Site-Specific Data Items: Pitfalls and Obstacles

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Objectives

- Know and understand the many variables concerning accurate reporting of SSDIs including timing, rounding, and applicable sources.
- Know and understand the role of General Rules, and why they are so important.
- Know and understand the impact of inaccurate coding to your organization and/or cancer program.

Site-Specific Data Item (SSDI) Manual

Effective with Cases Diagnosed 1/1/2018 and Forward

Published October 2022

Version 3.0

Timing

The SSDIs are to be collected during initial diagnosis, work up and first course of treatment

Some have specific instructions as to when the SSDIS are collected

CEA prior to polypectomy
PSA prior to needle biopsy

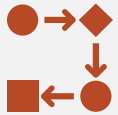
Active surveillance is first course of treatment

Consult Reports

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

Understanding Specific Statements

"Cannot be determined by pathologist" primarily used when a tissue specimen is not adequate for testing.



"Not identified" means 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 (you would document this as "not documented in medical record" or "NR").

"Unknown" indicates the test/evaluation/assessment was ***not*** done or unknown if done.

Source Documents

Source documents are suggested for some data items as the most likely source 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

- Addendum or revisions
- Gross and microscopic description
- Synoptic reports
- CAP protocol, or cancer checklist information provided by the pathologist

Rules for Recording Lab Values

SSDIs follow general rounding rules

- 0-4 round down (example: PSA 7.14, record value as 7.1)
- 5-9 round up (example: ER 96.6%, record value as 097)

Whole percentages

- Greater than and less than values (ER >95%, record 096; PR <89%, record 088)

Percentages with decimals

- Greater than or less than values (Ki67 >20%, value is reported as XX.X, record as 20.1)

Special circumstances

- Values reported in 10 step ranges (example: 50-60%)
- Multiple tests for a single tumor
- Multiple tumors with different values

Schema Discriminators

The following are Schema Discriminator 1

- 3926: Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct
- 3926: Schema Discriminator 1: EsophagusGEJunction (EGJ)/Stomach
- 3926: Schema Discriminator 1: Histology Discriminator for 9591/3
- 3926: Schema Discriminator 1: Lacrimal Gland/Sac
- 3926: Schema Discriminator 1: Melanoma Ciliary Body/Melanoma Iris
- 3926: Schema Discriminator 1: Nasopharynx/Pharyngeal Tonsil
- 3926: Schema Discriminator 1: Occult Head and Neck Lymph Nodes
- 3926: Schema Discriminator 1: Plasma Cell Myeloma Terminology
- 3926: Schema Discriminator 1: Primary Peritoneum Tumor
- 3926: Schema Discriminator 1: Thyroid Gland/Thyroglossal Duct
- 3926: Schema Discriminator 1: Urethra/Prostatic Urethra

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)

- Epstein-Barr Virus (EBV): EBV positive cancers are associated with nasopharyngeal cancer.
  - If the EBV (EBER) test is done and is positive, the primary site should be assigned to C119 (nasopharynx, NOS) instead of C760, so that the Nasopharynx staging system can be used. Nasopharynx has a T0, for no evidence of primary tumor
- p16: p16 positive cancers in the head and neck are associated with oropharyngeal cancer. p16 is a surrogate marker for Human Papilloma Virus (HPV).
  - If the p16 test is done and positive (and EBV is negative or unknown), the primary site should be assigned to C109 (oropharynx, NOS) instead of C760, so that the Oropharynx staging system can be used. Oropharynx has a T0, for no evidence of primary tumor.
  - ***Note***: p16 is the only test that can be used for this discriminator. If there is another HPV test that is positive, the p16 would still be negative for purposes of this data item.

	EBV Positive	EBV Negative	EBV Unknown
p16 Positive	C11.9 Nasopharynx (00090: Nasopharynx)	C10.9 Oropharynx (00100: Oropharynx HPV-Mediated (p16+))	C10.9 Oropharynx (00100: Oropharynx HPV-Mediated (p16+))
p16 Negative	C11.9 Nasopharynx (00090: Nasopharynx)	C76.0 Ill-Defined Site of the Head and Neck (00060: Cervical Lymph Nodes and Unknown Primary)	C76.0 Ill-Defined Site of the Head and Neck (00060: Cervical Lymph Nodes and Unknown Primary)
p16 Unknown	C11.9 Nasopharynx (00090: Nasopharynx)	C76.0 Ill-Defined Site of the Head and Neck (00060: Cervical Lymph Nodes and Unknown Primary)	C76.0 Ill-Defined Site of the Head and Neck (00060: Cervical Lymph Nodes and Unknown Primary)

Occult Head and Neck Lymph Nodes

(Occult tumors/when a primary tumor is not evident)

Schema Discriminator 1:
Esophagus/GEJunction/Stomach

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

Note 1: Use 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)

Note 1: Use code 0 when only the cardia is documented as involved (no mention of EGJ)

Note 2: Use 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

Note 3: Use 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 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 distance unknown)	00170: Stomach
<Blank>	Primary site is NOT C160, Discriminator is not necessary	

- Codes in mm
- For colon primaries, primary surgery code must be coded 30-80 (if surgery code 00-29, code XX.7)
- For rectal primaries, primary surgery code must be 27, or 30-80 (if surgery code 00-26 or 28, code XX.7)

Note 5: The CRM may be referred to as

- Circumferential radial margin
- Circumferential resection margin
- Mesenteric (mesocolon) (mesorectal) margin
- Radial margin
- Soft tissue margin

- Rounding rules apply (if CRM is 2.78mm, code 2.8)
- If value is reported in cm, multiple by 10 (example: CRM 0.2cm, 0.2 x 10 – 2.0mm)
- Involved margins code to 0.0
- Margins described as <0.1mm code to 0.0
- XX.2 is only used when path report states the margin cannot be assessed
- Exact measurement always the priority
- Use XX.9 for in situ, when checked N/A, or not mentioned on path report

00200: Colon and Rectum (2018+)

3823: Circumferential Resection Margin (CRM)

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

- 00200: Colon and Rectum (2018+)

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.

