- Physician statement of ALK rearrangement can be used to code this data item when no other information is available.
- This data item only includes rearrangements. Ignore any amplification or point mutations

Note 3: Applicable histologies/stages

- ALK may be recorded for all histologies and stages; however, it is primarily performed for advanced non-small cell carcinomas. If information is not available, code 9.

Note 4: Neoadjuvant Therapy

- Record the assay from tumor specimens prior to neoadjuvant therapy.
- If neoadjuvant therapy is given and there are no ALK results from pre-treatment specimens, report the findings from post-treatment specimens.

Coding Guidelines

1) Code 0 when ALK normal/negative/not identified

2) Code 1 or 2 when ALK identified/detected (EML4-ALK, KIF5B-ALK, TFG-ALK, KLC1-ALK)

3) Code 4 for when ALK identified/detected, and there is no mention of the specific rearrangement

4) Code 9 when

- Insufficient amount of tissue available to perform test
- Test done and documented to be equivocal
- No microscopic confirmation of tumor
- ALK Rearrangement not ordered or not done, or unknown if ordered or done

Code	Description
0	Normal ALK negative Negative for rearrangement, no rearrangement identified, no mutations (somatic) identified, not present, not detected
1	Abnormal Rearrangement identified/detected: EML4-ALK, KIF5B-ALK, TFG-ALK, and/or KLC1-ALK
2	Rearrangement identified/detected: Other ALK Rearrangement not listed in code 1
4	Rearrangement, NOS
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record ALK Rearrangement not assessed or unknown if assessed
<Blank>	Must be blank if diagnosis year is before 2021

00360: Lung [8th: 2018-2024]

3939: EGFR Mutational Analysis

Item Length: 1
NAACCR Item #: 3939
XML Parent-NAACCR ID: Tumor-egfrMutationalAnalysis
NAACCR Alternate Name: EGFR Mutational Analysis
Active years: 2021+
Schema(s):

- 00360: Lung [8th: 2018-2024]
- 09360: Lung [V9: 2025+]

Description

Epidermal growth factor receptor (EGFR) mutational analysis is performed for patients with advanced non-small cell lung cancer (NSCLC) to identify patients with certain activating mutations in the EGFR gene which are sensitive to tyrosine kinase Inhibitors.

"EGFR (epidermal growth factor receptor) is a protein found on certain types of cells that binds to a substance called epidermal growth factor. The EGFR protein is involved in cell signaling pathways that control cell division and survival. Sometimes, mutations (changes) in the EGFR gene cause EGFR proteins to be made in higher-than-normal amounts on some types of cancer cells. This causes cancer cells to divide more rapidly." (NCI Dictionary of Cancer Terms)

The presence of Exon 20 EGFR activating mutations are associated with a resistance to EGFR tyrosine kinase inhibits, such as erlotinib, afatinib, and gefitinib. There is limited data available on response for some of the other uncommon EGFR mutations (other than Exon 20). (CAP Cancer Protocol).

The most common EGFR mutations are

- Exon 18 Gly719
- Exon 19 deletion
- Exon 20 insertion
- Exon 20 Thr790Met
- Exon 21 Leu858Arg

Rationale

EGFR mutational analysis is recommended by treatment guidelines for patients with advanced lung cancer as a prognostic marker and factor in determining appropriate therapy. It is a new data item for cases diagnosed 1/1/2021+

Additional Information

Source documents: pathology report or clinical laboratory report

Other names include Epidermal growth factor receptor tyrosine kinase inhibitor, ERBB, ERBB1, ErbB1, HER1

For further information, refer to the **Lung Biomarker Reporting** cancer protocol published by the College of American Pathologists.

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2021+
- For cases diagnosed 2018-2020, this SSDI must be blank

Note 2: Physician Statement

- Physician statement of EGFR can be used to code this data item when no other information is available.

Note 3: Applicable histologies/stages

- EGFR may be recorded for all histologies and stages; however, it is primarily performed for advanced non-small cell carcinomas. If information is not available, code 9.

Note 4: Neoadjuvant Therapy

- Record the assay from tumor specimens prior to neoadjuvant therapy.
- If neoadjuvant therapy is given and there are no EGFR results from pre-treatment specimens, report the findings from post-treatment specimens.

Coding Guidelines

1) Code 0 when EGFR normal/negative/not identified

2) Code 1 or 2 when EGFR identified/detected

3) Code 4 when EGFR identified, and there is no mention of the specific mutation

4) Code 9 when

- Insufficient amount of tissue available to perform test
- Test done and documented to be equivocal
- No microscopic confirmation of tumor
- EGFR mutational analysis not ordered or not done, or unknown if ordered or done

Code	Description
0	Normal EGFR negative, EGFR wild type Negative for mutations, no alterations, no mutations (somatic) identified, not present, not detected
1	Abnormal (mutated)/detected in exon(s) 18, 19, 20, and/or 21
2	Abnormal (mutated)/detected but not in exon(s) 18, 19, 20, and/or 21
4	Abnormal (mutated)/detected, NOS, exon(s) not specified
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record EGFR not assessed or unknown if assessed
<Blank>	Must be blank if diagnosis year is before 2021

09360: Lung [V9: 2025+]

1174: PD-L1

Item Length: 5
NAACCR Item #: 1174
XML Parent-NAACCR ID: Tumor-pdl1
NAACCR Alternate Name: PD-L1
Active years: 2025+
Schema(s):

- 09360: Lung [V9: 2025+]

Description

The absence or presence of PD-L1 expression determines if the tumor will respond to treatment with a targeted inhibitor (immunotherapy). PD-L1 is done for Non-Small Cell lung cancers (NSCLC).

This test is usually done on metastatic non-small cell lung cancer (NSCLC) patients. An assay is performed on formalin-fixed, paraffin-embedded (FFPE) tissue specimen of at least 100 cells taken from the patient. The assay is used to determine the PD-L1 expression by IHC. Then the pathologist determines the tumor proportion score. The treating physician uses that information to determine what type of treatment the patient will receive.

Rationale

PD-L1 is recommended by treatment guidelines for lung cancer to determine if the patient may benefit from checkpoint inhibitor drugs (immunotherapy). **It is a new data item for cases diagnosed 1/1/2025+.**

Additional Information

Source documents: pathology report

For further information, refer to the **Lung Biomarker Reporting** cancer protocol published by the College of American Pathologists.

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2025+
- For cases diagnosed 2018-2024, this SSDI must be blank

Note 2: Physician Statement

- Physician statement PD-L1 can be used to code this data item when no other information is available.

Note 3: Purpose of PD-L1

- The absence or presence of PD-L1 expression determines if the tumor will respond to treatment with a targeted inhibitor (immunotherapy). PD-L1 is done for Non-Small Cell lung cancers (NSCLC).

Note 4: Tumor Proportion Score

- PD-L1 is documented by the tumor proportion score. Record the actual Tumor Proportion Score (0.0-100.0) as stated from the pathology report.
- An actual tumor proportion score (0.1-100.0) takes priority over XXX.2 (Stated as negative), XXX.3 (Stated as low), or XXX.4 (Stated as high/positive)

Note 5: Combined Proportion Score (CPS)

- Do not record the CPS score (0.0-100.0) in this data item.
    - If you have a CPS score WITH an interpretation, record the interpretation.
        - ***Example:*** Squamous cell carcinoma: NEGATIVE for PD-L1 Expression, CPS score <1. Record as XXX.2 for negative
    - If you have a CPS score WITHOUT an interpretation, record unknown (XXX.9).
        - ***Example:*** Squamous cell carcinoma: PD-L1, CPS score <1. Record as XXX.9 for unknown (interpretation not provided)

Note 6: Neoadjuvant therapy If neoadjuvant therapy is given, record the assay from tumor specimens prior to neoadjuvant therapy.

- If neoadjuvant therapy is given and there are no PD-L1 results from pre-treatment specimens, report the findings from post-treatment specimens

Code	Description
0.0	No PD-L1 expression identified Tumor Proportion Score (TPS) = 0%
0.1-100.0	0.1-100.0 PD-L1 expression Tumor Proportion Score (TPS) = 0.1%-100.0%
XXX.2	PD-L1 expression absent ANDTumor Proportion Score (TPS) stated as negative
XXX.3	PD-L1 expression present ANDTumor Proportion Score (TPS) stated as low
XXX.4	PD-L1 expression present ANDTumor Proportion Score (TPS) stated as high/positive

Code	Description
XXX.7	Test ordered, results not in chart
XXX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error)
XXX.9	Not documented in medical record No microscopic confirmation of tumor PD-L1 cannot be determined PD-L1 not assessed or unknown if assessed
<Blank>	N/A - Diagnosis year is prior to 2025

09360: Lung [V9: 2025+]

1176: Lung STAS

Item Length: 1
NAACCR Item #: 1176
XML Parent-NAACCR ID: Tumor-spreadThroughAirSpacesStas
NAACCR Alternate Name: Lung Spread Through Air Spaces (STAS)
Active years: 2026+
Schema(s):

- 09360: Lung [V9: 2025+]

Description

Spread Through Air Spaces (STAS) is defined as micropapillary clusters, solid nests, or single cells of tumor extending beyond the edge of the tumor into the air spaces of the surrounding lung parenchyma.

Rationale

Initial studies have shown that the presence of STAS is associated with an increased incidence of recurrence in tumors that have undergone limited resection (e.g., segmentectomy, wedge resection).

Additional Information

Source documents: CAP protocol or synoptic pathology report

For further information, refer to the **Lung Resection cancer protocol** published by the College of American Pathologists for the AJCC Staging System *Lung*.

Any questions regarding this SSDI are to be posted in the AJCC Forum.

Notes

Any questions regarding this SSDI are to be posted in the AJCC CAnswer Forum

Note 1: Effective years

- This SSDI is effective for diagnosis years 2026+.
- For cases diagnosed 2018-2025, this SSDI must be blank.

Note 2: Physician Statement

- Physician statement of STAS can be used to code this data item when no other information is available.

Note 3: Criteria for coding

- A surgical resection must be done to determine if there is STAS.

- ***Exception:*** In situ tumors (/2) can be coded 0 based on biopsy or surgical resection
- If no surgical resection done, see code 9

Note 4: CAP Protocol or Synoptic Pathology Report

- Only record the information from the CAP Protocol or synoptic pathology report
  - Codes 0, 1, 7 may not be assigned if they are not included in the CAP Protocol or synoptic pathology report

Coding Guidelines

1) Record the STAS score as stated on the CAP Protocol or synoptic pathology report

2) Code 9 when

- Surgical resection of the primary site is performed and the presence/absence of STAS is not documented in the CAP Protocol or synoptic pathology report
- No surgical resection is done
- Surgical pathology report is not available

Code	Description
0	Not identified
1	Present
8	Not applicable: information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error).
9	No surgical resection done Surgical resection done and STAS not documented in the CAP Protocol or synoptic pathology report STAS not assessed or unknown if assessed or cannot be determined
<Blank>	Must be blank if diagnosis year is before 2026

00370: Pleural Mesothelioma [8th: 2018-2024]

3913: Pleural Effusion

Item Length: 1
NAACCR Item #: 3913
XML Parent-NAACCR ID: Tumor-pleuralEffusion
NAACCR Alternate Name: Pleural Effusion
Active years: 2018+
Schema(s):

- 00370: Pleural Mesothelioma [8th: 2018-2024]
- 09370: Pleural Mesothelioma [V9: 2025+]

Description

Pleural effusion is the accumulation of fluid between the parietal pleura (the pleura covering the chest wall and diaphragm) and the visceral pleura (the pleura covering the lungs).

Pleural effusion is the accumulation of fluid between the two layers of pleura: visceral (covering the lungs) and parietal (lining the chest wall and covering the diaphragm). Pleural effusion is a symptom of mesothelioma that increases the Summary Stage from local or regional direct extension to distant involvement.

Rationale

Pleural Effusion can be collected by the surveillance community for pleura cancers. Prior to 2018, Pleura SSF #1 was used for Pleural Effusion.

Additional Information

Source documents: imaging, pathology, and cytology reports

Other names include: pleural fluid, thoracentesis

Notes

Note: Definition of pleural effusion

- One of the most common symptoms of mesothelioma is a pleural effusion, or an accumulation of fluid between the parietal pleura (the pleura covering the chest wall and diaphragm) and the visceral pleura (the pleura covering the lungs).
- Record the absence or presence of pleural effusion and specifically, if present, whether the pleural effusion is non-malignant, malignant, atypical or NOS.

Coding Guidelines

1) Record the absence or presence of pleural effusion

- If pleural effusion is present and examined microscopically, record whether the pleural effusion is non-malignant, malignant, or not specified.

2) Code 0 when there is no evidence of pleural effusion

3) Code 1 when

- Pleural effusion microscopically confirmed to be non-malignant
- Pleural effusion is stated to be negative for malignant cells
- Pleural effusion is seen on imaging, but pleural fluid cytology is negative for malignant cells

4) Code 2 when

- Pleural effusion microscopically confirmed to be malignant
- Pleural effusion is stated to be positive for malignant cells
- Pleural fluid cytology described as suspicious or suspicious for mesothelioma
- Physician states pleural effusion is positive in the absence of positive cytology

5) Code 3 when

- Pleural fluid cytology is described as atypical or atypical mesothelial cells but not specifically as non-malignant or malignant

6) Code 4 when

- Pleural effusion is reported on imaging, but there is no cytology
- Pleural effusion is reported on imaging, but there is no physician's statement on whether it is positive

7) Code 9 when

- Not documented in the medical report
- Presence or absence of pleural effusion not evaluated (assessed)
- Unknown if Pleural Effusion evaluated (assessed)

Code	Description
0	Pleural effusion not identified/not present
1	Pleural effusion present, non-malignant (negative)
2	Pleural effusion present, malignant (positive) Physician states pleural effusion is malignant in the absence of positive cytology
3	Pleural effusion, atypical/atypical mesothelial cells
4	Pleural effusion, NOS
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Pleural effusion not assessed or unknown if assessed

09370: Pleural Mesothelioma [V9: 2025+]

See **00370: Pleural Mesothelioma [8th: 2018-2024]**

- 3913: Pleural Effusion

00381: Bone Appendicular Skeleton

3908: Percent Necrosis Post Neoadjuvant

Item Length: 5
NAACCR Item #: 3908
XML Parent-NAACCR ID: Tumor-percentNecrosisPostNeoadjuvant
NAACCR Alternate Name: Percent Necrosis Post Neoadjuvant
Active years: 2018+
Schema(s):

- 00381: Bone Appendicular Skeleton
- 00382: Bone Spine
- 00383: Bone Pelvis

Description

Percent Necrosis Post Neoadjuvant is a prognostic factor for bone sarcomas.

For osteosarcoma and Ewing's sarcoma/PNET, response to neoadjuvant chemotherapy is a prognostic factor. Patients with more than 90% tumor necrosis have a more favorable prognosis than those with less response. The CAP protocol for bone tumor resection provides the pathologist with specific instructions for determining the percentage of tumor necrosis. A separate method (system of Picci) may describe response to treatment in grades: grade I (macroscopic viable tumor), grade II (microscopic viable tumor), or grade III (no viable tumor). Do not code the Picci grade system in this data item.

Rationale

Percent Necrosis Post Neoadjuvant is a Registry Data Collection Variable for AJCC. It was previously collected as Bone, CS SSF #3.

Additional Information

Source documents: pathology report

Other names include Histologic treatment response, therapy response, chemotherapy effect

For further information, refer to the **Bone** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Bone*.

Notes

Note: Physician Statement

- Physician statement of microscopically confirmed Percent Necrosis Post Neoadjuvant Chemotherapy can be used to code this data item if no other documentation is available.

Coding Guidelines

1) Record the highest percentage value of the tumor necrosis post neo-adjuvant therapy as stated by the pathologist or in the pathology report.

- Code the value of the tumor necrosis to the nearest tenth of a percent

2) Codes 001.0-100.0. Record the percentage value of tumor necrosis post neo-adjuvant chemotherapy as stated by the pathologist in the pathology report

3) Code XXX.9 when

- Surgical resection of the primary site is the initial therapy; therefore, no neoadjuvant therapy was performed
- Surgical resection of the primary site after neoadjuvant therapy is performed and there is no mention of percent necrosis

Code	Description
0.0	Tumor necrosis not identified/not present
0.1-100.0	0.1 - 100.0 percent tumor necrosis (Percentage of tumor necrosis to nearest tenth of a percent)
XXX.2	Tumor necrosis present, percent not stated
XXX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XXX.8 will result in an edit error.)
XXX.9	Not documented in medical record No histologic examined of primary site No neoadjuvant therapy No surgical resection of primary site is performed

00382: Bone Spine

See **00381: Bone Appendicular Skeleton**

- 3908: Percent Necrosis Post Neoadjuvant

00383: Bone Pelvis

See **00381: Bone Appendicular Skeleton**

- 3908: Percent Necrosis Post Neoadjuvant

00400: Soft Tissue Head and Neck

3815: Bone Invasion

Item Length: 1
NAACCR Item #: 3815
XML Parent-NAACCR ID: Tumor-boneInvasion
NAACCR Alternate Name: Bone Invasion
Active years: 2018+
Schema(s):

- 00400: Soft Tissue Head and Neck
- 00410: Soft Tissue Trunk and Extremities
- 00421: Soft Tissue Abdomen and Thoracic
- 00422: Heart, Mediastinum and Pleura
- 00440: Retroperitoneum
- 00450: Soft Tissue Rare
- 00459: Soft Tissue Other

Description

Bone invasion, the presence or absence of bone invasion based on imaging, is a prognostic factor for soft tissue sarcoma.

Direct tumor extension from the primary sarcoma into adjacent bone. This field does not include distant or discontinuous metastases to the skeletal system. Information in this field is based on radiology and other imaging techniques.

Rationale

Bone Invasion is a Registry Data Collection Variable in AJCC. This data item was previously collected for Soft Tissue, SSF #3.

Additional Information

Source documents: imaging

Notes

Note 1: Physician Staging

- Physician statement of Bone Invasion can be used to code this data item when no other information is available.

Note 2: Criteria for Coding

- Record bone invasion as determined by **relevant imaging only for the primary tumor**
- Imaging methodologies include computed tomography (CT) scans and magnetic resonance imaging (MRI).

Coding Guidelines

1) Code 0 when relevant imaging is performed and there is no mention of bone invasion

2) Code 1 when there is evidence of bone invasion on imaging

3) Code 9 when

- No information in the medical record
- Bone invasion not evaluated (assessed)
- No relevant imaging of the primary site
- Unknown if bone invasion evaluated (assessed)

Code	Description
0	Bone invasion not present/not identified on imaging
1	Bone invasion present/identified on imaging
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Bone invasion not assessed or unknown if assessed

00410: Soft Tissue Trunk and Extremities

3927: Schema Discriminator 2

Item Length: 1
NAACCR Item #: 3927
XML Parent-NAACCR ID: Tumor-schemaDiscriminator2
NAACCR Alternate Name: Schema Discriminator 2: Soft Tissue Trunk and Extremities/Soft Tissue Abdomen and Thoracic
Active years: 2018+
Schema(s):

- 00410: Soft Tissue Trunk and Extremities
- 00421: Soft Tissue Abdomen and Thoracic
- 00459: Soft Tissue Other

Description

The ICD-O-3 assigned topography codes for the peripheral nerve and autonomic nervous systems tumors (C47) and the connective, subcutaneous and other soft tissues (C49) primary sites are based on transverse or horizontal planes. The AJCC Staging System Soft Tissue Sarcoma of the Trunk and Extremities, and Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs base the eligible sites as either external structures or internal viscera. For example,

- C493 axilla is an external site using the AJCC Staging System Soft Tissue Sarcoma of the Trunk and Extremities
- C493 axillary artery is an internal site using the AJCC Staging System Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs
- C475 sacrococcygeal region is a large area that may be either external or internal
    - Need to determine the exact area involved to assign the correct chapter
    - C475 external area of sacrococcygeal region uses the AJCC Staging System Soft Tissue Sarcoma of the Trunk and Extremities
    - C475 intrapelvic area of sacrococcygeal region uses the AJCC Staging System Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs To develop a software algorithm that can be used to send the registrar to the correct system/schema, this schema discriminator was developed.

The schema discriminator is based on determining whether the structure involved is part of the external structures or the internal viscera. This is accomplished by

- Terms in ICD-O-3 topography codes sorted appropriately by the physician experts when possible

- Instructions on what to do when terms are not specific enough to be assigned as external structures or internal viscera
    - Without additional information, these may not be staged, for example C475 pelvis
    - With additional information, these may be determined to be external structures or internal viscera
- In addition to the topography codes and terms, there is also an option of "External sites, NOS" and "Internal sites, NOS" for registrars to use to assign the schema discriminator. Registrars may need to use additional information, including physician staging, to choose the appropriate schema discriminator.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Summary Stage and EOD data collection system.

Additional Information

Source documents: pathology report, imaging, physician documentation, physician staging

Notes

Note: Schema discriminator for C473, C475, C493-C495

- A schema discriminator is used to discriminate for peripheral nerve tumors (C473, C475) and connective tissue tumors (C493, C494, C495) for the subsite in which the tumor arose.

Coding Guidelines

1) Code 1 is used for external structures and is assigned to the AJCC Staging System Soft Tissue Sarcoma of the Trunk and Extremities (Schema ID 00410: Soft Tissue Sarcoma of the Trunk and Extremities).

- ***Example:*** Trapezius muscle (C493) is an external structure, on the outer layer or periphery of the body

2) Code 2 is used for internal structures and is assigned to the AJCC Staging System Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs (Schema ID 00421: Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs).

- ***Example:*** Aorta (C493) is an internal structure, in the inner parts of the body

3) Code 8 is only used for cases for 2018-2020 that have already been abstracted prior to the Version 2.0 update (2021 update). It can also be used for 2018-2020 cases that are abstracted after the 2021 updates.

- For cases diagnosed 2021+, code 8 cannot be used

4) Code 9 is used for when there is not enough specific information to determine if the structure is external or internal. These cases are collected in Schema ID 00459: Soft Tissue Other.

- ***Example***: Chest NOS (C493) does not provide enough information in order to determine if it is either an external structure, on the outer layer or periphery of the body, or an internal structure, in the inner parts of the body

Table begins on next page

Code	Description	Schema ID #/Description
1	External structures (sites), NOS Examples of terms include: Peripheral nerves and autonomic nervous system (C47) Pelvis (C475) Buttock Gluteal region Groin Inguinal region Perineum Sacrococcygeal region (stated as external) Thorax (C473) Axilla Chest wall Infraclavicular region Scapular region Thoracic wall Connective, subcutaneous and other soft tissues (C49) Abdomen (C494) Abdominal wall Abdominal wall muscle Iliopsoas muscle Psoas muscle Rectus abdominis muscle Umbilicus Pelvis (C495) Buttock Gluteal region Gluteus maximus muscle Groin Inguinal region Perineum Sacrococcygeal region Thorax (C493) Axilla Chest wall Infraclavicular region Intracostal muscle Latissimus dorsi muscle Pectoralis major muscle Scapular region Thoracic wall Trapezius muscle	00410: Soft Tissue Trunk and Extremities

Code	Description	Schema ID #/Description
2	Internal structures and viscera (sites), NOS Examples of terms include Peripheral nerves and autonomic nervous system (C47) Sacrococcygeal region (intrapelvic) Connective, subcutaneous and other soft tissues (C49) Abdomen (C494) Abdominal aorta Abdominal vena cava Celiac artery Inferior vena cava Mesenteric artery Renal artery Vena cava Pelvis (C495) Iliac artery Iliac vein Thorax (C493) Aorta Axillary artery Diaphragm Internal mammary artery Subclavian artery Superior vena cava Thoracic duct	00421: Soft Tissue Abdomen and Thoracic (excluding Heart, Mediastinum, Pleura)
8	Not applicable: Case abstracted prior to 2021 update	00421: Soft Tissue Abdomen and Thoracic (excluding Heart, Mediastinum, Pleura)

Code	Description	Schema ID #/Description
9	Not specific enough to determine if external or internal Examples of terms include Peripheral nerves and autonomic nervous system (C47) Pelvis (C475) Lumbosacral plexus Sacral nerve Sacral plexus Thorax (C473) Chest Intercostal nerve Connective, subcutaneous and other soft tissues (C49) Thorax (C493) Chest, NOS Thorax	00459: Soft Tissue Other
<Blank>	Primary Site is not C473, C475, C493-C495, Discriminator is not necessary	

00421: Soft Tissue Abdomen and Thoracic

See **00410: Soft Tissue Trunk and Extremities**

- 3927: Schema Discriminator 2

See 00400: Soft Tissue Head and Neck

- 3815: Bone Invasion

00422: Heart, Mediastinum and Pleura

See **00410: Soft Tissue Trunk and Extremities**

- 3815: Bone Invasion

00430: GIST

3926: Schema Discriminator 1

Item Length: 1
NAACCR Item #: 3926
XML Parent-NAACCR ID: Tumor-schemaDiscriminator1
NAACCR Alternate Name: Schema Discriminator 1: Primary Peritoneum Tumor
Active years: 2018+
Schema(s):

- 00430: GIST

Description

The GIST chapter includes a schema discriminator for C481 for location of the primary tumor because all the peritoneum structures are coded to C481, but two separate stage tables are used to derive the TNM values.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Grade, Summary Stage and EOD data collection system.

Additional Information

Source documents: pathology report, imaging, physician documentation, physician staging

Notes

Note: Schema discriminator for C481

- Since both omental and peritoneal gastrointestinal stromal tumors (GIST) are coded with the same ICD-O-3 topography code (C481), this data item must be used to identify the appropriate AJCC stage table.

Code	Description	Schema ID #/Description
1	Mesentery Mesoappendix Mesocolon Pelvic peritoneum Rectouterine pouch Cul de sac Pouch of Douglas Other specified peritoneal site	Small Intestinal, Esophageal, Colorectal, Mesenteric and Peritoneal GIST
2	Omentum	Gastric and Omental GIST

Code	Description	Schema ID #/Description
9	Unknown or no information Not documented in medical record	Small Intestinal, Esophageal, Colorectal, Mesenteric and Peritoneal GIST
<Blank>	Primary Site is NOT C481, Discriminator is not necessary	

00430: GIST

3865: KIT Gene Immunohistochemistry

Item Length: 1
NAACCR Item #: 3865
XML Parent-NAACCR ID: Tumor-kitGeneImmunohistochemistry
NAACCR Alternate Name: KIT Gene Immunohistochemistry (IHC)
Active years: 2018+
Schema(s):

- 00430: GIST

Description

KIT Gene Immunohistochemistry (IHC) is the expression of the KIT gene in tumor tissue specimens based on immunohistochemical (IHC) stains. A positive test is a diagnostic and predictive marker for GIST tumors.

KIT is a gene that regulates cell growth and differentiation. Mutations of this gene become oncogenes and cause a gastrointestinal stromal tumor to ignore cellular control signals. About 85-90% of GIST tumors contain oncogenic mutations of the KIT receptor gene. KIT immunohistochemistry is a special immunofluorescent stain that turns mutated cells brown and confirms a diagnosis of GIST. The presence of the KIT gene also indicates that the patient may respond to Gleevec or Sutent.

Rationale

KIT Gene Immunohistochemistry (IHC) is a Registry Data Collection Variable in AJCC. This data item was previously collected for GIST schemas in CS (different SSFs).

Additional Information

Source documents: pathology report (special stain)

Other names include CD117, c-kit receptor, KIT receptor tyrosine kinase, or SCFR (stem cell factor receptor)

Notes

Note 1: Physician Statement

- Physician statement of KIT IHC can be used to code this data item when no other information is available.

Note 2: Types of results

- Record results from Immunohistochemistry only. If there are results from DNA sequencing, or some other type of result, code 9

Note 3: Results from nodal or metastatic tissue

- May be used for KIT Gene immunohistochemistry

Code	Description
0	KIT negative/normal; within normal limits
1	KIT positive
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Cannot be determined by pathologist KIT not assessed or unknown if assessed

00440: Retroperitoneum

See **00400: Soft Tissue Head and Neck**

- 3815: Bone Invasion

00450: Soft Tissue Rare

See **00400: Soft Tissue Head and Neck**

- 3815: Bone Invasion

00459: Soft Tissue Other

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3926: Schema Discriminator 1

See **00410: Soft Tissue Trunk and Extremities**

- 3927: Schema Discriminator 2

See **00400: Soft Tissue Head and Neck**

- 3815: Bone Invasion

SKIN

00460: Merkel Cell Skin

3880: LN Isolated Tumor Cells

Item Length: 1
NAACCR Item #: 3880
XML Parent-NAACCR ID: Tumor-lnIsolatedTumorCells
NAACCR Alternate Name: Lymph Nodes Isolated Tumor Cells (ITC)
Active years: 2018+
Schema(s):

- 00460: Merkel Cell Skin

Description

Lymph Nodes Isolated Tumor Cells (ITC), the presence of isolated tumor cells in regional lymph node(s) that may be detected by hematoxylin and eosin or by immunohistochemical staining, is a potential prognostic factor for Merkel Cell Carcinoma.

Isolated tumor cells (ITCs) for Merkel cell carcinoma are defined as single tumor cells or small clusters of tumor cells not more than 0.2 mm in greatest dimension. ITCs are usually detected by immunohistochemistry on sentinel lymph node biopsies.

- **Note:** Examples of immunohistochemical staining methods are Cytokeratin 20 (CK20), CAM 5.2, pancytokeratin, and AE1/3. ITCs may be detected by routine H&E stains.

ITCs may be identified in lymph nodes by hematoxylin and eosin staining or by specialized pathological techniques, such as IHC for cytokeratin proteins for carcinomas. Specialized pathology techniques such IHC and molecular techniques are not recommended for routine examination of lymph nodes.

These cells usually are found in the subcapsular nodal sinuses but may be seen within the nodal parenchyma.

Rationale

Lymph Nodes, Isolated Tumor Cells (ITC) is a Registry Data Collection Variable in AJCC. This data item was previously collected for Merkel Cell Skin, SSF #18.

Additional Information

Source documents: pathology report

For further information, refer to the **Merkel Cell Carcinoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Merkel Cell Carcinoma*.

Notes

Note: Physician statement

- Physician statement of Isolated Tumor Cells (ITCs) can be used to code this data item when no other information is available.

Coding Guidelines

Record the status of ITCs as documented by the pathologist

Code	Description
0	Regional lymph nodes negative for ITCs
1	Regional lymph nodes positive for ITCs (Tumor cell clusters not greater than 0.2 millimeter (mm))
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Cannot be determined by pathologist ITCs not assessed or unknown if assessed

00460: Merkel Cell Skin

3918: Profound Immune Suppression

Item Length: 1
NAACCR Item #: 3918
XML Parent-NAACCR ID: Tumor-profoundImmuneSuppression
NAACCR Alternate Name: Profound Immune Suppression
Active years: 2018+
Schema(s):

- 00460: Merkel Cell Skin

Description

Profound Immune Suppression suppressed immune status that may be associated with HIV/AIDs, solid organ transplant, chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple conditions, or other conditions, increases the risk of developing Merkel Cell Carcinoma and is an adverse prognostic factor.

Profound immune suppression may greatly increase the risk of developing Merkel cell carcinoma. Immune suppression is suppression of the body's immune system and its ability to fight infections and other diseases. Immune suppression may be deliberately induced with drugs, as in preparation for bone marrow or other organ transplantation, to prevent rejection of the donor tissue. It may also result from certain diseases such as Acquired Immune Deficiency Syndrome (AIDS) or lymphoma, and from the use of anti-cancer drugs.

Rationale

Profound Immune Suppression is a Registry Data Collection Variable in AJCC. It was previously collected as Merkel Cell Penis, SSF #22, Merkel Cell Scrotum SSF #22, Merkel Cell Skin, SSF #22, and Merkel Cell Vulva, SSF #22.

Additional Information

Source documents: patient history, consultation notes, other statement in medical record

Other names (per AJCC experts) include immunosuppression, immunocompromised, immunosuppressed, suppressed immune status

Notes

Note 1: Physician statement

- Physician statement of Profound Immune Suppression must be used to code this data item.
- Do not assume that a patient is immune suppressed just because the patient has one of the conditions listed below in the table.

Note 2: Two-year limitation and exceptions

- Per AJCC experts, this data item is limited to the conditions in the table below occurring within two years of the diagnosis of Merkel cell carcinoma.
    - ***Exceptions***: For the following conditions ONLY, these patients will experience chronic immunosuppression. There are no time limits for these conditions. If a patient has a history (regardless of when diagnosed or treatment status), code as present
        - Human Immunodeficiency Virus (HIV)/acquired immunodeficiency syndrome (AIDS) (Code 1)
        - Solid organ transplant recipient (Code 2)
        - Chronic lymphocytic leukemia (Code 3)

Coding Guidelines

1) Code 0 when there is no evidence of immune suppression at the time of diagnosis OR within 2 years of diagnosis

2) Code 1 for HIV diagnosis regardless of when diagnosed or treatment status

3) Code 2 for Solid Organ transplant recipient regardless of when transplant was done

4) Code 3 for Chronic lymphocytic leukemia regardless of when diagnosed or treatment status

5) Code 4 for Non-Hodgkin lymphoma that has been diagnosed within the last two years

6) Code 5 when there are multiple immune suppression conditions (Codes 1-4) present at the same time

7) Code 6 when documentation states "profound immune suppression," but no information regarding which condition is given

8) Code 9 if conditions (other than those noted above) were not active within 2 years of (or resolved more than 2 years prior to) diagnosis, or if it is unknown when they existed.

Code	Description
0	No immune suppression condition(s) identified/not present
1	Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS)
2	Solid organ transplant recipient
3	Chronic lymphocytic leukemia

Code	Description
4	Non-Hodgkin lymphoma
5	Multiple immune suppression conditions
6	Profound immune suppression present
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Profound immune suppression not assessed or unknown if assessed

00460: Merkel Cell Skin

3830: Extranodal Extension Clinical

Item Length: 1
NAACCR Item #: 3830
XML Parent-NAACCR ID: Tumor-extranodalExtensionClin
NAACCR Alternate Name: Extranodal Extension Clinical
Active years: 2018+
Schema(s):

- 00460: Merkel Cell Skin
- 00570: Penis

Description

Extranodal Extension (ENE) Clinical is defined as "the extension of a nodal metastasis through the lymph node capsule into adjacent tissue" during the diagnostic workup. This data item defines clinical ENE for sites other than Head and Neck.

The presence of extranodal extension (ENE) from regional lymph nodes is an important prognostic factor in some cancers because these patients are rarely cured without some type of systemic chemotherapy or radiation.

Extranodal extension is defined as metastatic tumor growing from within the lymph node outward through the lymph node capsule and into surrounding connective tissues.

- "A regional node extending into a distant structure or organ is categorized as ENE and is not recorded as distant metastatic disease."

Clinical ENE is described as "Unambiguous evidence of gross ENE on clinical examination (e.g., invasion of skin, infiltration of musculature, tethering to adjacent structures, or cranial nerve, brachial plexus, sympathetic trunk, or phrenic nerve invasion with dysfunction)"

- The terms 'fixed' or 'matted' are used to describe lymph nodes

This data item is for ENE that is detected clinically.

Rationale

Extranodal Extension Clinical (non-Head and Neck) is a Registry Data Collection Variable for AJCC. This data item was previously collected for Penis, SSF #17.

Additional Information

Source documents: pathology report from surgical resection

Other names include ENE, extracapsular extension, ECE, extracapsular extension, ECE, extranodal spread, extracapsular extension, or extracapsular spread

- **Note**: ENE is the preferred terminology

For further information, refer to the **Merkel Cell Carcinoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Merkel Cell Carcinoma*.

Notes

Note 1: Physician Statement

- Physician statement of Extranodal Extension (ENE) Clinical or physician clinical staging can be used to code this data item when there is no other information available.

Note 2: Criteria for coding

- Code the status of extranodal extension assessed during the diagnostic working for the assignment of the clinical stage for the most involved regional lymph node(s)
- This is mainly determined by physical examination and included statements such as fixed or matted nodes
- The assessment for ENE **in addition to physical examination** may include imaging, biopsy of the regional lymph node, and/or biopsy of tissues surrounding the regional lymph node
- Do not code ENE for any distant nodes
- Be aware that the rules for coding ENE for head and neck sites compared to non-head and neck sites are different.

Coding Guidelines

1) Code 0 when lymph nodes are determined to be **clinically positive** and physical examination does not indicate any signs of extranodal extension

2) Code 1 when **ENE** is unquestionable as determined by physical examination

3) Code 2 when there are positive nodes clinically, ENE is identified by biopsy (microscopically confirmed)

4) Code 4 when there are positive nodes clinically, ENE is identified, but not known how identified

5) Code 7 when nodes are clinically negative (cN0)

6) Code 9 when

- No information in the medical record
- Positive nodes clinically, not evaluated (assessed) for ENE
- Positive nodes clinically, unknown if evaluated (assessed) for ENE
- Lymph nodes not evaluated (assessed) clinically

- Unknown if lymph nodes evaluated (assessed) clinically
- Lymph node biopsy (e.g., FNA, core, incisional, excisional, sentinel node) performed and is negative for ENE or not stated

Code	Description
0	Regional lymph node(s) involved, ENE not present/not identified during diagnostic workup
1	Regional lymph node(s) involved, ENE present/identified during diagnostic workup, based on physical exam WITH or WITHOUT imaging
2	Regional lymph node(s) involved, ENE present/identified during diagnostic workup, based on microscopic confirmation
4	Regional lymph nodes involved, ENE present/identified, unknown how identified
7	No lymph node involvement identified during diagnostic workup (cN0) Non-invasive neoplasm (behavior /2)
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error)
9	Not documented in medical record Clinical ENE not assessed or unknown if assessed during diagnostic workup Clinical assessment of lymph node(s) not done, or unknown if done

00460: Merkel Cell Skin

3833: Extranodal Extension Pathological

Item Length: 1
NAACCR Item #: 3833
XML Parent-NAACCR ID: Tumor-extranodalExtensionPath
NAACCR Alternate Name: Extranodal Extension Pathological
Active years: 2018+
Schema(s):

- 00460: Merkel Cell Skin
- 00570: Penis

Description

Extranodal Extension (ENE) Pathological is defined as "the extension of a nodal metastasis through the lymph node capsule into adjacent tissue." This data item defines pathological ENE for sites other than Head and Neck.

Extranodal extension is defined as metastatic tumor growing from within the lymph node outward through the lymph node capsule and into surrounding connective tissues.

- "A regional node extending into a distant structure or organ is categorized as ENE and is not recorded as distant metastatic disease."

This data item is for ENE that is detected pathologically.

Rationale

Extranodal Extension Pathological (non-Head and Neck) is a Registry Data Collection Variable for AJCC. This data item was previously collected for Penis, SSF #17.

Additional Information

Source documents: pathology report from surgical resection

Other names include ENE, extracapsular extension, ECE, extracapsular extension, ECE, extranodal spread, extracapsular extension, or extracapsular spread

- **Note**: ENE is the preferred terminology

For further information, refer to the **Merkel Cell Carcinoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Merkel Cell Carcinoma*.

Notes

Note 1: Physician Statement

- Physician statement of Extranodal Extension (ENE) Pathological or physician pathological staging can be used to code this data item when there is no other information available.

- Note that the rules for coding ENE for head and neck sites compared to non-head and neck sites are different.

Note 2: Criteria for Coding

- Code the status of extranodal extension assessed on the **surgical resection** specimen for the most involved regional lymph node(s)
- Do not code ENE for any distant lymph nodes.
- Be aware that the rules for coding ENE for head and neck sites compared to non-head and neck sites are different.

Coding Guidelines

1) Code 0 when

- Absence of ENE, positive lymph nodes assessed by lymph node dissection
- 1292: Scope of Regional Lymph Node Surgery must be 3-7

2) Code 1 when

- Presence of ENE assessed by Sentinel Lymph Node biopsy
- Presence of ENE assessed by lymph node dissection
- 1292: Scope of Regional Lymph Node Surgery must be 2-7

3) Code 7 when

- Lymph nodes negative for cancer assessed by Sentinel lymph node biopsy or lymph node dissection
- 1292: Scope of Regional Lymph Node Surgery must be 2-7

4) Code 9 when

- Absence of ENE, positive lymph nodes assessed by Sentinel Lymph Node biopsy
    - A positive Sentinel Lymph Node biopsy cannot assess the absence of ENE, only the presence of it. This is because there is not enough surrounding tissue in a Sentinel Lymph node biopsy to accurately assess ENE
    - Scope of Regional Lymph Node Surgery [NAACCR Data Item: 1292] must be 2-7
- No information in the medical record
- Positive nodes pathologically, not evaluated (assessed) for ENE
- Positive nodes pathologically, unknown if evaluated (assessed) for ENE

- Lymph nodes not evaluated (assessed) pathologically (no surgical resection of lymph nodes)
- Unknown if lymph nodes evaluated pathologically (assessed)

Code	Description
0	Regional lymph node(s) involved, ENE not present/not identified from surgical resection
1	Regional lymph node(s) involved, ENE present/identified from surgical resection
7	No lymph node involvement identified from surgical resection (pN0)
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error)
9	Not documented in medical record No surgical resection of regional lymph node(s) Non-invasive neoplasm (behavior /2) Cannot be determined Pathological assessment of lymph node(s) not done, or unknown if done Extranodal Extension Pathological not assessed or unknown if assessed

00470: Melanoma Skin

3817: Breslow Thickness

Item Length: 4
NAACCR Item #: 3817
XML Parent-NAACCR ID: Tumor-breslowTumorThickness
NAACCR Alternate Name: Breslow Tumor Thickness
Active years: 2018+
Schema(s):

- 00470: Melanoma Skin

Description

Breslow Tumor Thickness, the measurement of the thickness of a melanoma as defined by Dr. Alexander Breslow, is a prognostic factor for Melanoma of the Skin.

A measure of how deeply a melanoma tumor has grown into the skin. The tumor thickness (depth) is usually measured from the top of the tumor to the deepest tumor cells. If the tumor is ulcerated (the skin is broken), it is measured from the base of the ulcer to the deepest tumor cells. Breslow thickness is used to help determine the stage of cancer. Thicker tumors are linked with lower survival rates.

Rationale

Breslow Tumor Thickness is a Registry Data Collection Variable in AJCC. It was previously collected as Melanoma Skin, CS SSF #1.

Additional Information

Source documents: pathology report

Other names include maximum tumor thickness, Breslow depth of invasion, Breslow thickness, Breslow measurement, Breslow's microstaging

For further information, refer to the **Melanoma of the Skin** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Melanoma of the Skin*.

Notes

Note 1: Physician Statement

- Physician statement of Breslow Tumor Thickness can be used to code this data item when no other information is available, or the available information is ambiguous.

Note 2: Breslow's depth

- Code a measurement specifically labeled as **thickness** or **depth** or **Breslow depth of invasion** from the pathology report.

- In the absence of this label, a measurement described as taken from the cut surface of the specimen may be coded. And in the absence of either of these labels, the third dimension in a statement of tumor size can be used to code this field.

Coding Guidelines

1) Code Breslow tumor thickness, not size. Record actual measurement in tenths of millimeters from the pathology report. Measurement given in hundredths of millimeters should be rounded to the nearest tenth.

2) Code the greatest measured thickness from any procedure performed on the lesion, whether it is described as a biopsy or an excision.

- Do not add measurements together from different procedures.
    - ***Example:*** A punch biopsy with a thickness of 0.5 mm is followed by a re-excision with a thickness of residual tumor of 0.2 mm. Code 0.5 mm.
    - ***Exception:*** If there are multiple procedures, and the pathologist adds the measurement together to get a final Breslow's depth, the registrar can use this.

3) If the pathologist describes the thickness as "at least," use the appropriate A code. An exact measurement takes precedence over A codes.

- If the pathologist states "greater than" instead of "at least", code to XX.9, unless it is greater than 9.9 mm (Code AX.0)

4) If the tumor is excised post-neoadjuvant treatment, tumor measurements **cannot be compared** before and after treatment to determine which would indicate the greater involvement.

- The same code (XX.9) is used for cases with no surgical procedure of the primary site and cases with surgical procedure of the primary site after neoadjuvant treatment.

5) Because the thickness table is similar to many other tables that collect a measurement, it is important to identify the correct unit of measurement.

- In the range 0.1-99.9, code the actual tumor thickness, tumor depth, or Breslow measurement in tenths of millimeters as stated in the pathology report. If the measurement is given in hundredths of millimeters, use the general rules for rounding to determine the value in tenths of millimeters. This is a four-digit field with a decimal point in the third digit.

Examples:

- 0.4 mm - 0.4
- 1.0 mm- 1.0

- 2.5 mm - 2.5
- 2.56 mm- 2.6
- 11 mm - 11.0
- 12.35 mm - 12.4
- Pathologist states the thickness is “at least 2.0 mm.” Code A2.0
- Pathologist states the thickness is “greater than 4 mm.” Code XX.9

Code	Description
0.0	No mass/tumor found
0.1	Greater than 0.0 mm and less than or equal to 0.1 mm
0.2-99.9	0.2 - 99.9 millimeters
XX.1	100 millimeters or larger
A0.1-A9.9	Stated as “at least” some measured value of 0.1 to 9.9 mm
AX.0	Stated as greater than 9.9 mm
XX.8	Not applicable: Information not collected for this schema (If this item is required by your standard setter, use of code XX.8 will result in an edit error)
XX.9	Not documented in medical record Microinvasion; microscopic focus or foci only and no depth given Cannot be determined by pathologist Non-invasive neoplasm (behavior /2) Breslow Tumor Thickness not assessed or unknown if assessed

00470: Melanoma Skin

3936: Ulceration

Item Length: 1
NAACCR Item #: 3936
XML Parent-NAACCR ID: Tumor-ulceration
NAACCR Alternate Name: Ulceration
Active years: 2018+
Schema(s):

- 00470: Melanoma Skin

Description

Ulceration, the absence of an intact epidermis overlying the primary melanoma based upon histopathological examination, is a prognostic factor for melanoma of the skin.

Ulceration is the formation of a break on the skin or on the surface of an organ. An ulcer forms when the surface cells die and are cast off. Ulcers may be associated with cancer and other diseases.

Primary tumor ulceration has been shown to be a dominant independent prognostic factor, and if present, changes the pT stage from T1a to T1b, T2a to T2b, etc., depending on the thickness of the tumor.

The presence or absence of ulceration must be confirmed on microscopic examination. Melanoma ulceration is defined as the combination of the following features

- Full-thickness epidermal defect (including absence of stratum corneum and basement membrane)
- Evidence of reactive changes (i.e., fibrin deposition, neutrophils); and thinning, effacement, or reactive hyperplasia of the surrounding epidermis in the absence of trauma or a recent surgical procedure
- Ulcerated melanomas typically show invasion through the epidermis, whereas nonulcerated melanomas tend to lift the overlying epidermis

Additional Information

Source documents: pathology report

For further information, refer to the **Melanoma of the Skin** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Melanoma of the Skin*.

Notes

Note 1: Physician Statement

- Physician statement of microscopically confirmed ulceration (e.g., based on biopsy or surgical resection) can be used to code this data item when no other information is available.

Note 2: Ulceration defined

- Melanoma ulceration is the absence of an intact epidermis overlying the primary melanoma based upon microscopic (histopathological) examination.
- Ulceration can only be confirmed by microscopic examination. Do not use findings from physical exam.
- It is possible for a patient to present with an ulcerated lesion noted on physical exam, but this is not the same thing as ulceration seen on a microscopic exam

Coding Guidelines

1) Code 0 when

- There is a statement in the pathology report that no ulceration is present
- All specimens are negative OR one specimen is negative, and the other is unknown

2) Code 1 when

- Any biopsy (punch, shave, excisional, etc.) or wide excision is positive for ulceration in the presence of an underlying melanoma
- Ulceration must be caused by an underlying melanoma.
    - Ulceration caused by trauma from a previous procedure should not be coded as positive for this SSDI

3) Code 9 when

- No information in the medical record
- Pathology report is not available
- Ulceration not evaluated (not assessed)
- Unknown if Ulceration evaluated (assessed)
- There is microscopic examination and there is no mention of ulceration.
    - This instruction **does** apply to non-invasive neoplasms (behavior /2)

Code	Description
0	Ulceration not identified/not present
1	Ulceration present
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Cannot be determined by the pathologist Pathology report does not mention ulceration Ulceration not assessed or unknown if assessed

00470: Melanoma Skin

3893: Mitotic Rate Melanoma

Item Length: 2
NAACCR Item #: 3893
XML Parent-NAACCR ID: Tumor-mitoticRateMelanoma
NAACCR Alternate Name: Mitotic Rate Melanoma
Active years: 2018+
Schema(s):

- 00470: Melanoma Skin

Description

Mitotic Rate Melanoma, the number of mitoses per square millimeter based on pathological evaluation, is a prognostic factor for melanoma of the skin.

Mitotic count is a way of describing the potential aggressiveness of a tumor. Record the number of cells actively dividing as determined by the pathologist. The count will vary according to the type of tumor.

Rationale

Mitotic Rate Melanoma is a Registry Data Collection Variable in AJCC. It was previously collected as Melanoma Skin, CS SSF #7.

Additional Information

Source documents: pathology report

Other names include mitotic rate, mitotic index (a ratio—do not record this measurement), mitotic activity

For further information, refer to the **Melanoma of the Skin** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Melanoma of the Skin*.

Notes

Note: Physician Statement

- Physician statement of the Mitotic Rate Melanoma can be used to code this data item when no other information is available.

Coding Guidelines

1) Record the mitotic rate/count as documented in the pathology report.

2) If there is more than one pathology report for the same melanoma at initial diagnosis and different mitotic counts are documented, code the highest mitotic count from any of the pathology reports.

3) The term “mitotic figures” is the same as mitoses.

Code	Description
00	0 mitoses per square millimeter (mm) Mitoses absent No mitoses present
01-99	1 - 99 mitoses/square mm (Exact measurement in mitoses/square mm)
X1	100 mitoses/square mm or more
X2	Stated as “less than 1 mitosis/square mm” Stated as “nonmitogenic”
X3	Stated as “at least 1 mitosis/square mm” Stated as “mitogenic”
X4	Mitotic rate described with denominator other than square millimeter (mm)
X7	Test ordered, results not in chart
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record Mitotic Rate Melanoma not assessed or unknown if assessed

00470: Melanoma Skin

3932: LDH Lab Value

Item Length: 7
NAACCR Item #: 3932
XML Parent-NAACCR ID: Tumor-ldhPretreatmentLabValue
NAACCR Alternate Name: LDH Lab Value
Active years: 2018+
Schema(s):

- 00470: Melanoma Skin

Description

LDH (Lactate Dehydrogenase) Lab Value, measured in serum, is a predictor of treatment response, progression-free survival, and overall survival for patients with Stage IV melanoma of the skin.

When cells (normal or tumor) are damaged or destroyed, an enzyme called lactate dehydrogenase (LDH) is released into the bloodstream. LDH is an indirect indication of possible tumor burden or damage to an organ, which may be caused by metastatic involvement of liver or lung, or a myocardial infarction. The total LDH should be the test value that is coded, but there are five fractions of LDH that measure tissue specific cellular damage: LD1 and LD2: heart, red blood cells and kidneys; LD3: lung; LD4 and LD5: liver, skin, and skeletal muscles. LDH is elevated in 60% of patients with non-seminomatous germ cell tumors of the testis. LDH is not a screening test, nor is it diagnostic of melanoma, ocular adnexal lymphoma, or testicular cancer.

LDH is important in melanoma staging in the setting of DISTANT metastasis. LDH level might only be ordered after re-excision/wide excision and/or nodal evaluation indicates a higher risk of distant metastasis. Imaging may then be performed and if distant metastasis are identified, LDH is ordered.

Rationale

LDH Lab Value is a Registry Data Collection Variable in AJCC. It was previously collected as Melanoma Skin, CS SSF #5.

Additional Information

Source documents: clinical laboratory report; may be included in a liver or hepatic panel/profile, a cardiac panel, or a general metabolic panel of tests

Other names include: LDH, Lactate dehydrogenase, lactase dehydrogenase, lactic acid dehydrogenase

Notes

Note 1: Physician Statement

- Physician statement of LDH Lab Value can be used to code this data item when no other information is available.

Note 2: Pre systemic treatment results

- Record the lab value of the highest serum LDH test results documented in the medical record either before or after surgical resection of the primary tumor with or without regional lymph node dissection.
- The LDH must be taken prior to systemic (chemo, immunotherapy, hormone), radiation therapy or surgery to a metastatic site.

Note 3: Related data item

- The same laboratory test should be used to record the related data items 3869: LDH Level and 3870: LDH Upper Limits of Normal.

Coding Guidelines

1) Record the lab value of the highest serum LDH test results documented in the medical record **either before or after surgical resection** of the primary tumor with or without regional lymph node dissection.

2) Code 0.0 for a test result of 0 (U/L).

3) Code 0.1-99,999.9 for the highest exact LDH lab value prior to systemic (chemo, immunotherapy, hormone), radiation therapy or surgery to a metastatic site

4) Code XXXXX.1 for a total LDH lab value of 100,000 or greater.

5) Code XXXXX.7 if the test was ordered and the results are not in the medical record.

6) Code XXXXX.9 when

- There is no information in the medical record about the LDH lab value
- Test is not done or unknown if the test was done

Code	Description
0.0	0.0 (U/L)
0.1-99999.9	0.1 - 99,999.9 U/L
XXXXX.1	100,000 U/L or greater

Code	Description
XXXXX.7	Test ordered, results not in chart
XXXXX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XXXXX.8 will result in an edit error.)
XXXXX.9	Not documented in medical record LDH Lab Value not assessed or unknown if assessed

00470: Melanoma Skin

3870: LDH Upper Limits of Normal

Item Length: 3
NAACCR Item #: 3870
XML Parent-NAACCR ID: Tumor-ldhUpperLimitsOfNormal
NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Upper Limits of Normal
Active years: 2018+
Schema(s):

- 00470: Melanoma Skin

Description

LDH (Lactate Dehydrogenase), an enzyme involved in converting sugars to energy in the body, is elevated in some malignancies. LDH level is a prognostic factor for patients with Stage IV melanoma. This data Item refers to the Upper Limit of Normal in the laboratory test used to interpret the Serum LDH result.

When cells (normal or tumor) are damaged or destroyed, an enzyme called lactate dehydrogenase (LDH) is released into the bloodstream. LDH is an indirect indication of possible tumor burden or damage to an organ, which may be caused by metastatic involvement of liver or lung, or a myocardial infarction. The total LDH should be the test value that is coded, but there are five fractions of LDH that measure tissue specific cellular damage: LD1 and LD2: heart, red blood cells and kidneys; LD3: lung; LD4 and LD5: liver, skin, and skeletal muscles. LDH is elevated in 60% of patients with non-seminomatous germ cell tumors of the testis. LDH is not a screening test, nor is it diagnostic of melanoma, ocular adnexal lymphoma, or testicular cancer.

Rationale

LDH (Lactate Dehydrogenase) Upper Limits of Normal is a Registry Data Collection Variable in AJCC. It was previously collected as Melanoma Skin, CS SSF #6.

Additional Information

Source documents: clinical laboratory report; may be included in a liver or hepatic panel/profile, a cardiac panel, or a general metabolic panel of tests

Other names include: LDH, Lactate dehydrogenase, lactase dehydrogenase, lactic acid dehydrogenase

Normal reference range varies widely by laboratory, patient age, and the units of measurement.

- Upper limits of normal for LDH vary widely depending on the lab.
- Common upper limits can be 200, 250, 618, or other values.

Examples of reference range lab values:

- Lab A Total LDH 71 – 207 U/L
- Lab B Total LDH 300 – 600 U/L
- Lab C LDH 45 – 90 U/L
- Lab D Total LDH 150 – 250 U/L

Notes

Note 1: Physician Statement

- Physician statement of LDH (Lactate Dehydrogenase) Upper Limit of Normal can be used to code this data item when no other information is available.

Note 2: Recording upper limits

- Record the value of the highest serum LDH test results documented in the medical record either before or after surgical resection of the primary tumor with or without regional lymph node dissection. The LDH must be taken prior to systemic (chemo, immunotherapy, hormone), radiation therapy or surgery to a metastatic site. The lab value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Related data items

- The same laboratory test should be used to record the related data items 3932: LDH Lab Value and 3869: LDH Level.

Code	Description
001-999	001 - 999 upper limit of normal (Exact upper limit of normal)
XX8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XX8 may result in an edit error.)
XX9	Not documented in medical record LDH Upper Limit not assessed or unknown if assessed

00470: Melanoma Skin

3869: LDH Level

Item Length: 1
NAACCR Item #: 3869
XML Parent-NAACCR ID: Tumor-ldhPretreatmentLevel
NAACCR Alternate Name: LDH Level
Active years: 2018+
Schema(s):

- 00470: Melanoma Skin

Description

LDH (Lactate Dehydrogenase) is an enzyme involved in conversion of sugars to energy and present in most cells in the body. Elevated LDH is an adverse prognostic factor for plasma cell myeloma and melanoma of the skin.

Rationale

LDH (Lactate Dehydrogenase) Level is a prognostic factor required in AJCC 8th edition for Chapter 82 Plasma Cell Myeloma and Plasma Cell Disorders and Chapter 47 Melanoma Skin. For Plasma Cell Myeloma, LDH is part of the RISS Stage and is new for cases diagnosed 1/1/2018+. For Melanoma Skin, LDH is used to define the M subcategories and was previously collected as Melanoma Skin, SSF #4.

Additional Information

Source documents: clinical laboratory report; may be included in a liver or hepatic panel/profile, a cardiac panel, or a general metabolic panel of tests

Other names include: LDH, Lactate dehydrogenase, lactase dehydrogenase, lactic acid dehydrogenase

Notes

Note 1: Physician Statement

- Physician statement of LDH Level can be used to code this data item when no other information is available.

Note 2: Coding criteria

- Record the interpretation of the highest serum LDH test results documented in the medical record either before or after surgical resection of the primary tumor with or without regional lymph node dissection
- The LDH must be taken prior to systemic (chemo, immunotherapy, hormone), radiation therapy or surgery to a metastatic site

- Use the reference ranges from your lab to determine if LDH is normal

Note 3: Related data item

- The same laboratory test should be used to record the related data items 3869: LDH Level and 3870: LDH Upper Limits of Normal

Code	Description
0	Normal LDH level Low, below normal
1	Above normal LDH level; High
7	Test ordered, results not in chart
9	Not documented in medical record LDH Level not assessed or unknown if assessed

00470: Melanoma Skin

3961: Clinical Margin Width

Item Length: 4
NAACCR Item #: 3961
XML Parent-NAACCR ID: Tumor-clinicalMarginWidth
NAACCR Alternate Name: Clinical Margin Width
Active years: 2023+
Schema(s):

- 00470: Melanoma Skin

Description

Clinical margin width describes the margins from a wide excision for a melanoma primary. The margin width is measured by the surgeon prior to the procedure. The measurement is taken, in centimeters, from the edge of the lesion or the prior excision scar to the peripheral margin of the specimen.

Rationale

Per the American College of Surgeons Optimal Resources for Cancer Care-2020 Standards Standard 5.5 Local Excision for Primary Cutaneous Melanoma, the clinical margin width for wide local excision of invasive melanoma should be 1 cm for melanomas <1 mm thick, 1 to 2 cm for invasive melanomas 1 to 2 mm thick, and 2 cm for invasive melanomas >2 mm thick. The clinical margin width for wide local excision of a melanoma in situ should be at least 5 mm.

Additional Information

Current version of the Commission on Cancer's STORE Manual, Appendix M

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2023+ AND **primary sites C440-C449 only**. For all other primary sites, code XX.9
    - See https://www.facs.org/media/sgod24u4/guidelines-for-registrars-to-identify-eligible-cases-for-standard-55.pdf
- For cases diagnosed 2018-2022, this SSDI must be blank

Note 2: Measuring the margins

- "The appropriate [wide local excision] margins are measured from the periphery of any gross residual tumor or the edges of the entire previous biopsy scar (shave or excisional)." Operative Standards for Cancer Surgery, Volume 2, page 392.

Note 3: Code peripheral surgical margins from the operative report from a wide excision

- Do not use the pathology report to code this data item.
- Margins from wide excision-Measured from the edge of the lesion or the prior excision scar to the peripheral margin of the specimen, do not use deep margin
- Do not add margins together
- If multiple wide excisions are performed, code the clinical margin width from the procedure with the largest margin
- If a range is listed, code the lower range
    - *Example:* Clinical Width Margin documented as 1-1.2 cm. Code 1 cm

Note 4: Physician statement

- Physician statement of clinical margin width can be used to code this data item when no other information is available, or the available information is ambiguous
    - Order of priority:
        - Operative Note
        - Physician statement in medical record

Note 5: Code formats

- Record stated margin in centimeters. Include decimal point.
  Examples:
    - 0.5 cm - 0.5
    - 1 cm- 1.0
    - 2.5 cm - 2.5

Code	Description
0.1	Documented as 0.1 cm or less (1 mm or less)
0.2-9.9	0.2 cm – 9.9 cm
XX.1	10 centimeters or greater
XX.8	Not Applicable. Information not collected for this schema (If this information is required by your standard setter, use of code XX.8 may result in an edit error)

Code	Description
XX.9	Not documented in medical record No Wide Excision performed Mohs or similar procedure Wide Excision performed, but clinical margin width not documented. No surgical resection performed (B000) Unknown if procedure performed.
<Blank>	Must be blank if diagnosis year is before 2023

BREAST

For the following SSDIs, please see SSDIs No Longer Required by the Standard Setters section at the end of the SSDI manual.

- 3828: Estrogen Receptor Total Allred Score
- 3850: HER2 IHC Summary
- 3851: HER2 ISH Dual Probe Copy Number
- 3852: HER2 ISH Dual Probe Ratio
- 3853: HER2 ISH Single Probe Copy Number
- 3854: HER2 ISH Summary
- 3916: Progesterone Receptor Total Allred Score
- 3894: Multigene Signature Method
- 3895: Multigene Signature Result

00480: Breast

3882: LN Positive Axillary Level I-II

Item Length: 2
NAACCR Item #: 3882
XML Parent-NAACCR ID: Tumor-lnPositiveAxillaryLevel1To2
NAACCR Alternate Name: Lymph Nodes Positive Axillary Level I-II
Active years: 2018+
Schema(s):

- 00480: Breast

Description

This data item pertains to the number of positive ipsilateral level I and II axillary lymph nodes and intramammary lymph nodes based on pathological information.

This data items records the low axillary (level I and intramammary) and mid-axillary (level II, also called interpectoral or Rotter's nodes).

This data item excludes level III (high axillary, also called apical or infraclavicular), internal mammary and supraclavicular lymph nodes.

Do not confuse intramammary nodes, which are within breast tissue and are included in level I, with internal mammary nodes, which are along the sternum.

This field is based on pathological examination of ipsilateral (same side as the primary cancer) level I and II axillary lymph nodes, so pathological information is included even if the patient had neoadjuvant therapy prior to lymph node removal.

Do not include lymph nodes containing only isolated tumor cells (ITCs—metastases less than 0.2 mm in size) in the count of positive nodes.

Rationale

Lymph Nodes Positive Axillary Level I-II can be collected by the surveillance community for breast cancers. Prior to 2018, Breast SSF#3 was used for Lymph Nodes Positive Axillary Level I-II.

Additional Information

Required for Staging: EOD only

Source documents: pathology report

Notes

Note 1: Physician Statement

- Physician statement of number of positive ipsilateral Level I-II axillary nodes can be used to code this data item, when no other specific information is available.

Note 2: Axillary Level I and II lymph nodes

- Include only the number of positive ipsilateral level I and II axillary lymph nodes and intramammary lymph nodes in this field. Intramammary nodes, located within the breast, are not the same as internal mammary nodes, located along the sternum.

Note 3: Microscopic confirmation

- This field is based on microscopic information only. If no ipsilateral axillary nodes are examined, or if an ipsilateral axillary lymph node drainage area is removed but no lymph nodes are found, code X9.

Note 4: Isolated tumor cells

- Lymph nodes with only isolated tumor cells (ITCs) are not counted as positive lymph nodes. Only lymph nodes with metastases greater than 0.2 mm (micrometastases or larger) should be counted as positive. If the pathology report indicates that axillary nodes are positive, but size of the metastases is not stated, assume the metastases are greater than 0.2 mm and code the lymph nodes as positive in this field.

Note 5: Positive Axillary lymph nodes compared to Regional Nodes Positive

- When positive ipsilateral axillary lymph nodes are coded in this field, the number of positive ipsilateral axillary lymph nodes must be less than or equal to the number coded in Regional Nodes Positive (i.e., the number of positive ipsilateral axillary nodes will always be a subset of the number of positive regional nodes.)

Note 6: Neoadjuvant Therapy:

- If clinical nodal involvement is more extensive, include only those nodes that are positive during clinical workup
    - Positive nodes can be from an FNA, core biopsy or sentinel lymph node biopsy
        - ***Example:*** Patient with positive FNA of axillary lymph node, neoadjuvant therapy administered. Lymph node dissection revealed negative lymph nodes. Code X6 for the positive FNA.
- If the post-neoadjuvant nodal involvement is more extensive, include only those nodes positive during surgery

- Positive nodes can be from an FNA, core biopsy, sentinel lymph node biopsy or lymph node dissection
    - ***Example:*** Patient with large breast mass, lymph node negative on clinical exam. Neoadjuvant therapy administered. Mastectomy and sentinel lymph node biopsy done, 1 of 2 SLN's positive. Code 01.

Coding Guidelines

1) Code 00 when all level I and II axillary lymph nodes are negative on pathological examination

2) Code 01-99 for the exact number of positive nodes for levels I and II

3) Code X1 if more than 99 level I and II axillary lymph nodes are positive

4) Code X5 if level I and II axillary lymph nodes were positive, but the number is not specified

5) Code X6 if there was only a positive aspiration of level I or II axillary lymph node(s)

6) Code X9 when

- No axillary nodes were examined
- Axillary dissection was performed but no axillary lymph nodes were found
- Clinical diagnosis only (no axillary lymph nodes were removed)
- Unknown whether axillary lymph nodes are positive

Code	Description
00	All ipsilateral axillary nodes examined negative
01-99	1 - 99 nodes positive (Exact number of nodes positive)
X1	100 or more nodes positive
X5	Positive nodes, number unspecified
X6	Positive aspiration or needle core biopsy of lymph node(s)
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record Level I-II axillary nodes not assessed or unknown if assessed

00480: Breast

3827: Estrogen Receptor Summary

Item Length: 1
NAACCR Item #: 3827
XML Parent-NAACCR ID: Tumor-estrogenReceptorSummary
NAACCR Alternate Name: ER (Estrogen Receptor) Summary
Active years: 2018+
Schema(s):

- 00480: Breast

Description

Estrogen Receptor Summary is a summary of results of the estrogen receptor (ER) assay.

Estrogen receptor (ER) positivity and progesterone receptor (PR) positivity are favorable prognostic factors in breast cancer, as well as endometrial carcinoma and meningioma. Positive results predict a favorable response to endocrine (hormonal) therapy. Combined ER and PR positivity is associated with increased response to antiestrogen therapies.

There are a variety of ways to report information on ER and PR results, but there is almost always a summary statement that the result is positive or negative.

Rationale

This data item is required for prognostic stage grouping in AJCC 8th edition, Chapter 48, Breast. It was previously collected as Breast CS SSF # 1.

Additional Information

Source documents: pathology report

For further information, refer to the **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System Breast.

Notes

Note 1: Physician Statement

- Physician statement of ER (Estrogen Receptor) Summary status can be used to code this data item when no other information is available.

Note 2: In-situ and Invasive components present

- If ER is positive on an in-situ component and ER is negative on all tested invasive components in the primary tumor, code ER as negative (code 0)
- If in situ and invasive components present and ER only done on the in-situ component in the primary tumor, code unknown (code 9)

Note 3: Single tumor, multiple biopsies or surgical resection, different results

- Use the highest (positive versus negative)

Note 4: Multiple tumors, different results

- Code the results from the largest tumor size (determined either clinically or pathologically) when multiple tumors are present.
    - Do not use specimen size to determine the largest tumor size

Note 5: Results from nodal or metastatic tissue

- May be used ONLY when there is no evidence of primary tumor
    - **Note:** In-situ is evidence of primary tumor

Note 6: Neoadjuvant Therapy

- Record the assay from tumor specimens prior to neoadjuvant therapy.
- If neoadjuvant therapy is given and there are no ER results from pre-treatment specimens, report the findings from post-treatment specimens

Note 7: ER Positive and Oncotype

- If the patient is ER positive and node negative, a multigene test such as Oncotype Dx may be performed, in which case another ER test will be performed. Do not record the results of that test in this field.
- Record only the results of the test which made the patient eligible to be given the multigene test

Note 8: Other tests for ER

- Do not use results from the following tests to record ER or PR results
    - MammaPrint
    - EndoPredict
    - PAM 50 (Prosigna)
    - Any other test that records ER

Coding Guidelines

1) Code 0 when the ER is reported as negative or normal

2) Code 1 when the ER is reported as positive or elevated

3) Code 7 when the ER test was ordered but the results are not available

4) Code 9 when the ER is

- Reported as borderline; undetermined whether positive or negative
- Cannot be determined by the pathologist (e.g., inadequate specimen)
- It is unknown whether the ER test was performed
- The patient has only a clinical diagnosis of breast cancer (no tissue diagnosis)

Code	Description
0	ER negative (0.0% or less than 1%)
1	ER positive
7	Test ordered, results not in chart
9	Not documented in medical record Cannot be determined (indeterminate) ER (Estrogen Receptor) Summary status not assessed or unknown if assessed

00480: Breast

3826: Estrogen Receptor Percent Positive or Range

Item Length: 3
NAACCR Item #: 3826
XML Parent-NAACCR ID: Tumor-estrogenReceptorPercntPosOrRange
NAACCR Alternate Name: ER (Estrogen Receptor) Percent Positive or Range
Active years: 2018+
Schema(s):

- 00480: Breast

Description

Estrogen Receptor Percent Positive or Range is the percent of cells staining estrogen receptor positive by IHC.

The two most common ways to report ER and PR results are the percentage of cells with nuclear positivity and the average intensity of staining. Both the PS and IS are based on immunohistochemical staining of tumor cells.

ER and PR status, the percentage of tumor cells with positive nuclear staining, may be reported as a specific number or a range if more than 10%. Intensity refers to degree of nuclear positivity (i.e., pale to dark); average intensity of staining is recorded as weak, moderate, or strong.

Rationale

Estrogen Receptor Percent Positive or Range is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: pathology report

For further information, refer to the **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast*.

Notes

Note 1: Physician Statement

- Physician statement of ER (Estrogen Receptor) Percent Positive or Range can be used to code this data item when no other information is available.

Note 2: Related data item

- Code this data item using the same report used to record the related data item 3827: Estrogen Receptor Summary.

Coding Guidelines

1) Code 000 when ER is negative, or percentage is less than 1%

2) Code 01-100 for the actual percentage

- The actual ER (1-100%) percent takes priority over the range codes

3) Code XX7 if ER is positive, but percentage is unknown

4) R10-R99 Ranges for the codes in this data item are defined in steps of 10 which correspond to the CAP protocol. If a range in a report is given in steps other than those provided in the R codes, code per the following.

- If the range is less than or equal to 10, then code the appropriate R code based on the lower number
    - ***Example 1***: Report documents 1-5%. Code R10 (1-10%)
    - ***Example 2***: Report documents 25-34%. Code R30 (21-30%)
- If the range is greater than 10, then code to unknown
    - ***Example 1***: Report documents 10-25%. Code XX9
    - ***Example 2:*** Report documents 67-100%. Code XX9

Code	Description
000	ER negative, or stated as less than 1%
001-100	1-100 percent
R10	Stated as 1-10%
R20	Stated as 11-20%
R30	Stated as 21-30%
R40	Stated as 31-40%
R50	Stated as 41-50%
R60	Stated as 51-60%
R70	Stated as 61-70%
R80	Stated as 71-80%
R90	Stated as 81-90%

Code	Description
R99	Stated as 91-100%
XX7	Test done, results not in chart
XX8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX8 will result in an edit error.)
XX9	Not documented in medical record ER (Estrogen Receptor) Percent Positive or Range not assessed or unknown if assessed

00480: Breast

3915: Progesterone Receptor Summary

Item Length: 1
NAACCR Item #: 3915
XML Parent-NAACCR ID: Tumor-progesteroneRecepSummary
NAACCR Alternate Name: PR (Progesterone Receptor) Summary
Active years: 2018+
Schema(s):

- 00480: Breast

Description

Progesterone Receptor Summary is a summary of results from the progesterone receptor (PR) assay.

Estrogen receptor (ER) positivity and progesterone receptor (PR) positivity are favorable prognostic factors in breast cancer, as well as endometrial carcinoma and meningioma. Positive results predict a favorable response to endocrine (hormonal) therapy. Combined ER and PR positivity is associated with increased response to antiestrogen therapies.

There are a variety of ways to report information on ER and PR results, but there is almost always a summary statement that the result is positive or negative.

Rationale

This data item is required for prognostic stage grouping in AJCC 8th edition, Chapter 48 Breast. It was previously collected as Breast CS SSF # 2.

Additional Information

Source documents: pathology report

For further information, refer to the **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System Breast.

Notes

Note 1: Physician Statement

- Physician statement of PR (Progesterone Receptor) Summary status can be used to code this data item when no other information is available.

Note 2: In-situ and Invasive components present

- If PR is positive on an in-situ component and PR is negative on all tested invasive components in the primary tumor, code PR as negative (code 0)

- If in situ and invasive components present and PR only done on the in-situ component in the primary tumor, code unknown (code 9)

Note 3: Single tumor, multiple biopsies or surgical resection, different results

- Use the highest (positive versus negative)

Note 4: Multiple tumors, different results

- Code the results from the largest tumor size (determined either clinically or pathologically) when multiple tumors are present.
    - Do not use specimen size to determine the largest tumor size

Note 5: Results from nodal or metastatic tissue

- May be used ONLY when there is no evidence of primary tumor
    - **Note:** In-situ is evidence of primary tumor

Note 6: Neoadjuvant Therapy

- Record the assay from tumor specimens prior to neoadjuvant therapy.
- If neoadjuvant therapy is given and there are no ER results from pre-treatment specimens, report the findings from post-treatment specimens

Note 7: Other tests for PR

- Do not use results from the following tests to record PR results
    - MammaPrint
    - EndoPredict
    - PAM 50 (Prosigna)
    - Any other test that records PR

Coding Guidelines

1) Code 0 when the PR is reported as negative or normal

2) Code 1 when the PR is reported as positive or elevated

3) Code 7 when the PR test was ordered but the results are not available

4) Code 9 when the PR is

- Reported as borderline; undetermined whether positive or negative
- Cannot be determined by the pathologist (e.g., inadequate specimen)

- It is unknown whether the PR test was performed
- The patient has only a clinical diagnosis of breast cancer (no tissue diagnosis)

Code	Description
0	PR negative (0.0% or less than 1%)
1	PR positive
7	Test ordered, results not in chart
9	Not documented in medical record Cannot be determined (indeterminate) PR (Progesterone Receptor) Summary status not assessed or unknown if assessed

00480: Breast

3914: Progesterone Receptor Percent Positive or Range

Item Length: 3
NAACCR Item #: 3914
XML Parent-NAACCR ID: Tumor-progesteroneRecepPrcntPosOrRange
NAACCR Alternate Name: PR (Progesterone Receptor) Percent Positive or Range
Active years: 2018+
Schema(s):

- 00480: Breast

Description

Progesterone Receptor Percent Positive or Range is the percent of cells staining progesterone receptor positive measured by IHC.

The two most common ways to report ER and PR results are the percentage of cells with nuclear positivity and the average intensity of staining. Both the PS and IS are based on immunohistochemical staining of tumor cells.

ER and PR status, the percentage of tumor cells with positive nuclear staining, may be reported as a specific number or a range if more than 10%. Intensity refers to degree of nuclear positivity (i.e., pale to dark); average intensity of staining is recorded as weak, moderate, or strong.

Rationale

Progesterone Receptor Percent Positive or Range is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: pathology report

For further information, refer to the **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast*.

Notes

Note 1: Physician Statement

- Physician statement of PR (Progesterone Receptor) Percent Positive or Range can be used to code this data item when no other information is available.

Note 2: Related Data Item

- Code this data item using the same report used to record the related data item 3915: Progesterone Receptor Summary.

Coding Guidelines

1) Code 000 when PR is negative, or percentage is less than 1%

2) Code 01-100 for the actual percentage

- The actual PR (1-100%) percent takes priority over the range codes

3) Code XX7 if PR is positive, but percentage is unknown

4) R10-R99 Ranges for the codes in this data item are defined in steps of 10 which correspond to the CAP protocol. If a range in a report is given in steps other than those provided in the R codes, code per the following.

- If the range is less than or equal to 10, then code the appropriate R code based on the lower number
    - ***Example 1***: Report documents 1-5%. Code R10 (1-10%)
    - ***Example 2***: Report documents 25-34%. Code R30 (21-30%)
- If the range is greater than 10, then code to unknown
    - ***Example 1***: Report documents 10-25%. Code XX9
    - ***Example 2:*** Report documents 67-100%. Code XX9

Code	Description
000	PR negative, or stated as less than 1%
001-100	1-100 percent
R10	Stated as 1-10%
R20	Stated as 11-20%
R30	Stated as 21-30%
R40	Stated as 31-40%
R50	Stated as 41-50%
R60	Stated as 51-60%
R70	Stated as 61-70%
R80	Stated as 71-80%
R90	Stated as 81-90%

Code	Description
R99	Stated as 91-100%
XX7	Test done, results not in chart
XX8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX8 will result in an edit error.)
XX9	Not documented in medical record PR (Progesterone Receptor) Percent Positive or Range not assessed or unknown if assessed

00480: Breast

3855: HER2 Summary

Item Length: 1
NAACCR Item #: 3855
XML Parent-NAACCR ID: Tumor-her2OverallSummary
NAACCR Alternate Name: HER2 Overall Summary
Active years: 2018+
Schema(s):

- 00480: Breast

Description

HER2 Overall Summary is a summary of results from HER2 testing.

A subset of breast carcinomas (approximately 15% to 20%) overexpress human epidermal growth factor receptor 2 (HER2). The presence of HER2 overexpression in untreated patients is associated with worse prognosis in both node-negative and node-positive patients. Protein overexpression is usually due to HER2 gene amplification. The HER2 protein may also be referred to as ERBB2 and the HER2 gene may also be referred to as the ERBB2 gene.

The development of HER-2 targeting agents for the treatment of HER2 positive breast cancer has dramatically improved outcomes for patients with HER2 positive breast cancers. HER2 status is primarily evaluated to determine patient eligibility for anti-HER2 therapy.

Rationale

This data item is required for prognostic stage grouping in AJCC 8th edition, Chapter 48 Breast. It was previously collected as Breast, CS SSF # 15. Experts recommend that every invasive breast cancer be tested for the presence of HER2 because anti-HER2 treatments are highly effective for these tumors.

Additional Information

Source documents: pathology report

For further information, refer to the **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast*.

Notes

Note 1: Physician Statement

- Physician statement of HER2 Overall Summary status can be used to code this data item when no other information is available.

Note 2: In-situ and Invasive components present

- If HER2 is positive on an in-situ component and HER2 is negative on all tested invasive components in the primary tumor, code HER2 as negative (code 0)
- If in situ and invasive components present and HER2 only done on the in-situ component in the primary tumor, code unknown (code 9)

Note 3: Single tumor, multiple biopsies or surgical resection, different results

- Use the highest (positive versus negative)

Note 4: Multiple tumors, different results

- Code the results from the largest tumor size (determined either clinically or pathologically) when multiple tumors are present.
    - Do not use specimen size to determine the largest tumor size

Note 5: Results from nodal or metastatic tissue

- May be used, ONLY when there is no evidence of primary tumor
    - **Note:** In-situ is evidence of primary tumor

Note 6: Neoadjuvant Therapy

- Record the assay from tumor specimens prior to neoadjuvant therapy.
- If neoadjuvant therapy is given and there are no ER results from pre-treatment specimens, report the findings from post-treatment specimens

Note 7: HER2 Positive and Oncotype

- In some cases, the Oncotype DX report may include a quantitative HER2 result. However, this value from the OncotypeDx report should not be recorded in the registry.
- The HER2 result recorded should be from the physician report based on the IHC and/or ISH as described for this element.

Note 8: HER2 and in situ tumors

- HER2 is not routinely done on pure in situ tumors (behavior /2); however, if you have an in-situ tumor and there are HER2 results, go ahead and record it. Otherwise, code 9

Coding Guidelines

Record the pathologist's interpretation of the HER2 test from the primary tumor specimen.

1) Code 0 when the HER2 is reported as negative or normal

2) Code 1 when the HER2 is reported as positive or elevated

3) Code 7 when the HER2 test was ordered but the results are not available

4) Code 9 when the HER2 is

- Reported as borderline; undetermined whether positive or negative
- Cannot be determined by the pathologist (e.g., inadequate specimen)
- It is unknown whether the HER2 test was performed
- The patient has only a clinical diagnosis of breast cancer (no tissue diagnosis)

Code	Description
0	HER2 negative; equivocal
1	HER2 positive
7	Test ordered, results not in chart
9	Not documented in medical record Cannot be determined (indeterminate) Borderline HER2 Overall Summary status not assessed or unknown if assessed

00480: Breast

3863: Ki-67

Item Length: 5
NAACCR Item #: 3863
XML Parent-NAACCR ID: Tumor-ki67
NAACCR Alternate Name: Ki-67 (MIB-1)
Active years: 2018+
Schema(s):

- 00480: Breast

Description

Ki-67 (MIB-1) (Proliferative Index) is a marker of cell proliferation. A high value indicates a tumor that is proliferating more rapidly. Codes and coding instructions for this data item are site-specific.

Rationale

Ki-67 (MIB-1) (Proliferative Index) is a Registry Data Collection Variable in AJCC. It was a new data item for breast cases diagnosed 1/1/2018+. It will apply to neuroendocrine tumors (NET) of the gastrointestinal tract (AJCC Chapters 29 – 34) for cases diagnosed 1/1/2021+. High Ki-67 is an adverse prognostic factor and Ki-67 is a component of grade for these tumors. NCCN guidelines recommend that tumor differentiation, mitotic rate and Ki-67 should be recorded in the pathology report for these tumors.

Additional Information

Source documents: pathology report

For further information, refer to the **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast*.

Notes

Note 1: Physician Statement

- Physician statement of Ki-67 (MIB-1), also referred to as the “Proliferative Index” can be used to code this data item when no other information is available.

Note 2: In-situ and Invasive components present

- If Ki-67 is done on both the in situ and invasive components in the primary tumor, code the Ki-67 value from the invasive component
- If in situ and invasive components present and Ki-67 only done on the in-situ component in the primary tumor, code unknown

Note 3: Results from nodal or metastatic tissue

- Results from nodal or metastatic tissue may be used ONLY when there is no evidence of primary tumor
    - *Note:* In-situ is evidence of primary tumor

Note 4: Neoadjuvant Therapy

- Record the assay from tumor specimens prior to neoadjuvant therapy.
- If neoadjuvant therapy is given and there are no Ki-67 results from pre-treatment specimens, report the findings from post-treatment specimens.

Coding Guidelines

Ki-67 results are reported as the percentage cell nuclei that stain positive. As of early 2017 there are no established standards for interpretation of results or for cutoffs for positive and negative.

- ***Examples:***
    - Ki-67 reported as 14%. Code 14.0
    - Ki-67 reported as 8.6%. Code 8.6

Code	Description
0.0-100.0	0.0 to 100.0 percent positive: enter percent positive
XXX.7	Test done, actual percentage not stated
XXX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XXX.8 will result in an edit error.)
XXX.9	Not documented in medical record Ki-67 (MIB-1) not assessed or unknown if assessed

00480: Breast

3904: Oncotype Dx Recurrence Score - Invasive

Item Length: 3
NAACCR Item #: 3904
XML Parent-NAACCR ID: Tumor-oncotypeDxRecurrenceScoreInvasiv
NAACCR Alternate Name: Oncotype Dx Recurrence Score - Invasive
Active years: 2018+
Schema(s):

- 00480: Breast

Description

Oncotype Dx Recurrence Score-Invasive is a numeric score of a genomic test to predict the likelihood of distant recurrence of invasive breast cancer based on the assessment of 21 genes.

The Oncotype DX Breast Recurrence Score test (Oncotype DX) test is a genomic test that predicts the risk of distant recurrence and likelihood of benefit chemotherapy for early-stage breast cancers. It is required for assigning prognostic stage in AJCC 8th edition for patients with T1-2 N0, M0, ER-positive, HER2 negative breast cancers. Oncotype DX provides a quantitative score, based on a continuous scale from 0-100, with higher scores reflecting higher risk of distant recurrence and higher likelihood of chemotherapy benefit.

Rationale

Oncotype Dx Recurrence Score-Invasive is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: Oncotype Dx Breast Recurrence Score laboratory report, other statements in medical record

Notes

Note 1: Physician Statement

- Physician statement of Oncotype Dx Recurrence Score-Invasive score can be used to code this data item when no other information is available.

Note 2: Type of Test

- Record only the results of an Oncotype Dx-Invasive recurrence score in this data item. If some other test is used for scoring, assign code XX9.
- Predicted Oncotype Dx Recurrence Score based on linear regression models and Magee equations should not be reported in this field.

- Code unknown If the only information you have on Oncotype Dx is based on a linear regression model and Magee score

Note 3: Staging related

- Staging for Breast cancer now depends on the Oncotype-Dx-Invasive recurrence score. Score of less than 11 indicates a pertinent cut off value for staging purposes.

Note 4: Results from nodal or metastatic tissue

- May be used, ONLY when there is no evidence of primary tumor
  - **Note:** In-situ is evidence of primary tumor

Note 5: Multiple tests, multiple results

- In cases where Oncotype DX is reported on more than one breast tumor specimen, record the highest value.

Note 6: Related data item

- Code this data item using the same report used to record the related data item 3906: Oncotype Dx Risk Level-Invasive.

Coding Guidelines

1) Code 01-100 for the actual recurrence score

- The actual recurrence score takes priority over codes XX4 and XX5.

2) Code XX6 if the case is in-situ (/2)

3) Code XX7 If the only information available is the Oncotype Dx-Invasive Risk Level

4) Code XX9 when Oncotype DX recurrence score

- Cannot be determined by the pathologist (e.g., inadequate specimen)
- It is unknown whether the Oncotype DX recurrence score test was performed
- The patient has only a clinical diagnosis of breast cancer (no tissue diagnosis)

Code	Description
000-100	Enter actual recurrence score between 0 and 100
XX4	Stated as less than 11
XX5	Stated as equal to or greater than 11
XX6	Not applicable, in situ case

Code	Description
XX7	Test ordered, results not in chart
XX9	Not documented in medical record Oncotype Dx Recurrence Score-Invasive not assessed or unknown if assessed

00480: Breast

3903: Oncotype Dx Recurrence Score DCIS

Item Length: 3
NAACCR Item #: 3903
XML Parent-NAACCR ID: Tumor-oncotypeDxRecurrenceScoreDcis
NAACCR Alternate Name: Oncotype Dx Recurrence Score - DCIS
Active years: 2018+
Schema(s):

- 00480: Breast

Description

Oncotype Dx Recurrence Score-DCIS is a numeric score of a genomic test to predict the likelihood of distant recurrence of invasive breast cancer based on the assessment of 21 genes.

The Oncotype DX DCIS score is a genomic test that estimates the likelihood of local recurrence (DCIS or invasive) for a patient with DCIS. The results may be used clinically to evaluate benefits of radiation therapy following surgery.

Rationale

Oncotype Dx Recurrence Score-DCIS is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: Oncotype Dx DCIS laboratory report, other statements in medical record

Notes

Note 1: Physician statement

- Physician statement of Oncotype Dx Recurrence Score-DCIS can be used to code this data item when no other is available.

Note 2: Type of Test

- Record only the results of an Oncotype Dx-DCIS recurrence score in this data item. If some other test is used for scoring, assign code XX9.

Note 3: Multiple tests, multiple results

- In cases where Oncotype Dx-DCIS is reported on more than one in situ breast tumor specimen, record the highest value.

Note 4: Related data item

- Code this data item using the same report used to record the related data item 3905: Oncotype Dx Risk Level-DCIS.

Coding Guidelines

1) Code 01-100 for the actual recurrence score

- The actual recurrence score takes priority over codes XX4 and XX5

2) Code XX6 if the case is invasive (/3)

3) Code XX7 If the only information available is the Oncotype Dx-DCIS Risk Level

4) Code XX9 when Oncotype DX recurrence score

- LCIS tumors
- Cannot be determined by the pathologist (e.g., inadequate specimen)
- It is unknown whether the Oncotype DX recurrence-DCIS score test was performed
- The patient has only a clinical diagnosis of breast cancer (no tissue diagnosis)

Code	Description
000-100	Enter actual recurrence score between 0 and 100
XX6	Not applicable, invasive case
XX7	Test ordered, results not in chart
XX8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX8 will result in an edit error.)
XX9	Not documented in medical record Oncotype Dx recurrence score-DCIS not assessed or unknown if assessed

00480: Breast

3894: Multigene Signature Method

Item Length: 1
NAACCR Item #: 3894
XML Parent-NAACCR ID: Tumor-multigeneSignatureMethod
NAACCR Alternate Name: Multigene Signature Method
Active years: 2018+
Schema(s):

- 00480: Breast

Description

Multigene signatures or classifiers are assays of a panel of genes from a tumor specimen, intended to provide a quantitative assessment of the likelihood of response to chemotherapy and to evaluate prognosis or the likelihood of future metastasis. This data item identifies the multigene signature method used. Oncotype Dx is coded elsewhere.

Multigene testing is usually done for node-negative female breast cancer patients to predict risk of recurrence within a specified time period or to predict the likelihood that the patient will respond to specific types of chemotherapy. Multigene testing helps tailor treatment for the woman's specific cancer characteristics. Recent studies indicate that these tests may also be helpful in planning treatment and predicting recurrence in node positive women with small tumors. Some types of tests may be specific to ER positive or negative patients or women in a certain age range. Many different types of genetic testing are available, including IHC-, FISH-, RT-PCR-, and genomic microarray-based multigene predictors.

Information is collected on the following tests

- **MammaPrint:** A genomic test that analyzes the activity of certain genes in early-stage breast cancer. Developed to help make treatment decisions based on the cancer's risk of coming back (recurrence) within 10 years after diagnosis.
- **PAM 50 (Prosigna):** PAM50 stands for Prediction Analysis of Microarray 50. It tests a sample of the tumor (removed during a biopsy or surgery) for a group of 50 genes. Along with other factors, the results of the PAM50 (Prosigna) test help predict the chance of metastasis (when cancer spreads to other organs). Prosigna also helps to determine the molecular subtype of breast cancer.
- **Breast Cancer Index:** Analyzes the activity of seven genes to help predict the risk of node-negative, hormone-receptor-positive breast cancer coming back 5 to 10 years after diagnosis. The test can help women and their doctors decide if extending hormonal therapy 5 more years (for a total of 10 years of hormonal therapy) would be beneficial. The Breast Cancer Index reports two scores: how likely the cancer is to recur

5 to 10 years after diagnosis and how likely a woman is to benefit from taking hormonal therapy for a total of 10 years.

- **EndoPredict:** A genomic test for people newly diagnosed with early-stage, estrogen-receptor-positive, HER2-negative breast cancer. May be used to help make treatment decisions based on the cancer's risk of coming back in a part of the body away from the breast (distant metastasis) within 10 years after diagnosis. The EndoPredict test provides a risk score that is either low-risk or high-risk of breast cancer recurring as distant metastasis. Knowing if the cancer has a high or low risk of recurrence can help women and their doctors decide if chemotherapy or other treatments to reduce risk after surgery are needed.

For the Breast cases, there are 2 related data items that record information on Multigene testing.

- 3894: Multigene Signature Method
- 3895: Multigene Signature Results

These two fields record the type of multigene signature test that was performed. Both fields should be coded from the same test, which may not be available at the time of diagnosis.

Rationale

Multigene Signature Method is a Registry Data Collection Variable in AJCC. It was previously collected as Breast, CS SSF #22. See also Multigene Signature Results.

Additional Information

Source documents: specialty reference laboratories (private companies with proprietary testing methods); the actual report may be included in the medical record or may be referenced by the clinician

Other names include: genomic profiling, multigene testing, multigene assay, microarray assay, molecular diagnostics for treatment planning

Notes

Note 1: Physician Statement

- Physician statement of the Multigene Signature Method can be used to code this data item when no other information is available.

Note 2: Multigene signatures/classifiers

- Multigene signatures or classifiers are assays of a panel of genes from a tumor specimen, intended to provide a quantitative assessment of the likelihood of response to chemotherapy and to evaluate prognosis or the likelihood of future metastasis.

- Only record tests done on tumor tissue that help determine if the cancer is likely to recur.
    - Don't include other tests, such as those that evaluate hereditary mutations that influence a patient's risk of developing cancer (e.g. myRisk, BRCA)
- Only record tests that are based on gene assays.
- Don't include other tests which use a multivariate data model to eliminate the need for genetic assays

Note 3: Oncotype Dx tests

- Oncotype Dx tests are not recorded in this data item. See the following related data items for Oncotype Dx.
    - 3903: Oncotype Dx Recurrence Score-DCIS
    - 3904: Oncotype Dx Recurrence Score-Invasive
    - 3905: Oncotype Dx Risk Level-DCIS
    - 3906: Oncotype Dx Risk Level-Invasive

Note 4: Related data item

- Code the type of test performed. The same test should be used to record the related data item 3895: Multigene Signature Results.

Code	Description
1	MammaPrint
2	PAM50 (Prosigna)
3	Breast Cancer Index
4	EndoPredict
5	Test performed, type of test unknown
6	Multiple tests, any tests in codes 1-4
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)

Code	Description
9	Not documented in medical record Multigene Signature Method not assessed or unknown if assessed

00480: Breast

3895: Multigene Signature Result

Item Length: 2
NAACCR Item #: 3895
XML Parent-NAACCR ID: Tumor-multigeneSignatureResults
NAACCR Alternate Name: Multigene Signature Result
Active years: 2018+
Schema(s):

- 00480: Breast

Description

Multigene signatures or classifiers are assays of a panel of genes from a tumor specimen, intended to provide a quantitative assessment of the likelihood of response to chemotherapy and to evaluate prognosis or the likelihood of future metastasis. This data item identifies the multigene signature result. Oncotype Dx is coded elsewhere.

Rationale

Multigene Signature Results is a Registry Data Collection Variable in AJCC. It was previously collected as Breast, CS SSF #23. See also Multigene Signature Method.

Additional Information

Source documents: specialty reference laboratories (private companies with proprietary testing methods); the actual report may be included in the medical record or may be referenced by the clinician

Other names include: genomic profiling, multigene testing, multigene assay, microarray assay, molecular diagnostics for treatment planning

Notes

Note 1: Physician Statement

- Physician statement of the Multigene Signature Results can be used to code this data item when no other information is available.

Note 2: Score or Risk

- Code the score or risk for the test performed. The same test should be used to record the related data item 3894: Multigene Signature Method.

Note 3: Oncotype Dx tests

- Oncotype Dx tests are not recorded in this data item. See the following related data items for Oncotype Dx.

- 3903: Oncotype Dx Recurrence Score-DCIS
- 3904: Oncotype Dx Recurrence Score-Invasive
- 3905: Oncotype Dx Risk Level-DCIS
- 3906: Oncotype Dx Risk Level-Invasive

Code	Description
00-99	Enter actual recurrence score Note: Depending on the test, the range of values may be different
X1	Score 100
X2	Low risk
X3	Moderate [intermediate] risk
X4	High risk
X7	Test done, results not in chart
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record Multigene Signature Results not assessed or unknown if assessed

00480: Breast

3922: Response to Neoadjuvant Therapy

Item Length: 1
NAACCR Item #: 3922
XML Parent-NAACCR ID: Tumor-responseToNeoadjuvantTherapy
NAACCR Alternate Name: Response to Neoadjuvant Therapy
Active years: 2018+
Schema(s):

- 00480: Breast

Description

This data item records the physician's statement of response to neoadjuvant chemotherapy.

Neoadjuvant therapy is defined as systemic, or radiation treatment administered prior to surgery in an attempt to shrink the tumor or destroy regional metastases. This data item documents whether that neoadjuvant therapy was successful.

This data item is coded based on the clinician's statement regarding response to neoadjuvant therapy. Do not try to interpret or infer a response based on the medical record. As a guide for the clinician, the definitions below are from the AJCC Cancer Staging Manual, 8th edition.

The registrar should not use these definitions to code this field

- Complete Response (CR) – absence of invasive carcinoma in breast and lymph nodes; must be determined by microscopic evaluation of tissues; residual in situ cancer at primary site
- Partial Response (PR) – a decrease in T and/or N category compared to pretreatment value and no increase, using same method of evaluation as baseline value, residual tumor in lymph nodes of any size
- No Response (NR) – no apparent change in the T or N category compared to pretreatment value, or an increase in T or N value at time of y pathological examination

Rationale

Response to Neoadjuvant Therapy is a Registry Data Collection Variable in AJCC. It was previously collected as Breast, CS SSF #21.

Additional Information

Source documents: physician statement

Other names include treatment effect

For further information, refer to the **Breast or Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast*.

Notes

Note 1: Physician Statement

- A statement from the managing physician for Response to Neoadjuvant Therapy ("treatment effect") **must be used to code this data item**.

Note 2: Criteria for coding

- This data item should not be coded based on the following pathological, radiological, and imaging findings
- **This data item should only be coded based on the managing physician's overall interpretation of the results**.

Note 3: SEER Data Item Neoadjuvant Therapy-Treatment effect

- The rules for this data item from SEER are different to Response to Neoadjuvant Therapy
- **Do not use the rules from SEER's Neoadjuvant Therapy-Treatment effect [NAACCR ID# 1634] to code Response to Neoadjuvant therapy**

Coding Guidelines

1) Code 0 if there is no neoadjuvant therapy given

- This includes in situ (behavior /2) cases

2) Code 1 for a Residual Cancer Burden (RCB) result of '0' or an RCB Class of pCR (pathological complete response).

- Code 1 is to be used only when the managing physician states the response is "total" or "complete"

3) Code 9 when

- There is no statement of complete, partial or no response by the clinician or when the response is not documented in the medical record
- Only the post neoadjuvant surgical pathology report is available

Code	Description
0	Neoadjuvant therapy not given Non-invasive neoplasm (behavior /2)
1	Stated as complete response (CR)
2	Stated as partial response (PR)

Code	Description
3	Stated as response to treatment, but not noted if complete or partial
4	Stated as no response (NR)
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Response to neoadjuvant therapy not assessed or unknown if assessed Unknown if neoadjuvant therapy given

00480: Breast

1178: Residual Cancer Burden (RCB)

Item Length: 5
NAACCR Item #: 1178
XML Parent-NAACCR ID: Tumor-residualCancerBurdenRCB
NAACCR Alternate Name: Residual Cancer Burden (RCB)
Active years: 2026+
Schema(s):

- 00480: Breast

Description

Residual Cancer Burden (RCB) is a score that measures the amount of cancer remaining in the breast and the regional lymph nodes after neoadjuvant therapy and surgical resection. The RCB score is based on 4 independent prognostic factors measuring the primary tumor bed and 2 independent factors measuring the lymph nodes.

The RCB score combines these 6 independently prognostic factors from the surgical specimen after neoadjuvant therapy into a single continuous score. This score is prognostic across breast cancer subtypes, different treatments, and within existing stage groups.

The independent prognostic factors include

- Primary Tumor Bed
    - Primary Tumor Bed area (measured in millimeters)
        - Includes the largest two dimensions
    - Overall Cancer Cellularity (as percentage of area)
    - Percentage of cancer that is invasive disease
    - Percentage of cancer that is in situ disease
- Lymph nodes
    - Number of positive lymph nodes
    - Diameter of largest metastasis

Rationale

Neoadjuvant therapy is now standard of care for HER2+ and triple negative breast carcinoma. Quantification of residual disease after neoadjuvant therapy determines further patient management in this setting. The Residual Cancer Burden (RCB) is the most validated measure of volume of residual disease post neoadjuvant for breast cancer and has prognostic value.

Additional Information

Source documents: pathology report, CAP synoptic report

For further information, refer to the **Breast Resection cancer protocol** published by the College of American Pathologists for the AJCC Staging System *Breast*.

Notes

Any questions regarding this SSDI are to be posted in the AJCC CAnswer Forum

Note 1: Effective years

- This SSDI is effective for diagnosis years 2026+.
- For cases diagnosed 2018-2025, this SSDI must be blank.

Note 2: Criteria for coding

- Neoadjuvant therapy **AND** a surgical resection must be done to determine score
- Leave data item blank if neoadjuvant therapy and a surgical resection are not done

Note 3: CAP Protocol or Synoptic Pathology Report

- Only record the information from the CAP Protocol or synoptic pathology report.

Coding Guidelines

1) Record the Residual Cancer Burden score to the nearest one thousandth. **All three digits beyond the decimal point must be filled in.**

- *Example:* CAP synoptic report states Residual Cancer Burden score 3.151
  - Code 3.151
- *Example:* CAP synoptic reports states Residual Cancer Burden score is 3.
  - Code 3.000

2) Code X.777 when the patient did not have neoadjuvant therapy or did not have surgery. The patient did not meet the criteria for an RCB Score.

3) Code X.999 when a patient has neoadjuvant therapy and post neoadjuvant surgery and information concerning the RCB score is not available.

- Pathologist does not document the RCB score in the synoptic pathology report or CAP protocol after patient had neoadjuvant therapy followed by surgical resection.
- Surgical pathology report is not available

Code	Description
0.000-9.999	0.000 – 9.999 score
X.777	Patient had no neoadjuvant therapy, but surgical resection done Patient had neoadjuvant therapy, but no surgical resection
X.888	Not applicable: information not collected for this case (If this item is required by your standard setter, use of code X.8 will result in an edit error).
X.999	Post neoadjuvant surgery completed and RCB burden not documented in CAP Protocol or synoptic pathology report
<Blank>	Must be blank if diagnosis year is before 2026

00480: Breast

1179: RCB Class

Item Length: 1
NAACCR Item #: 1179
XML Parent-NAACCR ID: Tumor-residualCancerBurdenClass
NAACCR Alternate Name: Residual Cancer Burden Class
Active years: 2026+
Schema(s):

- 00480: Breast

Description

Residual Cancer Burden (RCB) is a score that measures the amount of cancer remaining in the breast and the regional lymph nodes after neoadjuvant therapy and surgical resection. The RCB score is based on 4 independent prognostic factors measuring the primary tumor bed and 2 independent factors measuring the lymph nodes.

- See Residual Cancer Burden (RCB) Score for further information on these prognostic factors.

Based on the RCB score, patients are then divided into four different classes. These classes are used to determine the likelihood of a patient being cancer free after treatment.

- RCB-0 (pathologic complete response). No residual invasive cancer is present.
- RCB-1 (minimal burden). Very little residual invasive cancer is present.
- RCB-2 (moderate burden). A moderate amount of residual invasive cancer is present.
- RCB-3 (extensive burden). A large amount of residual invasive cancer is present.

Rationale

Neoadjuvant therapy is now standard of care for HER2+ and triple negative breast carcinoma. Quantification of residual disease after neoadjuvant therapy determines further patient management in this setting. The Residual Cancer Burden (RCB) is the most validated measure of volume of residual disease post neoadjuvant for breast cancer and has prognostic value.

Additional Information

Source documents: pathology report, CAP synoptic report

For further information, refer to the **Breast Resection cancer protocol** published by the College of American Pathologists for the AJCC Staging System *Breast*.

Notes

Any questions regarding this SSDI are to be posted in the AJCC CAnswer Forum

Note 1: Effective years

- This SSDI is effective for diagnosis years 2026+.
- For cases diagnosed 2018-2025, this SSDI must be blank.

Note 2: Criteria for coding

- Neoadjuvant therapy **AND** a surgical resection must be done to determine class.
    - See code 7 If neoadjuvant therapy AND a surgical resection have not been done

Note 3: CAP Protocol or Synoptic Pathology Report

- Only record the information from the CAP Protocol or synoptic pathology report
    - See code 9 if there is no mention of RCB Class on the CAP protocol or synoptic pathology report

Coding Guidelines

1) Record the Residual Cancer Burden Class as stated in the synoptic pathology report

2) Code 7 when the patient did not have neoadjuvant therapy or did not have surgery. The patient did not meet the criteria for an RCB Class

3) Code 9 when a patient has neoadjuvant therapy and post neoadjuvant surgery and information concerning the RCB Class is not available.

- Pathologist does not document the RCB Class in the synoptic pathology report or CAP protocol after patient had neoadjuvant therapy followed by surgical resection.
- Surgical pathology report is not available

Code	Description
0	RCB-0 (pCR)
1	RCB-I
2	RCB-II
3	RCB-III
7	Patient had no neoadjuvant therapy, but surgical resection done Patient had neoadjuvant therapy, but no surgical resection

Code	Description
8	Not applicable: information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error)
9	Post neoadjuvant surgery completed and RCB class not documented in CAP Protocol or synoptic pathology report
<Blank>	Must be blank if diagnosis year is before 2026

00480: Breast

3906: Oncotype DX Risk Level-Invasive

Item Length: 1
NAACCR Item #: 3906
XML Parent-NAACCR ID: Tumor-oncotypeDxRiskLevelInvasive
NAACCR Alternate Name: Oncotype Dx Risk Level-Invasive
Active years: 2018+
Schema(s):

- 00480: Breast

Description

Oncotype Dx Risk Level-Invasive stratifies Oncotype Dx recurrence scores into low, intermediate, and high risk of distant recurrence.

The numeric value of the recurrence score is coded in Data Item #3906. When the actual recurrence score is not available, there is an option for coding recurrence scores stated as less than 11 or greater than equal to 11 as this is the cut point determined to be clinically relevant for stage group in AJCC8. Oncotype DX Risk Level -Invasive, coded in NAACCR Data Item #3906, stratifies the Oncotype DX recurrence score into three risk levels

- **Low risk: Recurrence Score result less than 18:** The patient has a lower risk of having a recurrence, assuming 5 years of hormonal therapy is given. Chemotherapy is likely to have little or no benefit.
- **Intermediate Risk: Recurrence Score result between 18 and 30:** The patient has a tumor that is in the middle of the risk spectrum reflecting that biology is continuous and not all patients have a low or a high recurrence risk, assuming 5 years of hormonal therapy is given. The likelihood of distant recurrence and benefit from chemotherapy increases with an increase in the Recurrence Score result.
- **High risk: Recurrence Score result greater than or equal to 31:** The patient has a high risk of distant recurrence, assuming 5 years of hormonal therapy and is likely to benefit from chemotherapy.

Rationale

Oncotype Dx Risk Level-Invasive is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: Oncotype Dx Breast Recurrence Score laboratory report, other statements in medical record

Notes

Note 1: Physician Statement

- Physician statement of Oncotype Dx Risk Level-Invasive can be used to code this data item when no other information is available.

Note 2: Related data item

- Code this data item using the same report used to record the related data item 3904: Oncotype Dx Recurrence Score-Invasive.

Coding Guidelines

1) Record only the results of an Oncotype Dx Risk Level-Invasive in this data item. If some other test is used for scoring, assign code 9.

- Code 6 if case is in-situ (/2)

2) The Oncotype Dx Risk Level-Invasive test stratifies scores into low, intermediate, and high risk of distant recurrence.

- If only the score is stated, assign the risk level based on the score.

Code	Description
0	Low risk (recurrence score 0-17)
1	Intermediate risk (recurrence score 18-30)
2	High risk (recurrence score greater than or equal to 31)
6	Not applicable: DCIS case
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Oncotype Dx Risk Level-Invasive not assessed or unknown if assessed

00480: Breast

3905: Oncotype Dx Risk Level - DCIS

Item Length: 1
NAACCR Item #: 3905
XML Parent-NAACCR ID: Tumor-oncotypeDxRiskLevelDcis
NAACCR Alternate Name: Oncotype Dx Risk Level-DCIS
Active years: 2018+
Schema(s):

- 00480: Breast

Description

Oncotype Dx Risk Level-DCIS stratifies Oncotype Dx recurrence scores into low, intermediate, and high risk of local recurrence.

Oncotype DX DCIS Risk Level, coded in NAACCR Data Item #3905, stratifies the Oncotype DX DCIS Score into three risk levels

- **Low risk: Recurrence Score lower than 39:** The DCIS has a lower risk of recurrence.
- **Intermediate Risk: Recurrence Score between 39 and 54:** The DCIS has an intermediate risk of recurrence.
- **High risk: Recurrence Score greater than 54:** The DCIS has a higher risk of recurrence.