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.

Definition

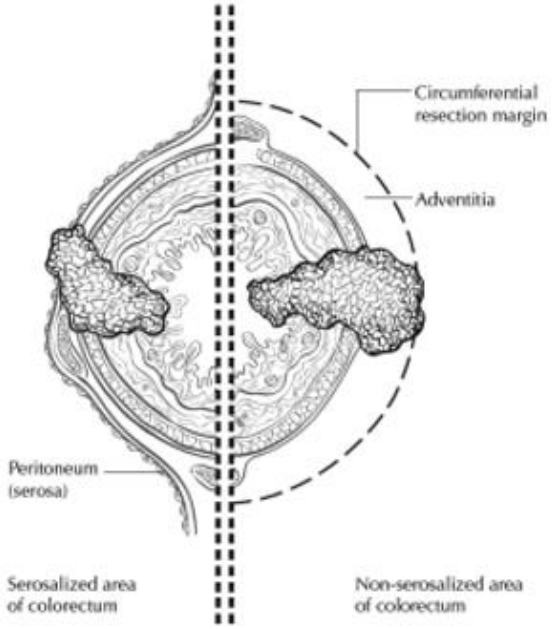
The CRM, also referred to as the radial margin or the mesenteric resection margin, is the measurement of the distance from the deepest invasion of the tumor to the margin of resection in the retroperitoneum or mesentery. In other words, the CRM is the width of the surgical margin at the deepest part 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).

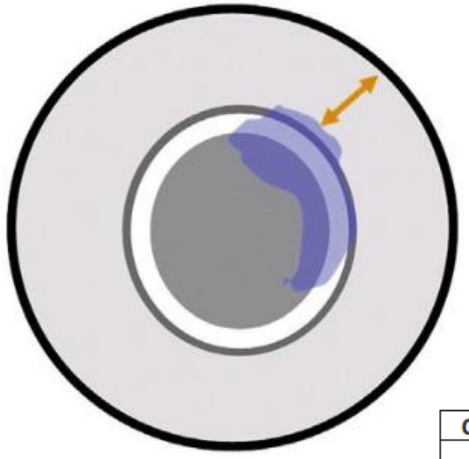
For segments of the colon completely encased by peritoneum, the mesenteric resection margin is the only relevant circumferential margin.

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.

Colon and Rectum

Circumferential Resection Margin (CRM)





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 Circumferential or radial resection margin not assessed or unknown if assessed

09210: Anus (2023+)

3956: p16

Item Length: 1
NAACCR Item #: 3956
XML Parent-NAACCR ID: Tumor-p16
NAACCR Alternate Name: None
Active years: 2022+
Schema(s):

- 09520: Cervix (2021+)
- 09210: Anus (2023+)

Description

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.

Definition

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.

Coding Instructions and Codes

Note 1: This SSDI is effective for diagnosis years 2023+.

- For cases diagnosed 2018-2022, leave this SSDI blank

Note 2: Code 0 for p16 expression of weak intensity or limited distribution.

Note 3: This data item must be based on testing results for p16 overexpression.

- A statement of a patient being HPV positive or negative is not enough to code this data item
- Testing for HPV by DNA, mRNA, antibody, or other methods should not be coded in this data item
- Do not confuse p16 with HPV 16, which is a specific strain of virus

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 prior to 2023

New for 2023

Anus p16

Liver

- A lab value expressed in micrograms per liter (ug/L) is equivalent to the same value expressed in ng/ml.
- Use the same lab test to record the value and interpretation.
- Highest value prior to treatment.
- Physician statement can be used.

00220: Liver (2018+)

3809, 3810: Alpha-Fetoprotein (AFP) Pretreatment Lab Value and Interpretation (Liver)

Definition

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.

For Liver, there are 2 data items that record information on AFP. These data items should be coded from the same test

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

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)

Coding guidelines

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

Examples for AFP Pretreatment Lab Value and Interpretation

Examples	Lab Value Code	Interpretation Code
0 ng/ml	0.0	1
23.6 ng/ml	23.6	2
127.8 ng/ml	127.8	2
3567 ng/ml	3567.0	2
11,000	XXXX.1	2
AFP test not done, or unknown if done	XXXX.9	9

00220: Liver (2018+)

3835: Fibrosis Score

Item Length: 1
NAACCR Item #: 3835
XML Parent-NAACCR ID: Tumor-fibrosisScore
NAACCR Alternate Name: None
Active years: 2018+
Schema(s):

- 00220: Liver (2018+)
- 00230: Bile Ducts Intrahepatic (2018+)

Description

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

Rationale

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

Definition

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

Additional Information

- **Source documents:** pathology report (biopsy or FNA path report), surgical resection
- **Other names:** Nontumoral hepatic parenchymal fibrosis/cirrhosis (Intrahepatic Bile Duct Tumors)

Coding Instructions and Codes

Note 1: Physician statement of fibrosis score can be used to code this data item when no other information is available. However, code 7 when the physician statement of fibrosis score is not based on histologic examination of the liver.