Rationale

Oncotype Dx Risk Level-DCIS is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: Oncotype Dx DCIS laboratory report, other statements in medical record

Notes

Note 1: Physician Statement

- Physician statement of Oncotype Dx Risk Level-DCIS can be used to code this data item when no other information is available.

Note 2: Related data item

- Code this data item using the same report used to record the related data item 3903: Oncotype Dx Recurrence Score-DCIS.

Coding Guidelines

1) Record only the results of an Oncotype Dx Risk Level-DCIS in this data item. If some other test is used for scoring, assign code 9.

- Code 6 if the case is malignant
- Code 9 for LCIS tumors

2) The Oncotype Dx Risk Level-DCIS test stratifies scores into low, intermediate, and high risk of distant recurrence

- If only the score is stated, assign the risk level based on the score.

Code	Description
0	Low risk (recurrence score less than 39)
1	Intermediate risk (recurrence score 39-54)
2	High risk (recurrence score greater than 54)
6	Not applicable: invasive case
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Oncotype Dx risk level not assessed or unknown if assessed

00500: Vulva [8th: 2018-2023]

3836: FIGO Stage

Item Length: 2
NAACCR Item #: 3836
XML Parent-NAACCR ID: Tumor-figoStage
NAACCR Alternate Name: FIGO Stage Vulva
Active years: 2018+
Schema(s):

- 00500: Vulva [8th: 2018-2023]
- 09500: Vulva [V9: 2024+]

Description

Federation Internationale de Gynecologie et d'Obstetrique (FIGO) is a staging system for female reproductive cancers.

FIGO is a worldwide organization of obstetricians and gynecologists who maintain the international staging systems for female genital organs. The FIGO staging system has been adapted into the AJCC staging manual. FIGO uses Roman numerals and subscripts to define a stage. There is no T, N, or M descriptor with FIGO stage, only a stage group. For example, FIGO Stage IA is equivalent to T1a, FIGO Stage III can be either T3_ or N1, and FIGO Stage IV is M1.

FIGO stages vary by primary site, but the structure is similar throughout. FIGO no longer includes an in-situ stage (Tis, Stage 0). For in situ tumors, code the following

- Code 97: Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)

Note: Do not confuse FIGO stage with FIGO grade.

Rationale

FIGO stage is a Registry Data Collection Variable in AJCC for the female genital cancers. This data item was previously collected for the female genital cancers as: Vulva SSF #10, Vagina SSF #1, Cervix SSF #1, Corpus Carcinoma SSF #1, Corpus Sarcoma SSF #1, Ovary SSF #2, Fallopian Tube SSF #1, Peritoneum Female Genital SSF #1, and Placenta SSF #2.

Additional Information

Source documents: clinician's notes, consultant notes, radiation therapy notes

Notes

Note 1: Physician Statement

- There must be a statement about FIGO stage from the managing physician in order to code this data item.

- Do not code FIGO stage based on the pathology report
- Do not code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do not assume it is a FIGO stage

Note 2: FIGO Stage vs FIGO Grade

- FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.
- Code FIGO grade in the grade fields

Note 3: Multiple FIGO stages

- If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

Note 4: FIGO Stage 0 (in-situ)

- The FIGO stage definitions do not include Stage 0 (Tis).
- Code 97 for any non-invasive neoplasm (behavior /2).

Code	Description
1	FIGO Stage I
1A	FIGO Stage IA
1B	FIGO Stage IB
2	FIGO Stage II
3	FIGO Stage III
3A	FIGO Stage IIIA
3B	FIGO Stage IIIB
3C	FIGO Stage IIIC
4	FIGO Stage IV
4A	FIGO Stage IVA
4B	FIGO Stage IVB
97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)

Code	Description
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage not assessed or unknown if assessed

00500: Vulva [8th: 2018-2023]

3959: LN Status: Femoral-Inguinal

Item Length: 1
NAACCR Item #: 3959
XML Parent-NAACCR ID: Tumor-lnStatusFemoralInguinal
NAACCR Alternate Name: LN Status: Femoral-Inguinal
Active years: 2018+
Schema(s):

- 00500: Vulva [8th: 2018-2023]
- 09500: Vulva [V9: 2024+]

Description

This data item describes the status of femoral-inguinal lymph nodes associated with certain female genital cancers.

In addition to assigning the N categories for vulva, vagina, and cervical cancers, the collection of specific lymph nodes and how they were assessed is important.

- Status refers to positive or negative involvement
- Assessment is the method by which the nodal status was determined
  There are 3 related data items that collect status information on regional lymph nodes, 1 data item for distant lymph nodes, and 1 data item for laterality.

The LN status data items collect the individual status (positive, negative, unknown) involvement of femoral-inguinal, para-aortic, and pelvic lymph nodes. These related data items include:

- 3957: LN Status: Pelvic
- 3958: LN Status: Para-Aortic
- 3959: LN Status: Femoral-Inguinal
- 3875: LN Distant: Mediastinal, Scalene
- 3831: LN Laterality

Rationale

Specific regional lymph node involvement is listed as a Registry Data Collection Variable in AJCC. This information was previously collected as Vulva, SSF #14

Additional Information

Source documents: pathology report, imaging, physical exam, other statement in record

Notes

Note 1: Physician Statement

- Physician statement of the femoral-inguinal status can be used to code this data item when no other information is available.

Note 2: Femoral-inguinal nodes

- Femoral
- Inguinal, NOS
    - Inguinofemoral (groin)
    - Node of Cloquet or Rosenmuller (highest deep inguinal)
    - Superficial inguinal

Note 3: Isolated tumor cells

- For this data item, do not include isolated tumor cells (ITCs).

Note 4: Related data item

- The assessment method is recorded in the related data item 3871: LN Assessment Method Femoral-Inguinal.

Coding Guidelines

1) Code 0 when

- Non-invasive neoplasm (behavior /2) (in-situ)
- All lymph nodes are negative and included an assessment of the femoral-inguinal lymph nodes
- If there is no mention of femoral-inguinal lymph node involvement in the area being imaged, biopsied, or in the surgical field and there is no mention of involvement, then assume that the femoral-inguinal lymph nodes are negative.

2) Code 9 when

- When there is no imaging, biopsy, surgical workup, or a physical exam only
- Not documented in medical record
- Regional/Distant lymph nodes not evaluated (assessed)
- Unknown if regional/distant lymph nodes evaluated (assessed)

Code	Description
0	Negative femoral-inguinal lymph nodes Non-invasive neoplasm (behavior /2)
1	Positive femoral-inguinal lymph nodes
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Femoral-Inguinal lymph node(s) not assessed or unknown if assessed

00500: Vulva [8th: 2018-2023]

3871: LN Assessment Method Femoral-Inguinal

Item Length: 1
NAACCR Item #: 3871
XML Parent-NAACCR ID: Tumor-lnAssessMethodFemoralInguinal
NAACCR Alternate Name: Lymph Nodes Assessment Method Femoral-Inguinal
Active years: 2018+
Schema(s):

- 00500: Vulva [8th: 2018-2023]
- 09500: Vulva [V9: 2024+]

Description

This data item describes the method used to assess involvement of femoral-inguinal lymph nodes associated with certain female genital cancers.

In addition to assigning the N categories for vulva, vagina, and cervical cancers, the collection of specific lymph nodes and how they were assessed is important.

- Status refers to positive or negative involvement
- Assessment is the method by which the nodal status was determined

There are 3 related data items that collect assessment method information on regional lymph nodes, and 1 data item for distant lymph nodes.

The LN assessment data items collect how the lymph nodes were assessed for femoral-inguinal, para-aortic, and pelvic lymph nodes, and distant lymph nodes scalene and mediastinal. These related data items include:

- 3871: LN Assessment Method Femoral-Inguinal
- 3872: LN Assessment Method Para-Aortic
- 3873: LN Assessment Method Pelvic
- 3874: LN Distant Assessment Method

Rationale

Method of assessment of regional nodal status is listed as a Registry Data Collection Variable in the AJCC GYN chapters. This data item was previously collected as Vulva, SSF #15.

Additional Information

Source documents: pathology report, imaging, physical exam, other statement in record

Notes

Note 1: Physician Statement

- Physician statement of the femoral-inguinal assessment method can be used to code this data item when no other information is available.

Note 2: Femoral-inguinal nodes

- Femoral
- Inguinal, NOS
    - Inguinofemoral (groin)
    - Node of Cloquet or Rosenmuller (highest deep inguinal)
    - Superficial inguinal

Note 3: Isolated tumor cells

- For this data item, do not include isolated tumor cells (ITCs).

Note 4: Related data item

- The status of the lymph nodes is recorded in the related data item 3959: LN Status Femoral-Inguinal.

Coding Guidelines

1) Assign the highest applicable code (0-2) in the case of multiple assessments

2) Code 0 when there is physical exam or imaging only

3) Code 1 when there is an incisional biopsy or FNA

4) Code 2 when there is an excisional biopsy or lymph node resection

5) Code 7 when lymph nodes are assessed, but it is unknown how

6) Code 9 when

- Not documented in medical record
- Regional/Distant lymph nodes not evaluated (assessed)
- Unknown if regional/distant lymph nodes evaluated (assessed)

Code	Description
0	Radiography, imaging (Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI), positron emission tomography scan (PET)) Physical exam only
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy Sentinel node biopsy Excisional biopsy or resection with microscopic confirmation
7	Femoral-inguinal lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Femoral-inguinal lymph node(s) not assessed or unknown if assessed

00500: Vulva [8th: 2018-2023]

3957: LN Status: Pelvic

Item Length: 1
NAACCR Item #: 3957
XML Parent-NAACCR ID: Tumor-lnStatusPelvic
NAACCR Alternate Name: LN Status: Pelvic
Active years: 2018+
Schema(s):

- 00500: Vulva [8th: 2018-2023]
- 09500: Vulva [V9: 2024+]

Description

This data item describes the status of pelvic lymph nodes associated with certain female genital cancers.

In addition to assigning the N categories for vulva, vagina, and cervical cancers, the collection of specific lymph nodes and how they were assessed is important.

- Status refers to positive or negative involvement
- Assessment is the method by which the nodal status was determined

There are 3 related data items that collect status information on regional lymph nodes, 1 data item for distant lymph nodes, and 1 data item for laterality.

The LN status data items collect the individual status (positive, negative, unknown) involvement of femoral-inguinal, para-aortic, and pelvic lymph nodes, and distant lymph nodes mediastinal and scalene. These related data items include:

- 3957: LN Status: Pelvic
- 3958: LN Status: Para-Aortic
- 3959: LN Status: Femoral-Inguinal
- 3875: LN Distant: Mediastinal, Scalene

Rationale

Specific regional lymph node involvement is listed as a Registry Data Collection Variable in AJCC. This information was previously collected as Vulva, SSF #12

Additional Information

Source documents: pathology report, imaging, physical exam, other statement in record

Notes

Note 1: Physician Statement

- Physician statement of pelvic status can be used to code this data item when no other information is available.

Note 2: Vulva and pelvic lymph nodes

- For Vulva, pelvic lymph nodes are distant

Note 3: Pelvic lymph nodes

- Iliac, NOS
    - Common
    - External
    - Internal (hypogastric) (obturator)
- Paracervical
- Parametrial
- Pelvic, NOS
- Sacral, NOS
    - Lateral (laterosacral)
    - Middle (promontorial) (Gerota's node)
    - Uterosacral

Note 4: Isolated tumor cells

- For this data item, do not include isolated tumor cells (ITCs).

Note 5: Related data item

- The assessment method is recorded in the related data item 3873: LN Assessment Method Pelvic.

Coding Guidelines

1) Code 0 when

- Non-invasive neoplasm (behavior /2) (in-situ)
- All lymph nodes are negative and included an assessment of the pelvic lymph nodes

- If there is no mention of pelvic lymph node involvement in the area being imaged, biopsied, or in the surgical field and there is no mention of involvement, then assume that the pelvic lymph nodes are negative.

2) Code 9 when

- When there is no imaging, biopsy, surgical workup, or a physical exam only
- Not documented in medical record
- Regional/Distant lymph nodes not evaluated (assessed)
- Unknown if regional/distant lymph nodes evaluated (assessed)

Code	Description
0	Negative pelvic lymph nodes Non-invasive neoplasm (behavior /2)
1	Positive pelvic lymph nodes
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Pelvic lymph node(s) not assessed or unknown if assessed

00500: Vulva [8th: 2018-2023]

3873: LN Assessment Method Pelvic Vulva

Item Length: 1
NAACCR Item #: 3873
XML Parent-NAACCR ID: Tumor-lnAssessMethodPelvic
NAACCR Alternate Name: Lymph Nodes Assessment Method Pelvic
Active years: 2018+
Schema(s):

- 00500: Vulva [8th: 2018-2023]
- 09500: Vulva [V9: 2024+]

Description

This data item describes the method used to assess involvement of pelvic lymph nodes associated with certain female genital cancers.

In addition to assigning the N categories for vulva, vagina, and cervical cancers, the collection of specific lymph nodes and how they were assessed is important.

- Status refers to positive or negative involvement
- Assessment is the method by which the nodal status was determined

There are 3 related data items that collect assessment method information on regional lymph nodes, and 1 data item for distant lymph nodes.

The LN assessment data items collect how the lymph nodes were assessed for femoral-inguinal, para-aortic, and pelvic lymph nodes, and distant lymph nodes scalene and mediastinal. These related data items include:

- 3871: LN Assessment Method Femoral-Inguinal
- 3872: LN Assessment Method Para-Aortic
- 3873: LN Assessment Method Pelvic
- 3874: LN Distant Assessment Method

Rationale

Method of assessment of regional nodal status is listed as a Registry Data Collection Variable in the AJCC GYN chapters. This data item was previously collected as Vulva, SSF #13.

Additional Information

Source documents: pathology report, imaging, physical exam, other statement in record

Notes

Note 1: Physician Statement

- Physician statement of pelvic status can be used to code this data item when no other information is available.

Note 2: Vulva and pelvic lymph nodes

- For Vulva, pelvic lymph nodes are distant

Note 3: Pelvic lymph nodes

- Iliac, NOS
    - Common
    - External
    - Internal (hypogastric) (obturator)
- Paracervical
- Parametrial
- Pelvic, NOS
- Sacral, NOS
    - Lateral (laterosacral)
    - Middle (promontorial) (Gerota's node)
    - Uterosacral

Note 4: Isolated tumor cells

- For this data item, do not include isolated tumor cells (ITCs).

Note 5: Related data item

- The status of the lymph nodes is recorded in the related data item 3957: LN Status: Pelvic

Coding Guidelines

1) Assign the highest applicable code (0-2) in the case of multiple assessments

2) Code 0 when there is physical exam or imaging only

3) Code 1 when there is an incisional biopsy or FNA

4) Code 2 when there is an excisional biopsy, sentinel lymph node biopsy, or lymph node resection

5) Code 7 when lymph nodes are assessed, but it is unknown how

6) Code 9 when

- Not documented in medical record
- Regional/Distant lymph nodes not evaluated (assessed)
- Unknown if regional/distant lymph nodes evaluated (assessed)

Code	Description
0	Radiography, imaging (Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI), positron emission tomography scan (PET)) Physical exam only
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy Sentinel node biopsy Excisional biopsy or resection with microscopic confirmation
7	Pelvic lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Pelvic lymph node(s) not assessed or unknown if assessed

00500: Vulva [8th: 2018-2023]

3881: LN Laterality

Item Length: 1
NAACCR Item #: 3881
XML Parent-NAACCR ID: Tumor-lnLaterality
NAACCR Alternate Name: Lymph Nodes Laterality
Active years: 2018+
Schema(s):

- 00500: Vulva [8th: 2018-2023]
- 09500: Vulva [V9: 2024+]

Description

This data item describes whether positive regional lymph nodes are unilateral or bilateral.

Rationale

Laterality of regional node metastasis is a Registry Data Collection Variable in AJCC. This data item was previously collected as Vulva, CS SSF #11.

Additional Information

Source documents: pathology report, imaging, physical exam, other statement in record

Notes

Note: Physician Statement

- Physician statement of lymph node laterality can be used to code this data item when no other information is available.

Coding Guidelines

1) Code the appropriate description of involved regional lymph nodes

2) Code 0 when all regional lymph nodes are negative

3) Code 1 when

- All positive regional nodes are ipsilateral
- Involved lymph nodes are described as unilateral
- Only one regional node positive

4) Code 2 when

- At least one regional lymph node is involved on each side of the body
- Involvement is described as bilateral or contralateral

5) Code 3 when regional lymph node(s) are described as positive, but the laterality of the involved nodes is unknown

6) Code 9 when

- Lymph nodes were not examined or assessed
- There is no information in the medical record about regional lymph node involvement
- The status of regional lymph nodes is unknown

Code	Description
0	No regional lymph node involvement Non-invasive neoplasm (behavior /2)
1	Unilateral - all positive regional nodes with same laterality OR only one regional node positive
2	Bilateral - positive bilateral regional lymph nodes
3	Laterality unknown - positive regional lymph nodes with unknown laterality
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Lymph node laterality not assessed or unknown if assessed

09500: Vulva [V9: 2024+]

3956: p16

Item Length: 1
NAACCR Item #: 3956
XML Parent-NAACCR ID: Tumor-p16
NAACCR Alternate Name: p16
Active years: 2024+
Schema(s):

- 09500: Vulva [V9: 2024+]

Description

The p16 biomarker is overexpressed (produced) in response to HPV. It is therefore a surrogate marker for HPV disease.

p16 is a tumor suppressor protein also known as cyclin-dependent kinase inhibitor 2A. The p16 biomarker is overexpressed (produced) in response to HPV. It is therefore a surrogate marker for HPV disease.

Rationale

Patients with HPV have a different survival or outcome, so it is important to be able to distinguish this by documenting the p16 results. Testing is performed by immunohistochemistry (IHC) which is inexpensive and has near universal availability. It has an easily standardized interpretation. HPV testing is usually performed through DNA testing which is more expensive and less widely available. HPV testing also has technically more variability with the interpretation.

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2024+
- For cases diagnosed 2018-2023, this SSDI must be blank

Note 2: p16 Results ONLY

- This data item must be based on testing results for p16 overexpression.
- Testing for HPV by DNA, mRNA, antibody, or other methods should not be coded in this data item
- Do not confuse p16 with HPV, which is a specific strain of virus. A statement of a patient being HPV positive, or negative is not enough to code this data item
- Code 0 for p16 expression of weak intensity or limited distribution.

Code	Description
0	p16 Negative; Nonreactive
1	p16 Positive; Diffuse, Strong reactivity
8	Not applicable: Information not collected for this case (If this time is required by your standard setter, use of code 8 will result in an edit error)
9	Not tested for p16; Unknown
<Blank>	N/A - Diagnosis year is prior to 2024

00510: Vagina

3836: FIGO Stage

Item Length: 2
NAACCR Item #: 3836
XML Parent-NAACCR ID: Tumor-figoStage
NAACCR Alternate Name: FIGO Stage Vagina
Active years: 2018+
Schema(s):

- 00510: Vagina

Description

Federation Internationale de Gynecologie et d'Obstetrique (FIGO) is a staging system for female reproductive cancers.

FIGO is a worldwide organization of obstetricians and gynecologists who maintain the international staging systems for female genital organs. The FIGO staging system has been adapted into the AJCC staging manual. FIGO uses Roman numerals and subscripts to define a stage. There is no T, N, or M descriptor with FIGO stage, only a stage group. For example, FIGO Stage IA is equivalent to T1a, FIGO Stage III can be either T3_ or N1, and FIGO Stage IV is M1.

FIGO stages vary by primary site, but the structure is similar throughout. FIGO no longer includes an in-situ stage (Tis, Stage 0). For in situ tumors, code the following

- Code 97: Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)

Note: Do not confuse FIGO stage with FIGO grade.

Rationale

FIGO stage is a Registry Data Collection Variable in AJCC for the female genital cancers. This data item was previously collected for the female genital cancers as: Vulva SSF #10, Vagina SSF #1, Cervix SSF #1, Corpus Carcinoma SSF #1, Corpus Sarcoma SSF #1, Ovary SSF #2, Fallopian Tube SSF #1, Peritoneum Female Genital SSF #1, and Placenta SSF #2.

Additional Information

Source documents: clinician's notes, consultant notes, radiation therapy notes

Notes

Note 1: Physician Statement

- There must be a statement about FIGO stage from the managing physician in order to code this data item.
    - Do not code FIGO stage based on the pathology report

- Do not code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do not assume it is a FIGO stage

Note 2: FIGO Stage vs FIGO Grade

- FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.
- Code FIGO grade in the grade fields

Note 3: Multiple FIGO stages

- If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

Note 4: FIGO Stage 0 (in-situ)

- The FIGO stage definitions do not include Stage 0 (Tis).
- Code 97 for any non-invasive neoplasm (behavior /2)

Code	Description
1	FIGO Stage I
2	FIGO Stage II
3	FIGO Stage III
4	FIGO Stage IV
4A	FIGO Stage IVA
4B	FIGO Stage IVB
97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage not assessed or unknown if assessed

00510: Vagina

3959: LN Status: Femoral-Inguinal Vagina

Item Length: 1
NAACCR Item #: 3959
XML Parent-NAACCR ID: Tumor-lnStatusFemoralInguinal
NAACCR Alternate Name: LN Status: Femoral-Inguinal
Active years: 2018+
Schema(s):

- 00510: Vagina

Description

This data item describes the status of femoral-inguinal lymph nodes associated with certain female genital cancers.

In addition to assigning the N categories for vulva, vagina, and cervical cancers, the collection of specific lymph nodes and how they were assessed is important.

- Status refers to positive or negative involvement
- Assessment is the method by which the nodal status was determined

There are 3 related data items that collect status information on regional lymph nodes, 1 data item for distant lymph nodes, and 1 data item for laterality.

The LN status data items collect the individual status (positive, negative, unknown) involvement of femoral-inguinal, para-aortic, and pelvic lymph nodes, and distant lymph nodes mediastinal and scalene. These related data items include:

- 3957: LN Status: Pelvic
- 3958: LN Status: Para-Aortic
- 3959: LN Status: Femoral-Inguinal
- 3875: LN Distant: Mediastinal, Scalene

Rationale

Specific regional lymph node involvement is listed as a Registry Data Collection Variable in AJCC. This information was previously collected as Vulva, SSF #14 and is now collected in Vagina.

Additional Information

Source documents: pathology report, imaging, physical exam, other statement in record

Notes

Note 1: Physician Statement

- Physician statement of the femoral-inguinal status can be used to code this data item when no other information is available.

Note 2: Lower third of vagina

- Code this data item for the lower third of the vagina only.
- Code 9 for upper two thirds of the vagina, or unknown whether it's the lower third or upper two thirds

Note 3: Femoral-inguinal nodes

- Femoral
- Inguinal, NOS
    - Inguinofemoral (groin)
    - Node of Cloquet or Rosenmuller (highest deep inguinal)
    - Superficial inguinal

Note 4: Isolated tumor cells

- For this data item, do not include isolated tumor cells (ITCs).

Note 5: Related data item

- The assessment method is recorded in the related data item 3871: LN Assessment Method Femoral-Inguinal.

Coding Guidelines

1) Code this data item for the **lower third of the vagina** only.

2) Code 0 when

- Non-invasive neoplasm (behavior /2) (in-situ)
- All lymph nodes are negative and included an assessment of the femoral-inguinal lymph nodes
- If there is no mention of femoral-inguinal lymph node involvement in the area being imaged, biopsied, or in the surgical field and there is no mention of involvement, then assume that the femoral-inguinal lymph nodes are negative

3) Code 9 when

- Primary site location is **upper two thirds of the vagina**, or **unknown** whether it's the lower third or upper two thirds
- When there is no imaging, biopsy, surgical workup, or a physical exam only
- Not documented in medical record
- Regional/Distant lymph nodes not evaluated (assessed)
- Unknown if regional/distant lymph nodes evaluated (assessed)

Code	Description
0	Negative femoral-inguinal lymph nodes Non-invasive neoplasm (behavior /2)
1	Positive femoral-inguinal lymph nodes
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Femoral-Inguinal lymph node(s) not assessed or unknown if assessed

00510: Vagina

3871: LN Assessment Method Femoral-Inguinal

Item Length: 1
NAACCR Item #: 3871
XML Parent-NAACCR ID: Tumor-lnAssessMethodFemoralInguinal
NAACCR Alternate Name: Lymph Nodes Assessment Method Femoral-Inguinal
Active years: 2018+
Schema(s):

- 00510: Vagina

Description

This data item describes the method used to assess involvement of femoral-inguinal lymph nodes associated with certain female genital cancers.

In addition to assigning the N categories for vulva, vagina, and cervical cancers, the collection of specific lymph nodes and how they were assessed is important.

- Status refers to positive or negative involvement
- Assessment is the method by which the nodal status was determined

There are 3 related data items that collect assessment method information on regional lymph nodes, and 1 data item for distant lymph nodes.

The LN assessment data items collect how the lymph nodes were assessed for femoral-inguinal, para-aortic, and pelvic lymph nodes, and distant lymph nodes scalene and mediastinal. These related data items include:

- 3871: LN Assessment Method Femoral-Inguinal
- 3872: LN Assessment Method Para-Aortic
- 3873: LN Assessment Method Pelvic
- 3874: LN Distant Assessment Method

Rationale

This data item describes the method used to assess involvement of femoral-inguinal lymph nodes associated with certain female genital cancers.

Additional Information

Source documents: pathology report, imaging, physical exam, other statement in record

Notes

Note 1: Physician Statement

- Physician statement of the femoral-inguinal assessment method can be used to code this data item when no other information is available.

Note 2: Lower third of vagina

- Code this data item for the lower third of the vagina only.
- Code 9 for upper two thirds of the vagina, or unknown whether it's the lower third or upper two thirds

Note 3: Femoral-inguinal nodes

- Femoral
- Inguinal, NOS
    - Inguinofemoral (groin)
    - Node of Cloquet or Rosenmuller (highest deep inguinal)
    - Superficial inguinal

Note 4: Isolated tumor cells

- For this data item, do not include isolated tumor cells (ITCs).

Note 5: Related data item

- The status of the lymph nodes is recorded in the related data item 3959: LN Status Femoral-Inguinal.

Coding Guidelines

1) Assign the highest applicable code (0-2) in the case of multiple assessments for the **lower third of the vagina only**

2) Code 0 when there is physical exam or imaging only

3) Code 1 when there is an incisional biopsy or FNA

4) Code 2 when there is an excisional biopsy, sentinel lymph node biopsy, or lymph node resection

5) Code 7 when lymph nodes are assessed, but it is unknown how

6) Code 9 when

- Primary site location is **upper two thirds of the vagina**, or **unknown** whether it's the lower third or upper two thirds
- Not documented in medical record
- Regional/Distant lymph nodes not evaluated (assessed)
- Unknown if regional/distant lymph nodes evaluated (assessed)

Code	Description
0	Radiography, imaging (Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI), positron emission tomography scan (PET)) Physical exam only
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy Sentinel node biopsy Excisional biopsy or resection with microscopic confirmation
7	Femoral-inguinal lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Femoral-inguinal lymph node(s) not assessed or unknown if assessed

00510: Vagina

3958: LN Status: Para-aortic

Item Length: 1
NAACCR Item #: 3958
XML Parent-NAACCR ID: Tumor-lnStatusParaAortic
NAACCR Alternate Name: LN Status: Para-aortic
Active years: 2018+
Schema(s):

- 00510: Vagina
- 00520: Cervix [8th: 2018-2020]
- 09520: Cervix [V9: 2021+]

Description

This data item describes the status of para-aortic lymph nodes associated with certain female genital cancers.

In addition to assigning the N categories for vulva, vagina, and cervical cancers, the collection of specific lymph nodes and how they were assessed is important.

- Status refers to positive or negative involvement
- Assessment is the method by which the nodal status was determined

There are 3 related data items that collect status information on regional lymph nodes, 1 data item for distant lymph nodes, and 1 data item for laterality.

The LN status data items collect the individual status (positive, negative, unknown) involvement of femoral-inguinal, para-aortic, and pelvic lymph nodes, and distant lymph nodes mediastinal and scalene. These related data items include:

- 3957: LN Status: Pelvic
- 3958: LN Status: Para-Aortic
- 3959: LN Status: Femoral-Inguinal
- 3875: LN Distant: Mediastinal, Scalene

Rationale

Specific regional lymph node involvement is listed as a Registry Data Collection Variable in AJCC. This information was previously collected as Vagina SSF #4.

Additional Information

Source documents: pathology report, imaging, physical exam, other statement in record

Notes

Note 1: Physician Statement

- Physician statement of para-aortic status can be used to code this data item when no other information is available.

Note 2: Para-aortic lymph nodes

- Aortic
- Lateral aortic/lumbar aortic
- Para-aortic, NOS
- Periaortic

Note 3: Isolated tumor cells

- For this data item, do not include isolated tumor cells (ITCs).

Note 4: Related data item

- The assessment method is recorded in the related data item 3872: LN Assessment Method Para-aortic.

Coding Guidelines

1) Code 0 when

- Non-invasive neoplasm (behavior /2) (in-situ)
- All lymph nodes are negative and included an assessment of the para-aortic lymph nodes
- If there is no mention of para-aortic lymph node involvement in the area being imaged, biopsied, or in the surgical field and there is no mention of involvement, then assume that the para-aortic lymph nodes are negative

2) Code 9 when

- When there is no imaging, biopsy, surgical workup, or a physical exam only
- Not documented in medical record
- Regional/Distant lymph nodes not evaluated (assessed)
- Unknown if regional/distant lymph nodes evaluated (assessed)

Code	Description
0	Negative para-aortic lymph nodes Non-invasive neoplasm (behavior /2)
1	Positive para-aortic lymph nodes
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Para-aortic lymph node(s) not assessed or unknown if assessed

00510: Vagina

3872: LN Assessment Method Para-aortic

Item Length: 1
NAACCR Item #: 3872
XML Parent-NAACCR ID: Tumor-lnAssessMethodParaaortic
NAACCR Alternate Name: Lymph Nodes Assessment Method Para-aortic
Active years: 2018+
Schema(s):

- 00510: Vagina
- 00520: Cervix [8th: 2018-2020]
- 09520: Cervix [V9: 2021+]

Description

This data item describes the method used to assess involvement of para-aortic lymph nodes associated with certain female genital cancers.

In addition to assigning the N categories for vulva, vagina, and cervical cancers, the collection of specific lymph nodes and how they were assessed is important.

- Status refers to positive or negative involvement
- Assessment is the method by which the nodal status was determined

There are 3 related data items that collect assessment method information on regional lymph nodes, and 1 data item for distant lymph nodes.

The LN assessment data items collect how the lymph nodes were assessed for femoral-inguinal, para-aortic, and pelvic lymph nodes, and distant lymph nodes scalene and mediastinal. These related data items include:

- 3871: LN Assessment Method Femoral-Inguinal
- 3872: LN Assessment Method Para-Aortic
- 3873: LN Assessment Method Pelvic
- 3874: LN Distant Assessment Method

Rationale

Method of assessment of regional nodal status is listed as a Registry Data Collection Variable in the AJCC GYN chapters. This data item was previously collected as Vagina, CS SSF #5.

Additional Information

Source documents: pathology report, imaging, physical exam, other statement in record

Notes

Note 1: Physician Statement

- Physician statement of para-aortic assessment method can be used to code this data item when no other information is available.

Note 2: Para-aortic lymph nodes

- Aortic
- Lateral aortic/lumbar aortic
- Para-aortic, NOS
- Periaortic

Note 3: Isolated tumor cells

- For this data item, do not include isolated tumor cells (ITCs).

Note 4: Related data item

- The status of the lymph nodes is recorded in the related data item 3959: LN Status Para-aortic.

Coding Guidelines

1) Assign the highest applicable code (0-2) in the case of multiple assessments

2) Code 0 when there is physical exam or imaging only

3) Code 1 when there is an incisional biopsy or FNA

4) Code 2 when there is an excisional biopsy, sentinel lymph node biopsy, or lymph node resection

5) Code 7 when lymph nodes are assessed, but it is unknown how

6) Code 9 when

- Not documented in medical record
- Regional/Distant lymph nodes not evaluated (assessed)
- Unknown if regional/distant lymph nodes evaluated (assessed)

Code	Description
0	Radiography, imaging (Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI), positron emission tomography scan (PET)) Physical exam only
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy Sentinel node biopsy Excisional biopsy or resection with microscopic confirmation
7	Para-aortic lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Para-aortic lymph node(s) not assessed or unknown if assessed

00510: Vagina

3957: LN Status: Pelvic

Item Length: 1
NAACCR Item #: 3957
XML Parent-NAACCR ID: Tumor-lnStatusPelvic
NAACCR Alternate Name: LN Status: Pelvic
Active years: 2018+
Schema(s):

- 00510: Vagina
- 00520: Cervix [8th: 2018-2020]
- 09520: Cervix [V9: 2021+]

Description

This data item describes the status of pelvic lymph nodes associated with certain female genital cancers.

This data item describes the status of pelvic lymph nodes associated with certain female genital cancers.
In addition to assigning the N categories for vulva, vagina, and cervical cancers, the collection of specific lymph nodes and how they were assessed is important.

- Status refers to positive or negative involvement
- Assessment is the method by which the nodal status was determined

There are 3 related data items that collect status information on regional lymph nodes, 1 data item for distant lymph nodes, and 1 data item for laterality.

The LN status data items collect the individual status (positive, negative, unknown) involvement of femoral-inguinal, para-aortic, and pelvic lymph nodes, and distant lymph nodes mediastinal and scalene. These related data items include:

- 3957: LN Status: Pelvic
- 3958: LN Status: Para-Aortic
- 3959: LN Status: Femoral-Inguinal
- 3875: LN Distant: Mediastinal, Scalene

Rationale

Specific regional lymph node involvement is listed as a Registry Data Collection Variable in AJCC. This information was previously collected as Cervix, SSF #2 and Vagina, SSF # 2.

Additional Information

Source documents: pathology report, imaging, physical exam, other statement in record

Notes

Note 1: Physician Statement

- Physician statement of pelvic status can be used to code this data item when no other information is available.

Note 2: Pelvic lymph nodes

- Iliac, NOS
    - Common
    - External
    - Internal (hypogastric) (obturator)
- Paracervical
- Parametrial
- Pelvic, NOS
- Sacral, NOS
    - Lateral (laterosacral)
    - Middle (promontorial) (Gerota's node)
    - Uterosacral

Note 3: Isolated tumor cells

- For this data item, do not include isolated tumor cells (ITCs).

Note 4: Related data item

- The assessment method is recorded in the related data item 3873: LN Assessment Method Pelvic.

Coding Guidelines

1) Code 0 when

- Non-invasive neoplasm (behavior /2) (in-situ)
- All lymph nodes are negative and included an assessment of the pelvic lymph nodes

- If there is no mention of pelvic lymph node involvement in the area being imaged, biopsied, or in the surgical field and there is no mention of involvement, then assume that the pelvic lymph nodes are negative

2) Code 9 when

- When there is no imaging, biopsy, surgical workup, or a physical exam only
- Not documented in medical record
- Regional/Distant lymph nodes not evaluated (assessed)
- Unknown if regional/distant lymph nodes evaluated (assessed)

Code	Description
0	Negative pelvic lymph nodes Non-invasive neoplasm (behavior /2)
1	Positive pelvic lymph nodes
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Pelvic lymph node(s) not assessed or unknown if assessed

00510: Vagina

3873: LN Assessment Method Pelvic

Item Length: 1
NAACCR Item #: 3873
XML Parent-NAACCR ID: Tumor-lnAssessMethodPelvic
NAACCR Alternate Name: Lymph Nodes Assessment Method Pelvic
Active years: 2018+
Schema(s):

- 00510: Vagina
- 00520: Cervix [8th: 2018-2020]
- 09520: Cervix [V9: 2021+]

Description

This data item describes the method used to assess involvement of pelvic lymph nodes associated with certain female genital cancers.

In addition to assigning the N categories for vulva, vagina, and cervical cancers, the collection of specific lymph nodes and how they were assessed is important.

- Status refers to positive or negative involvement
- Assessment is the method by which the nodal status was determined

There are 3 related data items that collect assessment method information on regional lymph nodes, and 1 data item for distant lymph nodes.

The LN assessment data items collect how the lymph nodes were assessed for femoral-inguinal, para-aortic, and pelvic lymph nodes, and distant lymph nodes scalene and mediastinal. These related data items include:

- 3871: LN Assessment Method Femoral-Inguinal
- 3872: LN Assessment Method Para-Aortic
- 3873: LN Assessment Method Pelvic
- 3874: LN Distant Assessment Method

Rationale

Specific regional lymph node involvement is listed as a Registry Data Collection Variable in AJCC. This information was previously collected as Cervix, SSF #2 and Vagina, SSF # 2.

Additional Information

Source documents: pathology report, imaging, physical exam, other statement in record

Notes

Note 1: Physician Statement

- Physician statement of pelvic assessment method can be used to code this data item when no other information is available.

Note 2: Pelvic lymph nodes

- Iliac, NOS
    - Common
    - External
    - Internal (hypogastric) (obturator)
- Paracervical
- Parametrial
- Pelvic, NOS
- Sacral, NOS
    - Lateral (laterosacral)
    - Middle (promontorial) (Gerota's node)
    - Uterosacral

Note 3: Isolated tumor cells

- For this data item, do not include isolated tumor cells (ITCs).

Note 4: Related data item

- The status of the lymph nodes is recorded in the related data item 3959: LN Status Pelvic.

Coding Guidelines

1) Assign the highest applicable code (0-2) in the case of multiple assessments

2) Code 0 when there is physical exam or imaging only

3) Code 1 when there is an incisional biopsy or FNA

4) Code 2 when there is an excisional biopsy, sentinel lymph node biopsy, or lymph node resection

5) Code 7 when lymph nodes are assessed, but it is unknown how

6) Code 9 when

- Not documented in medical record
- Regional/Distant lymph nodes not evaluated (assessed)
- Unknown if regional/distant lymph nodes evaluated (assessed)

Code	Description
0	Radiography, imaging (Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI), positron emission tomography scan (PET)) Physical exam only
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy Sentinel node biopsy Excisional biopsy or resection with microscopic confirmation
7	Pelvic lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Pelvic lymph node(s) not assessed or unknown if assessed

00510: Vagina

3875: LN Distant: Mediastinal, Scalene

Item Length: 1
NAACCR Item #: 3875
XML Parent-NAACCR ID: Tumor-lnDistantMediastinalScalene
NAACCR Alternate Name: Lymph Nodes Distant: Mediastinal, Scalene
Active years: 2018+
Schema(s):

- 00510: Vagina
- 00520: Cervix [8th: 2018-2020]
- 09520: Cervix [V9: 2021+]

Description

This data item describes the status of Distant (mediastinal, scalene) nodes associated with certain female genital cancers.

In addition to assigning the N categories for vulva, vagina, and cervical cancers, the collection of specific lymph nodes and how they were assessed is important.

- Status refers to positive or negative involvement
- Assessment is the method by which the nodal status was determined

There are 3 related data items that collect status information on regional lymph nodes, 1 data item for distant lymph nodes, and 1 data item for laterality.

The LN status data items collect the individual status (positive, negative, unknown) involvement of femoral-inguinal, para-aortic, and pelvic lymph nodes, and distant lymph nodes mediastinal and scalene. These related data items include:

- 3957: LN Status: Pelvic
- 3958: LN Status: Para-Aortic
- 3959: LN Status: Femoral-Inguinal
- 3875: LN Distant: Mediastinal, Scalene

Rationale

Specific distant lymph node involvement is listed as a Registry Data Collection Variable in the AJCC. This data was previously collected as Vagina, CS SSF #6.

Additional Information

Source documents: pathology report, imaging, physical exam, other statement in record

Notes

Note 1: Physician Statement

- Physician statement of mediastinal and scalene nodal status can be used to code this data item when no other information is available.

Note 2: Related data item

- The assessment method is recorded in the related data item 3874: LN Distant Assessment Method.

Coding Guidelines

1) Code 0 when

- Non-invasive neoplasm (behavior /2) (in-situ)
- All lymph nodes are negative and included an assessment of the mediastinal and scalene lymph nodes
- If there is no mention of mediastinal or scalene lymph node involvement in the area being imaged, biopsied, or in the surgical field and there is no mention of involvement, then assume that the mediastinal and scale lymph nodes are negative

2) Code 9 when

- When there is no imaging, biopsy, surgical workup, or a physical exam only
- Not documented in medical record
- Regional/Distant lymph nodes not evaluated (assessed)
- Unknown if regional/distant lymph nodes evaluated (assessed)

Code	Description
0	Negative mediastinal and scalene lymph nodes Non-invasive neoplasm (behavior /2)
1	Positive mediastinal lymph nodes
2	Positive scalene lymph nodes
3	Positive mediastinal and scalene lymph nodes
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Mediastinal and scalene lymph node(s) not assessed or unknown if assessed

00510: Vagina

3874: LN Distant Assessment Method

Item Length: 1
NAACCR Item #: 3874
XML Parent-NAACCR ID: Tumor-lnDistantAssessMethod
NAACCR Alternate Name: Lymph Nodes Distant Assessment Method
Active years: 2018+
Schema(s):

- 00510: Vagina
- 00520: Cervix [8th: 2018-2020]
- 09520: Cervix [V9: 2021+]

Description

This data item describes the method used to assess involvement of Distant (mediastinal, scalene) nodes associated with certain female genital cancers.

In addition to assigning the N categories for vulva, vagina, and cervical cancers, the collection of specific lymph nodes and how they were assessed is important.

- Status refers to positive or negative involvement
- Assessment is the method by which the nodal status was determined

There are 3 related data items that collect assessment method information on regional lymph nodes, and 1 data item for distant lymph nodes.

The LN assessment data items collect how the lymph nodes were assessed for femoral-inguinal, para-aortic, and pelvic lymph nodes, and distant lymph nodes scalene and mediastinal. These related data items include:

- 3871: LN Assessment Method Femoral-Inguinal
- 3872: LN Assessment Method Para-Aortic
- 3873: LN Assessment Method Pelvic
- 3874: LN Distant Assessment Method

Rationale

Method of assessment of distant nodal status is listed as a Registry Data Collection Variable in the AJCC GYN chapters. This data item was previously collected as Vagina, CS SSF #7.

Additional Information

Source documents: pathology report, imaging, physical exam, other statement in record

Notes

Note 1: Physician Statement

- Physician statement of Mediastinal and Scalene assessment method can be used to code this data item when no other information is available.

Note 2: Related data item

- The status of the lymph nodes is recorded in the related data item 3875: LN Distant: Mediastinal, Scalene.

Coding Guidelines

1) Assign the highest applicable code (0-2) in the case of multiple assessments

2) Code 0 when there is physical exam or imaging only

3) Code 1 when there is an incisional biopsy or FNA

4) Code 2 when there is an excisional biopsy, sentinel lymph node biopsy, or lymph node resection

5) Code 7 when lymph nodes are assessed, but it is unknown how

6) Code 9 when

- Not documented in medical record
- Regional/Distant lymph nodes not evaluated (assessed)
- Unknown if regional/distant lymph nodes evaluated (assessed)

Code	Description
0	Radiography, imaging (Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI), positron emission tomography scan (PET)) Physical exam only
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy Excisional biopsy or resection with microscopic confirmation
7	Distant lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Distant lymph node(s) not assessed or unknown if assessed

00520: Cervix [8th: 2018-2020]

3836: FIGO Stage

Item Length: 3
NAACCR Item #: 3836
XML Parent-NAACCR ID: Tumor-figoStage
NAACCR Alternate Name: FIGO Stage Cervix
Active years: 2018+
Schema(s):

- 00520: Cervix [8th: 2018-2020]
- 09520: Cervix [V9: 2021+]

Description

Federation Internationale de Gynecologie et d'Obstetrique (FIGO) is a staging system for female reproductive cancers.

FIGO is a worldwide organization of obstetricians and gynecologists who maintain the international staging systems for female genital organs. The FIGO staging system has been adapted into the AJCC staging manual. FIGO uses Roman numerals and subscripts to define a stage. There is no T, N, or M descriptor with FIGO stage, only a stage group. For example, FIGO Stage IA is equivalent to T1a, FIGO Stage III can be either T3_ or N1, and FIGO Stage IV is M1.

FIGO stages vary by primary site, but the structure is similar throughout. FIGO no longer includes an in-situ stage (Tis, Stage 0). For in situ tumors, code the following

- Code 97: Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)

Note: Do not confuse FIGO stage with FIGO grade.

Rationale

FIGO stage is a Registry Data Collection Variable in AJCC for the female genital cancers. This data item was previously collected for the female genital cancers as: Vulva SSF #10, Vagina SSF #1, Cervix SSF #1, Corpus Carcinoma SSF #1, Corpus Sarcoma SSF #1, Ovary SSF #2, Fallopian Tube SSF #1, Peritoneum Female Genital SSF #1, and Placenta SSF #2.

Additional Information

Source documents: clinician's notes, consultant notes, radiation therapy notes

Notes

Note 1: Physician Statement

- There must be a statement about FIGO stage from the managing physician in order to code this data item.
    - Do not code FIGO stage based on the pathology report

- Do not code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do not assume it is a FIGO stage

Note 2: FIGO Stage vs FIGO Grade

- FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.
- Code FIGO grade in the grade fields

Note 3: Multiple FIGO stages

- If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

Note 4: FIGO Stage 0 (in-situ)

- The FIGO stage definitions do not include Stage 0 (Tis).
- Code 97 for any non-invasive neoplasm (behavior /2)

Code	Description
1	FIGO Stage I
1A	FIGO Stage IA
1A1	FIGO Stage IA1
1A2	FIGO Stage IA2
1B	FIGO Stage IB
1B1	FIGO Stage IB1
1B2	FIGO Stage IB2
1B3	FIGO Stage IB3
2	FIGO Stage II
2A	FIGO Stage IIA
2A1	FIGO Stage IIA1
2A2	FIGO Stage IIA2
2B	FIGO Stage IIB
3	FIGO Stage III

Code	Description
3A	FIGO Stage IIIA
3B	FIGO Stage IIIB
3C	FIGO Stage IIIC
3C1	FIGO Stage IIIC1
3C2	FIGO Stage IIIC2
4	FIGO Stage IV
4A	FIGO Stage IVA
4B	FIGO Stage IVB
97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage not assessed or unknown if assessed

09520: Cervix [V9: 2021+]

3956: p16

Item Length: 1
NAACCR Item #: 3956
XML Parent-NAACCR ID: Tumor-p16
NAACCR Alternate Name: p16
Active years: 2021+
Schema(s):

- 09520: Cervix [V9: 2021+]

Description

The p16 biomarker is overexpressed (produced) in response to HPV. It is therefore a surrogate marker for HPV disease.

p16 is a tumor suppressor protein also known as cyclin-dependent kinase inhibitor 2A. The p16 biomarker is overexpressed (produced) in response to HPV. It is therefore a surrogate marker for HPV disease.

Rationale

Patients with HPV have a different survival or outcome, so it is important to be able to distinguish this by documenting the p16 results. Testing is performed by immunohistochemistry (IHC) which is inexpensive and has near universal availability. It has an easily standardized interpretation. HPV testing is usually performed through DNA testing which is more expensive and less widely available. HPV testing also has technically more variability with the interpretation.

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2021+
- For cases diagnosed 2018-2020, this SSDI must be blank

Note 2: p16 Results ONLY

- This data item must be based on testing results for p16 overexpression.
- Testing for HPV by DNA, mRNA, antibody, or other methods should not be coded in this data item
- Do not confuse p16 with HPV, which is a specific strain of virus. A statement of a patient being HPV positive, or negative is not enough to code this data item
- Code 0 for p16 expression of weak intensity or limited distribution.

Code	Description
0	p16 Negative; Nonreactive
1	p16 Positive; Diffuse, Strong reactivity
8	Not applicable: Information not collected for this case (If this time is required by your standard setter, use of code 8 will result in an edit error)
9	Not tested for p16; Unknown
<Blank>	N/A - Diagnosis year is prior to 2021

00528: Cervix Sarcoma

3836: FIGO Stage

Item Length: 2
NAACCR Item #: 3836
XML Parent-NAACCR ID: Tumor-figoStage
NAACCR Alternate Name: FIGO Stage Corpus Sarcoma
Active years: 2018+
Schema(s):

- 00528: Cervix Sarcoma
- 00541: Corpus Sarcoma

Description

Federation Internationale de Gynecologie et d'Obstetrique (FIGO) is a staging system for female reproductive cancers.

FIGO is a worldwide organization of obstetricians and gynecologists who maintain the international staging systems for female genital organs. The FIGO staging system has been adapted into the AJCC staging manual. FIGO uses Roman numerals and subscripts to define a stage. There is no T, N, or M descriptor with FIGO stage, only a stage group. For example, FIGO Stage IA is equivalent to T1a, FIGO Stage III can be either T3_ or N1, and FIGO Stage IV is M1.

FIGO stages vary by primary site, but the structure is similar throughout. FIGO no longer includes an in-situ stage (Tis, Stage 0). For in situ tumors, code the following

- Code 97: Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)

Note: Do not confuse FIGO stage with FIGO grade.

Rationale

FIGO stage is a Registry Data Collection Variable in AJCC for the female genital cancers. This data item was previously collected for the female genital cancers as: Vulva SSF #10, Vagina SSF #1, Cervix SSF #1, Corpus Carcinoma SSF #1, Corpus Sarcoma SSF #1, Ovary SSF #2, Fallopian Tube SSF #1, Peritoneum Female Genital SSF #1, and Placenta SSF #2.

Additional Information

Source documents: clinician's notes, consultant notes, radiation therapy notes

Notes

Note 1: Physician Statement

- There must be a statement about FIGO stage from the managing physician in order to code this data item.

- Do not code FIGO stage based on the pathology report
- Do not code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do not assume it is a FIGO stage

Note 2: FIGO Stage vs FIGO Grade

- FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.
- Code FIGO grade in the grade fields

Note 3: Multiple FIGO stages

- If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

Note 4: FIGO Stage 0 (in-situ)

- The FIGO stage definitions do not include Stage 0 (Tis).
- Code 97 for any non-invasive neoplasm (behavior /2)

Code	Description
1	FIGO Stage I
1A	FIGO Stage IA
1B	FIGO Stage IB
2	FIGO Stage II
2A	FIGO Stage IIA
2B	FIGO Stage IIB
3	FIGO Stage III
3A	FIGO Stage IIIA
3B	FIGO Stage IIIB
3C	FIGO Stage IIIC
4	FIGO Stage IV
4A	FIGO Stage IVA
4B	FIGO Stage IVB

Code	Description
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage not assessed or unknown if assessed

00528: Cervix Sarcoma

3902: Number of Positive Pelvic Nodes

Item Length: 2
NAACCR Item #: 3902
XML Parent-NAACCR ID: Tumor-numberOfPositivePelvicNodes
NAACCR Alternate Name: Number of Positive Pelvic Nodes
Active years: 2018+
Schema(s):

- 00528: Cervix Sarcoma
- 00530: Corpus Carcinoma and Carcinosarcoma
- 00541: Corpus Sarcoma
- 00542: Corpus Adenosarcoma

Description

Number of Positive Pelvic Nodes is the number of positive nodes based on pelvic nodal dissection.

For the Corpus schemas (3) and the Cervix Sarcoma schema, there are 4 data items that record information on the number of positive and examined para-aortic and pelvic lymph nodes. These related data items should be coded from the same procedure.

- 3899: Number of Examined Para-Aortic Nodes
- 3900: Number of Examined Pelvic Nodes
- 3901: Number of Positive Para-Aortic Nodes
- 3902: Number of Positive Pelvic Nodes

Rationale

Number of Positive Pelvic Nodes is the number of positive nodes based on pelvic nodal dissection.

Additional Information

Source documents: pathology report, imaging reports, physical exam, other statements in medical record

Notes

Note 1: Physician Statement

- Physician statement of positive pelvic nodes can be used to code this data item when no other information is available.

Note 2: Pelvic lymph nodes

- Iliac, NOS
    - Common
    - External
    - Internal (hypogastric) (obturator)
- Paracervical
- Parametrial
- Pelvic, NOS
- Sacral, NOS
    - Lateral (laterosacral)
    - Middle (promontorial) (Gerota's node)
    - Uterosacral

Note 3: Isolated tumor cells

- For this data item, do not include isolated tumor cells (ITCs).

Note 4: Micrometastasis and macrometastasis

- Micrometastasis and macrometastasis may be listed separately on the pathology report. Add these two together to get the total number of positive nodes.

Note 5: Related data item

- The number of examined pelvic nodes is recorded in the related data item 3900: Number of Examined Pelvic Nodes.

Coding Guidelines

1) Record the number of positive pelvic lymph nodes documented in the medical record.

- Number of nodes positive must ALWAYS be less than or equal to number of nodes examined

2) Record the number of positive pelvic lymph nodes documented in the medical record.

3) Code 00 for when there are no positive nodes

4) Code 01-99 for the exact number of positive nodes

5) Code X1 for 100 or more positive nodes

6) Code X2 for positive nodes, but unknown how many

7) Code X6 if only a FNA or core biopsy is done, and it is positive

8) Code X9 when

- If only a FNA or core biopsy is done, and it is negative
- Not documented in the medical record
- Pelvic lymph nodes not evaluated (assessed)
- No lymph nodes removed
- Unknown if Pelvic lymph nodes evaluated (assessed)

Code	Description
00	All pelvic nodes examined negative
01-99	1 - 99 pelvic nodes positive (Exact number of nodes positive)
X1	100 or more pelvic nodes positive
X2	Positive pelvic nodes identified; number unknown
X6	Positive aspiration or core biopsy of pelvic lymph node(s)
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record Cannot be determined, indeterminate if positive pelvic nodes present No lymph nodes removed Pelvic lymph nodes not assessed or unknown if assessed

00528: Cervix Sarcoma

3900: Number of Examined Pelvic Nodes

Item Length: 2
NAACCR Item #: 3900
XML Parent-NAACCR ID: Tumor-numberOfExaminedPelvicNodes
NAACCR Alternate Name: Number of Examined Pelvic Nodes
Active years: 2018+
Schema(s):

- 00528: Cervix Sarcoma
- 00530: Corpus Carcinoma and Carcinosarcoma
- 00541: Corpus Sarcoma
- 00542: Corpus Adenosarcoma

Description

Number of Examined Pelvic Nodes is the number of nodes examined based on pelvic nodal dissection.