Note 2: 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 3: AJCC classifies Ishak fibrosis scores 0-4 (none to moderate fibrosis) as F0, and Ishak fibrosis scores 5-6 (cirrhosis/severe fibrosis) as F1. This is not the same as METAVIR score F0 or F1.

Note 4: 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 5: 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.

Note 6: Use code 7 if there is a clinical diagnosis (no microscopic confirmation) of severe fibrosis or cirrhosis.

Note 7: If no score is mentioned, descriptive terms may be used to assign codes 0 and 1 – see specific terms in the table below.

Note 8: If a fibrosis score is stated but the scoring system is not recorded, consult with the physician. If no further information is available, code 9.

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, probably 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

Coding Instructions and Codes

Note 1: 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 4.

- Separate tumor nodules in the contralateral lung are not coded in this data item.

Note 2: Code the presence and location of separate tumor nodules, 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. Their location is used to assign the T in the TNM system.

Note 3: For this item, only code separate tumor nodules of the same histologic type as the primary tumor, also referred to as intrapulmonary metastases.

- In the case of multiple tumor nodules determined to be the same primary, if not all nodules are biopsied, assume they are the same histology

Note 4: 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 Manual 8th Edition for standardized and precise definitions of the situations which aren't separate tumor nodules. They are

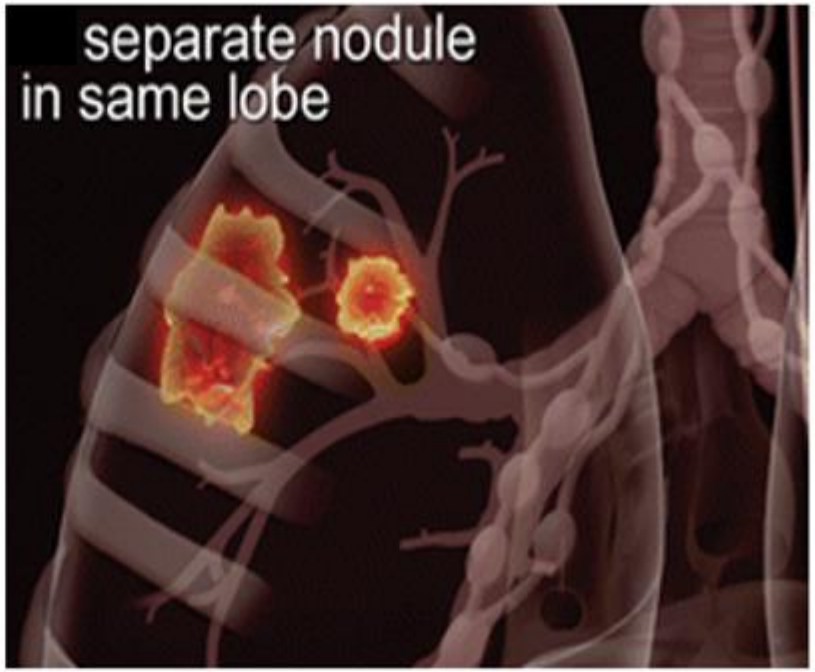
- second primary tumors, also called synchronous primary tumors (not the same histology as the primary tumor)
- multifocal lung adenocarcinoma with ground glass/lepidic features
- diffuse pneumonic adenocarcinoma

Note 5: "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.

Note 6: If there are multiple tumor nodules or foci and the terminology used is not readily identifiable as one of the situations described in Note 4, consult with the pathologist or clinician. If no further information is available, assign code 7 and DO NOT use the information to assign a T category or extent of disease.

Note 7: Code 0 if relevant imaging or resection is performed and there is no mention of separate tumor nodules.

Note 8: Code 9 if 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
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 3 and 4
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 Primary tumor is in situ Separate Tumor Nodules not assessed or unknown if assessed

Coding Instructions and Codes

Note 1: Physician statement of Visceral and Parietal Pleural Invasion can be used to code this data item when no other information is available.

Note 2: Code 0 for in situ (behavior/2) tumors.

Note 3: A surgical resection must be done to determine if the visceral and/or parietal pleural are involved.