For the Corpus schemas (3) and the Cervix Sarcoma schema, there are 4 data items that record information on the number of positive and examined para-aortic and pelvic lymph nodes. These related data items should be coded from the same procedure

- 3899: Number of Examined Para-Aortic Nodes
- 3900: Number of Examined Pelvic Nodes
- 3901: Number of Positive Para-Aortic Nodes
- 3902: Number of Positive Pelvic Nodes

Rationale

Number of Examined Pelvic Nodes is listed as a Registry Data Collection Variable in AJCC. This data item was previously collected as Corpus, CS SSF #4.

Additional Information

Source documents: pathology report, imaging reports, physical exam, other statements in medical record

Notes

Note 1: Physician Statement

- Physician statement of examined pelvic nodes can be used to code this data item when no other information is available

Note 2: Pelvic lymph nodes

- Iliac, NOS
    - Common
    - External
    - Internal (hypogastric) (obturator)
- Paracervical
- Parametrial
- Pelvic, NOS
- Sacral, NOS
    - Lateral (laterosacral)
    - Middle (promontorial) (Gerota's node)
    - Uterosacral

Note 3: Isolated tumor cells

- For this data item, do not include isolated tumor cells (ITCs).

Note 4: Related data item

- The number of positive pelvic nodes is recorded in the related data item 3902: Number of Positive Pelvic Nodes.

Coding Guidelines

1) Record the number of examined pelvic lymph nodes documented in the medical record.

- Number of nodes examined must ALWAYS be **equal to or greater** than the number of nodes positive.
- If a lymph node dissection is done and only "nodes" are documented without specifying pelvic or para-aortic, assume they are pelvic

2) Code 00 when no lymph nodes are examined by FNA, core biopsy or removal of lymph node(s) (e.g., sentinel lymph node biopsy or lymph node dissection)

3) Code 01-99 for the exact number of examined

4) Code X1 for 100 or more examined nodes

5) Code X2 for nodes examined, but unknown how many

6) Code X6 for aspiration or core biopsy of pelvic node(s)

7) Code X9 when

- Not documented in the medical record
- Pelvic lymph nodes not evaluated (assessed)
- Unknown if Pelvic lymph nodes not evaluated (assessed)

Code	Description
00	No pelvic lymph nodes examined
01-99	1 - 99 pelvic lymph nodes examined (Exact number of pelvic lymph nodes examined)
X1	100 or more pelvic nodes examined
X2	Pelvic nodes examined; number unknown
X6	No pelvic lymph nodes removed, but aspiration or core biopsy of pelvic node(s) only
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record Cannot be determined, indeterminate if examined pelvic nodes present Pelvic lymph nodes not assessed or unknown if assessed

00528: Cervix Sarcoma

3901: Number of Positive Para-Aortic Nodes

Item Length: 2
NAACCR Item #: 3901
XML Parent-NAACCR ID: Tumor-numberOfPositiveParaAorticNodes
NAACCR Alternate Name: Number of Positive Para-Aortic Nodes
Active years: 2018+
Schema(s):

- 00528: Cervix Sarcoma
- 00530: Corpus Carcinoma and Carcinosarcoma
- 00541: Corpus Sarcoma
- 00542: Corpus Adenosarcoma

Description

Number of Positive Para-Aortic Nodes is the number of positive nodes based on para-aortic nodal dissection.

Information on the number of positive and examined para-aortic and pelvic lymph nodes. These related data items should be coded from the same procedure.

- 3899: Number of Examined Para-Aortic Nodes
- 3900: Number of Examined Pelvic Nodes
- 3901: Number of Positive Para-Aortic Nodes
- 3902: Number of Positive Pelvic Nodes

Rationale

Number of Positive Para-Aortic Nodes is listed as a Registry Data Collection Variable in AJCC. This data item was previously collected as Corpus, CS SSF #5.

Additional Information

Source documents: pathology report, imaging reports, physical exam, other statements in medical record

Notes

Note 1: Physician Statement

- Physician statement of positive para-aortic nodes can be used to code this data item when no other information is available.

Note 2: Para-aortic nodes

- Aortic
- Lateral aortic/lateral lumbar
- Para-aortic, NOS
- Periaortic

Note 3: Isolated tumor cells

- For this data item, do not include isolated tumor cells (ITCs).

Note 4: Micrometastasis and macrometastasis

- Micrometastasis and macrometastasis may be listed separately on the pathology report. Add these two together to get the total number of positive nodes.

Note 5: Related data item

- The number of examined pelvic nodes is recorded in the related data item 3899: Number of Examined Para-Aortic Nodes.

Coding Guidelines

1) Record the number of positive para-aortic lymph nodes documented in the medical record.

2) Code 00 for when there are no positive nodes

3) Code 01-99 for the exact number of positive nodes

4) Code X1 for 100 or more positive nodes

5) Code X2 for positive nodes, but unknown how many

6) Code X6 if only a FNA or core biopsy is done, and it is positive

7) Code X9 when

- If only a FNA or core biopsy is done, and it is negative
- Not documented in the medical record
- Para-aortic lymph nodes not evaluated (assessed)
- No lymph nodes removed
- Unknown if Para-aortic lymph nodes evaluated (assessed)

Code	Description
00	All para-aortic lymph nodes examined negative
01-99	1-99 para-aortic lymph nodes positive (Exact number of nodes positive)
X1	100 or more para-aortic nodes positive
X2	Positive para-aortic nodes identified; number unknown
X6	Positive aspiration or core biopsy of para-aortic lymph node(s)
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record Cannot be determined, indeterminate if positive para-aortic nodes present No lymph nodes removed Para-aortic lymph nodes not assessed or unknown if assessed

00528: Cervix Sarcoma

3899: Number of Examined Para-Aortic Nodes

Item Length: 2
NAACCR Item #: 3899
XML Parent-NAACCR ID: Tumor-numberOfExaminedParaAorticNodes
NAACCR Alternate Name: Number of Examined Para-Aortic Nodes
Active years: 2018+
Schema(s):

- 00528: Cervix Sarcoma
- 00530: Corpus Carcinoma and Carcinosarcoma
- 00541: Corpus Sarcoma
- 00542: Corpus Adenosarcoma

Description

Number of Examined Para-Aortic nodes is the number of nodes examined based on para-aortic nodal dissection.

Information on the number of positive and examined para-aortic and pelvic lymph nodes. These related data items should be coded from the same procedure.

- 3899: Number of Examined Para-Aortic Nodes
- 3900: Number of Examined Pelvic Nodes
- 3901: Number of Positive Para-Aortic Nodes
- 3902: Number of Positive Pelvic Nodes

Rationale

Number of Examined Para-Aortic Nodes is listed as a Registry Data Collection Variable in AJCC. This data item was previously collected as Corpus, CS SSF #6.

Additional Information

Source documents: pathology report, imaging reports, physical exam, other statements in medical record

Notes

Note 1: Physician Statement

- Physician statement of examined para-aortic nodes can be used to code this data item when no other information is available.

Note 2: Para-aortic nodes

- Aortic
- Lateral aortic/lateral lumbar
- Para-aortic, NOS
- Periaortic

Note 3: Related data item

- The number of para-aortic nodes positive is recorded in the related data item 3901: Number of Positive Para-aortic Nodes.

Note 4: Related data item

- The number of examined pelvic nodes is recorded in the related data item 3899: Number of Examined Para-Aortic Nodes.

Coding Guidelines

1) Record the number of examined pelvic lymph nodes documented in the medical record.

- Number of nodes examined must ALWAYS be **equal to or greater** than the number of nodes positive.
- If a lymph node dissection is done and only "nodes" are documented without specifying pelvic or para-aortic, assume they are pelvic
    - Para-aortic nodes are not routinely examined unless there is suspected involvement

2) Code 00 when no lymph nodes are examined by FNA, core biopsy or removal of lymph node(s) (e.g., sentinel lymph node biopsy or lymph node dissection)

3) Code 01-99 for the exact number of examined

4) Code X1 for 100 or more examined nodes

5) Code X2 for nodes examined, but unknown how many

6) Code X6 for aspiration or core biopsy of para-aortic node(s)

7) Code X9 when

- Not documented in the medical record
- Para-aortic lymph nodes not evaluated (assessed)
- Unknown if Para-aortic lymph nodes not evaluated (assessed)

Code	Description
00	No para-aortic nodes examined
01-99	1 - 99 para-aortic nodes examined (Exact number of para-aortic lymph nodes examined)
X1	100 or more para-aortic nodes examined
X2	Para-aortic nodes examined; number unknown
X6	No para-aortic lymph nodes removed, but aspiration or core biopsy of para-aortic node(s) only
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record Cannot be determined, indeterminate if examined para-aortic nodes present Para-aortic lymph nodes not assessed or unknown if assessed

00528: Cervix Sarcoma

3911: Peritoneal Cytology

Item Length: 1
NAACCR Item #: 3911
XML Parent-NAACCR ID: Tumor-peritonealCytology
NAACCR Alternate Name: Peritoneal Cytology
Active years: 2018+
Schema(s):

- 00528: Cervix Sarcoma
- 00530: Corpus Carcinoma and Carcinosarcoma
- 00541: Corpus Sarcoma
- 00542: Corpus Adenosarcoma

Description

Peritoneal cytology pertains to the results of cytologic examination for malignant cells performed on fluid that is obtained from the peritoneal cavity.

Peritoneal cytology looks for malignant cells in the fluid in the pelvic and peritoneal cavities. Excess natural fluid accumulation is called ascites. If, at laparotomy an analyzable amount of ascites is not present, the surgeon may flood the pelvis and abdomen with saline solution then suction it out and send the fluid for cytologic examination.

Rationale

Peritoneal Cytology is listed as a Registry Data Collection Variable in AJCC. This data item was previously collected as Corpus, CS SSF #2.

Additional Information

Source documents: cytology reports (look for multiple reports), pathology report

Other names include peritoneal washings, peritoneal lavage, possibly paracentesis (if no surgery), peritoneal ascitic fluid instead of peritoneal washing or pelvic washing

Notes

Note 1: Physician Statement

- Physician statement of Peritoneal Cytology can be used to code this data item when no other information is available.

Note 2: Other names for Peritoneal cytology

- Peritoneal cytology may also be called peritoneal ascitic fluid instead of peritoneal washing or pelvic washing (see also Additional information)

Note 3: Ascites examination

- Cytologic examination for malignant cells may be performed on ascites (fluid that has accumulated in the peritoneal cavity in excess amount) or the fluid (saline) that is introduced into the peritoneal cavity or pelvis, and then removed by suction. The introduction of fluid may be termed peritoneal or pelvic washing or peritoneal lavage

Coding Guidelines

1) Code 0 when the peritoneal cytology is reported as negative or normal

2) Code 1 when the peritoneal cytology test was done, and the results were reported as suspicious, undetermined if negative or positive

3) Code 2 when the peritoneal cytology is reported as positive

4) Code 7 when test was ordered but the results are not in the medical record

5) Code 9 when

- No cytological specimen is available
- Peritoneal cytology not evaluated (assessed)
- Unknown if Peritoneal Cytology evaluated (assessed)

Code	Description
0	Peritoneal cytology/washing negative for malignancy
1	Peritoneal cytology/washing atypical and/or suspicious
2	Peritoneal cytology/washing malignant (positive for malignancy)
3	Unsatisfactory/nondiagnostic
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Peritoneal cytology not assessed or unknown if assessed

00530: Corpus Carcinoma and Carcinosarcoma

3836: FIGO Stage

Item Length: 3
NAACCR Item #: 3836
XML Parent-NAACCR ID: Tumor-figoStage
NAACCR Alternate Name: FIGO Stage Corpus Carcinoma and Carcinosarcoma
Active years: 2018+
Schema(s):

- 00530: Corpus Carcinoma and Carcinosarcoma

Description

Federation Internationale de Gynecologie et d'Obstetrique (FIGO) is a staging system for female reproductive cancers.

FIGO is a worldwide organization of obstetricians and gynecologists who maintain the international staging systems for female genital organs. The FIGO staging system has been adapted into the AJCC staging manual. FIGO uses Roman numerals and subscripts to define a stage. There is no T, N, or M descriptor with FIGO stage, only a stage group. For example, FIGO Stage IA is equivalent to T1a, FIGO Stage III can be either T3_ or N1, and FIGO Stage IV is M1.

FIGO stages vary by primary site, but the structure is similar throughout. FIGO no longer includes an in-situ stage (Tis, Stage 0). For in situ tumors, code the following

- Code 97: Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)

Note: Do not confuse FIGO stage with FIGO grade

Rationale

FIGO stage is a Registry Data Collection Variable in AJCC for the female genital cancers. This data item was previously collected for the female genital cancers as: Vulva SSF #10, Vagina SSF #1, Cervix SSF #1, Corpus Carcinoma SSF #1, Corpus Sarcoma SSF #1, Ovary SSF #2, Fallopian Tube SSF #1, Peritoneum Female Genital SSF #1, and Placenta SSF #2.

Additional Information

Source documents: clinician's notes, consultant notes, radiation therapy notes

Notes

Note 1: Physician Statement

- There must be a statement about FIGO stage from the managing physician in order to code this data item.
    - Do not code FIGO stage based on the pathology report

- Do not code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do not assume it is a FIGO stage

Note 2: FIGO Stage vs FIGO Grade

- FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.
- Code FIGO grade in the grade fields

Note 3: Multiple FIGO stages

- If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

Note 4: EIC, SEIC, EIN

- For Endometrial intraepithelial carcinoma **(EIC)** (8380/2) and Serous endometrial intraepithelial carcinoma **(SEIC)** (8441/2), assign the FIGO staged based on the managing physician's documentation of FIGO. (See Note 1).
- If FIGO stage for EIC or SEIC is not documented by the managing physician, code unknown (code 99)
- Do not code 97 (in situ) for EIC or SEIC since FIGO does not have a Stage 0
- If diagnosis is Endometrial intraepithelial neoplasia **(EIN)** (8380/2), code 97.

Note 5: Remaining in situ histologies

- Code 97 for any remaining in situ histologies (/2) since the FIGO stage definitions do not include Stage 0.

Code	Description
1	FIGO Stage I
1A	FIGO Stage IA
1B	FIGO Stage IB
2	FIGO Stage II
3	FIGO Stage III
3A	FIGO Stage IIIA
3B	FIGO Stage IIIB

Code	Description
3C	FIGO Stage IIIC
3C1	FIGO Stage IIIC1
3C2	FIGO Stage IIIC2
4	FIGO Stage IV
4A	FIGO Stage IVA
4B	FIGO Stage IVB
97	Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage not assessed or unknown if assessed

00530: Corpus Carcinoma and Carcinosarcoma

3890: Microsatellite Instability

Item Length: 1
NAACCR Item #: 3890
XML Parent-NAACCR ID: Tumor-microsatelliteInstability
NAACCR Alternate Name: Microsatellite Instability (MSI)
Active years: 2026+
Schema(s):

- 00530: Corpus Carcinoma and Carcinosarcoma

Description

The microsatellite instability (MSI) test is a genetic test performed on tumor tissue to look for differences in length of certain non-functioning sections of DNA. The differences are caused by problems with the genes that encode proteins that normally repair certain types of DNA damage. Knowing whether cancer is microsatellite instability high may help plan the best treatment.

Microsatellites are short, repeated, sequences of DNA. Cancer cells that have large numbers of microsatellites that may have defects in the ability to correct mistakes that occur when DNA is copied in the cell. Microsatellite instability is found most often in colorectal cancer, other types of gastrointestinal cancer, and endometrial cancer. It may also be found in cancers of the breast, prostate, bladder, and thyroid.

Additional Information

Source documents: pathology report

Other names include MSI, Mismatch repair, MMR, MSI-H

For further information, refer to the **Carcinoma of the Endometrium** Reporting cancer protocol published by the College of American Pathologists for the AJCC Staging System *Corpus Uteri-Carcinoma and Adenocarcinoma*.

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2026+
- For cases diagnosed 2018-2025, this SSDI must be blank

Note 2: Physician Statement

- Physician statement of MSI can be used to code this data item when no other information is available.

Note 3: Applicable stages

- MSI may be recorded for all stages; however, it is primarily performed for invasive neoplasms
- For non-invasive neoplasms (behavior /2), code to 9 if no information available.

Note 4: Results from nodal or metastatic tissue

- Results from nodal or metastatic tissue may be used for Microsatellite Instability.

Coding Guidelines

Microsatellite Instability (MSI)

- Testing for MSI may be done by immunology or genetic testing. Only genetic testing results will specify whether the MSI is low or high.
- MSI is looking at instability in informative markers

1) Code 0

- MSS (Code 0)
- Stable (Code 0)
- Negative (Code 0)
- Low probability of MSI-H (Code 0)
- MSS/MSI-L (Code 0)

2) Code 1

- MSI-L (Code 1)

3) Code 2

- Unstable, high (Code 2)
- Unstable, NOS (no designation of high or low) (Code 2)
- MSI-H (Code 2)

4) Code 9

- MSI-I (intermediate) (Code 9)

Mismatch Repair (MMR)

- Testing for Mismatch Repair (MMR) is usually done by immunohistochemistry (IHC).
- Most common markers are MLH1, MSH2, MSH6, PMS2

1) Code 0

- No loss of nuclear expression (code 0)
- Mismatch repair (MMR) intact (code 0)
- MMR proficient (pMMR or MMR-P) (code 0)
- MMR normal (code 0)

2) Code 2

- Loss of nuclear expression (code 2)
- MMR deficient (dMMR or MMR-D) (code 2)
- MMR abnormal (code 2)

MSI and MMR

1) Code 0 If all tests done are negative

2) Code 2 If both tests are done and one or both are positive

Code	Description
0	Microsatellite instability (MSI) stable; microsatellite stable (MSS); negative, NOS AND/OR Mismatch repair (MMR) intact, no loss of nuclear expression of MMR proteins MMR proficient (pMMR or MMR-P)
1	MSI unstable low (MSI-L)
2	MSI unstable high (MSI-H) AND/OR MMR deficient (dMMR or MMR-D) loss of nuclear expression of one or more MMR proteins, MMR protein deficient)
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record MSI-indeterminate MSI-equivocal Microsatellite instability not assessed or unknown if assessed
<Blank>	Must be blank if diagnosis year is before 2026

00541: Corpus Sarcoma

See **00528: Cervix Sarcoma**

- 3836: FIGO Stage
- 3902: Number of Positive Pelvic Nodes
- 3900: Number of Examined Pelvic Nodes
- 3901: Number of Positive Para-Aortic Nodes
- 3899: Number of Examined Para-Aortic Nodes
- 3911: Peritoneal Cytology

00542: Corpus Adenosarcoma

3836: FIGO Stage

Item Length: 2
NAACCR Item #: 3836
XML Parent-NAACCR ID: Tumor-figoStage
NAACCR Alternate Name: FIGO Stage Corpus Adenosarcoma
Active years: 2018+
Schema(s):

- 00542: Corpus Adenosarcoma

Description

Federation Internationale de Gynecologie et d'Obstetrique (FIGO) is a staging system for female reproductive cancers.

FIGO is a worldwide organization of obstetricians and gynecologists who maintain the international staging systems for female genital organs. The FIGO staging system has been adapted into the AJCC staging manual. FIGO uses Roman numerals and subscripts to define a stage. There is no T, N, or M descriptor with FIGO stage, only a stage group. For example, FIGO Stage IA is equivalent to T1a, FIGO Stage III can be either T3_ or N1, and FIGO Stage IV is M1.

FIGO stages vary by primary site, but the structure is similar throughout. FIGO no longer includes an in-situ stage (Tis, Stage 0). For in situ tumors, code the following:

- Code 97: Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)

Note: Do not confuse FIGO stage with FIGO grade.

Rationale

FIGO stage is a Registry Data Collection Variable in AJCC for the female genital cancers. This data item was previously collected for the female genital cancers as: Vulva SSF #10, Vagina SSF #1, Cervix SSF #1, Corpus Carcinoma SSF #1, Corpus Sarcoma SSF #1, Ovary SSF #2, Fallopian Tube SSF #1, Peritoneum Female Genital SSF #1, and Placenta SSF #2.

Additional Information

Source documents: clinician's notes, consultant notes, radiation therapy notes

Notes

Note 1: Physician Statement

- There must be a statement about FIGO stage from the managing physician in order to code this data item.
    - Do not code FIGO stage based on the pathology report

- Do not code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do not assume it is a FIGO stage

Note 2: FIGO Stage vs FIGO Grade

- FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.
- Code FIGO grade in the grade fields

Note 3: Multiple FIGO stages

- If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

Note 4: FIGO Stage 0 (in-situ)

- The FIGO stage definitions do not include Stage 0 (Tis).
- Code 97 for any non-invasive neoplasm (behavior /2)

Code	Description
1	FIGO Stage I
1A	FIGO Stage IA
1B	FIGO Stage IB
1C	FIGO Stage IC
2	FIGO Stage II
2A	FIGO Stage IIA
2B	FIGO Stage IIB
3	FIGO Stage III
3A	FIGO Stage IIIA
3B	FIGO Stage IIIB
3C	FIGO Stage IIIC
4	FIGO Stage IV
4A	FIGO Stage IVA
4B	FIGO Stage IVB

Code	Description
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage not assessed or unknown if assessed

00551: Ovary

3836: FIGO Stage

Item Length: 4
NAACCR Item #: 3836
XML Parent-NAACCR ID: Tumor-figoStage
NAACCR Alternate Name: FIGO Stage Ovary, Fallopian Tube, and Primary Peritoneal Carcinoma
Active years: 2018+
Schema(s):

- 00551: Ovary
- 00552: Primary Peritoneal Carcinoma
- 00553: Fallopian Tube

Description

Federation Internationale de Gynecologie et d'Obstetrique (FIGO) is a staging system for female reproductive cancers.

FIGO is a worldwide organization of obstetricians and gynecologists who maintain the international staging systems for female genital organs. The FIGO staging system has been adapted into the AJCC staging manual. FIGO uses Roman numerals and subscripts to define a stage. There is no T, N, or M descriptor with FIGO stage, only a stage group. For example, FIGO Stage IA is equivalent to T1a, FIGO Stage III can be either T3_ or N1, and FIGO Stage IV is M1.

FIGO stages vary by primary site, but the structure is similar throughout. FIGO no longer includes an in-situ stage (Tis, Stage 0). For in situ tumors, code the following

- Code 97: Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)

Note: Do not confuse FIGO stage with FIGO grade.

Rationale

FIGO stage is a Registry Data Collection Variable in AJCC for the female genital cancers. This data item was previously collected for the female genital cancers as: Vulva SSF #10, Vagina SSF #1, Cervix SSF #1, Corpus Carcinoma SSF #1, Corpus Sarcoma SSF #1, Ovary SSF #2, Fallopian Tube SSF #1, Peritoneum Female Genital SSF #1, and Placenta SSF #2.

Additional Information

Source documents: clinician's notes, consultant notes, radiation therapy notes

Notes

Note 1: Physician Statement

- There must be a statement about FIGO stage from the managing physician in order to code this data item.

- Do not code FIGO stage based on the pathology report
- Do not code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do not assume it is a FIGO stage

Note 2: FIGO Stage vs FIGO Grade

- FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.
- Code FIGO grade in the grade fields

Note 3: Multiple FIGO stages

- If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

Note 4: HGSC, STIC, LGSC, and SIC (8441/2)

- For High-grade serous carcinoma **(HGSC)** (8441/2) or serous tubal intraepithelial carcinoma **(STIC)** (8441/2), assign the FIGO stage based on the managing physician's documentation of FIGO. (See Note 1).
- If FIGO stage for HGSC or STIC is not documented by the managing physician, code unknown (code 99)
  - Do not code 97 (in situ) for HGSC or STIC since FIGO does not have a Stage 0
- If diagnosis is low grade serous intraepithelial carcinoma **(LGSC)** (8441/2) or serous intraepithelial carcinoma **(SIC)** (no grade stated) (8441/2), code 97

Note 5: Remaining in situ histologies

- Code 97 for any remaining in situ histologies (/2) since the FIGO stage definitions do not include Stage 0.

Code	Description
1	FIGO Stage I
1A	FIGO Stage IA
1B	FIGO Stage IB
1C	FIGO Stage IC
1C1	FIGO Stage IC1
1C2	FIGO Stage IC2

Code	Description
1C3	FIGO Stage IC3
2	FIGO Stage II
2A	FIGO Stage IIA
2B	FIGO Stage IIB
3	FIGO Stage III
3A	FIGO Stage IIIA
3A1	FIGO Stage IIIA1
3A11	FIGO Stage IIIA1i
3A12	FIGO Stage IIIA1ii
3A2	FIGO Stage IIIA2
3B	FIGO Stage IIIB
3C	FIGO Stage IIIC
4	FIGO Stage IV
4A	FIGO Stage IVA
4B	FIGO Stage IVB
97	Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage not assessed or unknown if assessed

00551: Ovary

3818: CA-125 PreTx Interpretation

Item Length: 1
NAACCR Item #: 3818
XML Parent-NAACCR ID: Tumor-ca125PretreatmentInterpretation
NAACCR Alternate Name: CA-125 (Carbohydrate Antigen 125) Pretreatment Interpretation
Active years: 2018+
Schema(s):

- 00551: Ovary
- 00552: Primary Peritoneal Carcinoma
- 00553: Fallopian Tube

Description

Carbohydrate Antigen 125 (CA-125)/CA-125 II is a tumor marker that is useful for following the response to therapy in patients with ovarian cancer, who may have elevated levels of this marker.

CA-125/CA-125 II is a tumor marker that is not specific to ovarian or primary peritoneal cancer but is useful to monitor for success of treatment and recurrence. Because it can be elevated in many diseases affecting the peritoneal lining of the abdominal and pelvic cavity, it is not a screening test for women who have no history of cancer. Any value over 35 is highly linked with cancer and about 80% of ovarian cancers show an elevated CA-125/CA-125 II. However, a result in the normal range does not rule out cancer. Values up to 65 U/ml may be considered borderline, and values over 200 are unlikely to be due to a benign condition. CA-125/CA-125 II monitors for success of treatment and recurrence. After obtaining a baseline value prior to treatment, a lower result on a subsequent test indicates a response to treatment, and an increasing value indicates possible recurrence.

Rationale

Preoperative CA-125/CA-125 II is a Registry Data Collection Variable listed in AJCC. It was previously collected as Ovary, CS SSF #1.

Additional Information

Source documents: clinical laboratory report (blood or serum test); may be reported in history, clinician or consultant notes or pathology report

Other names include Cancer Antigen 125, CA 125, CA125, Carbohydrate Antigen 125, mucin 16, MUC16, CA 125 II

Normal reference range

- < 35 units per milliliter (U/ml); SI: < 35 kiloUnits/Liter (KU/L)
- May also be reported as micrograms/milliliter (µg/mL or ug/mL)
- Normal values may vary with patient age and from lab to lab.
- The typical human reference ranges are 0 to less than or equal 35 units per milliliter (U/mL). This is equivalent to kU/L.

Notes

Note 1: Physician Statement

- Physician statement of CA-125/CA-125 II pretreatment interpretation can be used to code this data item when no other information is available.

Note 2: Blood or Serum testing only

- Record only the blood or serum CA-125/CA-125 II interpretation for this data item.
- Do not record CA-125 test results based on fluid from the chest or abdominal cavity.

Note 3: Pretreatment results only

- Record the CA-125/CA-125 II status prior to treatment.

Coding Guidelines

1) Record the clinician's interpretation of the highest value prior to treatment from a blood or serum test, based on the reference range used by the lab.

2) Do **not** code the result from thoracentesis or paracentesis fluid.

3) Code 0 when the CA-125/CA-125 II is reported as negative or normal.

4) Code 1 when the CA-125/CA-125 II is reported as positive or elevated.

5) Code 2 when the CA-125/CA-125 II is reported as borderline; undetermined whether positive or negative.

6) Code 7 when the CA-125/CA-125 II test was ordered but the results are not in the medical record.

7) Code 9 when

- No information in the medical record
- CA-125/CA-125 II test not done (not assessed)
- Unknown if CA-125/CA-125 II test was performed (unknown if assessed)

- There is no statement that the CA-125/CA-125 II is positive/elevated, negative/normal, and the lab value with its normal range (from which you can determine interpretation) is not documented.

Code	Description
0	Negative/normal; within normal limits
1	Positive/elevated
2	Stated as borderline; undetermined whether positive or negative
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error)
9	Not documented in medical record CA-125 not assessed or unknown if assessed

00551: Ovary

3921: Residual Tumor Volume Post Cytoreduction

Item Length: 2
NAACCR Item #: 3921
XML Parent-NAACCR ID: Tumor-residualTumVolPostCytoreduction
NAACCR Alternate Name: Residual Tumor Volume Post Cytoreduction
Active years: 2018+
Schema(s):

- 00551: Ovary
- 00552: Primary Peritoneal Carcinoma
- 00553: Fallopian Tube

Description

Gross residual tumor after primary cytoreductive surgery is a prognostic factor for ovarian cancer and residual tumor volume after cytoreductive surgery is a prognostic factor for late-stage ovarian cancers.

The amount of ovarian tumor and the location of tumor remaining in the patient after initial ovarian or peritoneal cancer surgery are the most important prognostic factors for advanced disease. The intent of cytoreductive or debulking surgery—particularly for Stage III cancer—is to remove as much of the cancer in the pelvis and abdomen as possible so that chemotherapy will be more effective. The less tumor left behind, the more likely the patient will respond well to adjuvant hemotherapy. Information about residual tumor volume will be in the operative report.

Rationale

Residual Tumor Volume Post Cytoreduction is a Registry Data Collection Variable listed in AJCC. It was previously collected as Ovary, CS SSF # 3.

Additional Information

- **Source documents:** operative report, discharge summary, chemotherapy records (inpatient and outpatient)
- **Other names include** debulking, cytoreduction, residual tumor volume

For further information, refer to the **Ovary, Fallopian Tube, or Peritoneum** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Ovary, Fallopian Tube, and Primary Peritoneal Carcinoma*.

Notes

Note 1: Physician Statement

- Physician statement of residual tumor status after primary cytoreduction surgery can be used to code this data item when no other information is available.

Note 2: Optimal debulking surgery

- Optimal debulking is described as removal of all tumor except for residual nodules that measure no more than 1 centimeter (cm) in maximum diameter.

Note 3: Purpose of surgery

- The surgery to remove as much cancer in the pelvis and/or abdomen as possible, reducing the "bulk" of the cancer, is called **"debulking"** or **"cytoreductive"** surgery.
    - It is performed when there is widespread evidence of advanced stage of ovarian cancer with obvious spread to other organs outside the ovary, typically in the upper abdomen, intestines, the omentum (the fat pad suspended from the transverse colon like an apron), the diaphragm, or liver.

Note 4: Gross residual tumor

- Gross residual tumor after primary cytoreductive surgery is a prognostic factor that has been demonstrated in large studies. The best prognostic category after surgery includes those who are left with no gross residual tumor.
- Physicians should record the presence or absence of residual disease, if residual disease is observed, the size of the largest visible lesion should be documented

Code	Description
00	No gross residual tumor nodules
50	Residual tumor nodule(s) 1 centimeter (cm) or less
60	Residual tumor nodule(s) greater than 1 cm
70	Macroscopic residual tumor nodule(s), size not stated
80	Procedure described as optimal debulking and size of residual tumor nodule(s) not given
97	No cytoreductive surgery performed Non-invasive neoplasm (behavior /2)

Code	Description
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record Residual tumor status after cytoreductive surgery not assessed or unknown if assessed

00552: Primary Peritoneal Carcinoma

See **00551: Ovary**

- 3836: FIGO Stage
- 3818: CA-125 PreTx Interpretation
- 3921: Residual Tumor Volume Post Cytoreduction

00553: Fallopian Tube

See **00551: Ovary**

- 3836: FIGO Stage
- 3818: CA-125 PreTx Interpretation
- 3921: Residual Tumor Volume Post Cytoreduction

00560: Placenta

3836: FIGO Stage

Item Length: 2
NAACCR Item #: 3836
XML Parent-NAACCR ID: Tumor-figoStage
NAACCR Alternate Name: FIGO Stage Placenta
Active years: 2018+
Schema(s):

- 00560: Placenta

Description

Federation Internationale de Gynecologie et d'Obstetrique (FIGO) is a staging system for female reproductive cancers.

FIGO is a worldwide organization of obstetricians and gynecologists who maintain the international staging systems for female genital organs. The FIGO staging system has been adapted into the AJCC staging manual. FIGO uses Roman numerals and subscripts to define a stage. There is no T, N, or M descriptor with FIGO stage, only a stage group. For example, FIGO Stage IA is equivalent to T1a, FIGO Stage III can be either T3_ or N1, and FIGO Stage IV is M1.

FIGO stages vary by primary site, but the structure is similar throughout. FIGO no longer includes an in-situ stage (Tis, Stage 0). For in situ tumors, code the following

- Code 97: Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)

Note: Do not confuse FIGO stage with FIGO grade.

Rationale

FIGO stage is a Registry Data Collection Variable in AJCC for the female genital cancers. This data item was previously collected for the female genital cancers as: Vulva SSF #10, Vagina SSF #1, Cervix SSF #1, Corpus Carcinoma SSF #1, Corpus Sarcoma SSF #1, Ovary SSF #2, Fallopian Tube SSF #1, Peritoneum Female Genital SSF #1, and Placenta SSF #2.

Additional Information

Source documents: clinician's notes, consultant notes, radiation therapy notes

Notes

Note 1: Physician Statement

- There must be a statement about FIGO stage from the managing physician in order to code this data item.
    - Do not code FIGO stage based on the pathology report

- Do not code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do not assume it is a FIGO stage

Note 2: FIGO Stage vs FIGO Grade

- FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.
- Code FIGO grade in the grade fields

Note 3: Multiple FIGO stages

- If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

Note 4: FIGO Stage 0 (in-situ)

- The FIGO stage definitions do not include Stage 0 (Tis).
- Code 97 for any non-invasive neoplasm (behavior /2)

Code	Description
1	FIGO Stage I
2	FIGO Stage II
3	FIGO Stage III
4	FIGO Stage IV
97	Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage not assessed or unknown if assessed

00560: Placenta

3837: Gestational Prog Index

Item Length: 2
NAACCR Item #: 3837
XML Parent-NAACCR ID: Tumor-gestationalTrophoblasticPxIndex
NAACCR Alternate Name: Gestational Trophoblastic Prognostic Scoring Index
Active years: 2018+
Schema(s):

- 00560: Placenta

Description

Gestational Trophoblastic Prognostic Scoring Index, a score based on the FIGO-modified World Health Organization (WHO) Prognostic Scoring Index, is used to stratify women with gestational trophoblastic neoplasia in addition to the anatomical stage group. The risk score is appended to the anatomic stage.

The Prognostic Index is a non-anatomic risk factor scoring system that adds a fourth dimension to the stage grouping of gestational trophoblastic tumors (GTT) of the placenta. The score subcategorizes GTTs into low risk or high risk based on a point system. Code the clinician's statement of the total point value for the Prognostic Index in priority over the clinician's statement of risk. Registrars are NOT to calculate the score.

Rationale

This data item is required for prognostic stage grouping in AJCC 8th edition, Chapter 56 Gestational Trophoblastic Neoplasms. It was previously collected as Placenta, CS SSF # 1.

Notes

Note 1: Physician statement only

- This is based on clinician scoring only. The registrar is NOT to calculate the score based on available information.

Note 2: Prognostic Scoring Index

- The Prognostic Scoring Index is based on the following components
    - Age
    - Antecedent Pregnancy
    - Interval in Months from Index Pregnancy
    - Pretreatment Serum human chorionic gonadotropin (hCG) (mIU/ml)
    - Largest Tumor Size, Including Uterus

- Sites of Metastases
- Number of Metastases Identified
- Previous Failed Chemotherapy

Note 3: Score ranges

- The total score ranges from 00-25.

Note 4: Absence of clinician scoring

- If there is no clinician scoring, or a stated value is greater than 25, code X9.

Code	Description
00-25	Risk factor score
X9	Not documented in medical record Prognostic scoring index not assessed, or unknown if assessed

00570: Penis

See **00460: Merkel Cell Skin**

- 3830: Extranodal Extension Clinical
- 3833: Extranodal Extension Pathological

00580: Prostate

3920: PSA Lab Value

Item Length: 5
NAACCR Item #: 3920
XML Parent-NAACCR ID: Tumor-psaLabValue
NAACCR Alternate Name: PSA (Prostatic Specific Antigen) Lab Value
Active years: 2018+
Schema(s):

- 00580: Prostate

Description

PSA (Prostatic Specific Antigen) is a protein produced by cells of the prostate gland and is elevated in patients with prostate cancer. This data item pertains to PSA lab value.

Serum PSA is the most sensitive tumor marker for monitoring individuals with prostate cancer, including progression of disease and response to therapy. Although originally not intended to be a screening test, this relatively simple blood test has become a very common method of detecting new prostate cancer in its earliest stages. PSA can be totally negative when prostate cancer is found on digital rectal exam. In such cases, PSA will not be helpful in monitoring for recurrence.

- ***Note:*** Serum PSA is not the same as free PSA or precursor PSA—do not record values from either of these tests in this field.

Rationale

This data item is required for prognostic stage grouping in AJCC 8th edition, Chapter 58 Prostate. It was previously collected as Prostate, CS SSF #1.

Additional Information

Source documents: clinical laboratory report (blood or serum test), history, clinician note, pathology report

Other names include Prostate specific antigen, serum PSA, total PSA

Normal reference range varies by age and race of patient.

- The reference range should be shown on the clinical laboratory report. In general, normal findings are 0 – 4.0 nanograms per milliliter (ng/ml).
- Optimal normal range is 0 – 2.6 ng/ml. Nanograms per milliliter may be reported as micrograms per liter (mg/L or ug/L).

Notes

Note 1: Physician Statement

- Physician statement of prostatic specific antigen (PSA) pre-diagnosis can be used to code this data item when no other information is available.

Note 2: Staging related

- PSA is a prognostic factor required for AJCC staging. It affects the stage group in most cases.

Note 3: PSA criteria

- Diagnostic biopsy done
    - Record the last PSA lab value done prior to **AND** within 3 months of the diagnostic biopsy
- No diagnostic biopsy done (or unknown if diagnostic biopsy done)
    - Record the last PSA lab value done within 3 months of the date of diagnosis **or** additional confirmatory testing when no diagnostic biopsy is done, or unknown if diagnostic biopsy done
- ***Note: This is a change in the rules for Version 3.3 of the SSDI manual from the PSA had to be within 3 months and prior to the date of diagnosis AND within 3 months of the diagnostic biopsy***
    - *This change can be applied for cases diagnosed 2018+. There is no recommendation or expectation that registrars will review older cases.*
- ***Example 1:*** 5/17/25 PSA, 8.5. Date of diagnosis 6/6/25 based on MRI. Patient seeks a second opinion. Returns to physician in November 2025. 11/19/25 PSA, 8.6. 11/21/25 needle core biopsy.
    - Code PSA 8.6 based on the 11/19/25 PSA which was done prior to and within 3 months of the diagnostic biopsy
- ***Example 2:*** 6/4/25 PSA, 12.7. Additional PSA done 7/5/25, 10.6. Date of Diagnosis on 8/4/25 when the diagnostic biopsy was done.
    - Code PSA 10.6 based on the 7/5/25 PSA since that was the last PSA done prior to and within 3 months of the diagnostic biopsy
- ***Example 3:*** 4/15/25 PSA, 6.4. 5/2/25 MRI done, which confirms prostate cancer. No diagnostic biopsy done.

- Code PSA 6.4 based on the 4/15/25 PSA which was done within 3 months of the date of diagnosis and no diagnostic biopsy was done.

Note 4: PSA Adjustment

- A discrepancy between the PSA documented in the lab report and the PSA documented by the clinician may arise due to the clinician's adjusting the PSA value. Certain medications for benign prostatic hypertrophy (BPH) decrease the PSA.
  - If there is documentation by a clinician within the medical record of an adjusted PSA value, record the adjusted value.
  - The registrar does not adjust the PSA value based on BPH medication use.
  - If there is no documentation by a clinician within the medical record of an adjusted PSA value, record the PSA value provided.
  - The fact that an adjusted PSA value is being recorded should be documented in the Dx Proc - Lab Tests text field (NAACCR Item # 2550).

Coding Guidelines

1) Record to the nearest tenth in nanograms/milliliter (ng/ml) the last pre-diagnosis PSA lab value **prior to the diagnostic biopsy** of prostate and treatment.

2) The lab value may be recorded in the lab report, history and physical, or clinical statement in the pathology report, etc.

- A lab value expressed in micrograms per liter (ug/L) is e equivalent to the same value expressed in nanograms per milliliter (ng/ml)
- Record 0.1 when the lab results are stated as less than 0.1 ng/ml with no exact value.

3) A known lab value takes priority over codes XXX.2 and XXX.3.

- The lab value takes priority even if the physician documents the interpretation
- ***Example:*** Patient noted to have a PSA of 7.6. Physician notes that the value is elevated
  - Code 7.6 instead of XXX.3 (elevated)

Additional Examples

1) PSA of 11.56

- PSA 11.6. Per Coding Guideline #1, PSA is documented in tenths, not hundredths. Follow the general coding rules and round up (see Rounding Rules in the General instructions).

2) 12/19/2025: PSA 44.3, 3/11/2026: PSA 42.8, 5/1/2026: DRE positive for bilateral palpable nodularity, 5/5/2026: Casodex initiated without needle core biopsy

- PSA 42.8: Per Note #3, when diagnostic biopsy is not done, record the last PSA done within three months of the date of diagnosis.

3) 2/16/2025: PSA 18.6, adjusted PSA value due to patient taking Medication for benign prostatic hypertrophy

- PSA 18.6. Record the adjusted PSA value ONLY if documented by the clinician in the record
- Registrar does not adjust the PSA value due to BPH medication use

4) 12/13/25: PSA 8.2, 1/13/2026: PSA 7.3, 5/22/2026: Biopsy positive for adenocarcinoma

- PSA XXX.9. Neither PSA was within three months of the diagnostic biopsy and therefore they can't be used.

5) PSA 1,100 ng/ml

- XXX.1: XXX.1 is defined for values of 1,000 or greater

Code	Description
0.1	0.1 or less nanograms/milliliter (ng/ml) (Exact value to nearest tenth of ng/ml)
0.2-999.9	0.2 - 999.9 ng/ml (Exact value to nearest tenth of ng/ml)
XXX.1	1,000 ng/ml or greater
XXX.2	Lab value not available, physician states PSA is negative/normal
XXX.3	Lab value not available, physician states PSA is positive/elevated/high
XXX.7	Test ordered, results not in chart
XXX.9	Not documented in medical record PSA lab value not assessed or unknown if assessed

00580: Prostate

3898: Number of Cores Positive

Item Length: 2
NAACCR Item #: 3898
XML Parent-NAACCR ID: Tumor-numberOfCoresPositive
NAACCR Alternate Name: Number of Cores Positive
Active years: 2018+
Schema(s):

- 00580: Prostate

Description

This data item represents the number of positive cores documented in the pathology report from a needle core biopsy of the prostate gland.

Two data items record the number of positive and examined cores that are microscopically confirmed. A diagnostic procedure, such as a needle core biopsy, can take as many as 20 or more core biopsies to determine the extent of the cancer within the prostate.

Together these two data items can provide researchers with a surrogate estimate of the percentage of the prostate involved by tumor, if that figure is not stated in the pathology report

Number of Cores Positive must ALWAYS be less than or equal to Number of Cores Examined.

For Prostate, there are 2 data items that record information on the number of cores positive and examined. These related data items should be coded from the same test.

- 3897: Number of Cores Examined
- 3898: Number of Cores Positive

Note: Do not make assumptions about the number of cores positive or examined based on the number of areas biopsied within the prostate (laterality, lobes, apex, base, or mid-prostate). Several cores may be taken from each area.

Rationale

Number of Cores Positive is a Registry Data Collection Variable for AJCC. This data item was previously collected as Prostate, CS SSF #12.

Additional Information

Source documents: pathology reports from core needle biopsies

Other names for procedures include needle core biopsy, needle biopsy, core biopsy, prostate biopsy, sextant biopsy, transrectal biopsy, ultrasound-guided biopsy, transperineal prostate biopsy, triggered-needle biopsy

For further information, refer to the **Prostate** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Prostate*.

Notes

Note 1: Physician Statement

- Physician statement of Number of Cores Positive can be used to code this data item when there is no other information available, provided the priority order has been met (See Note 2).

Note 2: Priority order

- **Final diagnosis**
    - If the core biopsy pathology report contains a summary of the number of cores positive, use the summary provided
    - Do not include cores of other areas like seminal vesicles
- **Gross description**
    - Information from the gross description of the core biopsy pathology report can be used to code this data item when the final diagnosis is not available and the gross findings provide the actual number of cores and not pieces, chips, fragments, etc.
- **Physician statement (see Note 1)**

Note 3: Transperineal template-guided saturation biopsy (TTSB)

- A stereotactic prostate biopsy technique that typically produces 30 to 80 core biopsies. This is an alternative biopsy technique used for some high-risk patients including men with persistently elevated PSA, those who have atypia on prior prostate biopsies, or men with biopsies showing high grade prostatic intraepithelial neoplasia (PIN).

Note 4: If there is a targeted biopsy or a region of interest (ROI) biopsy done, count as 1 core positive/1 core examined, regardless of how many cores are actually taken from the targeted/ROI location.

- When doing a targeted or ROI biopsy, the region being biopsied is suspected of cancer (usually based on an MRI). Since the area is targeted, there will be many more cores removed. To record all these cores would be inflating the numbers.
    - ***Example:*** Standard/systematic core biopsy done, 2/16 cores positive, targeted biopsy done, 6/8 cores positive.
        - The total cores positive would be 2 + 1 (from the targeted biopsy), and total cores examined would be 16 + 1 (from the targeted biopsy).

- If there are multiple targeted or region of interest's biopsies done, count each one as 1/1 cores positive/examined.
    - ***Example:*** Standard/systematic core biopsy done, 3/8 cores positive. Two targeted biopsies done, one 5/11 cores positive and the other 7/10 cores positive.
        - The total cores positive would be 3 + 2 (for the two targeted biopsies) and total cores examined would be 8 + 2 (for the two targeted biopsies)

Note 5: Related data item

- The number of cores examined is recorded in the related data item 3897: Number of Cores Examined.

Coding Guidelines

1) Record the number of positive prostate core biopsies from the **first prostate core biopsy** diagnostic for cancer.

- Information from the first core biopsy is preferred since the physician is usually examining the entire prostate.
- If a second core biopsy is done, this is usually done on a specified area, so more cores will be found to be positive

2) Code 00 for all cores negative

3) Code 01-99 for the exact number of positive cores

4) Code X1 for 100 or more positive cores

5) Code X6 if positive cores are identified, and the number of positive cores are not specifically identified, this includes descriptions such as pieces, chips, or fragments

6) Code X9 when

- Not documented in the medical record
- Cores not evaluated (assessed)
- Unknown if Cores evaluated (assessed)

Code	Description
00	All examined cores negative
01-99	1 - 99 cores positive (Exact number of cores positive)
X1	100 or more cores positive

Code	Description
X6	Biopsy cores positive, number unknown
X7	No needle core biopsy performed
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record Number of cores positive not assessed or unknown if assessed

00580: Prostate

3897: Number of Cores Examined

Item Length: 2
NAACCR Item #: 3897
XML Parent-NAACCR ID: Tumor-numberOfCoresExamined
NAACCR Alternate Name: Number of Cores Examined
Active years: 2018+
Schema(s):

- 00580: Prostate

Description

This data item represents the number of cores examined as documented in the pathology report from a needle core biopsy of the prostate gland.

Two data items record the number of positive and examined cores that are microscopically confirmed. A diagnostic procedure, such as a needle core biopsy, can take as many as 20 or more core biopsies to determine the extent of the cancer within the prostate.

Together these two data items can provide researchers with a surrogate estimate of the percentage of the prostate involved by tumor, if that figure is not stated in the pathology report

Number of Cores Positive must ALWAYS be less than or equal to Number of Cores Examined.

For Prostate, there are 2 data items that record information on the number of cores positive and examined. These related data items should be coded from the same test.

- 3897: Number of Cores Examined
- 3898: Number of Cores Positive

Note: Do not make assumptions about the number of cores positive or examined based on the number of areas biopsied within the prostate (laterality, lobes, apex, base, or mid-prostate). Several cores may be taken from each area.

Rationale

Number of Cores Examined is a Registry Data Collection Variable for AJCC. This data item was previously collected as Prostate, CS SSF #13.

Additional Information

Source documents: pathology reports from core needle biopsies

Other names for procedures include needle core biopsy, needle biopsy, core biopsy, prostate biopsy, sextant biopsy, transrectal biopsy, ultrasound-guided biopsy, transperineal prostate biopsy, triggered-needle biopsy

For further information, refer to the **Prostate** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Prostate*.

Notes

Note 1: Physician Statement

- Physician statement of Number of Cores Examined can be used to code this data item when there is no other information available, provided the priority order has been met (See Note 2).

Note 2: Priority order

- **Final diagnosis**
    - If the core biopsy pathology report contains a summary of the number of cores examined from all specimens, use the summary provided
    - Do not include cores of other areas like seminal vesicles
- **Gross description**
    - Information from the gross description of the core biopsy pathology report can be used to code this data item when the final diagnosis is not available and the gross findings provide the actual number of cores and not pieces, chips, fragments, etc.
- **Physician statement (see Note 1)**

Note 3: Transperineal template-guided saturation biopsy (TTSB)

- A stereotactic prostate biopsy technique that typically produces 30 to 80 core biopsies. This is an alternative biopsy technique used for some high-risk patients including men with persistently elevated PSA, those who have atypia on prior prostate biopsies, or men with biopsies showing high grade prostatic intraepithelial neoplasia (PIN).

Note 4: If there is a targeted biopsy or a region of interest (ROI) biopsy done, count as 1 core positive/1 core examined, regardless of how many cores are actually taken from the targeted/ROI location.

- When doing a targeted or ROI biopsy, the region being biopsied is suspected of cancer (usually based on an MRI). Since the area is targeted, there will be many more cores removed. To record all these cores would be inflating the numbers.
    - ***Example:*** Standard/systematic core biopsy done, 2/16 cores positive, targeted biopsy done, 6/8 cores positive.
        - The total cores positive would be 2 + 1 (from the targeted biopsy), and total cores examined would be 16 + 1 (from the targeted biopsy).

- If there are multiple targeted or region of interest's biopsies done, count each one as 1/1 cores positive/examined.
    - ***Example:*** Standard/systematic core biopsy done, 3/8 cores positive. Two targeted biopsies done, one 5/11 cores positive and the other 7/10 cores positive.
        - The total cores positive would be 3 + 2 (for the two targeted biopsies) and total cores examined would be 8 + 2 (for the two targeted biopsies)

Note 5: Related data item

- The number of cores positive are recorded in the related data item 3898: Number of Cores Positive.

Coding Guidelines

1) Record the number of positive prostate core biopsies from the **first prostate core biopsy** diagnostic for cancer.

- Information from the first core biopsy is preferred since the physician is usually examining the entire prostate.
- If a second core biopsy is done, this is usually done on a specified area, so more cores will be found to be positive

2) Code 01-99 for the exact number of examined cores

3) Code X1 for 100 or more examined cores

4) Code X6 for examined cores, and the number of examined cores are not specifically identified, this includes descriptions such as pieces, chips, or fragments

5) Code X9 when

- Not documented in the medical record
- Cores not evaluated (assessed)
- Unknown if Cores evaluated (assessed)

Code	Description
01-99	1 - 99 cores examined (Exact number of cores examined)
X1	100 or more cores examined
X6	Biopsy cores examined; number unknown
X7	No needle core biopsy performed

Code	Description
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record Number of cores examined not assessed or unknown if assessed

00580: Prostate

3838: Gleason Patterns Clinical

Item Length: 2
NAACCR Item #: 3838
XML Parent-NAACCR ID: Tumor-gleasonPatternsClinical
NAACCR Alternate Name: Gleason Patterns Clinical
Active years: 2018+
Schema(s):

- 00580: Prostate

Description

Prostate cancers are graded using Gleason score or pattern. This data item represents the Gleason primary and secondary patterns from needle core biopsy or TURP.

The pathologist determines the Gleason patterns by looking at the prostate tissue under the microscope. The pathologist assigns a grade to the most predominant pattern (largest surface area of involvement, more than 50% of tissue) and a grade for the secondary pattern (second most predominant) based on published Gleason criteria. When a patient undergoes radical prostatectomy, the pathologist may look for a third or tertiary pattern in the specimen. When Gleason pattern 5 is present as a tertiary pattern, its presence should be indicated in the pathology report, as a high Gleason pattern appears to be an indicator for worse outcome (shortened time to recurrence). Studies indicate that a Gleason score 7, with tertiary pattern 5, is associated with a worse prognosis than without tertiary pattern 5 and is similar to the prognosis for Gleason score 8 – 10.

- For example, in a specimen where the primary Gleason pattern is 3, the secondary is 4 and there is less than 5% Gleason 5, the report should indicate a Gleason score of 7 (3+4) with tertiary Gleason pattern 5. Gleason grades (patterns) range from 1 (small, uniform gland) to 5 (lack of glands, sheets of cells.)

For the Gleason Patterns data items, there is a long list of codes and definitions in the table, but it may be easier to assign a value if you understand the structure of the code. This is a two-digit field.

- First digit is the Gleason primary pattern value
- Second digit is the Gleason secondary pattern value

The Gleason system for grading prostate cancer is the one recommended by the AJCC and College of American Pathologists. The following related data items are used to collect information on Gleason.

Rationale

Gleason Patterns Pathological is a Registry Data Collection Variable for AJCC. This data item was previously collected as Prostate, CS SSF #9.

Additional Information

Source documents: pathology reports from needle biopsies, transurethral resection of prostate/bladder, or simple prostatectomy that contains prostate tissue

For further information, refer to the **Prostate** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Prostate*.

Notes

Note 1: Physician Statement

- Physician statement of Gleason Patterns Clinical can be used to code this data item when there is no other information available.

Note 2: Procedures

- Code the Gleason Patterns Clinical from a needle core biopsy, trans rectal ultrasound (TRUS) guided biopsy, transurethral resection of prostate (TURP), and/or simple prostatectomy in this field.
- Gleason primary and secondary patterns provided for any prostate tissue identified from a transurethral resection of a bladder tumor (TURBT) specimen can also be used in this field

Note 3: Neoadjuvant Treatment

- Code the Gleason primary and secondary patterns prior to neoadjuvant treatment.

Note 4: Gleason Grading

- Usually, prostate cancers are graded using Gleason score or pattern. Gleason grading for prostate primaries is based on a 5-component system (5 histologic patterns). Prostatic cancer generally shows two main histologic patterns. The primary pattern, the pattern occupying greater than 50% of the cancer, is usually indicated by the first number of the Gleason grade, and the secondary pattern is usually indicated by the second number. These two numbers are added together to create a pattern score.
- If there are two numbers, assume that they refer to two patterns (the first number being the primary pattern and the second number the secondary pattern), and sum them to obtain the score.
- If only one number is given, and it is less than or equal to 5, assume that it describes a pattern (since scores of 5 or less would reflect Primary or Secondary Pattern Scores of 1

or 2). Code the number as the primary pattern and code the secondary pattern as Unknown.

  - For ***example,*** if only one number is given and it is a 3, code "39" for Gleason Patterns and "X9" for Gleason Score.

- If only one number is given, and it is greater than 5, assume that it is a score.

  - For ***example,*** if only one number is given, and it is a 7, code "X6" for Gleason Patterns and "07" for Gleason Score.

- If the pathology report specifies a specific number out of a total of 10, the first number given is the score.

  - For ***example,*** if the pathology report says Gleason 7/10, code "07' for Gleason Score and "X6" for Gleason Patterns.

Note 5: Different patterns

- If different patterns are documented on multiple needle core biopsies, code the pattern that reflects the highest or most aggressive score regardless of if the pathologist provides an overall pattern in a final summary. If different patterns equal the same high score, give priority to the highest primary pattern and then the highest secondary pattern.

  - For ***example,*** both Gleason 3, 4 and Gleason 4, 3 equal Gleason score 7; code 43. Do not mix patterns from multiple specimens.

Note 6: Multiple procedures

- If multiple procedures are performed (e.g., needle core biopsy, trans rectal ultrasound (TRUS) guided biopsy, transurethral resection of prostate (TURP), and/or simple prostatectomy), code the pattern that reflects the highest score.

Note 7: Related data item

- The clinical score is recorded in the related data item 3840: Gleason Score Clinical.

<u>Coding Guidelines</u>

1) Code X6 If the only information available is the Gleason Score

2) Code X7 if no needle core biopsy/TURP is done

3) Code X9 when only Grade Group is available, do not infer Gleason Primary and Secondary Pattern from Grade group

Examples

1) Gleason 3+3 = Patterns 33, Score 06

2) Gleason 4+3 = Patterns 43, Score 07

3) Gleason 4 (Assume a number in the range 2-5 is a primary pattern and code unknown (9) in the second digit) = Patterns 49, Score X9

4) Gleason 7 (Assume a number in the range 6-10 is a score) = Pattern X6, Score 07

5) Gleason 10 (only combination of values that equals 10 is 5+5) = Pattern 55, Score 10

6) Needle core biopsy or TURP not done = Patterns X7, Score X7

7) Gleason not done, or unknown if done = Patterns X9, Score X9

Code	Description
11	Primary pattern 1, secondary pattern 1
12	Primary pattern 1, secondary pattern 2
13	Primary pattern 1, secondary pattern 3
14	Primary pattern 1, secondary pattern 4
15	Primary pattern 1, secondary pattern 5
19	Primary pattern 1, secondary pattern unknown
21	Primary pattern 2, secondary pattern 1
22	Primary pattern 2, secondary pattern 2
23	Primary pattern 2, secondary pattern 3
24	Primary pattern 2, secondary pattern 4
25	Primary pattern 2, secondary pattern 5
29	Primary pattern 2, secondary pattern unknown
31	Primary pattern 3, secondary pattern 1
32	Primary pattern 3, secondary pattern 2
33	Primary pattern 3, secondary pattern 3
34	Primary pattern 3, secondary pattern 4
35	Primary pattern 3, secondary pattern 5
39	Primary pattern 3, secondary pattern unknown

Code	Description
41	Primary pattern 4, secondary pattern 1
42	Primary pattern 4, secondary pattern 2
43	Primary pattern 4, secondary pattern 3
44	Primary pattern 4, secondary pattern 4
45	Primary pattern 4, secondary pattern 5
49	Primary pattern 4, secondary pattern unknown
51	Primary pattern 5, secondary pattern 1
52	Primary pattern 5, secondary pattern 2
53	Primary pattern 5, secondary pattern 3
54	Primary pattern 5, secondary pattern 4
55	Primary pattern 5, secondary pattern 5
59	Primary pattern 5, secondary pattern unknown
X6	TURP and/or Biopsy done, primary pattern unknown, secondary pattern unknown
X7	No needle core biopsy/TURP performed
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record Gleason Patterns Clinical not assessed or unknown if assessed Unknown whether TURP and/or Biopsy done

00580: Prostate

3840: Gleason Score Clinical

Item Length: 2
NAACCR Item #: 3840
XML Parent-NAACCR ID: Tumor-gleasonScoreClinical
NAACCR Alternate Name: Gleason Score Clinical
Active years: 2018+
Schema(s):

- 00580: Prostate

Description

This data item records the Gleason score based on adding the values for primary and secondary patterns in Needle Core Biopsy or TURP.

The Gleason system for grading prostate cancer is the one recommended by the AJCC and College of American Pathologists. The following related data items are used to collect information on Gleason.

- 3838: Gleason Patterns Clinical
- 3839: Gleason Patterns Pathological
- 3840: Gleason Score Clinical
- 3841: Gleason Score Pathological
- 3842: Gleason Tertiary Pattern

The Gleason score is the sum of the values of the Gleason primary and secondary patterns. A low Gleason score means the cancer tissue is similar to normal prostate tissue and the tumor is less likely to spread; a high Gleason score means the cancer tissue is very different from normal and the tumor is more likely to spread.

Rationale

Gleason Score Clinical is a Registry Data Collection Variable for AJCC. This data item was previously collected as Prostate, CS SSF #8.

Additional Information

Source documents: pathology reports from needle biopsies, transurethral resection of prostate/bladder, or simple prostatectomy that contains prostate tissue

For further information, refer to the **Prostate** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Prostate.*

Notes

Note 1: Physician Statement

- Physician statement of Gleason Score Clinical can be used to code this data item when there is no other information available.

Note 2: Procedures

- Code the Gleason Score Clinical from a needle core biopsy, trans rectal ultrasound (TRUS) guided biopsy, transurethral resection of prostate (TURP), and/or simple prostatectomy in this field.
- Gleason primary and secondary patterns provided for any prostate tissue identified from a transurethral resection of a bladder tumor (TURBT) specimen can also be used in this field.

Note 3: Neoadjuvant Treatment

- Code the Gleason primary and secondary patterns prior to neoadjuvant treatment.

Note 4: Gleason Grading

- Usually, prostate cancers are graded using Gleason score or pattern. Gleason grading for prostate primaries is based on a 5-component system (5 histologic patterns). Prostatic cancer generally shows two main histologic patterns. The primary pattern, the pattern occupying greater than 50% of the cancer, is usually indicated by the first number of the Gleason grade, and the secondary pattern is usually indicated by the second number. These two numbers are added together to create a pattern score.
- If there are two numbers, assume that they refer to two patterns (the first number being the primary pattern and the second number the secondary pattern), and sum them to obtain the score.
- If only one number is given, and it is less than or equal to 5, assume that it describes a pattern (since scores of 5 or less would reflect Primary or Secondary Pattern Scores of 1 or 2). Code the number as the primary pattern and code the secondary pattern as Unknown.
    - For ***example,*** if only one number is given and it is a 3, code “39” for Gleason Patterns and “X9” for Gleason Score.
- If only one number is given, and it is greater than 5, assume that it is a score.
    - For ***example,*** if only one number is given, and it is a 7, code “X6” for Gleason Patterns and “07” for Gleason Score.

- If the pathology report specifies a specific number out of a total of 10, the first number given is the score.
    - For ***example***, if the pathology report says Gleason 7/10, code "07' for Gleason Score and "X6" for Gleason Patterns.

Note 5: Multiple procedures

- If multiple procedures are performed (e.g., needle core biopsy, trans rectal ultrasound (TRUS) guided biopsy, transurethral resection of prostate (TURP), and/or simple prostatectomy), code the pattern that reflects the highest score.

Note 6: Related data item

- Record the Gleason score based on the addition of the primary and secondary patterns coded in the related data item 3838: Gleason Patterns Clinical.

Coding Guidelines

1) Code X7 if no needle core biopsy/TURP is done

2) Code X9 when only Grade Group is available

Examples

1) Gleason 3+3 = Patterns 33, Score 06

2) Gleason 4+3 = Patterns 43, Score 07

3) Gleason 4 (Assume a number in the range 2-5 is a primary pattern and code unknown (9) in the second digit) = Patterns 49, Score X9

4) Gleason 7 (Assume a number in the range 6-10 is a score) = Pattern X6, Score 07

5) Gleason 10 (only combination of values that equals 10 is 5+5) = Pattern 55, Score 10

6) Needle core biopsy or TURP not done = Patterns X7, Score X7

7) Gleason not done, or unknown if done = Patterns X9, Score X9

Code	Description
02	Gleason score 2
03	Gleason score 3
04	Gleason score 4
05	Gleason score 5
06	Gleason score 6

Code	Description
07	Gleason score 7
08	Gleason score 8
09	Gleason score 9
10	Gleason score 10
X7	No needle core biopsy/TURP performed
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record Gleason Score Clinical not assessed or unknown if assessed

00580: Prostate

3839: Gleason Patterns Pathological

Item Length: 2
NAACCR Item #: 3839
XML Parent-NAACCR ID: Tumor-gleasonPatternsPathological
NAACCR Alternate Name: Gleason Patterns Pathological
Active years: 2018+
Schema(s):

- 00580: Prostate

Description

Prostate cancers are graded using Gleason score or pattern. This data item represents the Gleason primary and secondary patterns from a radical prostatectomy or autopsy.

The pathologist determines the Gleason patterns by looking at the prostate tissue under the microscope. The pathologist assigns a grade to the most predominant pattern (largest surface area of involvement, more than 50% of tissue) and a grade for the secondary pattern (second most predominant) based on published Gleason criteria. When a patient undergoes radical prostatectomy, the pathologist may look for a third or tertiary pattern in the specimen. When Gleason pattern 5 is present as a tertiary pattern, its presence should be indicated in the pathology report, as a high Gleason pattern appears to be an indicator for worse outcome (shortened time to recurrence). Studies indicate that a Gleason score 7, with tertiary pattern 5, is associated with a worse prognosis than without tertiary pattern 5 and is similar to the prognosis for Gleason score 8 – 10.

- For example, in a specimen where the primary Gleason pattern is 3, the secondary is 4 and there is less than 5% Gleason 5, the report should indicate a Gleason score of 7 (3+4) with tertiary Gleason pattern 5. Gleason grades (patterns) range from 1 (small, uniform gland) to 5 (lack of glands, sheets of cells.)

For the Gleason Patterns data items, there is a long list of codes and definitions in the table, but it may be easier to assign a value if you understand the structure of the code. This is a two-digit field.

- First digit is the Gleason primary pattern value
- Second digit is the Gleason secondary pattern value

The Gleason system for grading prostate cancer is the one recommended by the AJCC and College of American Pathologists. The following related data items are used to collect information on Gleason.

Rationale

Gleason Patterns Pathological is a Registry Data Collection Variable for AJCC. This data item was previously collected as Prostate, CS SSF #9.

Additional Information

Source documents: pathology report from a radical prostatectomy or autopsy report

For further information, refer to the **Prostate** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Prostate*.

Notes

Note 1: Physician Statement

- Physician statement of Gleason Patterns Pathological can be used to code this data item when there is no other information available.

Note 2: Procedures

- Code the Gleason primary and secondary patterns from a radical prostatectomy or autopsy only in this field. Unlike Grade Group Pathological, do not include patterns from tissues taken prior to prostatectomy.
    - Code results from a transurethral resection of prostate (TURP) or simple prostatectomy in Gleason Patterns Clinical

Note 3: Gleason Grading

- Usually, prostate cancers are graded using Gleason score or pattern. Gleason grading for prostate primaries is based on a 5-component system (5 histologic patterns). Prostatic cancer generally shows two main histologic patterns. The primary pattern, the pattern occupying greater than 50% of the cancer, is usually indicated by the first number of the Gleason grade, and the secondary pattern is usually indicated by the second number. These two numbers are added together to create a pattern score.
- If there are two numbers, assume that they refer to two patterns (the first number being the primary pattern and the second number the secondary pattern), and sum them to obtain the score.
- If only one number is given, and it is less than or equal to 5, assume that it describes a pattern (since scores of 5 or less would reflect Primary or Secondary Pattern Scores of 1 or 2). Code the number as the primary pattern and code the secondary pattern as Unknown.
    - For ***example***, if only one number is given, and it is a 3, code “39” for Gleason Patterns and “X9” for Gleason Score.
- If only one number is given, and it is greater than 5, assume that it is a score.

- For ***example***, if only one number is given, and it is a 7, code "X6" for Gleason Patterns and "07" for Gleason Score.

- If the pathology report specifies a specific number out of a total of 10, the first number given is the score.
    - For ***example,*** if the pathology report says Gleason 7/10, code "07' for Gleason Score and "X6" for Gleason Patterns.

Note 4: Different patterns

- If different patterns are documented on multiple specimens, code the pattern that reflects the highest or most aggressive score regardless of if the pathologist provides an overall pattern in a final summary. If different patterns equal the same high score, give priority to the highest primary pattern and then the highest secondary pattern.

Note 5: Tertiary pattern

- If a tertiary pattern is documented on prostatectomy or autopsy, code in the related data item 3842: Gleason Tertiary Pattern.

Note 6: Neoadjuvant therapy

- Code X9 when neoadjuvant therapy was given

Note 7: Active surveillance, then Radical Prostatectomy

- Code X9 when first course of treatment is active surveillance, but a radical prostatectomy is done at a later date due to disease progression or the patient changed their mind.

Note 8: Related data item

- The pathological score is recorded in the related data item 3841: Gleason Score Pathological.

<u>Coding Guidelines</u>

1) Code X6 If the only information available is the Gleason Score

2) Code X7 if no radical prostatectomy or autopsy is done

3) Code X9 when only Grade Group is available

Examples

1) Gleason 3+3 = Patterns 33, Score 06

2) Gleason 4+3 = Patterns 43, Score 07

3) Gleason 4 (Assume a number in the range 2-5 is a primary pattern and code unknown (9) in the second digit) = Patterns 49, Score X9

4) Gleason 7 (Assume a number in the range 6-10 is a score) = Pattern X6, Score 07

5) Gleason 10 (only combination of values that equals 10 is 5+5) = Pattern 55, Score 10

6) Needle core biopsy or TURP not done = Patterns X7, Score X7

7) Gleason not done, or unknown if done = Patterns X9, Score X9

Code	Description
11	Primary pattern 1, secondary pattern 1
12	Primary pattern 1, secondary pattern 2
13	Primary pattern 1, secondary pattern 3
14	Primary pattern 1, secondary pattern 4
15	Primary pattern 1, secondary pattern 5
19	Primary pattern 1, secondary pattern unknown
21	Primary pattern 2, secondary pattern 1
22	Primary pattern 2, secondary pattern 2
23	Primary pattern 2, secondary pattern 3
24	Primary pattern 2, secondary pattern 4
25	Primary pattern 2, secondary pattern 5
29	Primary pattern 2, secondary pattern unknown
31	Primary pattern 3, secondary pattern 1
32	Primary pattern 3, secondary pattern 2
33	Primary pattern 3, secondary pattern 3
34	Primary pattern 3, secondary pattern 4
35	Primary pattern 3, secondary pattern 5
39	Primary pattern 3, secondary pattern unknown
41	Primary pattern 4, secondary pattern 1

Code	Description
42	Primary pattern 4, secondary pattern 2
43	Primary pattern 4, secondary pattern 3
44	Primary pattern 4, secondary pattern 4
45	Primary pattern 4, secondary pattern 5
49	Primary pattern 4, secondary pattern unknown
51	Primary pattern 5, secondary pattern 1
52	Primary pattern 5, secondary pattern 2
53	Primary pattern 5, secondary pattern 3
54	Primary pattern 5, secondary pattern 4
55	Primary pattern 5, secondary pattern 5
59	Primary pattern 5, secondary pattern unknown
X6	Radical prostatectomy done, primary pattern unknown, secondary pattern unknown
X7	No radical prostatectomy/autopsy performed
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record Gleason Patterns Pathological not assessed or unknown if assessed Unknown if radical prostatectomy done

00580: Prostate

3841: Gleason Score Pathological

Item Length: 2
NAACCR Item #: 3841
XML Parent-NAACCR ID: Tumor-gleasonScorePathological
NAACCR Alternate Name: Gleason Score Pathological
Active years: 2018+
Schema(s):

- 00580: Prostate

Description

This data item records the Gleason score based on adding the values for primary and secondary patterns from a radical prostatectomy or autopsy.

The Gleason system for grading prostate cancer is the one recommended by the AJCC and College of American Pathologists. The following related data items are used to collect information on Gleason.

- 3838: Gleason Patterns Clinical
- 3839: Gleason Patterns Pathological
- 3840: Gleason Score Clinical
- 3841: Gleason Score Pathological
- 3842: Gleason Tertiary Pattern

The Gleason score is the sum of the values of the Gleason primary and secondary patterns. A low Gleason score means the cancer tissue is similar to normal prostate tissue and the tumor is less likely to spread; a high Gleason score means the cancer tissue is very different from normal and the tumor is more likely to spread.

Rationale

Gleason Score Pathological is a Registry Data Collection Variable for AJCC. This data item was previously collected as Prostate, CS SSF #10.

Additional Information

Source documents: pathology report from a radical prostatectomy or autopsy report

For further information, refer to the **Prostate** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Prostate*.

Notes

Note 1: Physician Statement

- Physician statement of Gleason Score Pathological can be used to code this data item when there is no other information available.

Note 2: Procedures

- Code the Gleason Score Pathological from a radical prostatectomy or autopsy only in this field. Unlike Grade Group Pathological, do not include patterns from tissues taken prior to a radical prostatectomy.
    - Code results from a transurethral resection of prostate (TURP) or simple prostatectomy in Gleason Score Clinical

Note 3: Gleason Grading

- Usually, prostate cancers are graded using Gleason score or pattern. Gleason grading for prostate primaries is based on a 5-component system (5 histologic patterns). Prostatic cancer generally shows two main histologic patterns. The primary pattern, the pattern occupying greater than 50% of the cancer, is usually indicated by the first number of the Gleason grade, and the secondary pattern is usually indicated by the second number. These two numbers are added together to create a pattern score, ranging from 2 to 10.
- If there are two numbers, assume that they refer to two patterns (the first number being the primary pattern and the second number the secondary pattern), and sum them to obtain the score.
- If only one number is given, and it is less than or equal to 5, code the total score to X9, unknown or no information.
- If only one number is given, and it is greater than 5, assume that it is a score and code as stated.
- If the pathology report specifies a specific number out of a total of 10, the first number given is the score.
- ***Example:*** The pathology report says Gleason 3/10. The Gleason score would be 3 and coded as 03.

Note 4: Neoadjuvant therapy

- Code X9 when neoadjuvant therapy was given

Note 5: Active surveillance, then Radical Prostatectomy

- Code X9 when first course of treatment is active surveillance, but a radical prostatectomy is done at a later date due to disease progression or the patient changed their mind

Note 6: Related data item

- Record the Gleason score based on the addition of the primary and secondary patterns coded in the related data item 3839: Gleason Patterns Pathological.

Coding Guidelines

1) Code X6 If the only information available is the Gleason Score

2) Code X7 if no radical prostatectomy or autopsy is done

3) Code X9 when only Grade Group is available

Examples

1) Gleason 3+3 = Patterns 33, Score 06

2) Gleason 4+3 = Patterns 43, Score 07

3) Gleason 4 (Assume a number in the range 2-5 is a primary pattern and code unknown (9) in the second digit) = Patterns 49, Score X9

4) Gleason 7 (Assume a number in the range 6-10 is a score) = Pattern X6, Score 07

5) Gleason 10 (only combination of values that equals 10 is 5+5) = Pattern 55, Score 10

6) Needle core biopsy or TURP not done = Patterns X7, Score X7

7) Gleason not done, or unknown if done = Patterns X9, Score X9

Code	Description
02	Gleason score 2
03	Gleason score 3
04	Gleason score 4
05	Gleason score 5
06	Gleason score 6
07	Gleason score 7
08	Gleason score 8

Code	Description
09	Gleason score 9
10	Gleason score 10
X7	No radical prostatectomy/autopsy performed
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record Gleason Score Pathological not assessed or unknown if assessed Unknown if radical prostatectomy done

00580: Prostate

3842: Gleason Tertiary Pattern

Item Length: 2
NAACCR Item #: 3842
XML Parent-NAACCR ID: Tumor-gleasonTertiaryPattern
NAACCR Alternate Name: Gleason Tertiary Pattern
Active years: 2018+
Schema(s):

- 00580: Prostate

Description

Prostate cancers are graded using Gleason score or pattern. This data item represents the tertiary pattern value from a radical prostatectomy or autopsy.

A high Gleason Tertiary Pattern appears to be an indication for a worse outcome.

The Gleason system for grading prostate cancer is the one recommended by the AJCC and College of American Pathologists. The following related data items are used to collect information on Gleason.

- 3838: Gleason Patterns Clinical
- 3839: Gleason Patterns Pathological
- 3840: Gleason Score Clinical
- 3841: Gleason Score Pathological
- 3842: Gleason Tertiary Pattern

Rationale

Tertiary Gleason pattern on prostatectomy is a Registry Data Collection Variable for AJCC. This data item was previously collected as Prostate, CS SSF #11.

Additional Information

Source documents: pathology report from a radical prostatectomy or autopsy report

For further information, refer to the **Prostate** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Prostate*.

Notes

Note 1: Physician Statement

- Physician statement of Gleason tertiary pattern can be used to code this data item when there is no other information available.

Note 2: Procedures

- Record the tertiary pattern documented on radical prostatectomy or autopsy only. Record the tertiary pattern prior to neoadjuvant treatment.
- If a tertiary pattern is documented on needle core biopsy or transurethral resection of prostate (TURP), it should be disregarded.
- Do not code the tertiary pattern on radical prostatectomy or autopsy in Gleason Patterns Pathological.

Note 3: Tertiary Patterns 1 and 2

- The CAP Prostate Protocol does not include Patterns 1 and 2 for Tertiary Pattern.

Note 4: Neoadjuvant therapy

- Code X9 when neoadjuvant therapy was given

Note 5: Active surveillance, then Radical Prostatectomy

- Code X9 when first course of treatment is active surveillance, but a radical prostatectomy is done at a later date due to disease progression or the patient changed their mind

Code	Description
10	Tertiary pattern 1
20	Tertiary pattern 2
30	Tertiary pattern 3
40	Tertiary pattern 4
50	Tertiary pattern 5
X7	No radical prostatectomy/autopsy performed
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record Gleason Tertiary Pattern not assessed or unknown if assessed

00590: Testis

3923: S Category Clinical

Item Length: 1
NAACCR Item #: 3923
XML Parent-NAACCR ID: Tumor-sCategoryClinical
NAACCR Alternate Name: Testis Serum Markers (S) Clinical (pre orchiectomy)
Active years: 2018+
Schema(s):

- 00590: Testis

Description

S Category Clinical combines the results of pre-orchiectomy Alpha Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG) and Lactate Dehydrogenase (LDH) into a summary S value.

In addition to T, N, and M, the S category is collected to stage Testicular cancers. There are three factors that make up the S stage: alpha-fetoprotein (AFP), beta-human chorionic gonadotropin (beta-hCG), and lactase dehydrogenase (LDH). These play an important role as serum tumor markers in the staging and monitoring of germ cell tumors and should be measured prior to removing the involved testicle. For patients with nonseminomas, the degree of tumor-marker elevation after the cancerous testicular has been removed is one of the most significant predictors of prognosis. Serum tumor markers are also very useful for monitoring all stages of nonseminomas and for monitoring metastatic seminomas because elevated marker levels are often the earliest sign of relapse.

There are several related data items pertinent to the collection of these variables.

For clinical staging

- 3807: AFP Pre-Orchiectomy Lab Value
- 3808: AFP Pre-Orchiectomy Range
- 3848: hCG Pre-Orchiectomy Lab Value
- 3849: hCG Pre-Orchiectomy Range
- 3868: LDH Pre-Orchiectomy Range
- 3923: S Category Clinical

Rationale

S Category Clinical is required for prognostic stage grouping in Chapter 59 Testis. It is a new data item for cases diagnosed 1/1/2018+.

Notes

Note 1: Physician Statement

- Code the S category as described by the physician. If the S category determined by available lab values or calculated by vendor software differs from the physician statement of the S category, the physician's statement takes precedence.

Note 2: Pre-orchiectomy S category

- Code the pre-orchiectomy S category (Clinical S) according to the table below. This table is also available in AJCC 8th edition, Chapter 59, Testis.
- For AFP, a lab value expressed in micrograms per liter (ug/L) is equivalent to the same value expressed in nanograms per milliliter (ng/ml).

Note 3: Clinical Stage

- Clinical stage values are those based on physician statement or lab values at diagnosis, prior to orchiectomy, and prior to any systemic treatment.

Note 4: AFP, hCG, LDH

- All three lab values are needed for S0-S1. Only one elevated test is needed to assign S2-3. If any individual test is not available and none of the available test results meet the S2-3 criterion for that test, assign code 9 (SX).

Code	Description
0	S0: Marker study levels within normal levels
1	S1: At least one of these values is elevated AND LDH less than 1.5 x N* AND hCG (mIU/L) less than 5,000 AND AFP (ng/mL) less than 1,000
2	S2: LDH 1.5 x N* to 10 x N* OR hCG (mIU/L) 5,000 to 50,000 OR AFP (ng/mL) 1,000 to 10,000
3	S3: Only one elevated test is needed LDH greater than 10 x N* OR hcG (mIU/mL) greater than 50,000 OR AFP (ng/mL) greater than 10,000
9	SX: Not documented in medical record S Category Clinical not assessed or unknown if assessed

00590: Testis

3924: S Category Pathological

Item Length: 1
NAACCR Item #: 3924
XML Parent-NAACCR ID: Tumor-sCategoryPathological
NAACCR Alternate Name: Testis Serum Markers (S) Pathological (post-orchiectomy)
Active years: 2018+
Schema(s):

- 00590: Testis

Description

S Category Pathological combines the results of post-orchiectomy Alpha Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG) and Lactate Dehydrogenase (LDH) into a summary S value.

In addition to T, N, and M, the S category is collected to stage Testicular cancers. There are three factors that make up the S stage: alpha-fetoprotein (AFP), beta-human chorionic gonadotropin (beta-hCG), and lactase dehydrogenase (LDH). These play an important role as serum tumor markers in the staging and monitoring of germ cell tumors and should be measured prior to removing the involved testicle. For patients with nonseminomas, the degree of tumor-marker elevation after the cancerous testicular has been removed is one of the most significant predictors of prognosis. Serum tumor markers are also very useful for monitoring all stages of nonseminomas and for monitoring metastatic seminomas because elevated marker levels are often the earliest sign of relapse.

There are several related data items pertinent to the collection of these variables.

For pathological staging

- 3805: AFP Post-Orchiectomy Lab Value
- 3806: AFP Post-Orchiectomy Range
- 3846: hCG Post-Orchiectomy Lab Value
- 3847: hCG Post-Orchiectomy Range
- 3867: LDH Post-Orchiectomy Range
- 3924: S Category Pathological

Rationale

S Category Pathological is required for prognostic stage grouping in AJCC 8th edition, Chapter 59 Testis. It is a new data item for cases diagnosed 1/1/2018+.

Notes

Note 1: Physician Statement

- Code the S category as described by the physician. If the S category determined by available lab values or calculated by vendor software differs from the physician statement of the S category, the physician's statement takes precedence.

Note 2: Post-orchiectomy S Category

- Code the post-orchiectomy S category (Pathological S) according to the table below. This table is also available in AJCC 8th edition, Chapter 59, Testis.
- For AFP, a lab value expressed in micrograms per liter (ug/L) is equivalent to the same value expressed in nanograms per milliliter (ng/ml).

Note 3: Timing

- Pathological stage values are those based on physician statement or lab values **after orchiectomy and prior to adjuvant therapy**.

Note 4: Lab values elevated after orchiectomy

- If the initial post-orchiectomy lab values remain elevated, review the subsequent tests and use the lowest lab values (normalization or plateau) prior to adjuvant therapy or before the value rises again.

Note 5: AFP, hCG, LDH

- All three lab values are needed for S0-S1. Only one elevated test is needed to assign S2-3. If any individual test is not available and none of the available test results meet the S2-3 criterion for that test, assign code 9 (SX).

Note 6: Normal Serum Tumor Markers (pre-orchiectomy)

- When all the serum tumor markers are normal pre-orchiectomy and they are not repeated post-orchiectomy, code 5.

Code	Description
0	S0: Marker study levels within normal levels
1	S1: At least one of these values is elevated AND LDH less than 1.5 x N* AND hCG (mIU/L) less than 5,000 AND AFP (ng/mL) less than 1,000

Code	Description
2	S2: LDH 1.5 x N* to 10 x N* OR hCG (mIU/L) 5,000 to 50,000 OR AFP (ng/mL) 1,000 to 10,000
3	S3: Only one elevated test is needed LDH greater than 10 x N* OR hCG (mIU/mL) greater than 50,000 OR AFP (ng/mL) greater than 10,000
5	Post orchiectomy serum tumor markers unknown or not done but pre orchiectomy serum tumor markers were normal
9	SX: Not documented in medical record S Category Pathological not assessed or unknown if assessed

00590: Testis

3807: AFP Pre-Orchiectomy Lab Value

Item Length: 7
NAACCR Item #: 3807
XML Parent-NAACCR ID: Tumor-afpPreOrchiectomyLabValue
NAACCR Alternate Name: AFP (Alpha Fetoprotein) Pre-Orchiectomy Lab Value
Active years: 2018+
Schema(s):

- 00590: Testis

Description

AFP (Alpha Fetoprotein) Pre-Orchiectomy Lab Value refers to the AFP value measured prior to treatment. AFP is a tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis.

Alpha-fetoprotein (AFP) is a protein normally made by immature liver cells in the fetus. In adults, high AFP levels (> 500 ng/ml) in the blood occur only in hepatocellular carcinoma (>1000), liver metastases (from a primary elsewhere), and germ cell tumors of the testes and ovaries. Elevated AFP values are found in non-seminomatous malignancies and mixed tumors of the testis. AFP is used with HCG to identify the specific cell type of testicular cancer. AFP is not secreted by pure seminoma or teratoma. If AFP > 500 ng/ml, the underlying condition is unlikely to be benign. If AFP > 10,000 ng/ml at diagnosis, the patient is likely to have a poor prognosis.

AFP is more useful in monitoring response to therapy than making a diagnosis. The half-life of AFP is 5 to 7 days. After orchiectomy, the AFP should fall to < 25 ng/ml in 25-35 days. If elevated AFP persists, this is an indication of residual tumor.

For Testis, there are 4 related data items that record information on AFP for Testis.

- 3805: AFP Post-Orchiectomy Lab Value
- 3806: AFP Post-Orchiectomy Range
- 3807: AFP Pre-Orchiectomy Lab Value
- 3808: AFP Pre-Orchiectomy Range

Rationale

AFP (Alpha Fetoprotein) Pre-Orchiectomy Lab Value is a Registry Data Collection Variable in AJCC. It was previously collected as Testis CS SSF #6.

Additional Information

Source documents: clinical laboratory report (blood serum radioimmunoassay or enzyme assay (EIA)); sometimes in history and physical or clinical statement in pathology report

Other names include AFP, aFP, Alpha Fetoprotein, Alpha-fetoprotein, alpha-fetoprotein, fetal alpha globulin

For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*.

Normal Reference Range

- Adult men 0-15 ng/ml (SI: 0-15 µg/L)

Measurements

- A lab value expressed in micrograms/liter (ug/L) is equivalent to the same value expressed in nanograms/milliliter (ng/mL).
    - ***Example***: 10 IU/mL: 10/0.83 = 12.04 ng/mL; 5 IU/mL: 5/0.83= 6.02 ng/mL
- If the lab value is expressed in IU/ml, use the following conversion: 1 ng/mL = 0.83 IU/mL.
    - To calculate ng from IU/mL, divide the value for IU by 0.83.
    - ***Example***: 10 IU/mL: 10/0.83 = 12.04 ng/mL; 5 IU/mL: 5/0.83= 6.02 ng/mL

Notes

Note 1: Physician Statement

- Physician statement of the AFP (Alpha Fetoprotein) Pre-Orchiectomy Lab Value can be used to code this data item when no other information is available.

Note 2: Timing

- Record the lab value of the highest AFP test result documented in the medical record **prior to orchiectomy** or prior to any systemic treatment. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Related data item

- The same laboratory test should be used to record the related data item 3808: AFP Pre-Orchiectomy Range.

Coding Guidelines

Examples

1) 1 ng/ml = Lab Value 1.0, Range 0

2) 270 ug/l = Lab Value 270.0 (ng/ml = ug/L), Range 1

3) 5500 ng/ml = Lab Value 5500.0, Range 2

4) 12,500 ng/ml = Lab Value 12500.0, Range 3

5) 110,000 ng/ml = Lab Value XXXXX.1, Range 3

6) Physician states “AFP elevated,” but no value documented = Lab value XXXXX.9, Range 4

7) S value stated (no other information available) = Lab Value XXXXX.9, Range 9

8) No AFP test done, or unknown if done = Lab Value XXXXX.9, Range 9

Code	Description
0.0	0.0 nanograms/milliliter (ng/mL)
0.1-99999.9	0.1 - 99,999.9 ng/mL
XXXXX.1	100,000 ng/mL or greater
XXXXX.7	Test ordered, results not in chart
XXXXX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XXXXX.8 may result in an edit error.)
XXXXX.9	Not documented in medical record AFP (Alpha Fetoprotein) Pre-Orchiectomy Lab Value not assessed or unknown if assessed

00590: Testis

3808: AFP Pre-Orchiectomy Range

Item Length: 1
NAACCR Item #: 3808
XML Parent-NAACCR ID: Tumor-afpPreOrchiectomyRange
NAACCR Alternate Name: AFP (Alpha Fetoprotein) Pre-Orchiectomy Range
Active years: 2018+
Schema(s):

- 00590: Testis

Description

AFP (Alpha Fetoprotein) Pre-Orchiectomy Range identifies the range category of the highest AFP value measured prior to treatment. AFP is a serum tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis.

For Testis, there are 4 related data items that record information on AFP for Testis.

- 3805: AFP Post-Orchiectomy Lab Value
- 3806: AFP Post-Orchiectomy Range
- 3807: AFP Pre-Orchiectomy Lab Value
- 3808: AFP Pre-Orchiectomy Range

Rationale

AFP (Alpha Fetoprotein) is a Registry Data Collection Variable in AJCC. AFP (Alpha Fetoprotein) Pre-Orchiectomy Range is used to assign the S Category Clinical and was previously collected as Testis CS SSF #7.

Additional Information

Source documents: clinical laboratory report (blood serum radioimmunoassay or enzyme assay (EIA)); sometimes in history and physical or clinical statement in pathology report

Other names include AFP, aFP, Alpha Fetoprotein, Alpha-fetoprotein, alpha-fetoprotein, fetal alpha globulin

For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*.

Normal Reference Range

- Adult men 0-15 ng/ml (SI: 0-15 µg/L)

Measurements

- A lab value expressed in micrograms/liter (ug/L) is equivalent to the same value expressed in nanograms/milliliter (ng/mL).
    - ***Example***: 10 IU/mL: 10/0.83 = 12.04 ng/mL; 5 IU/mL: 5/0.83= 6.02 ng/mL
- If the lab value is expressed in IU/ml, use the following conversion: 1 ng/mL = 0.83 IU/mL
    - To calculate ng from IU/mL, divide the value for IU by 0.83.
    - ***Example***: 10 IU/mL: 10/0.83 = 12.04 ng/mL; 5 IU/mL: 5/0.83= 6.02 ng/mL

Notes

Note 1: Physician Statement

- Physician statement of the AFP (Alpha Fetoprotein) Pre-Orchiectomy Range can be used to code this data item when no other information is available.

Note 2: Timing

- Record the range of the highest AFP test result documented in the medical record **prior to orchiectomy** or prior to any systemic treatment. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Related data item

- The same laboratory test should be used to record the related data item 3807: AFP Pre-Orchiectomy Lab Value.

Code	Description
0	Within normal limits
1	Above normal and less than 1,000 nanograms/milliliter (ng/mL)
2	1,000 -10,000 ng/mL
3	Greater than 10,000 ng/mL
4	Pre-Orchiectomy alpha fetoprotein (AFP) stated to be elevated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record AFP (Alpha Fetoprotein) Pre-Orchiectomy Range not assessed or unknown if assessed

00590: Testis

3848: hCG Pre-Orchiectomy Lab Value

Item Length: 7
NAACCR Item #: 3848
XML Parent-NAACCR ID: Tumor-hcgPreOrchiectomyLabValue
NAACCR Alternate Name: hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Lab Value
Active years: 2018+
Schema(s):

- 00590: Testis

Description

hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Lab Value refers to the hCG value measured prior to treatment. hCG is a serum tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis.

Human chorionic gonadotropin (hCG) is a hormone produced by the placenta and some germ cell tumors. Two subunits, alpha and beta, can be measured in blood or serum. The alpha subunit is a non-specific marker for pancreatic and pituitary tumors. Beta-hCG levels are never found in normal healthy men. When the presence of beta-hCG is detected in serum, it always indicates a malignancy. Beta-hCG is secreted by some non- seminomatous germ cell tumors and mixed tumors and is used with AFP to identify the specific cell type of testicular cancer. Beta-hCG is also useful in monitoring response to therapy. After orchiectomy, the hCG should be undetectable within 5 to 8 days. If elevated hCG persists, this is an indication of residual tumor.

For Testis, there are 4 related data items that record information on hCG.

- 3846: hCG Post-Orchiectomy Lab Value
- 3847: hCG Post-Orchiectomy Range
- 3848: hCG Pre-Orchiectomy Lab Value
- 3849: hCG Pre-Orchiectomy Range

Rationale

hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Lab Value is a Registry Data Collection Variable in AJCC. It was previously collected as Testis CS SSF #8.

Additional Information

Source documents: clinical laboratory report (blood or serum test), sometimes in history and physical or clinical statement in pathology report

Other names include: Human chorionic gonadotropin, b-hCG, beta subunit HCG, beta hCG, β-hCG

For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*.

Normal Reference Range

- < 2 ng/ml (SI: < 2 µg/L or < 2 ug/L) 1 ng/ml of HCG is approximately 5 mIU/ml.
- < 5 mIU/mL (< 5 IU/L) To record mIU/mL in ng/ml, divide the test result by 5.

Measurements

- A lab value expressed in International Units/liter (IU/L) is equivalent to the same value expressed in milli-International Units/milliliter (mIU/mL).

Notes

Note 1: Physician Statement

- Physician statement of the hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Lab Value can be used to code this data item when no other information is available.

Note 2: Timing

- Record the lab value of the highest hCG test result documented in the medical record prior to orchiectomy or prior to any systemic treatment. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Related data item

- The same laboratory test should be used to record the related data item 3849: hCG Pre-Orchiectomy Range.

Coding Guidelines

Examples

1) 2.0 mIU/mL = Lab Value 2.0, Range 0

2) 412 mIU/mL = Lab Value 412.0, Range1

3) 6213 mIU/mL = Lab Value 6213.0, Range 2

4) 14,724 mIU/mL = Lab Value 14724.0, Range 3

5) 108,325 mIU/mL = Lab Value XXXXX.1, Range 3

6) Physician states “hCG elevated,” but no value documented = Lab Value XXXXX.9, Range 4

7) S value stated (no other information available) = Lab Value XXXXX.9, Range 9

8) No hCG test done, or unknown if done = Lab Value XXXXX.9, Range 9

Code	Description
0.0	0.0 milli-International Units/milliliter (mIU/mL)
0.1-99999.9	0.1 - 99,999.9 mIU/mL
XXXXX.1	100,000 mIU/mL or greater
XXXXX.7	Test ordered, results not in chart
XXXXX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XXXXX.8 may result in an edit error.)
XXXXX.9	Not documented in medical record hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Lab Value not assessed or unknown if assessed

00590: Testis

3849: hCG Pre-Orchiectomy Range

Item Length: 1
NAACCR Item #: 3849
XML Parent-NAACCR ID: Tumor-hcgPreOrchiectomyRange
NAACCR Alternate Name: hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Range
Active years: 2018+
Schema(s):

- 00590: Testis

Description

Human Chorionic Gonadotropin (hCG) Pre-Orchiectomy Range identifies the range category of the highest hCG value measured prior to treatment. hCG is a serum tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis.

For Testis, there are 4 related data items that record information on hCG.

- 3846: hCG Post-Orchiectomy Lab Value
- 3847: hCG Post-Orchiectomy Range
- 3848: hCG Pre-Orchiectomy Lab Value
- 3849: hCG Pre-Orchiectomy Range

Rationale

hCG (Human Chorionic Gonadotropin) is a Registry Data Collection Variable in AJCC. hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Range is used to assign the S Category Clinical and was previously collected as Testis CS SSF #9.

Additional Information

Source documents: clinical laboratory report (blood or serum test), sometimes in history and physical or clinical statement in pathology report

Other names include Human chorionic gonadotropin, b-hCG, beta subunit HCG, beta hCG, β-hCG

For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*.

Normal Reference Range

- < 2 ng/ml (SI: < 2 µg/L or < 2 ug/L) 1 ng/ml of HCG is approximately 5 mIU/ml.
- < 5 mIU/mL (< 5 IU/L) To record mIU/mL in ng/ml, divide the test result by 5.

Measurements

- A lab value expressed in International Units/liter (IU/L) is equivalent to the same value expressed in milli-International Units/milliliter (mIU/mL).

Notes

Note 1: Physician Statement

- Physician statement of the hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Range can be used to code this data item when no other information is available.

Note 2: Timing

- Record the range of the highest hCG test result documented in the medical record **prior to orchiectomy** or prior to any systemic treatment. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Related data item

- The same laboratory test should be used to record the related data item 3848: hCG Pre-orchiectomy Lab Value.

Code	Description
0	Within normal limits
1	Above normal and less than 5,000 milli-International Units/milliliter (mIU/mL)
2	5,000 - 50,000 mIU/mL
3	Greater than 50,000 mIU/mL
4	Pre-orchiectomy human chorionic gonadotropin (hCG) stated to be elevated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record hCG Pre-Orchiectomy range not assessed or unknown if assessed

00590: Testis

3868: LDH Pre-Orchiectomy Range

Item Length: 1
NAACCR Item #: 3868
XML Parent-NAACCR ID: Tumor-ldhPreOrchiectomyRange
NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Pre-Orchiectomy Range
Active years: 2018+
Schema(s):

- 00590: Testis

Description

Lactate Dehydrogenase (LDH) Range identifies the range category of the highest LDH value measured prior to treatment. LDH is a nonspecific marker for testicular cancer that is elevated in some germ cell tumors. This data item refers to the Pre-Orchiectomy range.

When cells (normal or tumor) are damaged or destroyed, an enzyme called lactate dehydrogenase (LDH) is released into the bloodstream. LDH is an indirect indication of possible tumor burden or damage to an organ, which may be caused by metastatic involvement of liver or lung, or a myocardial infarction. The total LDH should be the test value that is coded, but there are five fractions of LDH that measure tissue specific cellular damage: LD1 and LD2: heart, red blood cells and kidneys; LD3: lung; LD4 and LD5: liver, skin, and skeletal muscles. LDH is elevated in 60% of patients with non-seminomatous germ cell tumors of the testis. LDH is not a screening test, nor is it diagnostic of melanoma, ocular adnexal lymphoma, or testicular cancer.

For testis, only the LDH Range is coded. LDH is non-specific for testicular cancer. Although part of the criteria for the S category in the TNM system, LDH is not routinely performed unless the patient has evidence of bulky or distant disease.

For Testis, there are 2 related data items that record information on LDH.

- 3867: LDH Post-Orchiectomy Range
- 3868: LDH Pre-Orchiectomy Range

Rationale

LDH (Lactate Dehydrogenase) is a Registry Data Collection Variable in AJCC. LDH (Lactate Dehydrogenase) Pre-Orchiectomy Range is used to assign the S Category Clinical and was previously collected as Testis CS SSF #10.

Additional Information

Source documents: clinical laboratory report; may be included in a liver or hepatic panel/profile, a cardiac panel, or a general metabolic panel of tests

Other names include LD, Lactate dehydrogenase, lactase dehydrogenase, lactic acid dehydrogenase

For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*.

Normal reference range

- Varies widely by laboratory, patient age, and the units of measurement.

Notes

Note 1: Physician Statement

- Physician statement of the LDH (Lactate Dehydrogenase) Pre-Orchiectomy Range can be used to code this data item when no other information is available.

Note 2: Timing

- Record the range of the highest LDH test result documented in the medical record **prior to orchiectomy** or prior to any systemic treatment. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Calculating the upper limit

- To calculate whether the lab result is in a particular range, multiply the lab's upper limit of normal (usually stated on the report) times the stated multiplier. If the test is elevated, determine whether it is less than 1.5 times the upper limit of normal (code 1), between 1.5 and 10 times the upper limit of normal (code 2), or more than 10 times the upper limit of normal (code 3). (*See coding guidelines for example*).

Note 4: LDH and Testis

- Of the three tumor markers, lactate dehydrogenase (LDH) is the least specific for testicular cancer. The magnitude of LDH elevation directly correlates with Testis tumor burden.

Coding Guidelines

Examples for LDH Pre-Orchiectomy and Post-Orchiectomy Range

- For these examples, the lab's normal reference range for LDH = 100-225
    - 1.5 X 225 (upper limit of normal) = 337.5
    - 10 x 225 (upper limit of normal) = 2250
- Therefore, for this lab, a value that is elevated and up to 337 = code 1, a value from 338 to 2250 = code 2, and a value greater than 2250 = code 3.

Code	Description
0	Within normal limits
1	Less than 1.5 x N (Less than 1.5 times the upper limit of normal for LDH)
2	1.5 to 10 x N (Between 1.5 and 10 times the upper limit of normal for LDH)
3	Greater than 10 x N (Greater than 10 times the upper limit of normal for LDH)
4	Pre-Orchiectomy lactate dehydrogenase (LDH) range stated to be elevated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record LDH (Lactate Dehydrogenase) Pre-Orchiectomy Range not assessed or unknown if assessed

00590: Testis

3805: AFP Post-Orchiectomy Lab Value

Item Length: 7
NAACCR Item #: 3805
XML Parent-NAACCR ID: Tumor-afpPostOrchiectomyLabValue
NAACCR Alternate Name: AFP (Alpha Fetoprotein) Post-Orchiectomy Lab Value
Active years: 2018+
Schema(s):

- 00590: Testis

Description

AFP (Alpha Fetoprotein) Post-Orchiectomy Lab Value refers to the lowest AFP value measured post-orchiectomy. AFP is a serum tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis. The Post-Orchiectomy lab value is used to monitor response to therapy.

Alpha-fetoprotein (AFP) is a protein normally made by immature liver cells in the fetus. In adults, high AFP levels (> 500 ng/ml) in the blood occur only in hepatocellular carcinoma (>1000), liver metastases (from a primary elsewhere), and germ cell tumors of the testes and ovaries. Elevated AFP values are found in non-seminomatous malignancies and mixed tumors of the testis. AFP is used with HCG to identify the specific cell type of testicular cancer. AFP is not secreted by pure seminoma or teratoma. If AFP > 500 ng/ml, the underlying condition is unlikely to be benign. If AFP > 10,000 ng/ml at diagnosis, the patient is likely to have a poor prognosis.

AFP is more useful in monitoring response to therapy than making a diagnosis. The half-life of AFP is 5 to 7 days. After orchiectomy, the AFP should fall to < 25 ng/ml in 25-35 days. If elevated AFP persists, this is an indication of residual tumor.

For Testis, there are 4 related data items that record information on AFP for Testis.

- 3805: AFP Post-Orchiectomy Lab Value
- 3806: AFP Post-Orchiectomy Range
- 3807: AFP Pre-Orchiectomy Lab Value
- 3808: AFP Pre-Orchiectomy Range

Rationale

AFP (Alpha Fetoprotein) Post-Orchiectomy Lab Value is a Registry Data Collection Variable in AJCC. It was previously collected as Testis CS SSF #12.

Additional Information

Source documents: clinical laboratory report (blood serum radioimmunoassay or enzyme assay (EIA)); sometimes in history and physical or clinical statement in pathology report

Other names include AFP, aFP, Alpha Fetoprotein, Alpha-fetoprotein, alpha-fetoprotein, fetal alpha globulin

For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*.

Normal Reference Range

- Adult men 0-15 ng/ml (SI: 0-15 µg/L)

Measurements

- A lab value expressed in micrograms/liter (ug/L) is equivalent to the same value expressed in nanograms/milliliter (ng/mL).
    - ***Example***: 10 IU/mL: 10/0.83 = 12.04 ng/mL; 5 IU/mL: 5/0.83= 6.02 ng/mL
- If the lab value is expressed in IU/ml, use the following conversion: 1 ng/mL = 0.83 IU/mL.
    - To calculate ng from IU/mL, divide the value for IU by 0.83.
    - ***Example***: 10 IU/mL: 10/0.83 = 12.04 ng/mL; 5 IU/mL: 5/0.83= 6.02 ng/mL

Notes

Note 1: Physician Statement

- Physician statement of the AFP (Alpha Fetoprotein) Post-Orchiectomy Lab Value can be used to code this data item when no other information is available.

Note 2: Timing

- Record the lab value of the AFP test results documented in the medical record **after orchiectomy** but prior to adjuvant therapy. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Lab values elevated after orchiectomy

- If the initial post-orchiectomy AFP remains elevated, review subsequent tests and record the lowest AFP value (normalization or plateau) prior to adjuvant therapy or before the value rises again.

Note 4: Related data item

- The same laboratory test should be used to record the related data item 3806: AFP Post-Orchiectomy Range.

Coding Guidelines

1) Code XXXXX.9 when

- The only information available is a statement of elevated or normal
- If the pre-orchiectomy AFP was normal; a post-orchiectomy AFP may not be performed. In this case, code XXXXX.9 should be recorded.

Examples

1) 1 ng/ml = Lab Value 1.0, Range 0

2) 270 ug/l = Lab Value 270.0 (ng/ml = ug/L), Range 1

3) 5500 ng/ml = Lab Value 5500.0, Range 2

4) 12,500 ng/ml = Lab Value 12500.0, Range 3

5) 110,000 ng/ml = Lab Value XXXXX.1, Range 3

6) Physician states "AFP elevated," but no value documented = Lab value XXXXX.9, Range 4

7) S value stated (no other information available) = Lab Value XXXXX.9, Range 9

8) No AFP test done, or unknown if done = Lab Value XXXXX.9, Range 9

Code	Description
0.0	0.0 nanograms/milliliter (ng/mL)
0.1-99999.9	0.1 - 99,999.9 ng/mL
XXXXX.1	100,000 ng/mL or greater
XXXXX.7	Test ordered, results not in chart
XXXXX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XXXXX.8 may result in an edit error.)
XXXXX.9	Not documented in medical record No orchiectomy performed AFP (Alpha Fetoprotein) Post-Orchiectomy Lab Value not assessed or unknown if assessed

00590: Testis

3806: AFP Post-Orchiectomy Range

Item Length: 1
NAACCR Item #: 3806
XML Parent-NAACCR ID: Tumor-afpPostOrchiectomyRange
NAACCR Alternate Name: AFP (Alpha Fetoprotein) Post-Orchiectomy Range
Active years: 2018+
Schema(s):

- 00590: Testis

Description

AFP (Alpha Fetoprotein) Post-Orchiectomy Range identifies the range category of the lowest AFP value measured post-orchiectomy. AFP is a serum tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis. The Post-Orchiectomy lab value is used to monitor response to therapy.

For Testis, there are 4 related data items that record information on AFP for Testis.

- 3805: AFP Post-Orchiectomy Lab Value
- 3806: AFP Post-Orchiectomy Range
- 3807: AFP Pre-Orchiectomy Lab Value
- 3808: AFP Pre-Orchiectomy Range

Rationale

AFP (Alpha Fetoprotein) Post-Orchiectomy Range is a Registry Data Collection Variable in AJCC. AFP (Alpha Fetoprotein) Post-Orchiectomy Range is used to assign the S Category Pathological and was previously collected as Testis CS SSF #13.

Additional Information

Source documents: clinical laboratory report (blood serum radioimmunoassay or enzyme assay (EIA)); sometimes in history and physical or clinical statement in pathology report

Other names include AFP, aFP, Alpha Fetoprotein, Alpha-fetoprotein, alpha-fetoprotein, fetal alpha globulin

For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*.

Normal Reference Range

- Adult men 0-15 ng/ml (SI: 0-15 µg/L)

Measurements

- A lab value expressed in micrograms/liter (ug/L) is equivalent to the same value expressed in nanograms/milliliter (ng/mL).
    - ***Example***: 10 IU/mL: 10/0.83 = 12.04 ng/mL; 5 IU/mL: 5/0.83= 6.02 ng/mL
- If the lab value is expressed in IU/ml, use the following conversion: 1 ng/mL = 0.83 IU/mL
    - To calculate ng from IU/mL, divide the value for IU by 0.83.
    - ***Example***: 10 IU/mL: 10/0.83 = 12.04 ng/mL; 5 IU/mL: 5/0.83= 6.02 ng/mL

Notes

Note 1: Physician Statement

- Physician statement of the AFP (Alpha Fetoprotein) Post-Orchiectomy Range can be used to code this data item when there is no other information available.

Note 2: Timing

- Record the range of the AFP test as documented in the medical record **after orchiectomy** but prior to adjuvant therapy. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Lab values elevated after orchiectomy

- If the initial post-orchiectomy AFP remains elevated, review subsequent tests and record the lowest AFP value (normalization or plateau) prior to adjuvant therapy or before the value rises again.

Note 4: Pre-orchiectomy AFP normal

- If the pre-orchiectomy AFP was normal, a post-orchiectomy AFP may not be performed. In this case, code 5 should be recorded.

Note 5: Related data item

- The same laboratory test should be used to record the related data item 3805: AFP Post-Orchiectomy Lab Value.