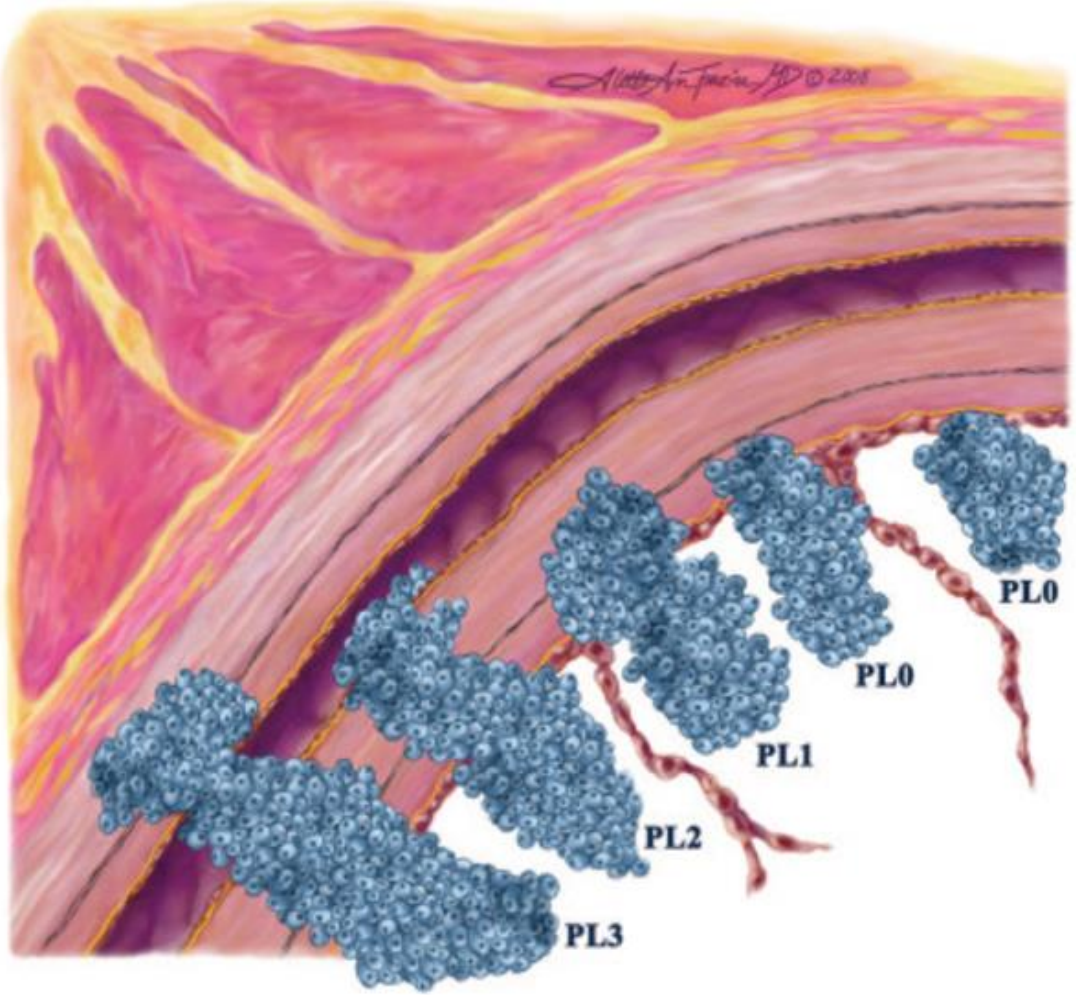
Note 4: Do not use imaging findings to code this data item

Note 5: Code 9 when

- A FNA only is 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

Code	Description
0	No evidence of visceral pleural invasion identified Tumor does not completely traverse the elastic layer of the pleura Stated as PL0
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

Pleural Invasion for Lung Cancers



Lung

ALK Rearrangement

Item Length: 1
NAACCR Item #: 3938
Applicable years: 2021+
AJCC 8th Edition Chapter(s): Chapter 36: Lung

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.

Additional Information

- **Source documents:** pathology report or clinical laboratory report, molecular report, immunohistochemistry report
- ***Other names:*** ALK tyrosine kinase receptor, anaplastic lymphoma kinase, anaplastic lymphoma receptor tyrosine kinase, CD246, CD246 antigen, NBLST3

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>	N/A-Diagnosis year is prior to 2021

EGFR Mutational Analysis

Item Length: 1
NAACCR Item #: 3939
Applicable years: 2021+
AJCC 8th Edition Chapter(s): Chapter 36: Lung

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.

Additional Information

- **Source documents:** pathology report or clinical laboratory report
- ***Other names:*** Epidermal growth factor receptor tyrosine kinase inhibitor, ERBB, ERBB1, ErbB1, HER1

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>	N/A-Diagnosis year is prior to 2021

Melanoma

LDH: Predictor of treatment response, progression-free survival and overall survival for patients with Stage IV melanoma of the skin.

LDH Upper Limits of Normal: Simply means the highest number in the normal range as displayed on the lab report (example: LDH 182 (71-207 U/L), record 207)

Clinical Margin Width (effective 2023+):

Do not use path report to code this item
Use distance from lesion or prior excision scar to peripheral margin of specimen
Do not use the deep margin
Do not add margins together
If multiple wide excisions are performed, code clinical margin width from procedure with the largest margin
Coded in centimeters (cm)

Priority order: Operative note, physician statement in medical record

Breast

Estrogen Receptor Percent Positive or Range

Coding Instructions and Codes

Note 1: Physician statement of ER Percent Positive or Range can be used to code this data item.

Note 2: Code this data item using the same report used to record Estrogen Receptor Summary [NAACCR Data Item #3827].

Note 3: If ER is negative, or percentage is less than 1%, code 000.

Note 4: The actual ER (1-100%) percent takes priority over the range codes.

Note 5: If ER is positive but percentage is unknown, code XX7.

Note 6: 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 codes, code to the range that contains the lowest number of the range in the report.

- *Example 1:* Report says 1-5%. Code R10 (1-10%)
- *Example 2*: Report says 90-95%. Code R90 (81-90%)

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%
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

Breast

Progesterone Receptor Percent Positive or Range

Coding Instructions and Codes

Note 1: Physician statement of PR (Progesterone Receptor) Percent Positive or Range can be used to code this data item.

Note 2: Code this data item using the same report used to record Progesterone Receptor Summary [NAACCR Data Item #3915].

Note 3: If PR is negative, or percentage is less than 1%, code 000.

Note 4: The actual PR (1-100%) percent takes priority over the range codes.

Note 5: If PR is positive but percentage is unknown, code XX7.

Note 6: 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 codes, code to the range that contains the lowest number of the range in the report.

- *Example 1:* Report says 1-5%. Code R10 (1-10%)
- *Example 2*: Report says 90-95%. Code R90 (81-90%)

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%
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

Breast

Estrogen Receptor Summary

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

Breast

Progesterone Receptor Summary

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

- Test is performed on tumor tissue
- LN or mets can be used **only** when there is no evidence of a primary tumor
- Invasive component always takes priority over in situ result
- Multiple tests for single tumor, use highest (pos vs neg)
- Multiple tumors, use result from largest tumor
- Result prior to treatment preferred (can use post treatment result if none were performed prior)

ER/PR positive patients with negative nodes may have an Oncotype Dx test performed, in which case the ER/PR will be reperformed. Do not record those ER/PR results in this field. Use the initial information from the breast tissue.

DISCONTINUED BEGINNING WITH CASES DIAGNOSED 1/1/23 AND LATER

Breast

Estrogen Receptor Total Allred Score

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.)
X9	Not documented in medical record ER (Estrogen Receptor) Total Allred Score not assessed, or unknown if assessed

Breast

Progesterone Receptor Total Allred Score

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.)
X9	Not documented in medical record PR (Progesterone Receptor) Total Allred Score not assessed, or unknown if assessed

Registrar should not calculate the Allred Score unless both components are available.

- If a range is recorded for the intensity (example: ER 80%, 2-3+ intensity), it cannot be calculated, and the score needs to be coded as X9.

How to calculate the Allred Score

Allred Score for Estrogen and Progesterone Receptor Evaluation

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).

Proportion Score	Positive Cells, %
0	0
1	<1
2	1 to 10
3	11 to 33
4	34 to 66
5	≥67

Intensity	Intensity Score
None	0
Weak	1
Intermediate/Moderate	2
Strong	3

ER 80% pos, 3+ intensity = 3 + 5, code Allred to 08

Proportion Score	Positive Cells, %
0	0
1	<1
2	1 to 10
3	11 to 33
4	34 to 66
5	≥67

Intensity	Intensity Score
None	0
Weak	1
Intermediate/Moderate	2
Strong	3

PR 25% positive, strong = 3 + 3, code Allred to 06

Breast

HER2

Definition

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.

The following data items are used to collect HER2 information:

- HER2 IHC Summary [NAACCR Data Item #3850]
- HER2 ISH Summary [NAACCR Data Item #3854]
- HER2 Overall Summary [NAACCR Data Item #3855]
- HER2 ISH Single Probe Copy Number [NAACCR Data Item #3853]
- HER2 ISH Dual Probe Copy Number [NAACCR Data Item #3851]
- HER2 ISH Dual Probe Ratio [NAACCR Data Item #3852]

The simplest test used is the IHC (immunohistochemistry). If the IHC test is borderline or indeterminate, an ISH (in situ hybridization) test may be performed.

The results of the IHC test are reported as follows:

Breast

HER2 Overall Summary

Item Length: 1
NAACCR Item #: 3855
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 48, Breast
Applicable years: 2018+
Required for Staging: AJCC 8th edition and EOD

Description

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

Coding guidelines

Record the pathologist's interpretation of the HER2 test from the tumor specimen. Results from the HER2 test done prior to neoadjuvant therapy take priority. If there are no results prior to neoadjuvant treatment, code the results from a post-treatment specimen. Do not report the results of a HER2 as part of a multigene test such as OncotypeDX or MammaPrint.

If assays are performed on more than one specimen and any result is interpreted as positive, code as 1 Positive/elevated.

Exception: If results from both an in situ specimen and an invasive component are given, record the results from the invasive specimen, even if the in situ is positive and the invasive specimen is negative.

- Code 0 when the HER2 is reported as negative or normal
- Code 1 when the HER2 is reported as positive or elevated
- Code 7 when the HER2 test was ordered but the results are not available
- 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)

- Test is performed on tumor tissue
- LN or mets can be used **only** when there is no evidence of a primary tumor
- Invasive component always takes priority over in situ result
- Multiple tests for single tumor, use highest (pos vs neg)
- Multiple tumors, use result from largest tumor
- Result prior to treatment preferred (can use post treatment result if none were performed prior)
- Not routinely done for in situ, but if performed on behavior /2 cases, record it

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

Breast

Ki-67

Item Length: 5
NAACCR Item #: 3863
NAACCR Alternate Name: None
Applicable years: 2018+
AJCC 8th Edition Chapter(s): Chapter 48, 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.

Coding Instructions

Note 1: Physician statement of Ki-67 (MIB-1) can be used to code this data item.

Note 2: Ki-67 is a marker of cell proliferation. A high value indicates a tumor that is proliferating more rapidly.

Note 3: Results from nodal or metastatic tissue may be used, ONLY when there is no evidence of primary tumor.

Note 4: 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

When Ki-67 is reported in a range, use lowest value and round up by .1 (example: Ki-67 reported as 30-40%, code 30.1 ~ per CA Forum 2022)

Breast

LN Positive Axillary Level I-II

Definition

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.

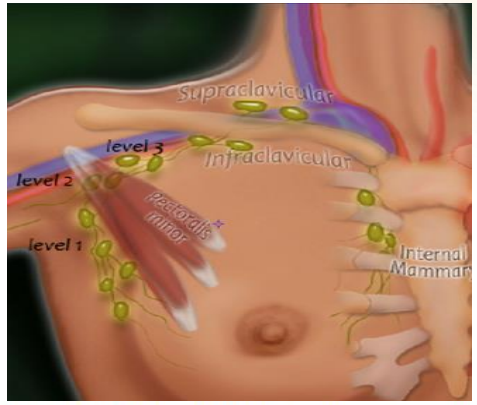
Do not confuse intramammary nodes, which are within breast tissue and are included in level I, with internal mammary nodes, which are along the sternum.

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.

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

If Scope of Regional LN Surgery is 0, this should be coded to X9.



Note 3: 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: For cases where neoadjuvant therapy is administered

- 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.

Note 5: 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 6: 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.)