Code	Description
0	Within normal limits
1	Above normal and less than 1,000 nanograms/milliliter (ng/mL)
2	1,000 -10,000 ng/mL

Code	Description
3	Greater than 10,000 ng/mL
4	Post-Orchiectomy alpha fetoprotein (AFP) stated to be elevated
5	Post-Orchiectomy alpha fetoprotein (AFP) unknown or not done but pre-orchiectomy AFP was normal
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record No orchiectomy performed AFP (Alpha Fetoprotein) Post-Orchiectomy Range not assessed or unknown if assessed

00590: Testis

3846: hCG Post-Orchiectomy Lab Value

Item Length: 7
NAACCR Item #: 3846
XML Parent-NAACCR ID: Tumor-hcgPostOrchiectomyLabValue
NAACCR Alternate Name: hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Lab Value
Active years: 2018+
Schema(s):

- 00590: Testis

Description

hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Lab Value refers to the lowest hCG value measured post-orchiectomy. hCG is a serum tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis. The Post-Orchiectomy lab value is used to monitor response to therapy.

Human chorionic gonadotropin (hCG) is a hormone produced by the placenta and some germ cell tumors. Two subunits, alpha and beta, can be measured in blood or serum. The alpha subunit is a non-specific marker for pancreatic and pituitary tumors. Beta-hCG levels are never found in normal healthy men. When the presence of beta-hCG is detected in serum, it always indicates a malignancy. Beta-hCG is secreted by some non- seminomatous germ cell tumors and mixed tumors and is used with AFP to identify the specific cell type of testicular cancer. Beta-hCG is also useful in monitoring response to therapy. After orchiectomy, the hCG should be undetectable within 5 to 8 days. If elevated hCG persists, this is an indication of residual tumor.

For Testis, there are 4 related data items that record information on hCG.

- 3846: hCG Post-Orchiectomy Lab Value
- 3847: hCG Post-Orchiectomy Range
- 3848: hCG Pre-Orchiectomy Lab Value
- 3849: hCG Pre-Orchiectomy Range

Rationale

hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Lab Value is a Registry Data Collection Variable in AJCC. It was previously collected as Testis CS SSF #14.

Additional Information

Source documents: clinical laboratory report (blood or serum test), sometimes in history and physical or clinical statement in pathology report

Other names include Human chorionic gonadotropin, b-hCG, beta subunit HCG, beta hCG, β-hCG

For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*.

Normal Reference Range

- < 2 ng/ml (SI: < 2 µg/L or < 2 ug/L) 1 ng/ml of HCG is approximately 5 mIU/ml.
- < 5 mIU/mL (< 5 IU/L) To record mIU/mL in ng/ml, divide the test result by 5

Measurements

- A lab value expressed in International Units/liter (IU/L) is equivalent to the same value expressed in milli-International Units/milliliter (mIU/mL).

Notes

Note 1: Physician Statement

- Physician statement of the hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Lab Value can be used to code this data item when no other information is available.

Note 2: Timing

- Record the value of the hCG test as documented in the medical record **after orchiectomy** but prior to adjuvant therapy. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Lab values elevated after orchiectomy

- If the initial post-orchiectomy hCG remains elevated, review subsequent tests and record the lowest hCG value (normalization or plateau) prior to adjuvant therapy or before the value rises again.

Note 4: Related Data Item

- The same laboratory test should be used to record the related data item 3847: hCG Post-Orchiectomy Range.

Coding Guidelines

1) Code XXXXX.9 when

- The only information available is a statement of elevated or normal
- If the pre-orchiectomy hCG was normal; a post-orchiectomy hCG may not be performed. In this case, code XXXXX.9 should be recorded.

Examples

1) 2.0 mIU/mL = Lab Value 2.0, Range 0

2) 412 mIU/mL = Lab Value 412.0, Range1

3) 6213 mIU/mL = Lab Value 6213.0, Range 2

4) 14,724 mIU/mL = Lab Value 14724.0, Range 3

5) 108,325 mIU/mL = Lab Value XXXXX.1, Range 3

6) Physician states "hCG elevated," but no value documented = Lab Value XXXXX.9, Range 4

7) S value stated (no other information available) = Lab Value XXXXX.9, Range 9

8) No hCG test done, or unknown if done = Lab Value XXXXX.9, Range 9

Code	Description
0.0	0.0 milli-International Units/milliliter (mIU/mL)
0.1-99999.9	0.1 - 99,999.9 mIU/mL
XXXXX.1	100,000 mIU/mL or greater
XXXXX.7	Test ordered, results not in chart
XXXXX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XXXXX.8 may result in an edit error.)
XXXXX.9	Not documented in medical record No orchiectomy performed hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Lab Value not assessed or unknown if assessed

00590: Testis

3847: hCG Post-Orchiectomy Range

Item Length: 1
NAACCR Item #: 3847
XML Parent-NAACCR ID: Tumor-hcgPostOrchiectomyRange
NAACCR Alternate Name: hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Range
Active years: 2018+
Schema(s):

- 00590: Testis

Description

Human Chorionic Gonadotropin (hCG) Post-Orchiectomy Range identifies the range category of the lowest hCG value measured post-orchiectomy. hCG is a serum tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis. The post-orchiectomy lab value is used to monitor response to therapy.

For Testis, there are 4 related data items that record information on hCG.

- 3846: hCG Post-Orchiectomy Lab Value
- 3847: hCG Post-Orchiectomy Range
- 3848: hCG Pre-Orchiectomy Lab Value
- 3849: hCG Pre-Orchiectomy Range

Rationale

hCG (Human Chorionic Gonadotropin) is a Registry Data Collection Variable in AJCC. hCG (Human Chorionic Gonadotropin) Post-orchiectomy Range is used to assign the S Category Pathological and was previously collected as Testis CS SSF #15.

Additional Information

Source documents: clinical laboratory report (blood or serum test), sometimes in history and physical or clinical statement in pathology report

Other names include Human chorionic gonadotropin, b-hCG, beta subunit HCG, beta hCG, β-hCG

For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*.

Normal Reference Range

- < 2 ng/ml (SI: < 2 µg/L or < 2 ug/L) 1 ng/ml of HCG is approximately 5 mIU/ml

- < 5 mIU/mL (< 5 IU/L) To record mIU/mL in ng/ml, divide the test result by 5

Measurements

- A lab value expressed in International Units/liter (IU/L) is equivalent to the same value expressed in milli-International Units/milliliter (mIU/mL).

Notes

Note 1: Physician Statement

- Physician statement of the hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Range can be used to code this data item when there is no other information available.

Note 2: Timing

- Record the range of the hCG test as documented in the medical record **after orchiectomy** but prior to adjuvant therapy. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Lab values elevated after orchiectomy

- If the initial post-orchiectomy hCG remains elevated, review subsequent tests and record the lowest hCG value (normalization or plateau) prior to adjuvant therapy or before the value rises again.

Note 4: Pre-orchiectomy hCG normal

- If the pre-orchiectomy hCG was normal, a post-orchiectomy hCG may not be performed. In this case, code 5 should be recorded.

Note 5: Related Data Item

- The same laboratory test should be used to record the related data item 3846: hCG Post-Orchiectomy Lab Value.

Code	Description
0	Within normal limits
1	Above normal and less than 5,000 milli-International Units/milliliter (mIU/mL)
2	5,000 - 50,000 mIU/mL
3	Greater than 50,000 mIU/mL
4	Post-orchiectomy human chorionic gonadotropin (hCG) stated to be elevated
5	Post-Orchiectomy human chorionic gonadotropin (hCG) unknown or not done but pre-orchiectomy hCG was normal

Code	Description
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record No orchiectomy performed hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Range not assessed or unknown if assessed

00590: Testis

3867: LDH Post-Orchiectomy Range

Item Length: 1
NAACCR Item #: 3867
XML Parent-NAACCR ID: Tumor-ldhPostOrchiectomyRange
NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Post-Orchiectomy Range
Active years: 2018+
Schema(s):

- 00590: Testis

Description

LDH (Lactate Dehydrogenase) Post-Orchiectomy Range identifies the range category of the lowest LDH value measured post-orchiectomy. LDH is a nonspecific marker for testicular cancer that is elevated in some germ cell tumors. The Post-Orchiectomy lab value is used to monitor response to therapy.

When cells (normal or tumor) are damaged or destroyed, an enzyme called lactate dehydrogenase (LDH) is released into the bloodstream. LDH is an indirect indication of possible tumor burden or damage to an organ, which may be caused by metastatic involvement of liver or lung, or a myocardial infarction. The total LDH should be the test value that is coded, but there are five fractions of LDH that measure tissue specific cellular damage: LD1 and LD2: heart, red blood cells and kidneys; LD3: lung; LD4 and LD5: liver, skin, and skeletal muscles. LDH is elevated in 60% of patients with non-seminomatous germ cell tumors of the testis. LDH is not a screening test, nor is it diagnostic of melanoma, ocular adnexal lymphoma, or testicular cancer.

For testis, only the LDH Range is coded. LDH is non-specific for testicular cancer. Although part of the criteria for the S category in the TNM system, LDH is not routinely performed unless the patient has evidence of bulky or distant disease.
For Testis, there are 2 related data items that record information on LDH.

- 3867: LDH Post-Orchiectomy Range
- 3868: LDH Pre-Orchiectomy Range

Rationale

LDH (Lactate Dehydrogenase) is a Registry Data Collection Variable in AJCC. LDH (Lactate Dehydrogenase) Post-Orchiectomy Range is used to assign the S Category Pathological and was previously collected as Testis CS SSF #16.

Additional Information

Source documents: clinical laboratory report; may be included in a liver or hepatic panel/profile, a cardiac panel, or a general metabolic panel of tests

Other names include LD, Lactate dehydrogenase, lactase dehydrogenase, lactic acid dehydrogenase

For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*.

Normal reference range

- Varies widely by laboratory, patient age, and the units of measurement.

Notes

Note 1: Physician Statement

- Physician statement of the LDH (Lactate Dehydrogenase) Post-Orchiectomy Range can be used to code this data item when there is no other information available.

Note 2: Timing

- Record the range of the LDH test as documented in the medical record after orchiectomy but prior to adjuvant therapy. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Calculating the upper limit

- To calculate whether the lab result is in a particular range, multiply the lab's upper limit of normal (usually stated on the report) times the stated multiplier. If the test is elevated, determine whether it is less than 1.5 times the upper limit of normal (code 1), between 1.5 and 10 times the upper limit of normal (code 2), or more than 10 times the upper limit of normal (code 3) (*See coding guidelines for example*).

Note 4: Lab values elevated after orchiectomy

- If the initial post-orchiectomy LDH remains elevated, review subsequent tests, and record the lowest LDH value (normalization or plateau) prior to adjuvant therapy or before the value rises again.

Note 5: LDH and Testis

- Of the three tumor markers, lactate dehydrogenase (LDH) is the least specific for testicular cancer. The magnitude of LDH elevation directly correlates with Testis tumor burden.

Note 6: Related data item

- If the pre-orchiectomy LDH was normal, a post-orchiectomy LDH may not be performed. In this case, code 5 should be recorded.

Coding Guidelines

LDH Pre-Orchiectomy and Post-Orchiectomy Range

- For these examples, the lab's normal reference range for LDH = 100-225
    - 1.5 X 225 (upper limit of normal) = 337.5
    - 10 x 225 (upper limit of normal) = 2250
- Therefore, for this lab, a value that is elevated and up to 337 = code 1, a value from 338 to 2250 = code 2, and a value greater than 2250 = code 3.

Code	Description
0	Within normal limits
1	Less than 1.5 x N (Less than 1.5 times the upper limit of normal for LDH)
2	1.5 to 10 x N (Between 1.5 and 10 times the upper limit of normal for LDH)
3	Greater than 10 x N (Greater than 10 times the upper limit of normal for LDH)
4	Post-Orchiectomy lactate dehydrogenase (LDH) range stated to be elevated
5	Post-Orchiectomy lactate dehydrogenase (LDH) unknown or not done but pre-orchiectomy LDH was normal
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record No orchiectomy performed LDH (Lactate Dehydrogenase) Post-Orchiectomy Range not assessed or unknown if assessed

00600: Kidney Parenchyma

3864: Invasion Beyond Capsule

Item Length: 1
NAACCR Item #: 3864
XML Parent-NAACCR ID: Tumor-invasionBeyondCapsule
NAACCR Alternate Name: Invasion Beyond Capsule
Active years: 2018+
Schema(s):

- 00600: Kidney Parenchyma

Description

Kidney Tumor Extension pertains to the pathologically confirmed invasion of the tumor beyond the fibrous capsule in which the kidney is enclosed.

This data item collects additional information on the description of tumor spread (invasion beyond capsule) as documented in the pathology report. Do not include clinical findings in this field.

Rationale

Kidney Tumor Extension into specific tissues for Kidney is a Registry Data Collection Variable in AJCC. It was previously collected as Kidney, CS SSF #1.

Additional Information

Source documents: surgical pathology report

For further information, refer to the **Kidney** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Kidney*.

Notes

Note 1: Physician Statement

- Physician statement of pathologically confirmed invasion of the tumor beyond the fibrous capsule (invasion beyond capsule) can be used to code this data item when no other information is available.

Note 2: Relevance to Staging

- Information about invasion beyond the capsule is collected in primary tumor as an element in anatomic staging. It is also collected in this field as it may have an independent effect on prognosis.

Note 3: Perinephric/sinus fat invasion

- Should be confirmed microscopically and is invasion into fat by tumor cells, with or without desmoplastic reaction, and vascular invasion into perinephric/sinus soft tissue.
    - Synonyms include renal sinus fat, medial invasion
- **Do not code invasion of renal hilum in this data item.**
    - Invasion of the renal hilum is invasion of vessels, nerves, lymphatics, and/or ureter before they enter the kidney parenchyma. If the only information you have is that the renal hilum is involved, code to 9 (unknown).

Coding Guidelines

1) Record invasion beyond capsule as documented in the surgical pathology report

- Surgical resection of primary site must be done
- Do not use imaging findings to code this data item.

2) Code 0: There is no invasion beyond capsule

- If surgical resection is done and tumor is "confined to kidney" and staging is based on size, then there has been no invasion through the capsule (no invasion into perinephric fat)

3) Code 1: Perinephric fat, which is the layer of fat (adipose tissue) outside the renal capsule but inside Gerota's fascia

4) Code 2: Renal sinus, which is the elongated oval indentation in the renal parenchyma occupied by the renal pelvis, renal calyces, blood vessels, nerves, and perisinus fat

- Synonyms include renal sinus fat, medial invasion

5) Code 3: Gerota's fascia (Gerota's capsule), which is a fibrous envelope of tissue that surrounds the kidney

6) Code 4: Any combination of codes 1-3

7) Code 5: Invasion beyond the capsule, NOS

8) Code 9 when

- There is no documentation in the medical record
- Clinical diagnosis only
- Evaluation of capsule invasion not done or unknown if done

- Surgical resection of the primary site is performed, tumor is **not** confined to the kidney and there is no mention of invasion beyond capsule

Code	Description
0	Invasion beyond capsule not identified
1	Perinephric (beyond renal capsule) fat or tissue
2	Renal sinus
3	Gerota's fascia
4	Any combination of codes 1-3
5	Invasion beyond capsule, NOS
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Invasion beyond capsule not assessed or unknown if assessed No surgical resection of primary site is performed

00600: Kidney Parenchyma

3861: Ipsilateral Adrenal Gland Involvement

Item Length: 1
NAACCR Item #: 3861
XML Parent-NAACCR ID: Tumor-ipsilateralAdrenalGlandInvolve
NAACCR Alternate Name: Ipsilateral Adrenal Gland Involvement
Active years: 2018+
Schema(s):

- 00600: Kidney Parenchyma

Description

Ipsilateral adrenal gland involvement pertains to direct extension of the tumor into the ipsilateral adrenal gland (continuous) or ipsilateral adrenal gland involvement by a separate nodule (discontiguous).

The adrenal gland is contained within Gerota's fascia and is contiguous with the kidney, but it has its own lymphatic and vascular drainage systems. Involvement of the ipsilateral (same side) adrenal gland by kidney tumor—an adverse prognostic indicator—may be by direct extension (contiguous) or hematogenous (through the bloodstream; discontiguous). Do not include clinical findings in this field.

Rationale

Ipsilateral adrenal gland involvement for Kidney is a Registry Data Collection Variable in AJCC. It was previously collected as Kidney, CS SSF #3.

Additional Information

Source documents: surgical pathology report

For further information, refer to the **Kidney** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Kidney*.

Notes

Note 1: Physician Statement

- Physician statement of Ipsilateral Adrenal Gland (suprarenal gland, same side [ipsilateral]) Involvement can be used to code this data item when no other information is available.

Note 2: Relevance to Staging

- Information about contiguous ipsilateral adrenal gland involvement is collected in primary tumor, and discontiguous ipsilateral adrenal gland involvement is collected in

distant metastasis, as elements in anatomic staging. This information is also collected in this field as it may have an independent effect on prognosis.

Coding Guidelines

1) Record ipsilateral adrenal gland involvement as documented in the surgical pathology report

- Surgical resection of primary site must be done
- Do not use imaging findings to code this data item.

2) Code 0: There is no involvement of the ipsilateral adrenal gland

- If surgical resection is done and tumor is "confined to kidney" and staging is based on size, then there is no involvement of the adrenal gland

3) Code 1: Ipsilateral adrenal gland involved by direct extension (contiguous involvement)

4) Code 2: Ipsilateral adrenal gland involved by separate nodule (discontiguous involvement)

5) Code 3: Ipsilateral adrenal gland involvement by contiguous and discontiguous involvement

6) Code 4: Ipsilateral adrenal gland involvement, unknown if contiguous or discontiguous involvement

7) Code 9 when

- There is no documentation in the medical record
- Clinical diagnosis only
- Evaluation of ipsilateral adrenal gland involvement not done or unknown if done
- Surgical resection of the primary site is performed, tumor is **not** confined to the kidney and there is no mention of ipsilateral adrenal gland involvement

Code	Description
0	Ipsilateral adrenal gland involvement not present/not identified
1	Adrenal gland involvement by direct involvement (contiguous involvement)
2	Adrenal gland involvement by separate nodule (noncontiguous involvement)
3	Combination of code 1-2
4	Ipsilateral adrenal gland involvement, unknown if direct involvement or separate nodule

Code	Description
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Ipsilateral adrenal gland not resected Ipsilateral adrenal gland involvement not assessed or unknown if assessed No surgical resection of primary site is performed

00600: Kidney Parenchyma

3886: Major Vein Involvement

Item Length: 1
NAACCR Item #: 3886
XML Parent-NAACCR ID: Tumor-majorVeinInvolvement
NAACCR Alternate Name: Major Vein Involvement
Active years: 2018+
Schema(s):

- 00600: Kidney Parenchyma

Description

Major vein involvement pertains to the invasion of the kidney tumor into major veins.

Involvement of veins from a renal cancer has prognostic implications because tumor cells can more easily disseminate through the bloodstream. This data item records information about the presence and level of involvement of specific major blood vessels. Do not code microscopically identified involvement of small unnamed blood vessels within the kidney; this information is coded in the field Lymph-Vascular Invasion (LVI). The tumor may be described as a thrombus, a cluster of tumor cells presents in the center of the vein but not attached to the wall of the vein. Tumor spread may resemble mud extruding along the inside of a pipe. Direct tumor invasion of the wall of the inferior vena cava is not coded in this field.
Record the code that best describes involvement of the renal vein and/or inferior vena cava (IVC) as described in the pathology report. Do not include clinical findings in this field.

Rationale

Involvement of major veins for Kidney is a Registry Data Collection Variable in AJCC. It was previously collected as Kidney, CS SSF #2.

Additional Information

Source documents: surgical pathology report

For further information, refer to the **Kidney** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Kidney*.

Notes

Note 1: Physician Statement

- Physician statement of Major Vein Involvement can be used to code this data item when no other information is available.
- The major veins include the renal vein or its segmental branches, and the inferior vena cava.

Note 2: Relevance to Staging

- Information about major vein involvement beyond the kidney is collected in primary tumor as an element in anatomic staging. It is also collected in this field as it may have an independent effect on prognosis.

Note 3: Major Vein Involvement

- Record the involvement of specific named veins as documented in the pathology report. Do not code invasion of small unnamed vein(s) of the type collected as lymph-vascular invasion. Lymph-vascular invasion is usually only seen microscopically.

Coding Guidelines

1) Record major vein involvement as documented in the surgical Pathology report

- Surgical resection of primary site must be done
- Do not use imaging findings to code this data item.

2) Code 0: There is no involvement of the major veins

- If surgical resection is done and tumor is "confined to kidney" and staging is based on size, then there is no involvement of major veins

3) Code 1: Involvement of the renal vein or segmental branches

4) Code 2: Involvement of the inferior vena cava (IVC)

5) Code 3: Involvement of major veins, but not specified which one (renal vein, segmental branches, or inferior vena cava (IVC))

6) Code 4: Involvement of more than one vein (any combination of codes 1-3)

7) Code 9 when

- There is no documentation in the medical record
- Clinical diagnosis only
- Evaluation of major vein involvement not done or unknown if done
- Surgical resection of the primary site is performed, tumor is **not** confined to the kidney and there is no mention of major vein involvement

Code	Description
0	Major vein involvement not present/not identified
1	Renal vein or its segmental branches

Code	Description
2	Inferior vena cava (IVC)
3	Major vein invasion, NOS
4	Any combination of codes 1-3
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Vein involvement not assessed or unknown if assessed No surgical resection of primary site is performed

00600: Kidney Parenchyma

3925: Sarcomatoid Features

Item Length: 3
NAACCR Item #: 3925
XML Parent-NAACCR ID: Tumor-sarcomatoidFeatures
NAACCR Alternate Name: Sarcomatoid Features
Active years: 2018+
Schema(s):

- 00600: Kidney Parenchyma

Description

Sarcomatoid features: present or absent and percentage refers to the observation of sheets and fascicles of malignant spindle cells in a kidney tumor which can occur across all histologic subtypes. The percentage of sarcomatoid component has been shown to correlate with cancer-specific mortality.

The presence of sarcomatoid or spindle cell features in a kidney tumor is a strong adverse prognostic factor. There is a specific ICD-O morphology code for renal cell carcinoma, sarcomatoid or spindle cell (8318/3), but this data item documents any sarcomatoid or spindle cell features in any renal cell cancer.

- **Note:** This data item applies to carcinomas only; rare sarcomas of the kidney should not be coded in this field
- Code the percentage of sarcomatoid features documented anywhere in the pathology report

Rationale

Sarcomatoid features for Kidney is a Registry Data Collection Variable in AJCC. It was previously collected as Kidney, CS SSF #4.

Additional Information

Source Documents: Surgical pathology report

For further information, refer to the **Kidney** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Kidney*.

Notes

Note 1: Physician Staging

- Physician statement of Sarcomatoid Features (spindle cell features) can be used to code this data item when no other information is available.

Note 2: Criteria for coding

- Surgical resection of primary site must be done
    - If no surgical resection of primary site, code unknown (code 9)
- Do not use imaging findings to code this data item.

Note 3: Sarcomatoid morphology/features

- Sarcomatoid morphology may be manifested by any renal cell carcinoma. The presence of sarcomatoid component in a renal cell carcinoma may be prognostically important.
- Sarcomatoid features is mostly seen with renal cell carcinoma (all variants); however, if it's seen with other carcinoma histologies, it can be coded.

Coding Guidelines

1) Record whether sarcomatoid features are present or absent as documented in the surgical pathology report

- Surgical resection of primary site must be done
- Do not use imaging findings to code this data item.

2) Code 000 when the surgical pathology report states that there are no sarcomatoid features

3) Code 001-100 code exact percentage of sarcomatoid features appropriately [1% (001) to 100% (100)]

4) Code R01-R05 when only range documented (specific percentage not available)

5) Code XX5 when the only information available about Sarcomatoid features is from a metastatic site

6) Code XX6 when sarcomatoid features present, percentage unknown

7) Code XX7 when histology is not renal cell carcinoma (includes other carcinomas that are not renal cell and sarcomas)

8) Code XX9 when

- There is no documentation in the medical record
- Clinical diagnosis only
- Evaluation of sarcomatoid features not done or unknown if done
- Surgical resection of the primary site is performed and there is no mention of sarcomatoid features

Code	Description
000	Sarcomatoid features not present/not identified
001-100	Sarcomatoid features 1-100%
R01	Sarcomatoid features stated as less than 10%
R02	Sarcomatoid features stated as range 10%-30% present
R03	Sarcomatoid features stated as a range 31% to 50% present
R04	Sarcomatoid features stated as a range 51% to 80% present
R05	Sarcomatoid features stated as greater than 80%
XX5	Sarcomatoid features present from metastatic site only AND Sarcomatoid features not present, or unknown if present, in primary site
XX6	Sarcomatoid features present, percentage unknown
XX7	Not applicable: Not a renal cell carcinoma morphology
XX8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XX8 may result in an edit error.)
XX9	Not documented in medical record Sarcomatoid features not assessed or unknown if assessed No surgical resection of primary site is performed

00631: Urethra

3926: Schema Discriminator 1

Item Length: 1
NAACCR Item #: 3926
XML Parent-NAACCR ID: Tumor-schemaDiscriminator1
NAACCR Alternate Name: Schema Discriminator 1: Urethra/Prostatic Urethra
Active years: 2018+
Schema(s):

- 00631: Urethra
- 00633: Urethra-Prostatic

Description

Urethra (male and female) and prostatic urethra have the same ICD-O topography code (C680). However, for purposes of stage grouping AJCC 8th edition, they each have different definitions for T or primary tumor extension. A schema discriminator is necessary to distinguish between these primary sites so that the appropriate sub(chapter)/schema is used.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Grade, Summary Stage and EOD data collection system.

Additional Information

Source documents: Pathology report, imaging

Notes

Note: Schema discriminator for C680

- A schema discriminator is used to discriminate between urethra (male and female) and prostatic urethra. Code the site in which the tumor arose.
- **Urethra: Male Penile Urethra and Female Urethra (see code 1)**
  Subsites include Urethra, NOS, Urethral Gland, Cowper gland
- **Urethra: Prostatic Urethra (see code 2)**
  Subsites include Prostatic urethra, Prostatic utricle

Code	Description	Schema ID #/Description
1	Male Penile Urethra Female Urethra Urethral Gland Cowper gland Urethra, NOS	00631: Urethra
2	Males only Prostatic urethra Prostatic utricle	00633: Urethra-Prostatic

00633: Urethra-Prostatic

See **00631: Urethra**

- 3926: Schema Discriminator 1

OPHTHALMIC SITES

00640: Skin Eyelid

3909: Perineural Invasion

Item Length: 1
NAACCR Item #: 3909
XML Parent-NAACCR ID: Tumor-perineuralInvasion
NAACCR Alternate Name: Perineural Invasion
Active years: 2018+
Schema(s):

- 00640: Skin Eyelid
- 00690: Lacrimal Gland

Description

Perineural Invasion, within or adjacent to the primary tumor, is a negative prognostic factor for cutaneous squamous cell carcinomas of the head and neck and carcinomas of the colon and rectum, eyelid, and lacrimal gland.

Perineural invasion is infiltration of nerves in the area of the lesion by tumor cells or spread of tumor along the nerve pathway. The presence of perineural invasion has been shown in several studies to be an indicator of poor patient prognosis. If perineural invasion is not mentioned in the pathology report, do not assume that there is no perineural invasion.

Rationale

Perineural Invasion is a Registry Data Collection Variable in AJCC. It was previously collected as Lacrimal Gland CS SSF #4.

Additional Information

Source Documents: pathology report (see **Note 3**)

Other names include PIN, neurotropism

Notes

Note 1: Physician Statement

- Physician statement of microscopically confirmed perineural invasion can be used to code this data item when no other information is available.

Note 2: Pathology report from a biopsy or surgical resection

- Information on **presence** of perineural invasion **must be from a pathology report** (biopsy or surgical resection)
- Absence of perineural invasion **can only be taken from a surgical resection pathology report**

Note 3: Perineural Invasion not documented on pathology report

- Code 9 if surgical resection of the primary site is performed and there is no mention of perineural invasion.
- Do not assume that there is no perineural invasion

Code	Description
0	Perineural invasion not identified/not present Non-invasive neoplasm (behavior /2)
1	Perineural invasion identified/present
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Pathology report does not mention perineural invasion Cannot be determined by the pathologist Perineural invasion not assessed or unknown if assessed

00660: Melanoma Conjunctiva

3888: Measured Thickness

Item Length: 4
NAACCR Item #: 3888
XML Parent-NAACCR ID: Tumor-measuredThickness
NAACCR Alternate Name: Measured Thickness
Active years: 2018+
Schema(s):

- 00660: Melanoma Conjunctiva
- 00671: Melanoma Iris
- 00672: Melanoma Choroid and Ciliary Body

Description

Measured Thickness, or height, the thickness of a uveal melanoma, is a prognostic indicator for this tumor.

This data items measures tumor thickness, height, or depth (vertical dimension), rather than size (lateral dimension) or basal diameter (horizontal dimension). (For basal diameter, see NAACCR Data Item #3887-Measured Basal Diameter).

The depth of invasion or tumor thickness measurement for melanomas of the choroid, ciliary body, and iris is collected in tenths of millimeters as stated in the pathology report for the resected specimen. (This is similar to, but not the same as, Breslow depth of invasion, which is measured in hundredths of millimeters.) Code a measurement specifically labeled as “thickness” “height” or “depth” in the pathology report. In the absence of this label, a measurement described as taken from the cut surface of the specimen can be coded. And in the absence of either of these labels, the third dimension in a statement of tumor size (length x width x depth) can be used by the registrar to code this field.

Per the CAP guidelines for Uveal Melanoma, “in clinical practice, tumor thickness may be estimated in diopters (average: 2.5 diopters = 1 mm). Techniques such as ultrasonography and fundus photography are used to provide more accurate measurement. When histopathological measurements are recorded after fixation, tumor diameter and thickness may be underestimated because of tissue shrinkage.”

Rationale

Measured Thickness is listed as a Registry Data Collection Variable in AJCC. It was previously collected as Uveal Melanoma, CS SSF #3.

Additional Information

Source Documents: High-frequency ultrasonography (ultrasound biomicroscopy) report, pathology report, wide-angle fundus camera measurement, clinician report or other documentation in medical record

Other names include maximum tumor thickness, depth of invasion, perpendicular tumor diameter (PTD), tumor height

For further information, refer to the **Uveal Melanoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Uveal Melanoma*.

Notes

Note 1: Physician Statement

- Physician statement of measured thickness, or height, can be used to code this data item when no other information is available.

Note 2: Code height not Tumor Size

- Record actual measurement in millimeters (mm) from clinical documentation, or from a pathology report if surgery performed.

Code	Description
0.0	No mass/tumor found
0.1-99.9	0.1 - 99.9 millimeters (mm) (Exact measurement to nearest tenth of mm)
XX.0	100 millimeters (mm) or larger
XX.1	Described as “less than 3 mm”
XX.2	Described as “at least” 3 mm
XX.3	Described as “at least” 6 mm
XX.4	Described as “at least” 9 mm
XX.5	Described as “at least” 12 mm
XX.6	Described as “greater than” 15 mm
XX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XX.8 may result in an edit error.)
XX.9	Not documented in medical record Cannot be determined Measured Thickness not assessed or unknown if assessed

00671: Melanoma Iris

3926: Schema Discriminator 1

Item Length: 1
NAACCR Item #: 3926
XML Parent-NAACCR ID: Tumor-schemaDiscriminator1
NAACCR Alternate Name: Schema Discriminator 1: Melanoma Ciliary Body/Melanoma Iris
Active years: 2018+
Schema(s):

- 00671: Melanoma Iris
- 00672: Melanoma Choroid and Ciliary Body

Description

Iris and ciliary body have the same ICD-O topography code (C694). However, for purposes of stage grouping AJCC 8th edition, they each have different definitions for T or primary tumor extension. A schema discriminator is necessary to distinguish between these primary sites so that the appropriate sub(chapter)/schema is used.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Grade, Summary Stage and EOD data collection system.

Additional Information

Source documents: Pathology report, imaging

Notes

Note: Schema discriminator for C694

- A schema discriminator is used to discriminate between melanoma tumors with primary site code C694: Ciliary Body/Iris. Code the site in which the tumor arose.
- **00672: Melanoma Ciliary Body (see code 1)**
  Subsites include Ciliary body, crystalline lens, sclera, uveal tract, intraocular, eyeball
- **00671: Melanoma Iris (see code 2)**
  Subsite includes Iris

Code	Description	Schema ID #/Description
1	Ciliary Body Crystalline lens Sclera Uveal tract Intraocular Eyeball	00672: Melanoma Choroid and Ciliary Body
2	Iris	00671: Melanoma Iris
<Blank>	Primary Site is NOT C694, Discriminator is not necessary	

00671: Melanoma Iris

3887: Measured Basal Diameter

Item Length: 4
NAACCR Item #: 3887
XML Parent-NAACCR ID: Tumor-measuredBasalDiameter
NAACCR Alternate Name: Measured Basal Diameter
Active years: 2018+
Schema(s):

- 00671: Melanoma Iris
- 00672: Melanoma Choroid and Ciliary Body

Description

Measured Basal Diameter, the largest basal diameter of a uveal melanoma, is a prognostic indicator for this tumor.

The basal diameter is the width (horizontal measurement) of the melanoma at its base (in contact with sclera). This is not the same as the depth of invasion (see NAACCR Data Item #3888-Measured Thickness). Clinical research has shown that as a uveal tumor becomes larger, the risk of hematogenous metastases and death increases. In addition, knowing the size of the melanoma is important for treatment planning.

Per the CAP guidelines for Uveal Melanoma, "in clinical practice, the largest tumor basal diameter may be estimated in optic disc diameters (dd, average: 1 dd = 1.5 mm). Techniques such as ultrasonography and fundus photography are used to provide more accurate measurement. When histopathological measurements are recorded after fixation, tumor diameter and thickness may be underestimated because of tissue shrinkage."

Rationale

Measured Basal Diameter is listed as a Registry Data Collection Variable in AJCC. It was previously collected as Uveal Melanoma, CS SSF #2.

Additional Information

Source documents: High-frequency ultrasonography (ultrasound biomicroscopy) report, pathology report, wide-angle fundus camera measurement, clinician report or other documentation in medical record

Other names include largest tumor diameter (LTD), tumor basal size; do not code tumor basal area (measured in square millimeters)

For further information, refer to the **Uveal Melanoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Uveal Melanoma*.

Notes

Note 1: Physician Statement

- Physician statement of measured basal diameter can be used to code this data item when no other information is available.

Note 2: Code measured basal diameter of tumor not Tumor size

- Record actual measurement in millimeters (mm) to nearest tenth from clinical documentation, or from a pathology report if surgery performed

Code	Description
0.0	No mass/tumor found
0.1-99.9	0.1 - 99.9 millimeters (mm) (Exact measurement to nearest tenth of mm)
XX.0	100 millimeters (mm) or larger
XX.1	Described as “less than 3 mm”
XX.2	Described as “at least” 3 mm
XX.3	Described as “at least” 6 mm
XX.4	Described as “at least” 9 mm
XX.5	Described as “at least” 12 mm
XX.6	Described as “at least” 15 mm
XX.7	Described as “at least” 18 mm
XX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XX.8 may result in an edit error.)
XX.9	Not documented in medical record Cannot be determined by pathologist Measured Basal Diameter not assessed or unknown if assessed

00671: Melanoma Iris

3834: Extravascular Matrix Patterns

Item Length: 1
NAACCR Item #: 3834
XML Parent-NAACCR ID: Tumor-extravascularMatrixPatterns
NAACCR Alternate Name: Extravascular Matrix Patterns
Active years: 2018+
Schema(s):

- 00671: Melanoma Iris
- 00672: Melanoma Choroid and Ciliary Body

Description

Extravascular Matrix Patterns, the presence of loops and networks in extracellular matrix patterns, is a prognostic factor for uveal melanoma.

The presence of extravascular matrix patterns is an indicator for shorter survival. There are two different types of patterns: loops only, or loops forming networks. The identification of the complex monocirculatory patterns (i.e., loops, networks, arcs with branching, parallel with cross-linking or a combination of these patterns) are done using confocal indocyanine green angiography. The patterns are assessed with light microscopy under a dark green filter after staining with periodic-acid Schiff without counterstain. This determines the presence or absence of each matrix pattern, which appear deep purple against a pink background.

Rationale

Extravascular Matrix Patterns is a Registry Data Collection Variable in AJCC 8. This data item was previously collected as Uveal Melanoma, CS SSF #11, and CS SSF #12. These two data items were combined into one data for cases diagnosed 1/1/2018+.

Additional Information

Source documents: pathology report, confocal indocyanine green angiography report, clinician comment.

For further information, refer to the **Uveal Melanoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Uveal Melanoma*.

Notes

Note: Physician Statement

- Physician statement of extravascular matrix patterns can be used to code this data item when no other information is available.

Coding Guidelines

1) Code 0 when pathology report states that loops and networks are not found

2) Code 1 when pathology reports states networks and/or loops present

3) Code 9 when

- Pathology report available and there is no mention of extravascular matrix patterns (loops or networks)
- Extravascular matrix patterns not assessed or unknown if assessed

Code	Description
0	Extravascular matrix patterns not present/not identified
1	Extravascular matrix patterns present/identified
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Extravascular Matrix Patterns not assessed or unknown if assessed

00671: Melanoma Iris

3891: Microvascular Density

Item Length: 2
NAACCR Item #: 3891
XML Parent-NAACCR ID: Tumor-microvascularDensity
NAACCR Alternate Name: Microvascular Density (MVD)
Active years: 2018+
Schema(s):

- 00671: Melanoma Iris
- 00672: Melanoma Choroid and Ciliary Body

Description

Microvascular Density, a quantitative measure of tumor vascularity, is a prognostic factor for uveal melanoma.

A high density of microvessels, identified immunohistochemically using antibodies for vascular endothelial cells (such as Factor VIII-associated antigen, CD34 epitope, etc.), has prognostic significance in a melanoma of the uvea. Higher counts have more unfavorable outcome. To obtain microvascular density, the pathologist, using a microscope with an eyepiece graticule (grid) of approximately 0.3 square mm and X200 magnification, counts microvessels from the most highly vascularized areas (“hot spots”) of the tumor, identified by scanning the entire immunostained tumor at lower magnification. Any immunolabeled element, clearly separate from an adjacent one and either totally inside the graticule or touching its top or left border, is counted as a microvessel. In several studies, the range of microvascular density was from 5 to 121 vessels, although this will vary depending on the type of immunostaining and area of graticule used.

Rationale

Microvascular Density is a Registry Data Collection Variable in AJCC. This data item was previously collected as Uveal Melanoma, CS SSF #13.

Additional Information

Source documents: pathology report

For further information, refer to the **Uveal Melanoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Uveal Melanoma*.

Notes

Note 1: Physician Statement

- Physician statement of microvascular density (MVD) can be used to code this data item when no other information is available.

Note 2: Recording the results

- Record the results as expressed on the laboratory test
- Record the information based on quartiles for laboratory standards if this is the only expression of results.
- Code the microvascular density (number of microvessels) in whole numbers as stated in the pathology report in the code range 001 (1 vessel per 0.3 square millimeters) to 500 (500 vessels per 0.3 square millimeters).

Code	Description
00	No vessels involved
01-99	01-99 vessels per 0.3 square millimeter (mm^2)
X1	Greater than or equal to 100 vessels per 0.3 square millimeter (mm^2)
X2	Lowest quartile for laboratory
X3	Second quartile for laboratory
X4	Third quartile for laboratory
X5	Highest quartile for laboratory
X7	Test ordered, results not in chart
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
X9	Not documented in medical record Microvascular Density (MVD) not assessed or unknown if assessed

00671: Melanoma Iris

3892: Mitotic Count Uveal Melanoma

Item Length: 4
NAACCR Item #: 3892
XML Parent-NAACCR ID: Tumor-mitoticCountUvealMelanoma
NAACCR Alternate Name: Mitotic Count Uveal Melanoma
Active years: 2018+
Schema(s):

- 00671: Melanoma Iris
- 00672: Melanoma Choroid and Ciliary Body

Description

Mitotic Count Uveal Melanoma, the number of mitoses per 40 high-power fields (HPF) based on pathological evaluation, is a prognostic factor for uveal melanoma.

Mitotic count is collected for several different types of cancers. For melanomas of the choroids, ciliary body and iris, the standard measurement is the total number of mitoses per 40 high power fields (HPF at 40 times magnification) per 0.152 square millimeters.

Rationale

Mitotic Count Uveal Melanoma is listed as a Registry Data Collection Variable in AJCC. It was previously collected as Uveal Melanoma, CS SSF #9.

Additional Information

Source documents: pathology report

For further information, refer to the **Uveal Melanoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Uveal Melanoma*.

Notes

Note 1: Physician Statement

- Physician statement of mitotic count for a uveal melanoma can be used to code this data item when no other information is available.

Note 2: Mitotic count defined

- The number of mitoses per 40 high-power fields (HPF), reflects the potential aggressiveness or prognosis of uveal melanomas
- This data item presumes the denominator of 40 HPF, so just the numerator (the mitotic count) is coded here.
- For other schemas in which mitotic count is collected, the denominator may vary.

Note 3: High Power Field (HPF) defined

- An HPF usually has a magnification objective of 40 (a 40x field)
- As described in the AJCC chapter on Uveal Melanomas, the typical field area is 0.152 square millimeters (mm^2).

Note 4: Recording the results

- Record mitotic count to the nearest tenth as documented in the pathology report.
- For example, a mitotic count of 6/40 HPF would be coded 6.0.

Code	Description
0.0	0 mitoses per 40 high-power fields (HPF) Mitoses absent, no mitoses present, no mitotic activity
0.1-99.9	0.1-99.9 mitosis per 40 HPF
XX.1	100 or more mitoses per 40 HPF
XX.2	Stated as low mitotic count or rate with no specific number
XX.3	Stated as high mitotic count or rate with no specific number
XX.4	Mitotic count described with denominator other than 40 HPF
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XX.8 may result in an edit error.)
XX.9	Not documented in medical record Mitotic Count Uveal Melanoma not assessed or unknown if assessed

00671: Melanoma Iris

3821: Chromosome 3 Status

Item Length: 1
NAACCR Item #: 3821
XML Parent-NAACCR ID: Tumor-chromosome3Status
NAACCR Alternate Name: Chromosome 3 Status
Active years: 2018+
Schema(s):

- 00671: Melanoma Iris
- 00672: Melanoma Choroid and Ciliary Body

Description

Chromosome 3 Status refers to the partial or total loss of Chromosome 3, which is a prognostic factor for uveal melanoma.

The loss of an entire copy of chromosome 3, which occurs in about half of patients, is the most important indicator of poor prognosis for the uveal melanomas, particularly melanoma of the choroids and ciliary body. A variety of sophisticated tests can be used to determine chromosome 3 status.

- Karyotyping
- Fluorescence in situ hybridization
- Comparative genomic hybridization
- DNA polymorphism analysis (e.g., single nucleotide polymorphism, microsatellite)
- Multiplex ligation probe amplification
- Monosomy 3 means loss of chromosome 3. Determination of chromosome status may be affected by prior irradiation

Monosomy 3, especially if combined with a frequently coexisting gain in chromosome 8q, is independently associated with metastatic risk. Chromosome 3 and 8 statuses may be determined with karyotyping or fluorescent in situ hybridization (FISH).

Rationale

Chromosome 3 Status is a Registry Data Collection Variable in AJCC. This data item was previously collected as Uveal Melanoma, CS SSF #5.

Additional Information

Source Documents: pathology report, specialty/reference lab report, gene expression profile report, other statement in medical record

Other names include Monosomy 3, loss of chromosome 3, chromosome 3 loss of heterozygosity (LOH), isodisomy 3 (rare)

For further information, refer to the **Uveal Melanoma** cancer protocol published by the College of American Pathologist for the AJCC Staging System *Uveal Melanoma*.

Notes

Note 1: Physician Statement

- Physician statement of chromosome 3 status can be used to code this data item when no other information is available.

Note 2: Related data item

- See related data item 3822: Chromosome 8q Status.

Coding Guidelines

1) Code 0 when there is no loss of chromosome 3, or disomy 3

2) Code 1 when there is partial loss of chromosome 3

3) Code 2 when there is complete loss of chromosome 3, or monosomy 3

4) Code 3 when there is loss of chromosome 3, how much not known

5) Code 9 when

- No documentation in the medical record
- Chromosome 3 not evaluated (assessed)
- Unknown if Chromosome 3 evaluated (assessed)
- Patients received radiation therapy prior to testing

Code	Description
0	No loss of chromosome 3
1	Partial loss of chromosome 3
2	Complete loss of chromosome 3
3	Loss of chromosome 3, NOS Loss of BAP1 expression
7	Test ordered, results not in chart

Code	Description
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Chromosome 3 status not assessed or unknown if assessed

00671: Melanoma Iris

3822: Chromosome 8q Status

Item Length: 1
NAACCR Item #: 3822
XML Parent-NAACCR ID: Tumor-chromosome8qStatus
NAACCR Alternate Name: Chromosome 8q Status
Active years: 2018+
Schema(s):

- 00671: Melanoma Iris
- 00672: Melanoma Choroid and Ciliary Body

Description

Chromosome 8q Status refers to gain in Chromosome 8q, which is a prognostic factor for uveal melanoma.

The loss of an entire copy of chromosome 8, which occurs in about half of patients, is the most important indicator of poor prognosis for the uveal melanomas, particularly melanoma of the choroids and ciliary body. A variety of sophisticated tests can be used to determine chromosome 8 status

- Karyotyping
- Fluorescence in situ hybridization
- Comparative genomic hybridization
- DNA polymorphism analysis (e.g., single nucleotide polymorphism, microsatellite).
- Multiplex ligation probe amplification

Monosomy 3, especially if combined with a frequently coexisting gain in chromosome 8q, is independently associated with metastatic risk. Chromosome 3 and 8 statuses may be determined with karyotyping or fluorescent in situ hybridization (FISH).

Rationale

Chromosome 8q Status is a Registry Data Collection Variable in AJCC. This data item was previously collected as Uveal Melanoma, CS SSF #7.

Additional Information

Source Documents: pathology report, specialty/reference lab report, gene expression profile report, other statement in medical record

Other names include: 8q duplication, 8q trisomy, duplication 8q, partial trisomy 8q, trisomy 8q

For further information, refer to the **Uveal Melanoma** cancer protocol published by the College of American Pathologist for the AJCC Staging System *Uveal Melanoma*.

Notes

Note 1: Physician Statement

- Physician statement of chromosome 8q status can be used to code this data item when no other information is available.

Note 2: Related data item

- See related data item 3821: Chromosome 3 Status.

Coding Guidelines

1) Code 0 when there is no gain in chromosome 8q

2) Code 1 when there is gain in chromosome 8q

3) Code 9 when

- No documentation in the medical record
- Chromosome 8q not evaluated (assessed)
- Unknown if Chromosome 8q evaluated (assessed)
- Patients received radiation therapy prior to testing

Code	Description
0	No gain in chromosome 8q
1	Gain in chromosome 8q
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Chromosome 8q status not assessed or unknown if assessed

00672: Melanoma Choroid and Ciliary Body

See **00671: Melanoma Iris**

- 3926: Schema Discriminator 1
- 3887: Measured Basal Diameter
- 3834: Extravascular Matrix Patterns
- 3891: Microvascular Density
- 3892: Mitotic Count Uveal Melanoma
- 3821: Chromosome 3 Status
- 3822: Chromosome 8q Status

See **00660: Melanoma Conjunctiva**

- 3888: Measured Thickness

00680: Retinoblastoma

3856: Heritable Trait

Item Length: 1
NAACCR Item #: 3856
XML Parent-NAACCR ID: Tumor-heritableTrait
NAACCR Alternate Name: Heritable Trait
Active years: 2018+
Schema(s):

- 00680: Retinoblastoma

Description

Heritable trait pertains to evidence that a tumor is associated with a heritable mutation. In retinoblastoma, the heritable trait is a germline mutation in the RB1 gene, which is associated with bilateral disease, family history of retinoblastoma, presence of concomitant CNS midline embryonic tumor (commonly in pineal region), or retinoblastoma with an intracranial primitive neuroectodermal tumor (i.e., trilateral retinoblastoma). Children with any of these features may be assigned the H1 status without molecular testing. High quality molecular testing for RB1 mutation is required to determine the presence or absence of RB1 mutation for children without clinical features of a heritable mutation.

Heritable disease (trait) is defined by the presence of a germline mutation of the RB1 gene. This germline mutation may have been inherited from an affected progenitor (25% of cases) or may have occurred in a germ cell before conception or in utero during early embryogenesis in patients with sporadic disease (75% of cases). The presence of positive family history or bilateral or multifocal disease is suggestive of heritable disease.

Heritable retinoblastoma may manifest as unilateral or bilateral disease. The penetrance of the RB1 mutation (laterality, age at diagnosis, and number of tumors) is probably dependent on concurrent genetic modifiers such as MDM2 and MDM4 polymorphisms. All children with bilateral disease and approximately 15% of patients with unilateral disease are presumed to have the heritable form, even though only 25% have an affected parent.

In heritable retinoblastoma, tumors tend to be diagnosed at a younger age than in the nonheritable form of the disease. Unilateral retinoblastoma in children younger than 1 year raises concern for heritable disease, whereas older children with a unilateral tumor are more likely to have the nonheritable form of the disease.

Children with a germline RB1 mutation may continue to develop new tumors for a few years after diagnosis and treatment; for this reason, they need to be examined frequently. It is common practice for examinations to occur every 2 to 4 months for at least 28 months. The interval between exams is based on the stability of the disease and age of the child (i.e., less frequent visits as the child ages).

Patients with heritable retinoblastoma are also at a greater risk for subsequent neoplasms.

Heritable trait is required for prognostic stage grouping in the AJCC Staging System Retinoblastoma. It is a new data item for cases diagnosed 1/1/2018+.

Rationale

Heritable trait is required for prognostic stage grouping in AJCC 8th edition, Chapter 68 Retinoblastoma. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: pathology report (tissue), lab reports (blood)

Definition of Heritable trait (H) is listed in the AJCC 8th edition Chapter 68: *Retinoblastoma*.

For further information, refer to the **Retinoblastoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Retinoblastoma*.

Notes

Note: Physician Statement

- Physician statement of retinoblastoma heritable trait can be used to code this data item when no other information is available.

Coding Guidelines

1) Code 0 (H0) when

- If clinical features do not exist OR
- Laboratory germline RB1 test is negative OR
- There is no clinical evidence of mutation
- Residual (false negative) risk for a mutation is less than 1% or at population risk (0.007%) in a laboratory with demonstrated sensitivity greater than 97%.

2) Code 1 (H1) when

- Positive molecular testing for germline RB1 gene
- May be assigned based on clinical evidence of any of the following features even without molecular testing (in particular for children). When discrete clinical evidence of heritable trait is not present, high-quality molecular evidence is mandatory before designating a child as H1 positive
    - Bilateral disease
    - Family history of retinoblastoma

- Presence of concomitant CNS midline embryonic tumor (commonly in pineal region)
- Retinoblastoma with an intracranial primitive neuroectodermal tumor (i.e., trilateral retinoblastoma)

3) Code 9 (HX) when

- Results are stated as variants of unknown significance
- Insufficient evidence of a constitutional RB1 gene mutation
- Not documented in medical record

Code	Description
0	H0: Normal RB1 alleles No clinical evidence of mutation
1	H1: RB1 gene mutation OR Clinical evidence of mutation
7	Test ordered, results not in chart
9	HX: Not documented in medical record Test not done, or unknown if done Insufficient evidence of a constitutional RB1 gene mutation

00690: Lacrimal Gland

3926: Schema Discriminator 1

Item Length: 1
NAACCR Item #: 3926
XML Parent-NAACCR ID: Tumor-schemaDiscriminator1
NAACCR Alternate Name: Schema Discriminator 1: Lacrimal Gland/Lacrimal Sac
Active years: 2018+
Schema(s):

- 00690: Lacrimal Gland
- 00698: Lacrimal Sac

Description

Lacrimal gland and lacrimal sac have the same ICD-O topography code (C695). However, for purposes of the AJCC Staging System stage grouping, lacrimal gland is AJCC staged while lacrimal sac is not (Summary Stage only). A schema discriminator is necessary to distinguish between these primary sites so that the appropriate system/schema is used.

The lacrimal (also spelled lachrymal) gland is the only epithelial structure normally present within the orbit. Its composition is the same as epithelial salivary glands and AJCC TNM staging parallels that of the major salivary gland classification

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Grade, Summary Stage and EOD data collection system.

Additional Information

Source documents: pathology report, imaging

Notes

Note: Schema Discriminator for C695

- A schema discriminator is used to discriminate between lacrimal gland and lacrimal sac tumors with primary site code C695: Lacrimal Gland. Code the site in which the tumor arose.
- **Lacrimal Gland (see code 1)**
- **Lacrimal Sac (see code 2)**
    - Histology is transitional cell carcinoma (8120/3, 8130/3)
    - Subsites include lacrimal sac, lacrimal duct (NOS), nasal lacrimal duct

Code	Description	Schema ID #/Description
1	Lacrimal gland	00690: Lacrimal Gland
2	Lacrimal sac Lacrimal duct, NOS Nasal lacrimal duct/sac Nasolacrimal duct	00698: Lacrimal Sac
9	Lacrimal, NOS	00698: Lacrimal Sac

00690: Lacrimal Gland

3803: Adenoid Cystic Basaloid Pattern

Item Length: 5
NAACCR Item #: 3803
XML Parent-NAACCR ID: Tumor-adenoidCysticBasaloidPattern
NAACCR Alternate Name: Adenoid Cystic Basaloid Pattern
Active years: 2018+
Schema(s):

- 00690: Lacrimal Gland

Description

Adenoid Cystic Basaloid Pattern, the presence of a basaloid pattern on pathological examination, is a prognostic factor for adenoid cystic carcinoma of the lacrimal gland.

Adenoid cystic carcinoma (ICD-O-3 morphology code 8200/3) is the most common malignant epithelial tumor of the lacrimal gland. Adenoid cystic carcinoma is a tumor composed of modified myoepithelial and ductal differentiated cells. A genetic alteration (i.e., fusion oncogene MYB-NFIB) is found in the majority of adenoid cystic carcinomas There are three histologic patterns within the adenoid cystic carcinoma group: cribriform, solid, and tubular.

Rationale

Adenoid Cystic Basaloid Pattern is a Registry Data Collection Variable in AJCC 8. This data item was previously collected as Lacrimal Gland, CS SSF #6.

Additional Information

Source documents: pathology report

Other names include ACC, basaloid type adenoid cystic carcinoma

Notes

Note 1: Physician Statement

- Physician statement of basaloid pattern can be used to code this data item when no other information is available.