Breast

Response to Neoadjuvant Therapy

Item Length: 1
NAACCR Item #: 3922
NAACCR Alternate Name: None
Applicable years: 2018+
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

This data item records the physician's statement of response to neoadjuvant chemotherapy.

Rationale

Response to Neoadjuvant Therapy is a Registry Data Collection Variable in AJCC. It was previously collected as Breast, CS SSF #21.

Definition

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

Coding guidelines

- Code 0 if there is no neoadjuvant therapy given
  - This includes in situ (behavior /2) cases
- Code 1 for a Residual Cancer Burden (RCB) result of '0' or an RCB Class of pCR (pathological complete response).
- 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

Additional Information

- For further information, refer to the **Breast** cancer protocol published by the College of American Pathologists for AJCC 8th edition
- **Other names:** treatment effect

3836: FIGO

Item Length: 5
NAACCR Item #: 3836
XML Parent-NAACCR ID: Tumor-figoStage
NAACCR Alternate Name: FIGO Stage
Active years: 2018+
Schema(s):

- 00500: Vulva (FIGO: Vulva) (2018+)
- 00510: Vagina (FIGO: Vagina) (2018+)
- 00520: Cervix Uteri (2018-2020) (FIGO: Cervix) (2018+)
- 09520: Cervix Uteri (2021+) (FIGO: Cervix) (2018+)
- 00528: Cervix Sarcoma (2021+) (FIGO Stage (Sarcoma)) (2018+)
- 00530: Carcinoma and Carcinosarcoma (FIGO: Corpus Carcinoma and Carcinosarcoma) (2018+)
- 00541: Corpus Sarcoma (FIGO Stage (Adenosarcoma) (2018+)
- 00542: Corpus Adenosarcoma (FIGO Stage (Sarcoma)) (2018+)
- 00551: Ovary (FIGO: Ovary, Fallopian Tube, and Peritoneal Carcinoma) (2018+)
- 00552: Primary Peritoneal Carcinoma (FIGO: Ovary, Fallopian Tube, and Peritoneal Carcinoma) (2018+)
- 00553: Fallopian Tube (FIGO: Ovary, Fallopian Tube, and Peritoneal Carcinoma) (2018+)
- 00560: Placenta (FIGO: Gestational Trophoblastic Tumors (Placenta)) (2018+)

Description

Federation Internationale de Gynecologie et d'Obstetrique (FIGO) is a staging system for female reproductive cancers.

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.

Definition

FIGO is the French acronym for the Federation Internationale de Gynecologie et d'Obstetrique, the worldwide organization of obstetricians and gynecologists who maintain the international staging systems for female genital organs. In English, the organization is the International Federation of Gynecology and Obstetrics. 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.

Definitions of the various FIGO stages vary from primary to primary, 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.

- Statement from managing physician to code this data item
- Do not code FIGO stage based on path report
- Do not code FIGO stage based only on T,N,M
- FIGO stage and FIGO grade are NOT the same thing
- If more than one FIGO stage given, code most extensive
- Code 97 for any non-invasive neoplasm (behavior code /2)
- If "FIGO" is not included in the stated stage, do not assume it is the FIGO stage

00551: Ovary (2018+)

3921: Residual Tumor Volume Post Cytoreduction

Item Length: 2
NAACCR Item #: 3921
XML Parent-NAACCR ID: Tumor-residualTumVolPostCytoreduction
NAACCR Alternate Name: None
Active years: 2018+
Schema(s):

- 00551: Ovary (2018+)
- 00552: Primary Peritoneal Carcinoma (2018+)
- 00553: Fallopian Tube (2018+)

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.

Rationale

Residual Tumor Volume Post Cytoreduction is a Registry Data Collection Variable listed in AJCC. It was previously collected as Ovary, CS SSF # 3.

Definition

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.

Additional Information

- **Source documents:** operative report, discharge summary, chemotherapy records (inpatient and outpatient)
- 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*
- **Other names:** debulking, cytoreduction, residual tumor volume
- ***Change for SSDI (effective v2.0):*** Further review of this SSDI indicated that the distinction of whether patient had neoadjuvant therapy or not was not needed. The purpose of this data item is to determine the residual tumor left behind. The codes have been redone so that they only collect that information.

Coding Instructions and Codes

Note 1: 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: Information for this SSDI is found in the operative report, procedure report, or managing physician notes.

Note 3: 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: 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 5: 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, 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)
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

PSA

- Serum PSA or Total PSA is the value being recorded
- Do not use free PSA or precursor PSA values
- Record the last pre-diagnosis PSA prior to diagnostic biopsy and initiation of treatment
- Use 0.1 when the result is <0.1 with no exact value
- Standard rounding rules apply
- Actual value takes priority over XXX.2 or XXX.3

Gleason Patterns and Scores

- Clinical patterns and scores are coded from needle core biopsy, TRUS biopsy, TURP and/or simple prostatectomy
- Coded prior to neoadjuvant therapy
- Code the highest or most aggressive pattern and score

- Pathologic patterns and scores are coded from total/radical prostatectomy or autopsy only
- Code highest most aggressive pattern and score
- If neoadjuvant therapy is given, code patterns and scores as X9
- Use X7 when no prostatectomy is done

Cores Positive / Examined

- Information from the gross description of the pathology report can be used
- Do not include cores from other areas like the seminal vesicles
- Use X7 when TURP is performed

Code	Description
00	All examined cores negative
01-99	1 - 99 cores positive (Exact number of cores positive)
X1	100 or more cores positive
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

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
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

AFP: Pre and Post Orchiectomy Values

Record the highest AFP test prior to orchiectomy or any systemic therapy

Lab value expressed in micrograms/liter ug/l is equivalent to the same value in ng/ml

If the lab value is expressed in IU/ml, you will need to convert you values before coding AFP related fields

- To calculate ng from IU/ml, divide the value for IU by 0.83

Example: Your lab reports the AFP as 10 IU/ml. 10/0.83 = 12.04ng/ml

LDH: Pre and Post Orchiectomy Range

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)

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).

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.

Examples	Code
118 (within normal range 100-225)	0
282 (elevated but less than 337.5)	1
1081 (elevated and between 337.5 and 2250)	2
2795 (elevated and greater than 2250)	3
Physician states "LDH elevated," but no value documented	4
No LDH test done, or unknown if done	9
S value stated (no other information available)	9

00590: Testis (2018+)

3923: S Category Clinical

Item Length: 1
NAACCR Item #: 3923
XML Parent-NAACCR ID: Tumor-sCategoryClinical
NAACCR Alternate Name: None
Active years: 2018+
Schema(s):

- 00590: Testis (2018+)

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.

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+.

Additional Information

- For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*

Coding Instructions and Codes

Note 1: 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: Code the pre-orchiectomy S category 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 values are those based on physician statement or lab values at diagnosis, prior to orchiectomy, and prior to any systemic treatment.

Note 4: 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 tests results meets 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

*N indicates the upper limit of normal for the LDH assay.

00590: Testis (2018+)

3924: S Category Pathological

Item Length: 1
NAACCR Item #: 3924
XML Parent-NAACCR ID: Tumor-sCategoryPathological
NAACCR Alternate Name: None
Active years: 2018+
Schema(s):

- 00590: Testis (2018+)

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.

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+.

Additional Information

- For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*

Coding Instructions and Codes

Note 1: 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: Code the post-orchiectomy S category 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: Pathological stage values are those based on physician statement or lab values after orchiectomy and prior to adjuvant therapy.

Note 4: 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: 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 tests results meets the S2-3 criterion for that test, assign code 9 (SX).

Note 6: 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
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

*N indicates the upper limit of normal for the LDH assay.

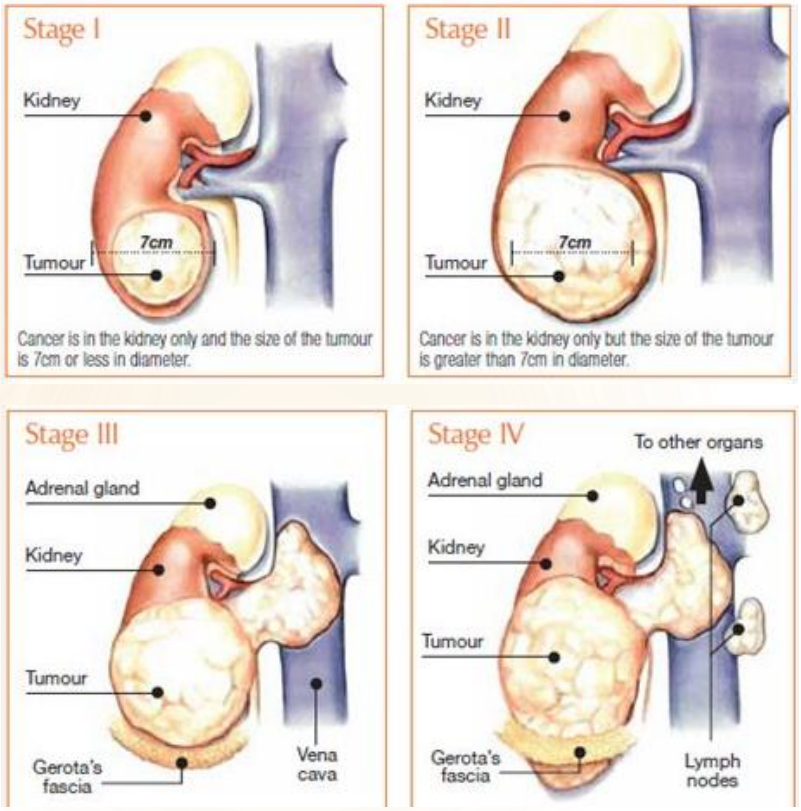
3864: Invasion Beyond Capsule

Item Length: 1
NAACCR Item #: 3864
XML Parent-NAACCR ID: Tumor-invasionBeyondCapsule
NAACCR Alternate Name: None
Active years: 2018+
Schema(s):

- 00600: Kidney (2018+)

Description

Kidney Tumor Extension pertains to the pathologically confirmed invasion of the tumor beyond the fibrous capsule in which the kidney is enclosed.



Coding Instructions and Codes

Note 1: Physician statement of pathologically confirmed invasion of the tumor beyond the fibrous capsule (invasion beyond capsule) can be used to code this data item.

Note 2: 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.

- 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)

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.

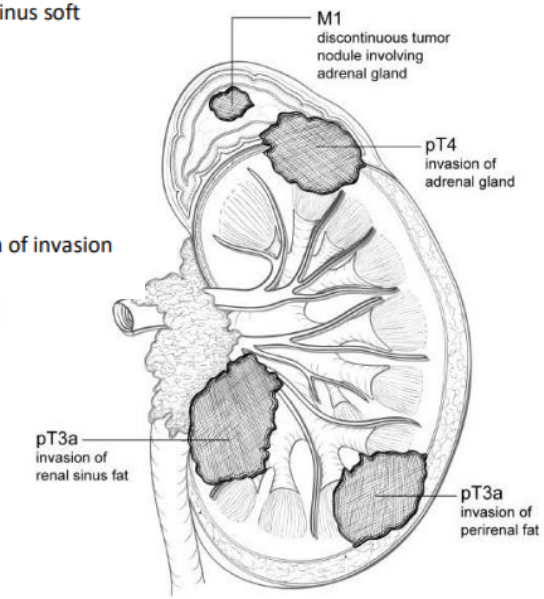
- Synonyms include: renal hilum, renal sinus fat, medial invasion

Note 4: Record invasion beyond capsule as documented in the pathology report.