Note 2: Applicable histologies

- This is most commonly found in Adenoid Cystic Carcinoma (8200/3) but can be present in other histologies.

Coding Guidelines

1) Code 0.0 when the pathology report states that basaloid or solid pattern is not present

2) Code 0.1-100.0 when the pathology report states the percent of basaloid or solid pattern that is present

3) Code XXX.5 when basaloid or solid pattern present but percentage not known

4) Code XXX.9 when

- Histopathologic pattern not documented in the medical record
- Histopathologic pattern not evaluated (assessed)
- Unknown if histopathologic pattern evaluated (assessed)
- When histologic type other than 8200 and there is no mention of basaloid pattern

Code	Description
0.0-100.0	0.0 to 100.0 percent basaloid pattern
XXX.5	Basaloid pattern present, percentage not stated
XXX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XXX.8 will result in an edit error.)
XXX.9	Not documented in medical record Adenoid Cystic Basaloid Pattern not assessed or unknown if assessed

00698: Lacrimal Sac

See **00690: Lacrimal Gland**

- 3926: Schema Discriminator 1

00721: Brain [8th: 2018-2022]

3816: Brain Molecular Markers (2018-2022)

Item Length: 2
NAACCR Item #: 3816
XML Parent-NAACCR ID: Tumor-brainMolecularMarkers
NAACCR Alternate Name: Brain Molecular Markers
Active years: 2018+
Schema(s):

- 00721: Brain [8th: 2018-2022]
- 00722: CNS Other [8th: 2018-2022]

Description

Multiple brain molecular markers have become standard pathology components necessary for diagnosis. This data item captures clinically important brain cancer subtypes identified by molecular markers that are not distinguishable by ICD-O-3 codes.

Only one code is applicable for each tumor.

- *IDH mutation status* distinguishes between clinically important subtypes within ICD-O-3 **9400/3**, Diffuse astrocytoma and **9401/3**, Anaplastic astrocytoma.
- *IDH mutant and 1p/19q co-deletion* distinguishes between clinically important subtypes within ICD-O-3 code **9450/3**, Oligodendroglioma and **9451/3**, Anaplastic Oligodendroglioma.
- *IDH-wildtype* distinguishes clinically important subtypes within ICD-O-3 **9400/3**, Diffuse astrocytoma, **9401/3**, Anaplastic astrocytoma and **9440/3**, Glioblastoma, Epithelioid glioblastoma and Glioblastoma, NOS (note that the new ICD-O-3 code **9445/3** applies to Glioblastoma, IDH-mutant; information regarding this subtype is not collected using this data item).
- *SHH-activation and TP53-wildtype* distinguishes between clinically important subtypes within ICD-O-3 histology code **9471/3**, Medulloblastoma.
- *C19MC alteration status* distinguishes a clinically important highly aggressive subtype within ICD-O-3 **9478/3**, Embryonal tumor with multilayered rosettes.

Rationale

Collection of these clinically important brain cancer subtypes has been recommended by CBTRUS.

Additional Information

Source documents: pathology report

For further information, refer to the **Central Nervous System** cancer protocol published by the College of American Pathologists.

Notes

Note: Physician statement

- Physician statement of histologic subtype can be used to code this data item when no other information is available.

Coding Guidelines

1) Codes 01-09 are for specific ICD-O-3 codes

2) Code 85 when histology is **NOT** 9400/3, 9401/3, 9440/3, 9450/3, 9451/3, 9471/3 and 9478/3

- This includes microscopically or non-microscopically confirmed cases

3) Code 86 when there is a **Benign (/0)** or **Borderline (/1)** tumor

- This includes microscopically or non-microscopically confirmed cases

4) Code 99 when

- Histology is 9400/3, 9401/3, 9440/3, 9450/3, 9451/3, 9471/3 and 9478/3
- **AND** there is no microscopic confirmation

Examples:

1. Biopsy of brain tumor, microscopic confirmation diagnosis: Diffuse Astrocytoma (9400/3). Additional testing done, and IDH-mutant is identified. Code 01.

2. Biopsy of brain tumor, microscopic confirmation diagnosis: Anaplastic astrocytoma (9401/3). No further testing or results unknown. Code 99.

3. MRI of brain tumor, clinical diagnosis: glioblastoma. No further workup. Code 99.

4. Biopsy of brain tumor, microscopic confirmation diagnosis: Mixed glioma (9382/3). Code 85.

Code	Description
01	Diffuse astrocytoma, IDH-mutant (9400/3)
02	Diffuse astrocytoma, IDH-wildtype (9400/3)
03	Anaplastic astrocytoma, IDH-mutant (9401/3)

Code	Description
04	Anaplastic astrocytoma, IDH-wildtype (9401/3)
05	Glioblastoma, IDH-wildtype (9440/3)
06	Oligodendroglioma, IDH-mutant and 1 p/19q co-deleted (9450/3)
07	Anaplastic oligodendroglioma, IDH-mutant and 1p/19q co-deleted (9451/3)
08	Medulloblastoma, SHH-activated and TP53-wildtype (9471/3)
09	Embryonal tumor with multilayered rosettes, C19MC-altered (9478/3)
85	Not applicable: Histology not 9400/3, 9401/3, 9440/3, 9450/3, 9451/3, 9471/3, 9478/3
86	Benign or borderline tumor
87	Test ordered, results not in chart
88	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 88 will result in an edit error.)
99	Not documented in medical record No microscopic confirmation Brain molecular markers not assessed or unknown if assessed

00721: Brain [8th: 2018-2022]

3801: Chromosome 1p Status

Item Length: 1
NAACCR Item #: 3801
XML Parent-NAACCR ID: Tumor-chromosome1pLossHeterozygosity
NAACCR Alternate Name: Chromosome 1p: Loss of Heterozygosity (LOH)
Active years: 2018+
Schema(s):

- 00721: Brain [8th: 2018-2022]
- 09721: Brain [V9: 2023+]
- 00722: CNS Other [8th: 2018-2022]
- 09722: CNS Other [V9: 2023+]

Description

Chromosome 1p: Loss of Heterozygosity (LOH) refers to the loss of genetic material normally found on the short arm of one of the patient's two copies of chromosome 1. Codeletion of Chromosome 1p and 19q is a diagnostic, prognostic and predictive marker for gliomas and is strongly associated with the oligodendroglioma phenotype.

Loss of Heterozygosity Chromosome 1 p and Chromosome 19q are two genetic tests that are frequently done at the same time and reported together. Loss of heterozygosity (LOH) in a chromosome means that genetic material normally found in a specific area of a chromosome is missing. In other words, this is damage to the chromosome that results in failure of tumor suppression, which in turn may cause the development or progression of a malignancy. For 1p LOH, the specific chromosomal defect is on the short arm (p) of chromosome 1. For 19q LOH, the specific chromosomal defect is on the long arm (q) of chromosome 19.

Normal cells have two complete copies of each chromosome, a state called heterozygosity. The loss of this section of the chromosome is associated with improved outcome. It can be used to aid diagnosis and to make treatment decisions because sensitivity to chemotherapy agents, such as lomustine, procarbazine, and vincristine, is increased with either 1p or 19q LOH. Special molecular diagnostic (polymerase chain reaction or gene amplification) tests look for missing genetic material. LOH for chromosome 1p and 19q is tested primarily for oligodendroglioma, anaplastic oligodendroglioma, oligoastrocytoma, and anaplastic oligoastrocytoma. It is infrequently tested for other gliomas, such as glioblastoma multiforme.

Rationale

Chromosome 1p: Loss of Heterozygosity (LOH) is a Registry Data Collection Variable in AJCC. It was previously collected as Brain, CS SSF #5.

Additional Information

Source documents: pathology report

Other names include whole arm loss, allelic loss, gene deletion, 1p/19q fragment analysis

Notes

Note 1: Physician Statement

- Physician statement of Chromosome 1p deletion/LOH can be used to code this data item when no other information is available.

Note 2: Applicable histologies

- Below is a list of histologies/terms for which the Chromosome 1p test is commonly done. If the test was done, record the results, regardless of the histology. If the histology is not listed among those for which the Chromosome 1p test is commonly done, and the test result is not readily available, assume it was not done and code 9 for unknown.
    - 9382/3: Oligoastrocytoma (anaplastic, or NOS)
    - 9400/3: Diffuse astrocytoma (IDH mutant, IDH wild type, or NOS)
    - 9401/3: Anaplastic astrocytoma (IDH mutant, IDH wild type, or NOS)
    - 9411/3: Gemistocytic astrocytoma, IDH mutant
    - 9424/3: Anaplastic pleomorphic xanthoastrocytoma
    - 9430/3: Astroblastoma
    - 9440/3: Glioblastoma (epithelioid, IDH wild type, or NOS)
    - 9441/3: Giant cell glioblastoma
    - 9442/3: Gliosarcoma
    - 9445/3: Glioblastoma, IDH mutant
    - 9450/3: Oligodendroglioma (IDH mutant and 1p/19q codeleted, or NOS)
    - 9451/3: Anaplastic oligodendroglioma (IDH mutant and 1p/19q codeleted, or NOS)
    - 9505/3: Anaplastic ganglioglioma
    - 9530/3: Anaplastic (malignant) meningioma

Note 3: Related data item

- See also 3802: Chromosome 19q: Loss of Heterozygosity (LOH).

Coding Guidelines

1) Code 0 when the 1p/19q is not identified/not present

2) Code 1 when the 1p/19q is present

3) Code 6 for **Benign (/0)** or **Borderline (/1) tumors**

4) Code 9 when

- No documentation in the medical record
- 1p/19q test not done (not assessed)
- Unknown if 1p/19q test was performed (unknown if assessed)

Code	Description
0	Chromosome 1p deletion/LOH not identified/not present
1	Chromosome 1p deletion/LOH identified/present
6	Benign or borderline tumor
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Cannot be determined by the pathologist Chromosome 1p deletion/LOH not assessed or unknown if assessed

00721: Brain [8th: 2018-2022]

3802: Chromosome 19q Status

Item Length: 1
NAACCR Item #: 3802
XML Parent-NAACCR ID: Tumor-chromosome19qLossHeterozygosity
NAACCR Alternate Name: Chromosome 19q: Loss of Heterozygosity (LOH)
Active years: 2018+
Schema(s):

- 00721: Brain [8th: 2018-2022]
- 09721: Brain [V9: 2023+]
- 00722: CNS Other [8th: 2018-2022]
- 09722: CNS Other [V9: 2023+]

Description

Chromosome 19q: Loss of Heterozygosity (LOH) refers to the loss of genetic material normally found on the long arm of one of the patient's two copies of chromosome 19. Codeletion of Chromosome 1p and 19q is a diagnostic, prognostic and predictive marker for gliomas and is strongly associated with the oligodendroglioma phenotype.

Loss of Heterozygosity Chromosome 1 p and Chromosome 19q are two genetic tests that are frequently done at the same time and reported together. Loss of heterozygosity (LOH) in a chromosome means that genetic material normally found in a specific area of a chromosome is missing. In other words, this is damage to the chromosome that results in failure of tumor suppression, which in turn may cause the development or progression of a malignancy. For 1p LOH, the specific chromosomal defect is on the short arm (p) of chromosome 1. For 19q LOH, the specific chromosomal defect is on the long arm (q) of chromosome 19.

Normal cells have two complete copies of each chromosome, a state called heterozygosity. The loss of this section of the chromosome is associated with improved outcome. It can be used to aid diagnosis and to make treatment decisions because sensitivity to chemotherapy agents, such as lomustine, procarbazine, and vincristine, is increased with either 1p or 19q LOH. Special molecular diagnostic (polymerase chain reaction or gene amplification) tests look for missing genetic material. LOH for chromosome 1p and 19q is tested primarily for oligodendroglioma, anaplastic oligodendroglioma, oligoastrocytoma, and anaplastic oligoastrocytoma. It is infrequently tested for other gliomas, such as glioblastoma multiforme.

Rationale

Chromosome 19q: Loss of Heterozygosity (LOH) is a Registry Data Collection Variable in AJCC. It was previously collected as Brain, CS SSF #6.

Additional Information

Source documents: pathology report

Other names include whole arm loss, allelic loss, gene deletion, 1p/19q fragment analysis

Notes

Note 1: Physician Statement

- Physician statement of Chromosome 19qp deletion/LOH can be used to code this data item when no other information is available.

Note 2: Applicable histologies

- Below is a list of histologies/terms for which the Chromosome 1p test is commonly done. If the test was done, record the results, regardless of the histology. If the histology is not listed among those for which the Chromosome 1p test is commonly done, and the test result is not readily available, assume it was not done and code 9 for unknown.
    - 9382/3: Oligoastrocytoma (anaplastic, or NOS)
    - 9400/3: Diffuse astrocytoma (IDH mutant, IDH wild type, or NOS)
    - 9401/3: Anaplastic astrocytoma (IDH mutant, IDH wild type, or NOS)
    - 9411/3: Gemistocytic astrocytoma, IDH mutant
    - 9424/3: Anaplastic pleomorphic xanthoastrocytoma
    - 9430/3: Astroblastoma
    - 9440/3: Glioblastoma (epithelioid, IDH wild type, or NOS)
    - 9441/3: Giant cell glioblastoma
    - 9442/3: Gliosarcoma
    - 9445/3: Glioblastoma, IDH mutant
    - 9450/3: Oligodendroglioma (IDH mutant and 1p/19q codeleted, or NOS)
    - 9451/3: Anaplastic oligodendroglioma (IDH mutant and 1p/19q codeleted, or NOS)
    - 9505/3: Anaplastic ganglioglioma
    - 9530/3: Anaplastic (malignant) meningioma

Note 3: Related data item

- See also 3801: Chromosome 1p: Loss of Heterozygosity (LOH).

Coding Guidelines

1) Code 0 when the 1p/19q is not identified/not present

2) Code 1 when the 1p/19q is present

3) Code 6 for **Benign (/0)** or **Borderline (/1) tumors**

4) Code 9 when

- No documentation in the medical record
- 1p/19q test not done (not assessed)
- Unknown if 1p/19q test was performed (unknown if assessed)

Code	Description
0	Chromosome 19q deletion/LOH not identified/not present
1	Chromosome 19q deletion/LOH present
6	Benign or borderline tumor
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Cannot be determined by the pathologist Chromosome 19q: LOH not assessed or unknown if assessed

00721: Brain [8th: 2018-2022]

3889: Methylation of O6-Methylguanine-Methyltransferase

Item Length: 1
NAACCR Item #: 3889
XML Parent-NAACCR ID: Tumor-methylationOfO6MGMT
NAACCR Alternate Name: Methylation of O6-Methylguanine-Methyltransferase (MGMT)
Active years: 2018+
Schema(s):

- 00721: Brain [8th: 2018-2022]
- 09721: Brain [V9: 2023+]
- 00722: CNS Other [8th: 2018-2022]
- 09722: CNS Other [V9: 2023+]

Description

O6-Methylguanine-Methyltransferase (MGMT) is an enzyme in cells that repairs DNA. Methylation of the MGMT gene reduces production of the MGMT enzyme and the ability of tumor cells to repair damage caused by chemotherapy. Methylation of MGMT is a prognostic and predictive factor for high grade gliomas.

O6-Methylguanine-Methyltransferase (MGMT) is an enzyme in cells that repairs DNA. DNA repair is undesirable in tumors, because it may enable them to overcome the DNA damage done by chemotherapy. With methylation, less MGMT enzyme is produced, which may lead to prolonged survival compared to unmethylated MGMT.

A patient with increased MGMT methylation is more likely to respond to alkylating agents such as temozolomide (Temodar) and the nitrosoureas, some of the few drugs effective for brain tumors. MGMT methylation is a special (not routine) molecular test done on tumor tissue. It is used primarily for anaplastic oligodendroglioma, anaplastic astrocytoma and glioblastoma multiforme, but can also be done for low grade malignant central nervous system tumors.

Rationale

Methylation of O6-Methylguanine-Methyltransferase (MGMT) is a Registry Data Collection Variable in AJCC. It was previously collected as Brain, CS SSF #4.

Additional Information

Source documents: pathology report, specialty, or reference laboratory report

Other names include MGMT promoter methylation, methylation status

Notes

Note 1: Physician Statement

- Physician statement of the methylation status of the MGMT, also termed MGMT promoter, gene can be used to code this data item when no other information is available.

Note 2: Applicable histologies

- Below is a list of histologies/terms for which the MGMT test is commonly done. If the test was done, record the results, regardless of the histology. If the histology is not listed among those for which the MGMT test is commonly done, and the test result is not readily available, assume it was not done and code 9 for unknown.
    - 9382/3: Anaplastic oligoastrocytoma, NOS
    - 9382/3: Oligoastrocytoma, NOS
    - 9400/3: Diffuse astrocytoma (IDH mutant, IDH wild type, NOS)
    - 9401/3: Anaplastic astrocytoma (IDH mutant, IDH wild type, NOS)
    - 9411/3: Gemistocytic astrocytoma, IDH mutant
    - 9424/3: Anaplastic pleomorphic xanthoastrocytoma
    - 9440/3: Glioblastoma (epithelioid, IDH wild type, NOS)
    - 9441/3: Giant cell glioblastoma
    - 9442/3: Gliosarcoma
    - 9445/3: Glioblastoma, IDH mutant
    - 9450/3: Oligodendroglioma (IDH mutant and 1p/19q codeleted, NOS)
    - 9451/3: Anaplastic oligodendroglioma (IDH mutant and 1p/19 codeleted, NOS)
    - 9505/3: Anaplastic ganglioglioma
    - 9530/3: Anaplastic (malignant)meningioma

Coding Guidelines

1) Code 0 when the MGMT is not identified/not present

2) Code 1 when the MGMT is low

3) Code 2 when the MGMT is high

4) Code 3 when the MGMT is mentioned, but not stated as low or high

5) Code 6 for a **Benign (/0)** or **Borderline (/1) tumor**

6) Code 9 when

- No information in the medical record about MGMT
- MGMT test not done (not assessed)
- Unknown if MGMT test was performed (unknown if assessed)

Code	Description
0	MGMT methylation absent/not present, unmethylated MGMT
1	MGMT methylation present, low level Hypomethylated Partial methylated
2	MGMT methylation present, high level Hypermethylated
3	MGMT methylation present, level unspecified
6	Benign or borderline tumor
7	Test ordered, result not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Cannot be determined by the pathologist MGMT not assessed or unknown if assessed

09721: Brain [V9: 2023+]

3816: Brain Molecular Markers (2023+)

Item Length: 2
NAACCR Item #: 3816
XML Parent-NAACCR ID: Tumor-brainMolecularMarkers
NAACCR Alternate Name: Brain Molecular Markers
Active years: 2018+
Schema(s):

- 09721: Brain [V9: 2023+]
- 09722: CNS Other [V9: 2023+]
- 09724: Medulloblastoma [V9: 2023+]

Description

Multiple brain molecular markers have become standard pathology components necessary for diagnosis. This data item captures clinically important brain cancer subtypes identified by molecular markers that are not distinguishable by ICD-O-3 codes.
If a mutation or alteration is in the name of the histopathology, it is required for diagnosis as it helps distinguish among clinically important subtypes within ICD-O-3.

- *IDH mutation status* distinguishes between clinically important subtypes within ICD-O-3 **9400/3**, Diffuse astrocytoma and **9401/3**, Anaplastic astrocytoma.
- *IDH mutant and 1p/19q co-deletion* distinguishes between clinically important subtypes within ICD-O-3 code **9450/3**, Oligodendroglioma and **9451/3**, Anaplastic Oligodendroglioma.
- *IDH-wildtype* distinguishes clinically important subtypes within ICD-O-3 **9400/3**, Diffuse astrocytoma, **9401/3**, Anaplastic astrocytoma and **9440/3**, Glioblastoma, Epithelioid glioblastoma and Glioblastoma, NOS (note that the new ICD-O-3 code **9445/3** applies to Glioblastoma, IDH-mutant; information regarding this subtype is not collected using this data item).
- *SHH-activation and TP53-wildtype* distinguishes between clinically important subtypes within ICD-O-3 histology code **9471/3**, Medulloblastoma.
- *C19MC alteration* status distinguishes a clinically important highly aggressive subtype within ICD-O-3 **9478/3**, Embryonal tumor with multilayered rosettes
- *Pediatric-type diffuse low-grade gliomas*: **9385/3** Diffuse hemispheric glioma, H3-G34-mutant, Diffuse midline glioma, H3 K27-altered, Diffuse pediatric-type high-grade glioma, H3-wildtype and IDH-wildtype, and Infant-type hemispheric glioma.
- *Ependymal tumors* are distinguished by mutations required for diagnosis among clinically important subtypes: **9396/3** Posterior fossa group A (PFA) ependymoma,

Posterior fossa group B (PFB) ependymoma, Spinal ependymoma, MYCN-amplified, Supratentorial ependymoma, YAPI fusion-positive, and Supratentorial ependymoma, ZFTA fusion-positive.

- *Pediatric-type diffuse low-grade gliomas* are distinguished among subtypes by mutations required for diagnosis: **9421/1** Diffuse astrocytoma, MYB-or MYBL1-altered, Diffuse low-grade glioma, MAPK pathway-altered, and Pilocytic astrocytoma.
- *Circumscribed astrocytic tumors* are distinguished among subtypes by mutations required for diagnosis: **9430/3** Astroblastoma, MN1-altered and Astroblastoma.
- *Other CNS embryonal tumors* are distinguished among subtypes by mutations required for diagnosis: **9500/3** CNS neuroblastoma, FOXR2-activated, CNS tumor with BCOR internal tandem duplication, and Neuroblastoma, NOS.

Rationale

Collection of these clinically important brain cancer subtypes has been recommended by CBTRUS.

Additional Information

Source documents: pathology report

For further information, refer to the **Central Nervous System** cancer protocol published by the College of American Pathologists.

Notes

Note 1: Physician Statement

- Physician statement of histologic subtype can be used to code this data item when no other information is available.

Note 2: Data item history

- This data item was introduced in 2018 and applied to the following ICD-O-3 histology codes: 9400/3, 9401/3, 9440/3, 9450/3, 9451/3, 9471/3, 9478/3
    - These are codes 01-09 and are applicable for cases diagnosed 2018+ and are in ICD-O-3 order
- In 2022, the 5th edition of the CNS WHO Blue Book was released and the following histologies were added: 9385/3, 9396/3, 9421/1, 9430/3, 9500/3
    - These are codes 10-23 and are applicable for cases diagnosed 2024+ and are in ICD-O-3 order

Coding Guidelines

1) Codes 01-23 are for specific ICD-O-3 codes

2) Code 85 when histology is **NOT** 9385/3, 9396/3, 9400/3, 9401/3, 9430/3, 9440/3, 9450/3, 9451/3, 9471/3, 9478/3, 9421/1, 9430/3, 9500/3

- This includes microscopically or non-microscopically confirmed cases

3) Code 86 when there is a **benign (/0)** or **borderline (/1)** tumor

- This includes microscopically or non-microscopically confirmed cases
- ***Exception***: 9421/1 (see codes 19-20 when microscopically confirmed)
    - If codes 19 or 20 don't apply, or not microscopically confirmed, code 99

4) Code 99 when

- Histology is 9385/3, 9396/3, 9400/3, 9401/3, 9430/3, 9440/3, 9450/3, 9451/3, 9471/3, 9478/3, 9421/1, 9430/3, 9500/3
- **AND** there is no microscopic confirmation

Examples:

1. Biopsy of brain tumor, microscopic confirmation diagnosis: Diffuse Astrocytoma (9400/3). Additional testing done, and IDH-mutant is identified. Code 01.

2. Biopsy of brain tumor, microscopic confirmation diagnosis: Anaplastic astrocytoma (9401/3). No further testing or results unknown. Code 99.

3. MRI of brain tumor, clinical diagnosis: glioblastoma. No further workup. Code 99.

4. Biopsy of brain tumor, microscopic confirmation diagnosis: Mixed glioma (9382/3). Code 85.

Code	ICD-O-3 Code	ICD-O-Description
01	9400/3	Astrocytoma, IDH-mutant, grade 2
02	9400/3	Diffuse astrocytoma, IDH-wildtype
03	9401/3	Astrocytoma, IDH-mutant, grade 3
04	9401/3	Anaplastic astrocytoma, IDH-wildtype
05	9440/3	Glioblastoma, IDH-wildtype
06	9450/3	Oligodendroglioma, IDH-mutant and 1 p/19q co-deleted
07	9451/3	Oligodendroglioma, IDH-mutant and 1p/19q co-deleted, grade 3

Code	ICD-O-3 Code	ICD-O-Description
08	9471/3	Medulloblastoma, SHH-activated and TP53-wildtype
09	9478/3	Embryonal tumor with multilayered rosettes, C19MC-altered
10	9385/3	Diffuse hemispheric glioma, H3-34 mutant
11	9385/3	Diffuse midline glioma, H3 K27-altered
12	9385/3	Diffuse pediatric-type high-grade glioma, H3-wildtype and IDH-wildtype
13	9385/3	Infant-type hemispheric glioma
14	9396/3	Posterior fossa group A (PFA) ependymoma
15	9396/3	Posterior fossa group B (PFB) ependymoma
16	9396/3	Spinal ependymoma, MYCN-amplified
17	9396/3	Supratentorial ependymoma, YAP1 fusion-positive
18	9396/3	Supratentorial ependymoma, ZFTA fusion-positive
19	9421/1	Diffuse astrocytoma, MYB- or MYBL1-altered
20	9421/1	Diffuse low-grade glioma, MAPK pathway-altered
21	9430/3	Astroblastoma, MN1-altered
22	9500/3	CNS neuroblastoma, FOXR2-activated
23	9500/3	CNS tumor BCOR internal tandem duplication
85	NA	Not applicable: Histology not 9385/3, 9396/3, 9400/3, 9401/3, 9421/1, 9430/3, 9440/3, 9450/3, 9451/3, 9471/3, 9478/3, 9421/1, 9430/3, 9500/3
86	NA	Benign or borderline tumor Excludes: 9421/1 (codes 19-20)
87	NA	Test ordered, results not in chart
88	NA	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 88 will result in an edit error.)
99	NA	Not documented in medical record No microscopic confirmation Brain molecular markers not assessed or unknown if assessed

09721: Brain [V9: 2023+]

3964: Brain Primary Tumor Location

Item Length: 1
NAACCR Item #: 3964
XML Parent-NAACCR ID: Tumor-brainPrimaryTumorLocation
NAACCR Alternate Name: Brain Primary Tumor Location
Active years: 2024+
Schema(s):

- 09721: Brain [V9: 2023+]

Description

The Pons and other subsites of the Brain Stem have the same ICD-O topography code (C717), which is for subsites of the Brain Stem. Clinically, information regarding the Pons is very important, especially for pediatric cases.

A data item is needed to distinguish between the Pons and all other subsites within the Brain Stem (C717). Code the site in which the tumor arose.

- Review of radiology reports and physician's notes are needed to determine the appropriate code. Needle biopsies and surgery are usually too dangerous for these types of tumors, so the best information will be available from radiology reports.

Rationale

The pons site is the third most common site for pediatric brain tumors and there is currently no way to identify tumors that occur in this site. Surgery is too dangerous for these types of tumors. Needle biopsies are also dangerous and extremely rare. Without pathology specimens, accurate histology is elusive making accurate incidence not possible. A cascade of implications results without accurate incidence including support for drug development.

Additional Information

Source documents: imaging, physician's notes

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2024+
    - For cases diagnosed 2018-2023, this SSDI must be blank

Note 2: Physician Statement

- Physician statement of primary tumor location in the brain stem can be used to code this data item when no other information is available.

Code	Description
1	Pons
2	Subsite other than Pons Basis peduncle Cerebral peduncle Choroid plexus of fourth ventricle Fourth ventricle, NOS Infratentorial brain, NOS Medulla oblongata Midbrain Olive Pyramid
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Brain stem, NOS Unknown subsite of Brain Stem
<Blank>	Primary Site is NOT C717 Must be blank if diagnosis year is before 2024

00722: CNS Other [8th: 2018-2022]

See **00721: Brain [8th: 2018-2022]**

- 3816: Brain Molecular Markers (2018-2022)
- 3801: Chromosome 1p Status
- 3802: Chromosome 19q Status
- 3889: Methylation of O6-Methylguanine-Methyltransferase

09722: CNS Other [V9: 2023+]

See **09721: Brain [V9: 2023+]**

- 3816: Brain Molecular Markers (2023+)

See **00721: Brain [8th: 2018-2022]**

- 3801: Chromosome 1p Status
- 3802: Chromosome 19q Status
- 3889: Methylation of O6-Methylguanine-Methyltransferase

09724: Medulloblastoma [V9: 2023+]

See **09721: Brain [V9: 2023+]**

- 3816: Brain Molecular Markers (2023+)

ENDOCRINE SYSTEM

00730: Thyroid

3926: Schema Discriminator 1

Item Length: 1
NAACCR Item #: 3926
XML Parent-NAACCR ID: Tumor-schemaDiscriminator1
NAACCR Alternate Name: Schema Discriminator 1: Thyroid Gland/Thyroglossal Duct
Active years: 2018+
Schema(s):

- 00730: Thyroid
- 00740: Thyroid Medullary

Description

Thyroid, NOS and thyroglossal duct have the same ICD-O topography code (C739). However, for purposes of the AJCC Staging Systems Thyroid and Thyroid Medullary stage groupings, Thyroid, NOS is applicable for AJCC staging while thyroglossal duct is not (Summary Stage only). A schema discriminator is necessary to distinguish between these primary sites so that the appropriate system/schema is used.

Additional Information

Source documents: pathology report, imaging, clinician's notes

Notes

Note: Schema Discriminator for C739

- A schema discriminator is used to discriminate between thyroid gland and thyroglossal duct tumors with primary site code C739: Thyroid Gland. Code the site in which the tumor arose.
- **Thyroid gland (see code 1)**
  Subsites include Thyroid, NOS
- **Thyroglossal duct (see code 2)**

Code	Description
1	Thyroid gland Thyroid, NOS
2	Thyroglossal duct cyst

00740: Thyroid Medullary

See **00730: Thyroid**

- 3926: Schema Discriminator 1

00790: Lymphoma

3926: Schema Discriminator 1

Item Length: 1
NAACCR Item #: 3926
XML Parent-NAACCR ID: Tumor-schemaDiscriminator1
NAACCR Alternate Name: Schema Discriminator 1: Histology Discriminator for 9591/3
Active years: 2018+
Schema(s):

- 00790: Lymphoma
- 00830: HemeRetic

Description

There are multiple hematopoietic terms that have the same ICD-O histology code (9591/3). However, for purposes of stage grouping AJCC 8th edition, they are in different chapters. A schema discriminator is necessary to distinguish between these histology terms so that the appropriate sub(chapter)/schema is used.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Grade, Summary Stage and EOD data collection system.

Additional Information

Source documents: pathology report

Notes

Note: Schema Discriminator for 9591/3

- A schema discriminator is used to discriminate for histology 9591/3: Non-Hodgkin lymphoma to determine which Stage Group table to use.

Coding Guidelines

1) Code 1: Splenic B-cell lymphoma/leukemia, unclassifiable

- Abstracted and staged as a **leukemia**

2) Code 2: Hairy cell leukemia variant

- Abstracted and staged as a **leukemia**

3) Code 3: Splenic diffuse red pulp small B-cell lymphoma

- Abstracted and staged as a **lymphoma**

4) Code 9: Non-Hodgkin lymphoma, NOS

- Abstracted and staged as a **lymphoma**

Code	Description	Schema ID #/Description
1	Splenic B-cell lymphoma/leukemia, unclassifiable	00830: HemeRetic
2	Hairy cell leukemia variant Prolymphocytic variant of hairy cell leukemia	00830: HemeRetic
3	Splenic diffuse red pulp small B-cell lymphoma Splenic marginal zone lymphoma, diffuse variant Splenic red pulp lymphoma with numerous basophilic villous lymphocytes Splenic lymphoma with villous lymphocytes	00790: Lymphoma (excluding CLL/SLL)
9	Non-Hodgkin lymphoma, NOS Any other terminology describing non-Hodgkin lymphoma, NOS	00790: Lymphoma (excluding CLL/SLL)
<Blank>	Histology is NOT 9591, Discriminator is not necessary	

00790: Lymphoma

3812: B Symptoms

Item Length: 1
NAACCR Item #: 3812
XML Parent-NAACCR ID: Tumor-bSymptoms
NAACCR Alternate Name: B Symptoms
Active years: 2018+
Schema(s):

- 00790: Lymphoma
- 00795: Lymphoma-CLL/SLL

Description

B symptoms refer to systemic symptoms of fever, night sweats, and weight loss which can be associated with both Hodgkin lymphoma and some non-Hodgkin lymphomas. The presence of B symptoms is a prognostic factor for some lymphomas.

The stages of Hodgkin Lymphoma are classified as either A or B according to the absence or presence of defined constitutional symptoms. The stage group suffix for a patient without these systemic symptoms is "A," meaning absence of symptoms or asymptomatic; for example, Stage IIA. The stage group suffix for a patient with any of the symptoms listed below is "B," such as Stage IIIB. The symptoms are carefully defined.

- Fevers: Unexplained fever with temperature above 38 degrees centigrade or 100.4 degrees Fahrenheit.
- Night sweats: Drenching sweats (e.g., those that require change of bedclothes)
- Weight loss: Unexplained weight loss of more than 10% of the usual body weight in the 6 months prior to diagnosis.

Other symptoms, such as chills, pruritic, alcohol-induced pain, and fatigue, are not included in the A or B designation but are recorded in the medical record, as the reappearance of these symptoms may be a harbinger of recurrence. The designation A or B is not included in the revised staging of NHL in AJCC 8th edition, although clinicians are encouraged to record the presence of these symptoms in the medical record. The presence or absence of B symptoms may be collected in registries for both HL and NHL.

Rationale

B symptoms is a Registry Data Collection Variable in AJCC. This data item was previously collected for Lymphomas, SSF #2.

Additional Information

Source documents: patient history, progress notes, consultant notes, other statements in medical record

Other names include B symptoms fever, Palestine fever, hyperpyrexia, febrile response, sleep hyperhidrosis, nocturnal hyperhidrosis

Notes

Note 1: Physician Statement

- Physician statement of B Symptoms can be used to code this data item when no other information is available.

Note 2: Defining B symptoms

- Each stage should be classified as either A or B according to the absence or presence of defined constitutional symptoms, such as:
    - Fevers: Unexplained fever with temperature above 38 degrees C (100.4 F)
    - Night sweats: Drenching sweats that require change of bedclothes
    - Weight loss: Unexplained weight loss of more than 10% of the usual body weight in the six months prior to diagnosis.

Note 3: Conditions that are not B symptoms

- Pruritus alone does not qualify for B classification, nor does alcohol intolerance, fatigue, or a short, febrile illness associated with suspected infections

Coding Guidelines

- **Code 0** when there is no evidence of B symptoms present, per physician or physical exam
- **Code 1** when the physician states the patient has B symptoms
- **Code 9** when
    - No mention of B symptoms
    - Not documented in the medical record
    - B symptoms not evaluated (assessed)
    - Unknown if B symptoms evaluated (assessed)

Code	Description
0	No B symptoms (asymptomatic) Classified as “A” by physician when asymptomatic
1	Any B symptom(s) Night sweats (drenching) Unexplained fever (above 38 degrees C) (100.4 F) Unexplained weight loss (generally greater than 10% of body weight in the six months before admission) B symptoms, NOS Classified as “B” by physician when symptomatic
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record B symptoms not assessed or unknown if assessed

00790: Lymphoma

3859: HIV Status

Item Length: 1
NAACCR Item #: 3859
XML Parent-NAACCR ID: Tumor-hivStatus
NAACCR Alternate Name: HIV Status
Active years: 2018+
Schema(s):

- 00790: Lymphoma
- 00795: Lymphoma-CLL/SLL

Description

HIV status refers to infection with the Human Immunodeficiency Virus which causes Acquired Immune Deficiency Syndrome (AIDS). AIDS is associated with increased risk of developing some lymphomas.

Human immunodeficiency virus (HIV) is the causal agent for acquired immune deficiency syndrome (AIDS). Certain types of cancer are associated with HIV and AIDS, including Hodgkin lymphoma, diffuse large B-cell lymphoma, and primary central nervous system lymphoma. These diseases in patients with HIV or AIDS have different clinical and pathological features from the same diseases when they occur in the general population, such as more extranodal involvement. This data item documents whether the patient has HIV infection or AIDS at the time of diagnosis.

Rationale

HIV status can be collected by the surveillance community for neoplasms (e.g., Kaposi Sarcoma, Lymphomas) that are closely associated with HIV/AIDS. Prior to 2018, Lymphoma SSF#1 was used for HIV Status.

Additional Information

Source documents: clinical laboratory test, statement in medical record.

Other names include HIV type 1, HIV type 2, ARC (AIDS-related complex), PWA (person with AIDS), PWARC (person with ARC); older terms for HIV type 1: HTLV-3, LAV

Notes

Note: Physician Statement

- Physician statement of HIV status can be used to code this data item when no other information is available.

Coding Guidelines

1) Code whether the patient has HIV or AIDS, based on statements in the medical record.

2) Do not assume that the patient is negative for HIV or AIDS

- See code 9 if there is no documentation regarding HIV or AIDS status

3) Code 0 when there is a statement in the record that

- An HIV or AIDS test has been done and is negative
- HIV or AIDS is not present (patient negative or not infected)
- The malignancy is not associated with HIV or AIDS

4) Code 1 when there is a statement in the record that

- An HIV or AIDS test has been done and is positive
- HIV or AIDS is present (patient positive or infected)
- Patient has a history of HIV: however, is not currently detectable

5) Code 9 when

- There is no mention of HIV or AIDS status in the medical record

Code	Description
0	Not associated with Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS) HIV negative
1	Associated with HIV/AIDS HIV positive
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record HIV status not assessed or unknown if assessed

00790: Lymphoma

3896: NCCN International Prognostic Index (IPI)

Item Length: 2
NAACCR Item #: 3896
XML Parent-NAACCR ID: Tumor-nccnInternationalPrognosticIndex
NAACCR Alternate Name: NCCN International Prognostic Index (IPI)
Active years: 2018+
Schema(s):

- 00790: Lymphoma
- 00795: Lymphoma-CLL/SLL

Description

The NCCN International Prognostic Index (IPI) (previously only "IPI") is used to define risk groups for specific lymphomas using a 0-8 score range, based on age, stage, number of extranodal sites of involvement, patient's performance status and LDH level.

The NCCN International Prognostic Index (IPI) has been developed for lymphomas and predicts outcome based on the following adverse factors:

- Age greater than or equal to 60 years
- Serum LDH greater than normal
- Performance status 2-4
- Stage III or IV
- Extranodal involvement greater than 1 site
- Kidney and Adrenal Involvement (CNS Lymphomas only)

Rationale

NCCN International Prognostic Index (IPI) is a Registry Data Collection Variable in AJCC. It was previously collected for Lymphomas, SSF #3.

Additional Information

Source documents: patient history, progress notes, consultant notes, other statements in medical record

Other names include: NCCN CNS IPI (for CNS primaries)

Notes

Note 1: Physician Statement

- Physician statement of NCCN IPI **must** be used to code this data item.
    - Do not calculate points or assign risk. Only record points or risk if a physician has documented them
    - Use points over risk if both are available

Note 2: NCCN is applicable for non-Hodgkin lymphomas only.

- If you have a score for Hodgkin lymphomas (IPS), do not record that information here. Code X9.

Note 3: NCCN and Rai Stage

- A low, intermediate or high risk associated with a Rai Stage is not recorded in this data item.

Code	Description
00-08	0-8 points
X1	Stated as low risk (0-1 point)
X2	Stated as low intermediate risk (2-3 points)
X3	Stated as intermediate risk (4-5 points)
X4	Stated as high risk (6-8 points)
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record NCCN International Prognostic Index (IPI) not assessed or unknown if assessed

00790: Lymphoma

1172: PTLD

Item Length: 1
NAACCR Item #: 1172
XML Parent-NAACCR ID: Tumor-ptld
NAACCR Alternate Name: Post Transplant Lymphoproliferative Disorder-PTLD
Active years: 2025+
Schema(s):

- 00790: Lymphoma
- 00795: Lymphoma-CLL/SLL
- 00812: Primary Cutaneous Lymphoma (excluding MF and SS)
- 00821: Plasma Cell Myeloma
- 00822: Plasma Cell Disorders

Description

Post Transplant Lymphoproliferative Disorder (PTLD) is a lymphoid proliferation arising in a recipient of a solid organ transplant, allogeneic bone marrow transplantation, or an umbilical cord blood transfusion. The patient must have a history of a solid organ transplant or an allogeneic bone marrow transplant. Both polymorphic and monomorphic PTLD are actually caused by post-transplant immunosuppression. Most cases of PTLD occur within a year of transplantation; however, they can occur any time after the transplant. Monomorphic PTLD may have histology indistinguishable from that of various malignant hematopoietic neoplasms, particularly lymphomas such as Diffuse Large B-cell Lymphoma.

Rationale

The presence of PTLD, either polymorphic or monomorphic, has clinical significance and prognostic value, especially in the Pediatric and Adolescence and Young Adult (AYA) populations.

Notes

Note 1: Effective years

- This SSDI is effective for diagnosis years 2025+
- For cases diagnosed 2018-2024, this SSDI must be blank

Note 2: Definition of PTLD

- Post Transplant Lymphoproliferative Disorder (PTLD) is a lymphoid proliferation arising in a recipient of a solid organ transplant, allogeneic bone marrow transplantation, or an umbilical cord blood transfusion.
- The development of PTLD is clinically significant and a prognostic indicator

- See the Hematopoietic database for more information

Note 3: Types of PTLD

- **Polymorphic PTLD**: This is a PTLD by itself, there is no accompanying lymphoma, plasmacytoma or other type of Hematopoietic neoplasm. This type of PTLD is NOT collected in this data item.
- **Monomorphic PTLD (Code 1)**: This is the most common PTLD and is associated with a malignant hematopoietic neoplasm. Most common, but not limited to, diffuse large B-cell lymphoma (DLBCL) and Burkitt lymphoma
- **(Classic Hodgkin lymphoma-PTLD type (Code 2)**: Under the microscope, Reed-Sternberg cells, which are associated with Hodgkin lymphoma are present
- **PTLD, NOS (Code 4)**: Used when only PTLD (NOS) is documented and there is no mention of monomorphic or Hodgkin like type

Coding Guidelines

See the Hematopoietic manual (Rules M14 and PH1. Hematopoietic Project - SEER Registrars (cancer.gov))

1) Code 0 when there is no mention of PTLD on the pathology report or medical record

2) Code 1 when the pathology report describes monomorphic PTLD with a lymphoma

3) Code 2 when the pathology report describes Classic Hodgkin lymphoma-PTLD type

4) Code 4 when the pathology report describes a Burkitt like PTLD or doesn't specify what type of PTLD

Examples (Courtesy of Ask a SEER Registrar)

1. Staining supports the diagnosis of PTLD, monomorphic type, EBV+ diffuse large b-cell lymphoma (non-germinal center) *(Code histology 9680/3, PTLD data item-1)*

2. Monomorphic post-transplant lymphoproliferative disorder (Plasma cell myeloma), EBV negative. Monoclonal kappa plasmacytosis (estimated 20% by CD138 IHC). *(Code histology, 9732/3, PTLD data item: 1)*

3. Per Physician, Stage IIA (bulk) PTLD - Hodgkin-like morphology, Intermediate risk. *(Code histology 9650/3, PTLD data item: 2)*

4. High grade b cell lymphoma/Burkitt like post-transplant lymphoproliferative disorder. *(Code histology 9687/3, PTLD data item-4)*

5. Non-Hodgkin malignant lymphoma with plasmablastic features. Represents a post-transplant/immunodeficiency-related malignant lymphoma. *(Code histology 9590/3, PTLD data item: 4)*

6. Colonoscopy w/bx showed diffuse large B-cell lymphoma w/PTLD. *(Code histology 9680/3, PTLD data item 4)*

7. Right inguinal lymph node biopsy that shows a CD20+ polymorphic PTLD *(Not collected in this schema. Effective 2025+, this would be abstracted as 9971/3 and collected in the HemeRetic schema)*

Code	Description
0	PTLD not documented on the pathology report or in the medical record
1	Monomorphic PTLD PTLD WITH a specified histology (lymphoma, plasmacytoma, plasma cell myeloma)
2	Classic Hodgkin lymphoma-PTLD type PTLD, Hodgkin like
4	PTLD not specified as monomorphic or Hodgkin lymphoma-PTLD type • WITH a specified histology (lymphoma, plasmacytoma, plasma cell myeloma) • Includes Burkitt type PTLD
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error)
<Blank>	Diagnosis year prior to 2025

00795: Lymphoma-CLL/SLL

3885: Lymphocytosis

Item Length: 1
NAACCR Item #: 3885
XML Parent-NAACCR ID: Tumor-lymphocytosis
NAACCR Alternate Name: Lymphocytosis
Active years: 2018+
Schema(s):

- 00795: Lymphoma-CLL/SLL

Description

Lymphocytosis is defined by an excess of lymphocytes in the blood. In staging of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL), lymphocytosis is defined as an absolute lymphocyte count (ALC) > 5,000 cells/µL.

For cases diagnosed 1/1/2018 and later, all cases of CLL and SLL will require both the **Lugano classification, which is captured in the AJCC stage group data item, and the five components of the modified Rai staging system, which are captured in Site-Specific Data Items (adenopathy, anemia, lymphocytosis, organomegaly, and thrombocytopenia).**

The terms B-cell lymphocytic leukemia/chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are different clinical presentations of the same disease, with both terms coded 9823.

Traditionally the lymphoma diagnosis was staged with the Ann Arbor staging system and it is now staged with the Lugano classification. In North America, CLL was staged with the Rai system.

See 3955: Derived Rai stage for additional information on the related data items.

Rationale

Lymphocytosis is a prognostic factor required for staging of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL) in AJCC 8th edition, Chapter 79 *Hodgkin, and Non-Hodgkin Lymphomas*. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: laboratory results, clinician's notes

Notes

Note 1: Physician Statement

- Physician statement of lymphocytosis or Rai Stage can be used to code this data item when no other information is available.

- The physician's stated Rai stage always takes priority when there is conflicting information

Note 2: Rai Stage Criteria

- Rai stage is only applicable for CLL, in which the bone marrow and/or peripheral blood are involved (primary site C421 for bone marrow, see Hematopoietic Manual, Module 3: PH 5, 6).

Note 3: Pretreatment results only

- Record this data item based on a blood test (CBC and differential) performed at diagnosis (pre-treatment)
    - Do not use results from a urine test

Note 4: Values for Lymphocytosis

- Lymphocytosis (lymphocyte number) is defined by an absolute lymphocyte count (ALC) > 5,000 cells/µL and is part of the staging criteria.
    - Use the cut points listed in the table regardless of the lab's reference range
    - For cases that document lymphocyte count in SI (Systeme Internationale) units as any of 10*9/L, 10^9/L, or 10E9/L, the cut point of 5,000 cells/µL is equivalent to (5 cells x 10*9/L), (5 cells X 10^9/L), or (5 cells x10E9/L)

Coding Guidelines

1) Code 0 when primary Site **is C421** AND absolute lymphocyte count (ALC) < 5,000 cells/µL

2) Code 1 when primary Site **is C421** AND absolute lymphocyte count (ALC) is equal or greater than 5,000 cells/µL

3) Code 5 when primary site **is NOT C421**

4) Code 6 when primary site **is C421,** AND lymphocytosis is based on a physician's statement of lymphocytosis or a Rai Stage

- Physician documentation of Rai Stage 0-IV

5) Code 9 when primary site **is C421** AND there is no mention of lymphocytosis

Code	Description
0	Lymphocytosis not present Absolute lymphocyte count <= 5,000 cells/µL
1	Lymphocytosis present Absolute lymphocyte count > 5,000 cells/µL

Code	Description
5	Not applicable: Primary site is not C421
6	Lab value unknown, physician states lymphocytosis is present Physician states Rai stage 0-IV
7	Test ordered, results not in chart
9	Not documented in medical record Lymphocytosis not assessed or unknown if assessed No Rai stage is documented in the record and there is no documentation of lymphocytosis

00795: Lymphoma-CLL/SLL

3804: Adenopathy

Item Length: 1
NAACCR Item #: 3804
XML Parent-NAACCR ID: Tumor-adenopathy
NAACCR Alternate Name: Adenopathy
Active years: 2018+
Schema(s):

- 00795: Lymphoma-CLL/SLL

Description

Adenopathy is defined as the presence of lymph nodes > 1.5 cm on physical examination (PE) and is part of the staging criteria for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL).

For cases diagnosed 1/1/2018 and later, all cases of CLL and SLL will require both the **Lugano classification, which is captured in the AJCC stage group data item, and the five components of the modified Rai staging system, which are captured in Site-Specific Data Items (adenopathy, anemia, lymphocytosis, organomegaly, and thrombocytopenia).**

The terms B-cell lymphocytic leukemia/chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are different clinical presentations of the same disease, with both terms coded 9823.

Traditionally the lymphoma diagnosis was staged with the Ann Arbor staging system and it is now staged with the Lugano classification. In North America, CLL was staged with the Rai system.

See 3955: Derived Rai stage for additional information on the related data items.

Rationale

Adenopathy is a prognostic factor required for staging of CLL/SLL in AJCC 8th edition, Chapter 79 *Hodgkin, and Non-Hodgkin Lymphomas*. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: imaging, physical exam, clinician's notes

Notes

Note 1: Physician Statement

- Physician's statement regarding the presence of adenopathy (present or absent) takes priority. If a physician's statement and imaging are both available and in disagreement, go with the physician's statement

- If a physician's statement is not available, use the definition of adenopathy in the ***Description*** to determine if adenopathy is present or not

Note 2: Record information from physical exam only

- This data item is determined from physical exam alone. If a physical exam cannot be used to detect adenopathy due to issues linked to the patient's obesity, a physician statement of peripheral adenopathy based on a CT scan can be used.
    - A finding of retroperitoneal or mesenteric adenopathy on CT is not used in determining adenopathy and does not affect the assigned stage

Note 3: Rai Stage Criteria

- Rai stage is only applicable for CLL, in which the bone marrow and/or peripheral blood are involved (primary site C421 for bone marrow, see Hematopoietic Manual, Module 3: PH 5, 6).

Note 4: Pretreatment results only

- Record this data item based on physical exam, and physician's statement performed at diagnosis (pre-treatment)

Coding Guidelines

1) Code 0 when primary Site **is C421** AND there is no evidence of adenopathy

- Physician documentation of Rai Stage 0

2) Code 1 when primary Site **is C421** AND there is evidence of adenopathy

- Physician documentation of Rai Stage I

3) Code 5 when primary site **is NOT C421**

4) Code 9 when primary site **is C421**, AND there is no mention of adenopathy

Code	Description
0	Adenopathy not identified/not present No lymph nodes > 1.5 cm Physician states Rai stage 0
1	Adenopathy present Presence of lymph nodes > 1.5 cm Physician states Rai stage I
5	Not applicable: Primary site is not C421

Code	Description
9	Not documented in medical record Adenopathy not assessed or unknown if assessed No Rai stage is documented in the record and there is no documentation of adenopathy Physician states Rai stage II-IV and there is no documentation of adenopathy

00795: Lymphoma-CLL/SLL

3907: Organomegaly

Item Length: 1
NAACCR Item #: 3907
XML Parent-NAACCR ID: Tumor-organomegaly
NAACCR Alternate Name: Organomegaly
Active years: 2018+
Schema(s):

- 00795: Lymphoma-CLL/SLL

Description

Organomegaly is defined as presence of enlarged liver and/or spleen on physical examination and is part of the staging criteria for Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL).

For cases diagnosed 1/1/2018 and later, all cases of CLL and SLL will require both the **Lugano classification, which is captured in the AJCC stage group data item, and the five components of the modified Rai staging system, which are captured in Site-Specific Data Items (adenopathy, anemia, lymphocytosis, organomegaly, and thrombocytopenia).**

The terms B-cell lymphocytic leukemia/chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are different clinical presentations of the same disease, with both terms coded 9823.

Traditionally the lymphoma diagnosis was staged with the Ann Arbor staging system and it is now staged with the Lugano classification. In North America, CLL was staged with the Rai system.

See 3955: Derived Rai stage for additional information on the related data items.

Rationale

Organomegaly is a prognostic factor required for staging of CLL/SLL in AJCC 8th edition, Chapter 79 *Hodgkin, and Non-Hodgkin Lymphomas*. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: physical exam, clinician's notes

Notes

Note 1: Physician Statement

- Physician's statement regarding the presence of organomegaly (present or absent) takes priority. If a physician's statement and imaging are both available and in disagreement, go with the physician's statement.

- If a physician's statement is not available, use the definition of adenopathy in the ***Description*** to determine if organomegaly is present or not

Note 2: Record information from physical exam only

- This data item is determined from physical exam alone. If a physical exam cannot be used to detect organomegaly due to issues linked to the patient's obesity, a physician statement of organomegaly based on a CT scan can be used.
- If there is no mention of the presence or absence of organomegaly (hepatomegaly and splenomegaly), code 9.
    - **Both the liver and spleen must be evaluated** and determined to be normal to code 0. If only one is evaluated and determined to be normal, code 9.

Note 3: Rai Stage Criteria

- Rai stage is only applicable for CLL, in which the bone marrow and/or peripheral blood are involved (primary site C421 for bone marrow, see Hematopoietic Manual, Module 3: PH 5, 6).

Note 4: Pretreatment results only

- Record this data item based on physical exam, and physician's statement performed at diagnosis (pre-treatment)

Coding Guidelines

1) Code 0 when primary Site **is C421** AND there is no evidence of organomegaly

- Physician documentation of Rai Stage 0-I

2) Code 1 when primary Site **is C421** AND there is evidence of organomegaly

- Physician documentation of Rai Stage II

3) Code 5 when primary site **is NOT C421**

4) Code 9 when primary site **is C421**, AND there is no mention of organomegaly

Code	Description
0	Neither hepatomegaly (liver) nor splenomegaly (spleen) present Physician states Rai stage 0-I
1	Hepatomegaly (liver) and/or splenomegaly (spleen) present Physician states Rai stage II
5	Not applicable: Primary site is not C421

Code	Description
9	Not documented in medical record Organomegaly (hepatomegaly and/or splenomegaly) not assessed or unknown if assessed No Rai stage is documented in the record and there is no documentation of organomegaly Physician states Rai stage III-IV and there is no documentation of organomegaly

00795: Lymphoma-CLL/SLL

3811: Anemia

Item Length: 1
NAACCR Item #: 3811
XML Parent-NAACCR ID: Tumor-anemia
NAACCR Alternate Name: Anemia
Active years: 2018+
Schema(s):

- 00795: Lymphoma-CLL/SLL

Description

Anemia is defined by a deficiency of red blood cells or of hemoglobin in the blood. In staging of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL), anemia is defined as Hgb <11.0 g/dL.

For cases diagnosed 1/1/2018 and later, all cases of CLL and SLL will require both the **Lugano classification, which is captured in the AJCC stage group data item, and the five components of the modified Rai staging system, which are captured in Site-Specific Data Items (adenopathy, anemia, lymphocytosis, organomegaly, and thrombocytopenia).**

The terms B-cell lymphocytic leukemia/chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are different clinical presentations of the same disease, with both terms coded 9823.

Traditionally the lymphoma diagnosis was staged with the Ann Arbor staging system and it is now staged with the Lugano classification. In North America, CLL was staged with the Rai system.

See 3955: Derived Rai stage for additional information on the related data items.

Rationale

Anemia is a prognostic factor required for staging of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL) in AJCC 8th edition, Chapter 79 *Hodgkin, and Non-Hodgkin Lymphomas*. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: laboratory results, clinician's notes

Notes

Note 1: Physician Statement

- Physician statement of anemia or Rai Stage can be used to code this data item when no other information is available.

- The physician's stated Rai stage always takes priority when there is conflicting information

Note 2: Rai Stage Criteria

- Rai stage is only applicable for CLL, in which the bone marrow and/or peripheral blood are involved (primary site C421 for bone marrow, see Hematopoietic Manual, Module 3: PH 5, 6).

Note 3: Pretreatment results only

- Record this data item based on a blood test (CBC and differential) performed at diagnosis (pre-treatment)

Note 4: Values for Anemia

- Anemia is defined as Hgb <11.0 g/dL and is part of the staging criteria.
- Use the cut points listed in the table regardless of the lab's reference range
- A lab value expressed in grams per liter (g/L) is 10 times the same value expressed in g/dL; therefore, the cut point of 11.0 g/dL is equivalent to 110 g/L

Coding Guidelines

1) Code 0 when primary Site is C421 AND there is no evidence of anemia

- Physician documentation of Rai Stage 0-II

2) Code 1 when primary Site is C421 AND there is evidence of anemia

3) Code 5 when primary site is NOT C421

4) Code 6 when primary site is C421, AND anemia is based on a physician's statement of anemia or a Rai Stage

- Physician states Rai Stage III

5) Code 9 when primary site is C421, AND there is no mention of anemia

Code	Description
0	Anemia not present Hgb >=11.0 g/dL Physician states Rai stage 0-II
1	Anemia present Hgb <11.0 g/dL
5	Not applicable: Primary site is not C421

Code	Description
6	Lab value unknown, physician states patient is anemic Physician states Rai stage III
7	Test ordered, results not in chart
9	Not documented in medical record Anemia not assessed or unknown if assessed No Rai stage is documented in the record and there is no documentation of anemia Physician states Rai stage IV and there is no documentation of anemia

00795: Lymphoma-CLL/SLL

3933: Thrombocytopenia

Item Length: 1
NAACCR Item #: 3933
XML Parent-NAACCR ID: Tumor-thrombocytopenia
NAACCR Alternate Name: Thrombocytopenia
Active years: 2018+
Schema(s):

- 00795: Lymphoma-CLL/SLL

Description

Thrombocytopenia is defined by a deficiency of platelets in the blood. In staging of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL), thrombocytopenia is defined as Platelets (Plt) < 100,000/µL.

For cases diagnosed 1/1/2018 and later, all cases of CLL and SLL will require both the **Lugano classification, which is captured in the AJCC stage group data item, and the five components of the modified Rai staging system, which are captured in Site-Specific Data Items (adenopathy, anemia, lymphocytosis, organomegaly, and thrombocytopenia).**

The terms B-cell lymphocytic leukemia/chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are different clinical presentations of the same disease, with both terms coded 9823.

Traditionally the lymphoma diagnosis was staged with the Ann Arbor staging system and it is now staged with the Lugano classification. In North America, CLL was staged with the Rai system.

See 3955: Derived Rai stage for additional information on the related data items.

Rationale

Thrombocytopenia is a prognostic factor required for staging of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL) in AJCC 8th edition, Chapter 79 Hodgkin, and Non-Hodgkin Lymphomas. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: laboratory results, clinician's notes

Notes

Note 1: Physician Statement

- Physician statement of thrombocytopenia or Rai Stage can be used to code this data item when no other information is available.

- The physician's stated Rai stage always takes priority when there is conflicting information

Note 2: Rai Stage Criteria

- Rai stage is only applicable for CLL, in which the bone marrow and/or peripheral blood are involved (primary site C421 for bone marrow, see Hematopoietic Manual, Module 3: PH 5, 6).

Note 3: Pretreatment results only

- Record this data item based on a blood test (CBC and differential) performed at diagnosis (pre-treatment)
    - Do not use results from a urine test

Note 4: Values for Thrombocytopenia

- Thrombocytopenia is defined as platelets (Plt) <100,000/µL. This is part of the Modified Rai Staging System and not included as part of the AJCC Lugano staging.
- Use the cut points listed in the table regardless of the lab's reference range
- For cases that document platelet counts in SI (Systeme Internationale) units as any of 10*9/L, 10^9/L, or 10E9/L, the cut point of 100,000 cells/µL is equivalent to (100 cells x 10*9/L), (100 cells x 10^9/L), or (100 cells x 10E9/L)

Coding Guidelines

1) Code 0 when primary Site **is C421** AND there is no evidence of thrombocytopenia

- Physician documentation of Rai Stage 0-III

2) Code 1 when primary Site **is C421** AND there is evidence of thrombocytopenia

3) Code 5 when primary site **is NOT C421**

4) Code 6 when primary site **is C421,** AND thrombocytopenia is based on a physician's statement of lymphocytosis or a Rai Stage

- Physician documentation of Rai Stage IV

5) Code 9 when primary site **is C421** AND there is no mention of thrombocytopenia

Code	Description
0	Thrombocytopenia not present Platelets (Plt) >=100,000/µL Physician states Rai stage 0-III

Code	Description
1	Thrombocytopenia present Platelets (Plt) < 100,000/µL
5	Not applicable: Primary site is not C421
6	Lab value unknown, physician states thrombocytopenia is present Physician states Rai stage IV
7	Test ordered, results not in chart
9	Not documented in medical record Thrombocytopenia not assessed or unknown if assessed No Rai stage is documented in the record and there is no documentation of thrombocytopenia

00795: Lymphoma-CLL/SLL

3955: Derived Rai Stage

Item Length: 1
NAACCR Item #: 3955
XML Parent-NAACCR ID: Tumor-derivedRaiStage
NAACCR Alternate Name: Derived Rai Stage
Active years: 2018+
Schema(s):

- 00795: Lymphoma-CLL/SLL

Description

This data item stores the Derived Rai stage value derived from the values coded in the following related data items for the Lymphoma-CLL/SLL schema (9823/3).

Per confirmation from medical oncologists, Rai stage is only recorded for patients who have bone marrow and/or peripheral blood involvement. Per the Hematopoietic Rules, primary site would be C421 (See Hematopoietic Manual, Module 3: Rules PH 5, 6). Use code 5 for the 5 SSDIs when primary site is not C421.

The Rai classification system is now used to stage chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) (9823/3) when bone marrow and/or peripheral blood are involved using several different criteria. The stages are based on the absence or presence of the following related data items.

- 3885: Lymphocytosis
- 3804: Adenopathy
- 3907: Organomegaly
- 3811: Anemia
- 3933: Thrombocytopenia

Note: All of these data items are required for Staging for the AJCC Staging System Hodgkin and Non-Hodgkin Lymphomas (9823/3 only) and EOD.

Rai stages

- Stage 0 CLL is characterized by absolute lymphocytosis (>15,000/mm3) without adenopathy, hepatosplenomegaly, anemia, or thrombocytopenia
- Stage I CLL is characterized by absolute lymphocytosis with lymphadenopathy without hepatosplenomegaly, anemia, or thrombocytopenia

- Stage II CLL is characterized by absolute lymphocytosis with either hepatomegaly or splenomegaly with or without lymphadenopathy
- Stage III CLL is characterized by absolute lymphocytosis and anemia (hemoglobin <11 g/dL) with or without lymphadenopathy, hepatomegaly, or splenomegaly
- Stage IV CLL is characterized by absolute lymphocytosis and thrombocytopenia (<100,000/mm3) with or without lymphadenopathy, hepatomegaly, splenomegaly, or anemia

This table below* can be used when the **ONLY** information available is the documented Rai stage from the managing physician. (**Note**: The Rai stage cannot be found on a pathology report).

Rai Stage	Definition	Lymphocytosis	Adenopathy	Organomegaly	Anemia	Thrombocytopenia
0	Lymphocytosis only Absolute Lymphocyte count > 5,000 cell/uL	6	0	0	0	0
I	Lymphocytosis AND Adenopathy	6	1	0	0	0
II	Lymphocytosis AND Enlarged spleen and/or liver (Organomegaly)	6	9	1	0	0
III	Lymphocytosis AND Hemoglobin (Hgb) less than 11 g/dL (Anemia)	6	9	9	6	0
IV	Lymphocytosis AND Platelet count < 100,000 /uL (Thrombocytopenia)	6	9	9	9	6

Rationale

The Derived Rai stage can be used to evaluate disease spread at diagnosis, treatment patterns and outcomes over time.

Additional Information

Source documents: laboratory results, physical exam, clinician's notes

Notes

This field should be left blank for all cases diagnosed prior to 2018, for schemas other than 00795, and when not required by standard setter.

Rai Code	Rai Stage	Description
0	0	Lymphocytosis
1	I	Lymphocytosis and Adenopathy
2	II	Lymphocytosis and Organomegaly (Adenopathy is any value other than 5)
3	III	Lymphocytosis and Anemia (Adenopathy and Organomegaly are any value other than 5)
4	IV	Lymphocytosis and Thrombocytopenia (Adenopathy, Organomegaly and Anemia are any value other than 5)
8	N/A	Does not apply, primary site not bone marrow (C421) (All 5 SSDIs should be set to 5)
9	9	Unknown (All 5 SSDIs are 9 or blank OR At least one is set to 9 OR Lymphocytosis is 0,7,9 OR Lymphocytosis is blank and one of the other SSDIs is a value other than 5 or 9)
<Blank>		Not Calculated (DCO)

00811: Mycosis Fungoides

3910: Peripheral Blood Involvement

Item Length: 1
NAACCR Item #: 3910
XML Parent-NAACCR ID: Tumor-peripheralBloodInvolvement
NAACCR Alternate Name: Peripheral Blood Involvement
Active years: 2018+
Schema(s):

- 00811: Mycosis Fungoides

Description

Peripheral blood involvement, summarized in "B category", refers to the percentage of peripheral blood lymphocytes that are atypical (Sezary) cells and whether they are "Clone negative" or "Clone positive."

Mycosis fungoides is the most common type of primary cutaneous T-cell lymphoma. Sezary syndrome is a more aggressive type of primary cutaneous T-cell lymphoma in which a specific type of malignant T lymphocytes (Sezary cells) are present in the circulating blood. Staging of mycosis fungoides includes analysis of the circulating blood for Sezary cells. This analysis can be done by microscopy or flow cytometry. Results of microscopy are reported as counts of Sezary cells per cubic millimeter or the percentage of Sezary cells as a proportion of total lymphocytes. Flow cytometry looks for specific cell surface markers such as CD26.

Information about peripheral blood involvement and T-cell clonality identified by polymerase chain reaction (PCR) or Southern blot analysis is combined in a "B" category unique to mycosis fungoides staging in the TNM system.

Rationale

Peripheral blood involvement is a prognostic factor required in AJCC 8th edition, Chapter 81 *Primary Cutaneous Lymphomas*, for staging of Mycosis Fungoides and Sezary Syndrome. It was previously collected as Mycosis Fungoides, CS SSF #1.

Additional Information

Source documents: pathology report, clinical laboratory reports of blood analysis (tissue and blood samples)

Other names include circulating Sezary cells, T-cell clonality: T-cell receptor (TCR) gene rearrangement, Monoclonal: clone +, clone positive, Polyclonal: clone –, clone negative

Notes

Note 1: Physician statement

- Physician statement of Peripheral Blood Involvement and clonality can be used to code this data item when no other information is available
- If the physician does not provide a B rating but counts or percentages of neoplastic cells, flow cytometry test results, and/or clonality test results are performed, use the appropriate code for the amount of blood involvement with "clone unknown

Note 2: Categories for Peripheral Blood Involvement

- B0 (no significant blood involvement) (codes 0-2)
    - Categorized by clonality
- B1 (low blood tumor burden) (code 3-5)
    - Categorized by clonality
- B2 (high blood tumor burden) (code 6)
    - Any mention of B2 puts the case into Stage IV

Code	Description	B Map
0	Absence of significant blood involvement 5% or less of peripheral blood lymphocytes are atypical (Sezary) cells Clone unknown Stated as B0	B0
1	Absence of significant blood involvement 5% or less of peripheral blood lymphocytes are atypical (Sezary) cells Clone negative Stated as B0a	B0a
2	Absence of significant blood involvement: 5% or less of peripheral blood lymphocytes are atypical (Sezary) cells Clone positive Stated as B0b	B0b

Code	Description	B Map
3	Low blood tumor burden More than 5% of peripheral blood lymphocytes are atypical (Sezary) cells but does not meet the criteria of B2 Clone unknown Stated as B1	B1
4	Low blood tumor burden More than 5% of peripheral blood lymphocytes are atypical (Sezary) cells but does not meet the criteria of B2 Clone negative Stated as B1a	B1a
5	Low blood tumor burden More than 5% of peripheral blood lymphocytes are atypical (Sezary) cells but does not meet the criteria of B2 Clone positive Stated as B1b	B1b
6	High blood tumor burden Greater than or equal to 1000 Sezary cells per microliter (uL) Clone positive Stated as B2	B2
7	Test ordered, results not in chart	BX
9	Not documented in medical record Peripheral Blood Involvement not assessed or unknown if assessed	BX
<Blank>	Death Certificate Only, no value provided	BX

00812: Primary Cutaneous Lymphoma (excluding MF and SS)

See **00790: Lymphoma**

- 1172: PTLD

00821: Plasma Cell Myeloma

3926: Schema Discriminator 1

Item Length: 1
NAACCR Item #: 3926
XML Parent-NAACCR ID: Tumor-schemaDiscriminator1
NAACCR Alternate Name: Schema Discriminator 1: Myeloma Terminology
Active years: 2018+
Schema(s):

- 00821: Plasma Cell Myeloma

Description

A variety of descriptive terms refer to early phases of plasma cell myeloma, all of which are coded to 9732, and reportable based on the 2010 Hematopoietic and Lymphoid Neoplasms coding rules.

Per AJCC 8th edition, not all terms are applicable for the Revised International Staging System (RISS or R-ISS) stage. This schema discriminators collects the specific terminology used to describe the plasma cell myeloma at the time of diagnosis.

Rationale

A schema discriminator is used to assign AJCC ID when site and histology alone are insufficient to identify the applicable AJCC staging method and to assign Schema ID, which links each case to the appropriate SSDIs, Grade, Summary Stage and EOD data collection system.

Additional Information

Source documents: pathology report, clinician's statement

Notes

Note 1: Code Selection

- Select the code based on the terminology specified by the physician in the record. Do not attempt to determine the correct terminology based on the diagnostic criteria in the AJCC 8th table 82.1.
- Do not change the discriminator code if a term used later indicates progression to a more aggressive disease course.

Note 2: Plasma cell leukemia

- Code 0 if diagnosis is plasma cell leukemia variant and is diagnosed concomitant with plasma cell myeloma

Code	Description	Staging
0	Multiple myeloma Myeloma, NOS Non-secretory myeloma Plasma cell myeloma (PCM) Ultra-High-Risk Smoldering MM (SMM)	RISS Stage
1	Smoldering plasma cell myeloma (SPCM) Asymptomatic plasma cell myeloma Early myeloma Evolving myeloma	No RISS Stage
9	Other terminology describing myelomaUnknown terminology used	No RISS Stage

00821: Plasma Cell Myeloma

3931: Serum Beta-2 Microglobulin Pretreatment Level

Item Length: 1
NAACCR Item #: 3931
XML Parent-NAACCR ID: Tumor-serumBeta2MicroglobulinPretxLvl
NAACCR Alternate Name: Serum Beta-2 Microglobulin Pretreatment Level
Active years: 2018+
Schema(s):

- 00821: Plasma Cell Myeloma

Description

Serum Beta-2 Microglobulin is a protein that is found on the surface of many cells and plentiful on the surface of white blood cells. Increased production or destruction of these cells causes Serum β2 (beta-2) Microglobulin level to increase. Elevated Serum β2 (beta-2) Microglobulin level is a prognostic factor for plasma cell myeloma.

The Revised International Staging System (R-ISS or RISS) is now used to stage plasma cell myeloma (9732/3), using several different criteria. The stages are based on the absence or presence of the following related criteria.

- 3931: Serum Beta-2 Microglobulin Pretreatment Level
- 3930: Serum Albumin Pretreatment Level
- 3857: High Risk Cytogenetics
- 3869: LDH Level

Required for Staging: The AJCC Staging System Plasma Cell Myeloma and Plasma Cell Disorders (9732/3 only) and EOD.

- **Note**: R-ISS stage is not applicable for the descriptions of plasma multiple myeloma that are listed in the codes 1 and 9 in the SSDI Schema Discriminator 1: Plasma Cell Myeloma Terminology. If you have coded 1 or 9 for this Schema Discriminator, the four data items listed above are BLANK.

The R-ISS stages are

- Stage I: Serum Beta-2-microglobulin <3.5 mg/L and serum albumin > 3.5 g/dL and no high-risk cytogenetics and Normal LDH
- Stage II: Not R-ISS I or III
- Stage III: Serum Beta-2-microglobulin > 5.5 mg/L and high-risk cytogenetics and/or high LDH

Rationale

Serum Beta-2 Microglobulin Pretreatment Level is a prognostic factor required in AJCC 8th edition, Chapter 82 *Plasma Cell Myeloma and Plasma Cell Disorders*, for staging of plasma cell myeloma. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: laboratory tests (blood only)

Other names include B2M, Total Beta-2 microglobulin, B2-microglobulin, and B2M

Notes

Note 1: Physician statement

- Physician statement of Serum Beta-2-Microglobulin Pretreatment Level can be used to code this data item when no other information is available (See Note 3)

Note 2: Pretreatment results only

- Record this data item based on a **blood test** performed at diagnosis (pre-treatment). Use the highest value available.
    - Do not use results from a urine test

Note 3: Component of R-ISS Stage

- Serum Beta-2 Microglobulin is part of the Revised International Staging (R-ISS).
- Elevated serum microglobulin is defined as ≥ 5.5 mg/L
- Use the cut points listed in the table below regardless of the lab's reference range.
    - **Code 0** if physician states **RISS Stage 1** and there is no other information
    - **Code 2** if physician states **RISS Stage 3** and there is no other information

Coding Guidelines

1) Code 5 if Schema Discriminator 1: Plasma Cell Myeloma Terminology is coded to 1 or 9

2) Code 9 when there is no mention of the Serum beta-2-microglobulin

Code	Description
0	β2-microglobulin < 3.5 mg/L
1	β2-microglobulin ≥ 3.5 mg/L < 5.5 mg/L
2	β2-microglobulin ≥ 5.5 mg/L

Code	Description
5	Schema Discriminator 1: Plasma Cell Myeloma Terminology coded to 1 or 9
7	Test ordered, results not in chart
9	Not documented in medical record Serum Beta-2 Microglobulin Pretreatment Level not assessed or unknown if assessed

00821: Plasma Cell Myeloma

3930: Serum Albumin Pretreatment Level

Item Length: 1
NAACCR Item #: 3930
XML Parent-NAACCR ID: Tumor-serumAlbuminPretreatmentLevel
NAACCR Alternate Name: Serum Albumin Pretreatment Level
Active years: 2018+
Schema(s):

- 00821: Plasma Cell Myeloma

Description

Albumin is the most abundant protein in human blood plasma. Serum albumin pretreatment level is a prognostic factor for plasma cell myeloma.

The Revised International Staging System (R-ISS or RISS) is now used to stage plasma cell myeloma (9732/3), using several different criteria. The stages are based on the absence or presence of the following related criteria.

- 3931: Serum Beta-2 Microglobulin Pretreatment Level
- 3930: Serum Albumin Pretreatment Level
- 3857: High Risk Cytogenetics
- 3869: LDH Level

Required for Staging: The AJCC Staging System Plasma Cell Myeloma and Plasma Cell Disorders (9732/3 only) and EOD.

- **Note**: R-ISS stage is not applicable for the descriptions of plasma multiple myeloma that are listed in the codes 1 and 9 in the SSDI Schema Discriminator 1: Plasma Cell Myeloma Terminology. If you have coded 1 or 9 for this Schema Discriminator, the four data items listed above are BLANK.

The R-ISS stages are

- Stage I: Serum Beta-2-microglobulin <3.5 mg/L and serum albumin > 3.5 g/dL and no high-risk cytogenetics and Normal LDH
- Stage II: Not R-ISS I or III
- Stage III: Serum Beta-2-microglobulin > 5.5 mg/L and high-risk cytogenetics and/or high LDH

Rationale

Serum albumin pretreatment level is a prognostic factor required in AJCC 8th edition, Chapter 82 Plasma Cell Myeloma and Plasma Cell Disorders, for the Revised International Staging System (R-ISS). It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: laboratory tests (blood only)

- Albumin Blood Test
- Preoperative Blood Work
- Total Protein and Albumin/Globulin (A/G) Ratio Test
- Comprehensive metabolic profile (CMP)
- Liver Function Test (LFT)/Hepatic Panel
- Nutritional assessment Panels
- Renal Function Panel

Notes

Note 1: Physician statement

- Physician statement of Serum Albumin Pretreatment Level can be used to code this data item when no other information is available.

Note 2: Pretreatment results only

- Record this data item based on a **blood test** performed at diagnosis (pre-treatment). Use the highest value available.
    - The actual test may not state serum; however, as long as the test results are **based on blood (includes plasma)**, they can be used.
    - Albumin results from a **urine test cannot be used** to code this data item.
- To use the albumin test, **it must say "Serum/Plasma/Blood."**

Note 3: Component of R-ISS Stage

- Serum albumin is part of the Revised International Staging (R-ISS).
    - A lab value expressed in grams per liter (g/L) is 10 times the same value expressed in g/dL; therefore, the cut point of 3.5 g/dL is equivalent to 35 g/L.
- Elevated serum albumin is defined by ≥3.5 g/dL.

- Use the cut points listed in the table below regardless of the lab's reference range.
    - **Code 1** if physician states **RISS Stage 1** and there is no other information

Coding Guidelines

1) Code 5 if Schema Discriminator 1: Plasma Cell Myeloma Terminology is coded to 1 or 9

2) Code 9 when there is no mention of the serum albumin

Code	Description
0	Serum albumin <3.5 g/dL
1	Serum albumin ≥3.5 g/dL
5	Schema Discriminator 1: Plasma Cell Myeloma Terminology coded to 1 or 9
7	Test ordered, results not in chart
9	Not documented in medical record Serum Albumin not assessed or unknown if assessed

00821: Plasma Cell Myeloma

3857: High Risk Cytogenetics

Item Length: 1
NAACCR Item #: 3857
XML Parent-NAACCR ID: Tumor-highRiskCytogenetics
NAACCR Alternate Name: High Risk Cytogenetics
Active years: 2018+
Schema(s):

- 00821: Plasma Cell Myeloma

Description

High Risk Cytogenetics is defined as one or more of t(4;14), t(14;16), or del 17p identified from FISH test results and is part of the staging criteria for plasma cell myeloma.

The Revised International Staging System (R-ISS or RISS) is now used to stage plasma cell myeloma (9732/3), using several different criteria. The stages are based on the absence or presence of the following related criteria.

- 3931: Serum Beta-2 Microglobulin Pretreatment Level
- 3930: Serum Albumin Pretreatment Level
- 3857: High Risk Cytogenetics
- 3869: LDH Level

Required for Staging: The AJCC Staging System Plasma Cell Myeloma and Plasma Cell Disorders (9732/3 only) and EOD.

- **Note:** R-ISS stage is not applicable for the descriptions of plasma multiple myeloma that are listed in the codes 1 and 9 in the SSDI Schema Discriminator 1: Plasma Cell Myeloma Terminology. If you have coded 1 or 9 for this Schema Discriminator, the four data items listed above are BLANK.

The R-ISS stages are

- Stage I: Serum Beta-2-microglobulin <3.5 mg/L and serum albumin > 3.5 g/dL and no high-risk cytogenetics and Normal LDH
- Stage II: Not R-ISS I or III
- Stage III: Serum Beta-2-microglobulin > 5.5 mg/L and high-risk cytogenetics and/or high LDH

Rationale

High Risk Cytogenetics is a prognostic factor required in AJCC 8th edition, Chapter 82 *Plasma Cell Myeloma and Plasma Cell Disorders*, for staging of plasma cell myeloma. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: pathology report

Notes

Note 1: Physician statement

- Physician statement of presence or absence of high-risk cytogenetics can be used to code this data item when no other information is available
- Record this data item based on physician statement or FISH test interpretation performed at diagnosis (pre-treatment).
- If the presence/absence of high-risk cytogenetics determined by available test results differs from the physician statement of presence/absence, the physician's statement takes precedence.

Note 2: Component of RISS Stage

- High-risk cytogenetics is part of the Revised International Staging (R-ISS).
- **Code 0** if physician states **RISS Stage 1 or 2** and there is no other information

Coding Guidelines

1) Code 5 if Schema Discriminator 1: Plasma Cell Myeloma Terminology is coded to 1 or 9

2) Code 9 when there is no mention of high-risk cytogenetics

Code	Description
0	High-risk cytogenetics not identified/not present
1	High-risk cytogenetics present
5	Schema Discriminator 1: Plasma Cell Myeloma Terminology coded to 1 or 9
7	Test ordered, results not in chart
9	Not documented in medical record High Risk Cytogenetics not assessed or unknown if assessed

00821: Plasma Cell Myeloma

3869: LDH Level

Item Length: 1
NAACCR Item #: 3869
XML Parent-NAACCR ID: Tumor-ldhPretreatmentLevel
NAACCR Alternate Name: LDH Level
Active years: 2018+
Schema(s):

- 00821: Plasma Cell Myeloma

Description

LDH (Lactate Dehydrogenase) is an enzyme involved in conversion of sugars to energy and present in most cells in the body. Elevated LDH is an adverse prognostic factor for plasma cell myeloma and melanoma of the skin.

The Revised International Staging System (R-ISS or RISS) is now used to stage plasma cell myeloma (9732/3), using several different criteria. The stages are based on the absence or presence of the following related criteria.

- 3931: Serum Beta-2 Microglobulin Pretreatment Level
- 3930: Serum Albumin Pretreatment Level
- 3857: High Risk Cytogenetics
- 3869: LDH Level

Required for Staging: The AJCC Staging System Plasma Cell Myeloma and Plasma Cell Disorders (9732/3 only) and EOD.

- Note: R-ISS stage is not applicable for the descriptions of plasma multiple myeloma that are listed in the codes 1 and 9 in the SSDI Schema Discriminator 1: Plasma Cell Myeloma Terminology. If you have coded 1 or 9 for this Schema Discriminator, the four data items listed above are BLANK.

The R-ISS stages are

- Stage I: Serum Beta-2-microglobulin <3.5 mg/L and serum albumin > 3.5 g/dL and no high-risk cytogenetics and Normal LDH
- Stage II: Not R-ISS I or III
- Stage III: Serum Beta-2-microglobulin > 5.5 mg/L and high-risk cytogenetics and/or high LDH

Rationale

LDH (Lactate Dehydrogenase) Level is a prognostic factor required in AJCC 8th edition for Chapter 82 Plasma Cell Myeloma and Plasma Cell Disorders and Chapter 47 Melanoma Skin. For Plasma Cell Myeloma, LDH is part of the R-ISS Stage and is new for cases diagnosed 1/1/2018+. For Melanoma Skin, LDH is used to define the M subcategories and was previously collected as Melanoma Skin, SSF #4.

Additional Information

Source documents: clinical laboratory report; may be included in a liver or hepatic panel/profile, a cardiac panel, or a general metabolic panel of tests

Other names include LDH, Lactate dehydrogenase, lactase dehydrogenase, lactic acid dehydrogenase

Notes

Note 1: Physician statement

- Physician statement of LDH Level can be used to code this data item when no other information is available

Note 2: Pretreatment results only

- Record this data item based on a **blood test** performed at diagnosis (pre-treatment). Use the highest value available.
    - Do not use results from a urine test

Note 3: Component of R-ISS Stage

- LDH level is part of the Revised International Staging (R-ISS). Use the lab's reference range to determine if LDH is normal or elevated.
- **Code 0** if physician states **RISS Stage 1 or 2** and there is no other information

Coding Guidelines

1) Code 5 if Schema Discriminator 1: Plasma Cell Myeloma Terminology is coded to 1 or 9

2) Code 9 when there is no mention of LDH

Code	Description
0	Normal LDH level Low, below normal
1	Above normal LDH level; High

Code	Description
5	Schema Discriminator 1: Plasma Cell Myeloma Terminology coded to 1 or 9
7	Test ordered, results not in chart
9	Not documented in medical record LDH (Lactate Dehydrogenase) Level not assessed or unknown if assessed

00822: Plasma Cell Disorders

See **00790: Lymphoma**

- 1172: PTLD

00830: HemeRetic

3862: JAK2

Item Length: 1
NAACCR Item #: 3862
XML Parent-NAACCR ID: Tumor-jak2
NAACCR Alternate Name: Janus Kinase 2
Active years: 2018+
Schema(s):

- 00830: HemeRetic

Description

Janus Kinase 2 (JAK2, JAK 2) is a gene mutation that increases susceptibility to several myeloproliferative neoplasms (MPNs). Testing for the JAK2 mutation is done on whole blood. Nearly all people with polycythemia vera, and about half of those with primary myelofibrosis and essential thrombocythemia, have the mutation. JAK2 analysis continues to increase in use for hematopoietic neoplasms.

JAK2, a gene found in all humans, is involved in the development of blood cells. If JAK2 has mutated, the person is more susceptible to develop a myeloproliferative disorder (MPD). The JAK2 mutation, which is acquired rather than inherited, is found in as many as 90% of patients with polycythemia vera (PV), about half of patients with essential thrombocythemia (ET), and slightly fewer patients with primary myelofibrosis (also known as agnogenic myeloid metaplasia and other terms). JAK2 is used by clinicians to help classify MPDs. The most common histologies for which JAK-2 is tested are those listed above. Registrars can use JAK2 information to help determine whether the MPD is reportable. JAK2 positivity indicates a malignant (clonal, irreversible) reportable disease, but is not diagnostic of a specific MPD. Additional tests, such as a bone marrow biopsy, are necessary to determine the specific MPD histology. As the use of JAK2 increases and is investigated for other hematopoietic histologies, it also has future potential for development of targeted therapeutics for the MPDs.

The principal JAK2 test looks for a change (mutation) in an amino acid at a specific place on the JAK2 gene called V617F. If the V617F test is negative, other JAK2 mutation tests, such as those in exon 12 or 13 may be ordered to investigate a possible diagnosis of polycythemia vera. (An exon is a segment of a gene that contains instructions for making a protein.)

Rationale

JAK2 can be collected by the surveillance community for myeloproliferative neoplasms. Prior to 2018, HemeRetic SSF#1 was used for JAK2.

Additional Information

Source documents: clinical laboratory test (whole blood)

Other names include Janus kinase 2 gene, JAK2 V617F, JAK2 exon 12, JAK2 exon13

Notes

Note 1: Physician Statement

- Physician statement of JAK2 can be used to code this data item when no other information is available.

Note 2: Common histologies for JAK2

- Record JAK2 for any hematopoietic neoplasm. It is most commonly used for the following histologies listed below. Nearly all people with polycythemia vera, and about half of those with primary myelofibrosis and essential thrombocythemia, have the mutation.
    - Polycythemia Vera (9950/3)
    - Primary myelofibrosis (9961/3)
    - Essential Thrombocytopenia (9962/3)
    - Chronic myelomonocytic leukemia (9945/3)

Coding Guidelines

1) Code the result of the JAK2 test as documented in a laboratory test or elsewhere in the medical record.

2) Code this field for any hematopoietic, immunoproliferative, myeloproliferative, or myelodysplastic disease for which JAK2 is tested.

3) Code 0 when the JAK2 test result is stated as negative.

4) Code 1 when the JAK2 test was performed and was positive for mutation V617F in exon 14.

5) Code 2 when the JAK2 test was performed and was positive for mutation of exon 12.

6) Code 3 when the JAK2 test was performed and was positive for another specified mutation.

7) Code 4 when the JAK2 test was performed and was positive for more than one mutation.

8) Code 7 when there is a statement in the record that the test was ordered but the results are not available.

9) Code 9 when

- There is no information in the medical record about JAK2 testing
- The results of JAK2 testing are unknown
- HemeRetic schema disease such as leukemia where JAK2 is not normally tested.

Code	Description
0	JAK2 result stated as negative
1	JAK2 positive for mutation V617F WITH or WITHOUT other mutations
2	JAK2 positive for exon 12 mutation
3	JAK2 positive for other specified mutation
4	JAK2 positive for more than one mutation other than V617F
5	JAK2 positive NOS Specific mutation(s) not stated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record JAK2 not assessed or unknown if assessed

99999: Ill-Defined Other

See **00060: Cervical Lymph Nodes and Unknown Primary**

- 3926: Schema Discriminator 1

SSDIS NO LONGER REQUIRED BY THE STANDARD SETTERS

3828: ER Allred Score (2018-2022)
3850: HER2 IHC Summary (2018-2020)
3851: HER ISH DP Copy No (2018-2020)
3852: HER2 IS DP Ratio (2018-2020)
3853: HER2 ISH SP Copy No (2018-2020)
3854: HER2 ISH Summary (2018-2020)
3894: Multigene Signature Method (2018-2025)
3895: Multigene Signature Result (2018-2025)
3916: PR Allred Score (2018-2022)

3828: Estrogen Receptor Total Allred Score

Item Length: 2
NAACCR Item #: 3828
XML Parent-NAACCR ID: Tumor-estrogenReceptorTotalAllredScore
NAACCR Alternate Name: ER (Estrogen Receptor) Total Allred Score
Active years: 2018+
Schema(s):

- 00480: Breast

Description

Estrogen Receptor Total Allred Score is based on the percentage of cells that stain positive by IHC for estrogen receptor (ER) and the intensity of that staining.

The Allred Score is a method of quantifying ER and PR using both intensity and percentage of positive cells. The Allred Score is calculated by adding the Proportion Score and the Intensity Score, as defined in the tables below.

The Allred score combines the percentage of positive cells (proportion score) and the intensity score of the reaction product in most of the carcinoma. The 2 scores are added together for a final score with 8 possible values (00-08).

Positive cells = 0; Proportion score = 0
Positive cells = <1; Proportion score = 1
Positive cells = 1 to 10; Proportion score = 2
Positive cells = 11 to 33; Proportion score = 3
Positive cells = 34 to 66; Proportion score = 4
Positive cells = 67 or greater; Proportion score = 5

Intensity = None; Intensity Score = 0
Intensity = Weak; Intensity Score = 1
Intensity = Intermediate/Moderate; Intensity Score = 2
Intensity = Strong; Intensity Score = 3

Rationale

Estrogen Receptor Total Allred Score is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: pathology report

For further information, refer to the **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast*.

Notes

Note 1: No longer required by any standard setter

- This SSDI is no longer required by any of the standard setters starting with 2023 diagnoses
- For cases diagnosed 2023+, this SSDI may be left blank

Note 2: Physician Statement

- Physician statement of ER (Estrogen Receptor) Total Allred Score can be used to code this data item.

Note 3: Related data item

- Code this data item using the same report used to record the related data item 3827: Estrogen Receptor Summary.

Coding Guidelines

1) Registrar should not calculate the Allred Score unless both components are available (proportion score and intensity)

2) Code X9 if ER test is performed, but Allred score is not documented, or cannot be calculated

Code	Description
00	Total ER Allred score of 0
01	Total ER Allred score of 1
02	Total ER Allred score of 2
03	Total ER Allred score of 3
04	Total ER Allred score of 4
05	Total ER Allred score of 5
06	Total ER Allred score of 6
07	Total ER Allred score of 7
08	Total ER Allred score of 8
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)

Code	Description
X9	Not documented in medical record ER (Estrogen Receptor) Total Allred Score not assessed, or unknown if assessed
<Blank>	May be blank if diagnosis year is after 2022

3916: Progesterone Receptor Total Allred Score

Item Length: 2
NAACCR Item #: 3916
XML Parent-NAACCR ID: Tumor-progesteroneRecepTotalAllredScor
NAACCR Alternate Name: PR (Progesterone Receptor) Total Allred Score
Active years: 2018+
Schema(s):

- 00480: Breast

Description

Progesterone Receptor, Total Allred Score is based on the percentage of cells that stain by IHC for progesterone receptor (PR) and the intensity of that staining.

The Allred Score is a method of quantifying ER and PR using both intensity and percentage of positive cells. The Allred Score is calculated by adding the Proportion Score and the Intensity Score, as defined in the tables below.

The Allred score combines the percentage of positive cells (proportion score) and the intensity score of the reaction product in most of the carcinoma. The 2 scores are added together for a final score with 8 possible values (00-08).

Positive cells = 0; Proportion score = 0
Positive cells = <1; Proportion score = 1
Positive cells = 1 to 10; Proportion score = 2
Positive cells = 11 to 33; Proportion score = 3
Positive cells = 34 to 66; Proportion score = 4
Positive cells = 67 or greater; Proportion score = 5

Intensity = None; Intensity Score = 0
Intensity = Weak; Intensity Score = 1
Intensity = Intermediate/Moderate; Intensity Score = 2
Intensity = Strong; Intensity Score = 3

Rationale

Progesterone Receptor, Total Allred Score is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

Source documents: pathology report

For further information, refer to the **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast*.

Notes

Note 1: No longer required by any standard setter

- This SSDI is no longer required by any of the standard setters starting with 2023 diagnoses
- For cases diagnosed 2023+, this SSDI may be left blank

Note 2: Physician Statement

- Physician statement of PR (Progesterone Receptor) Total Allred Score can be used to code this data item when no other information is available.

Note 3: Related data item

- Code this data item using the same report used to record the related data item 3915: Progesterone Receptor Summary.

Coding Guidelines

1) Registrar should not calculate the Allred Score unless both components are available (proportion score and intensity)

2) Code X9 if PR test is performed, but Allred score is not documented, or cannot be calculated

Code	Description
00	Total PR Allred score of 0
01	Total PR Allred score of 1
02	Total PR Allred score of 2
03	Total PR Allred score of 3
04	Total PR Allred score of 4
05	Total PR Allred score of 5
06	Total PR Allred score of 6
07	Total PR Allred score of 7
08	Total PR Allred score of 8
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)

Code	Description
X9	Not documented in medical record PR (Progesterone Receptor) Total Allred Score not assessed, or unknown if assessed
<Blank>	May be blank if diagnosis year is after 2022

3850: HER2 IHC Summary

Item Length: 1
NAACCR Item #: 3850
XML Parent-NAACCR ID: Tumor-her2IhcSummary
NAACCR Alternate Name: HER2 IHC Summary
Active years: 2018+
Schema(s):

- 00480: Breast

Description

HER2 IHC Summary is the summary score for HER2 testing by IHC.

The simplest test used is the IHC (immunohistochemistry). An immunohistochemistry (IHC) test identifies the protein expressed by the gene (ERBB2), and an in-situ hybridization (ISH) test identifies the number of copies of the gene (ERBB2) itself. If the IHC test is borderline or indeterminate, an ISH (in situ hybridization) test may be performed.

Reporting Results of HER2 Testing by Immunohistochemistry (IHC)

- Negative (Score 0): No staining observed or incomplete, faint/barely perceptible membrane staining in ≤10% of invasive tumor cells
- Negative (Score 1+): Incomplete, faint/barely perceptible membrane staining in >10% of invasive tumor cells
- Equivocal (Score 2+): Incomplete and/or weak to moderate circumferential membrane staining in >10% of invasive tumor cells or complete, intense, circumferential membrane staining in ≤10% of invasive tumor cells
- Positive (Score 3+): Complete, intense, circumferential membrane staining in >10% of invasive tumor cells

Rationale

HER2 IHC Summary is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

- **Source documents:** pathology report
- **For further information,** refer to the **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast*.

Notes

Note 1: This SSDI is no longer required by any of the standard setters starting with 2021 diagnoses.

- For cases diagnosed 2021+, this SSDI may be left blank

Note 2: Physician statement of HER2 IHC Summary can be used to code this data item when no other information is available.

Note 3: The HER2 IHC test performed on the primary breast tissue is to be recorded in this data item.

Note 4: A 2+ (equivocal) finding by IHC should result in additional testing with ISH to determine gene copy number.

Note 5: Do not use results from the following tests to record HER2

- MammaPrint
- EndoPredict
- PAM 50 (Prosigna)
- Any other test that records HER2

Code	Description
0	Negative (Score 0)
1	Negative (Score 1+)
2	Equivocal (Score 2+) Stated as equivocal Borderline
3	Positive (Score 3+) Stated as positive
4	Stated as negative, but score not stated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Cannot be determined (indeterminate) HER2 IHC Summary not assessed or unknown if assessed
<Blank>	May be blank if diagnosis year is after 2020

3854: HER2 ISH Summary

Item Length: 1
NAACCR Item #: 3854
XML Parent-NAACCR ID: Tumor-her2IshSummary
NAACCR Alternate Name: HER2 ISH Summary
Active years: 2018+
Schema(s):

- 00480: Breast

Description

HER2 in situ hybridization (ISH) Summary is the summary score for results of testing for ERBB2 gene copy number by any ISH method. An immunohistochemistry (IHC) test identifies the protein expressed by the gene (ERBB2), and an ISH test identifies the number of copies of the gene (ERBB2) itself.

If an Immunochemistry (IHC) test is borderline or indeterminate, an ISH test may be performed. The ISH test is a method of testing for overexpression of the HER2 gene that uses fluorescent pieces of DNA that attach only to the HER2 gene copies in cells, which can then be counted under a special microscope. ISH studies determine the presence or absence of gene amplification and methods include fluorescence in situ hybridization (FISH), chromogenic in situ hybridization (CISH), and silver-enhanced in situ hybridization (SISH). Some assays use a single probe to determine the number of HER2 gene copies present (single-probe assays) and others include a chromosome enumeration probe (CEP17) to determine the ratio of HER2 signals to copies of chromosome 17 (dual-probe assays).

Results from single probe and dual probe ISH tests are reported differently and are collected in different data items. For dual probe tests, both HER2/CEP17 ratio and HER2 copy number results are collected in separate data items.

Rationale

HER2 ISH Summary is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

- **Source documents:** pathology report
- **For further information,** refer to the **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast*.

Notes

Note 1: This SSDI is no longer required by any of the standard setters starting with 2021 diagnoses.

- For cases diagnosed 2021+, this SSDI may be left blank

Note 2: Physician statement of HER2 in situ hybridization (ISH) Summary can be used to code this data item when no other information is available.

Note 3: The HER2 ISH test performed on the primary breast tissue is to be recorded in this data item.

Note 4: Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. The same test should be used to code all the HER2 ISH data items.

Code	Description
0	Negative [not amplified]
2	Equivocal
3	Positive [amplified]
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Results cannot be determined (indeterminate) Borderline HER2 ISH Summary not assessed or unknown if assessed
<Blank>	May be blank if diagnosis year is after 2020

3852: HER2 ISH DP Ratio

Item Length: 4
NAACCR Item #: 3852
XML Parent-NAACCR ID: Tumor-her2IshDualProbeRatio
NAACCR Alternate Name: HER2 ISH Dual Probe Ratio
Active years: 2018+
Schema(s):

- 00480: Breast

Description

HER2 ISH Dual Probe Ratio is the summary score for HER2 testing using a dual probe. The test will report results for both HER2 and CEP17, the latter used as a control. The HER2/CEP17 ratio is reported.

Rationale

HER2 ISH Dual Probe Ratio is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

- **Source documents:** pathology report
- **For further information,** refer to the **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast*.

Notes

Note 1: This SSDI is no longer required by any of the standard setters starting with 2021 diagnoses.

- For cases diagnosed 2021+, this SSDI may be left blank

Note 2: Physician statement of HER2 in situ hybridization (ISH) Dual Probe Ratio can be used to code this data item.

Note 3: A dual probe test will report results for both HER2 and CEP17, the latter used as a control. The HER2/CEP17 ratio will be reported. Record the ratio in this data item.

- ***Example:***
  SISH RESULTS: FINAL HER 2 IN SITU HYBRIDIZATION INTERPRETATION: EQUIVOCAL, INDETERMINATE. HER2 gene copy between 4 & 6 with HER2/CEP17 ratio <2.
  HER2/CEP17 RATIO: 4.26 / 3.13 = 1.36
  HER-2/neu SILVER IN SITU HYBRIDIZATION (SISH)
  HER-2neu gene (Inform HER2 DNA probe)
  Number of tumor cell nuclei counted: 120
  Number of Her-2/neu gene copies: 511

Mean HER-2/neu gene copy number: 4.26
CEP-17 SILVER IN SITU HYBRIDIZATION (SISH)
CEP-17 (Inform Chromosome 17 probe)
Number of cell nuclei counted: 60
Number of CEP-17 gene copies: 188
Mean CEP-17 gene copies/nucl: 3.13
Code Dual Probe HER2 Copy Number: 4.2
Code Dual Probe Ratio: 1.3

Note 4: Registrars are not to calculate the ratio.

Note 5: Following ASCO-CAP guidelines, a 2+ (equivocal) finding by immunohistochemistry (IHC) should result in additional testing with ISH to determine gene copy number.

Note 6: Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. Code this data item using the same report used to record information in the related data item 3854: HER2 ISH Summary.

Note 7: A HER2 ISH test may be called "ERBB2." ERBB2 is the standard symbol for the gene 'erb-b2 receptor tyrosine kinase 2.' An IHC test identifies the protein expressed by the gene, and an ISH test identifies the gene itself.

Note 8: If the test results are presented to the hundredth decimal, ignore the hundredth decimal. Do NOT round.

- ***Example:***
    - Reported as 1.99, code as 1.9

Code	Description
0.0-99.9	Ratio of 0.0 to 99.9
XX.2	Less than 2.0
XX.3	Greater than or equal to 2.0
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error.)
XX.9	Not documented in medical record Results cannot be determined (indeterminate) Dual probe test not done; only single probe test performed HER2 ISH dual probe ratio not assessed or unknown if assessed
<Blank>	May be blank if diagnosis year is after 2020

3851: HER2 ISH DP Copy No

Item Length: 4
NAACCR Item #: 3851
XML Parent-NAACCR ID: Tumor-her2IshDualProbeCopyNumber
NAACCR Alternate Name: HER2 ISH Dual Probe Copy Number
Active years: 2018+
Schema(s):

- 00480: Breast

Description

HER2 in situ hybridization (ISH) Dual Probe Copy Number is the HER2 copy number based on a dual probe test.

Reporting Results of HER2 Testing by In Situ Hybridization (dual-probe assay)

- Negative (not amplified): HER2/CEP17 ratio <2.0 AND average HER2 copy number <4.0 signals/cell
- Equivocal: HER2/CEP17 ratio <2.0 AND average HER2 copy number ≥4.0 but <6.0 signals/cell
- Positive (amplified): HER2/CEP17 ratio ≥2.0 (regardless of average HER2 copy number) or Average HER2 copy number ≥6.0 signals/cell (regardless of ratio)

Note: TP52, SMSCR and RARA are gene that are also on chromosome 17. However, they are not close to the centromere, and thus can be used to assess borderline/equivocal fish results (ratios) when the centromeric probe for chromosome 17 (CEP17) performance may be problematic. Although these may be helpful in some cases, they are not the same as the CEP17 result or the ratio determined from CEP17. There should always be a prior CEP17 result when these other results are found in the chart. If one of these tests (TP52, SMSCR, RARA, or others) are used and a dual probe copy number/ratio are documented, record that result in the appropriate data item.

- D17Z1 is the CEP17 probe used in the Vysis (Abbot) FISH kit. So, for the HER2 data items, D17Z1 and CEP17 are to be treated as the same thing.

Rationale

HER2 ISH Dual Probe Copy Number is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

- **Source documents:** pathology report
- **For further information,** refer to the **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast*.

Notes

Note 1: This SSDI is no longer required by any of the standard setters starting with 2021 diagnoses.

- For cases diagnosed 2021+, this SSDI may be left blank

Note 2: Physician statement of HER2 in situ hybridization (ISH) Dual Probe Copy Number can be used to code this data item.

Note 3: A dual probe test will report average number or mean signals per cell for both HER2 and CEP17, the latter used as a control. Record the HER2 average number or mean signals per cells in this data item. The average number or mean signals per cells is also called the copy number.

- ***Example:***
  SISH RESULTS: FINAL HER2 IN SITU HYBRIDIZATION INTERPRETATION: EQUIVOCAL, INDETERMINATE. HER2 gene copy between 4 & 6 with HER2/CEP17 ratio <2.
  HER2/CEP17 RATIO: 4.26 / 3.13 = 1.36
  HER-2/neu SILVER IN SITU HYBRIDIZATION (SISH)
  HER-2neu gene (Inform HER2 DNA probe)
  Number of tumor cell nuclei counted: 120
  Number of Her-2/neu gene copies: 511
  Mean HER-2/neu gene copy number: 4.26
  CEP-17 SILVER IN SITU HYBRIDIZATION (SISH)
  CEP-17 (Inform Chromosome 17 probe)
  Number of cell nuclei counted: 60
  Number of CEP-17 gene copies: 188
  Mean CEP-17 gene copies/nucl: 3.13
  Code Dual Probe HER2 Copy Number: 4.2
  [**Note**: This is calculated by dividing 511 by 120]

Note 4: Registrars are not to calculate the copy number.

Note 5: Following ASCO-CAP guidelines, a 2+ (equivocal) finding by **immunohistochemistry (IHC)** should result in additional testing with ISH to determine gene copy number.

Note 6: Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. Code this data item using the same report used to record information in the related data item 3854: HER2 ISH Summary.

Note 7: A HER2 ISH test may be called "ERBB2." ERBB2 is the standard symbol for the gene 'erb-b2 receptor tyrosine kinase 2.' An IHC test identifies the protein expressed by the gene, and an ISH test identifies the gene itself.

Note 8: If a HER2 ISH single probe copy number test is done, and the results are between 4 and 6 (equivocal), dual probe tests are recommended.

Note 9: If the test results are presented to the hundredth decimal, ignore the hundredth decimal. Do NOT round.

- ***Example:***Reported as 4.99, code as 4.9

Code	Description
0.0-99.9	Reported HER2 copy number of 0.0-99.9
XX.1	Reported HER2 copy number of 100 or greater
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error.)
XX.9	Not documented in medical record Cannot be determined (indeterminate) Dual probe test not done; only single probe test performed HER2 ISH Dual Probe Copy Number not assessed or unknown if assessed
<Blank>	May be blank if diagnosis year is after 2020

3853: HER2 ISH SP Copy No

Item Length: 4
NAACCR Item #: 3853
XML Parent-NAACCR ID: Tumor-her2IshSingleProbeCopyNumber
NAACCR Alternate Name: HER2 ISH Single Probe Copy Number
Active years: 2018+
Schema(s):

- 00480: Breast

Description

HER2 in situ hybridization (ISH) Single Probe Copy Number is the HER2 copy number based on a single probe test.

Reporting Results of HER2 Testing by In Situ Hybridization (single-probe assay)

- Negative (not amplified): Average HER2 copy number <4.0 signals/cell
- Equivocal: Average HER2 copy number ≥4.0 and <6.0 signals/cell
- Positive (amplified): Average HER2 copy number ≥6.0 signals/cell

Rationale

HER2 ISH Single Probe Copy Number is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

- **Source documents:** pathology report
- **For further information,** refer to the **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast*.

Notes

Note 1: This SSDI is no longer required by any of the standard setters starting with 2021 diagnoses.

- For cases diagnosed 2021+, this SSDI may be left blank

Note 2: Physician statement of HER2 in situ hybridization (ISH) Single Probe Copy Number can be used to code this data item.

Note 3: A single probe test will report average number or mean signals per cell for HER2. Record the HER2 average number or mean signals per cells in this data item. The average number or mean signals per cell is also called the copy number.

- ***Example:***
  SISH RESULTS: FINAL HER 2 IN SITU HYBRIDIZATION INTERPRETATION: POSITIVE (>6 gene copies) HER-2/neu gene amplification.

HER-2/neu SILVER IN SITU HYBRIDIZATION (SISH)
HER-2neu gene (Inform HER2 DNA probe)
Number of tumor cell nuclei counted: 60
Number of Her-2/neu gene copies: 418
Mean HER-2/neu gene copy number: 6.9
Code Single Probe HER2 Copy Number: 6.9
[Note: This is calculated by dividing 418 by 60]

Note 4: Registrars are not to calculate the copy number.

Note 5: Following ASCO-CAP guidelines, a 2+ (equivocal) finding by immunohistochemistry (IHC) should result in additional testing with ISH to determine gene copy number.

Note 6: Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. Code this data item using the same report used to record information in the related data item 3854: HER2 ISH Summary.

Note 7: A HER2 ISH test may be called "ERBB2." ERBB2 is the standard symbol for the gene 'erb-b2 receptor tyrosine kinase 2.' An IHC test identifies the protein expressed by the gene, and an ISH test identifies the gene itself.

Note 8: If a HER2 ISH single probe copy number test is done, and the results are between 4 and 6 (equivocal), dual probe tests are recommended.

Note 9: If the test results are presented to the hundredth decimal, ignore the hundredth decimal. Do NOT round.

- ***Example:***
  - Reported as 6.97, code 6.9

Code	Description
0.0-99.9	Reported HER2 copy number of 0.0-99.9
XX.1	Reported HER2 copy number of 100 or greater
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error.)
XX.9	Not documented in medical record Cannot be determined (indeterminate) Single probe test not done; only dual probe test performed HER2 ISH Single Probe Copy Number not assessed or unknown if assessed
<Blank>	May be blank if diagnosis year is after 2022