Note 5: Do not use imaging findings to code this data item.

Note 6: Code 9 if surgical resection of the primary site is performed 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



T1 and T2 tumors code to '0' when a resection is done.

3886: Major Vein Involvement

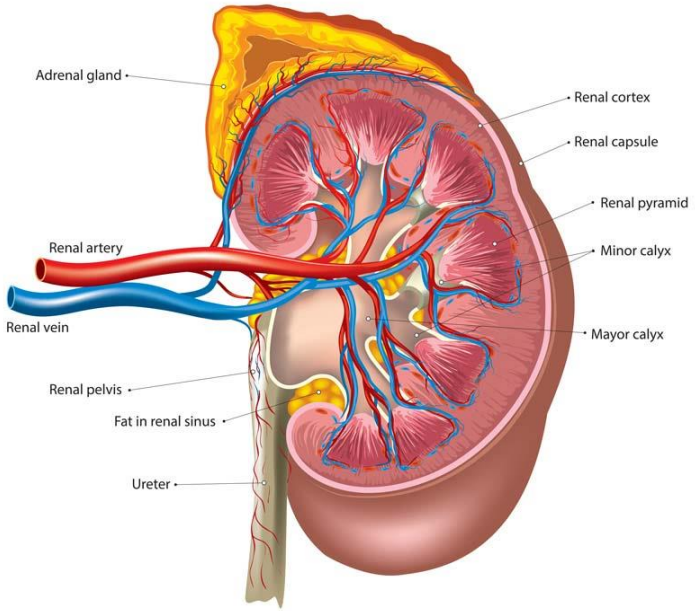
Item Length: 1
NAACCR Item #: 3886
XML Parent-NAACCR ID: Tumor-majorVeinInvolvement
NAACCR Alternate Name: None
Active years: 2018+
Schema(s):

- 00600: Kidney

Description

Major vein involvement pertains to the invasion of the kidney tumor into major veins.

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.



Coding Instructions and Codes

Note 1: Physician statement of Major Vein Involvement can be used to code this data item. The major veins include the renal vein or its segmental branches, and the inferior vena cava.

Note 2: 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.

- 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

Note 3: 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.

Note 4: Do not use imaging findings to code this data item.

Note 5: Code 9 if surgical resection of the primary site is performed 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
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

T1 and T2 tumors code to '0' when a resection is done.

3861: Ipsilateral Adrenal Gland Involvement

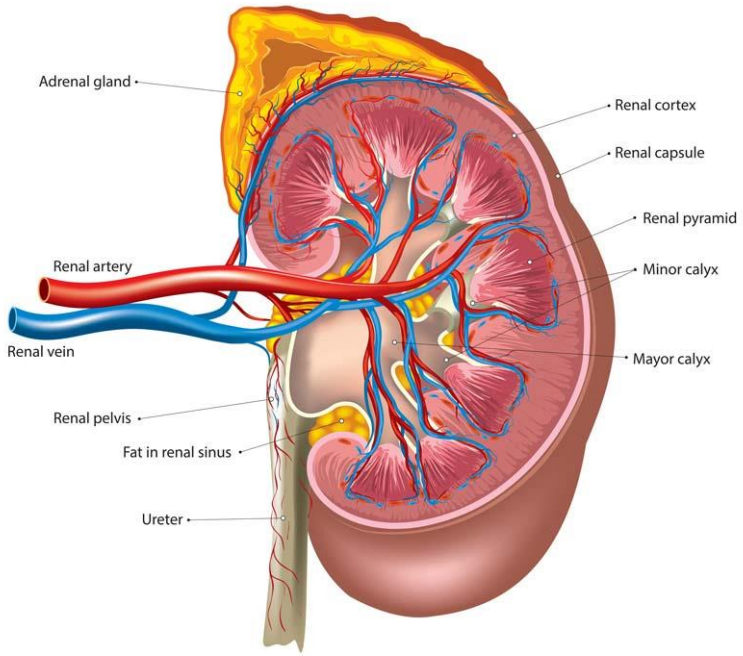
Item Length: 1
NAACCR Item #: 3861
XML Parent-NAACCR ID: Tumor-ipsilateralAdrenalGlandInvolve
NAACCR Alternate Name: None
Active years: 2018+
Schema(s):

- 00600: Kidney (2018+)

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).

Do not include clinical findings in this field.



Coding Instructions and Codes

Note 1: Physician statement of Ipsilateral Adrenal Gland Involvement can be used to code this data item.

Note 2: 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.

- 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

Note 3: Record ipsilateral adrenal gland involvement as documented in the pathology report.

Note 4: Do not use imaging findings to code this data item.

Note 5: Code 9 if surgical resection of the primary site is performed 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 (discontiguous involvement)
3	Combination of code 1-2
4	Ipsilateral adrenal gland involvement, unknown if direct involvement or separate nodule
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

T1 and T2 tumors code to '0' when a resection is done.

3925: Sarcomatoid Features

Item Length: 3
NAACCR Item #: 3925
XML Parent-NAACCR ID: Tumor-sarcomatoidFeatures
NAACCR Alternate Name: None
Active years: 2018+
Schema(s):

- 00600: Kidney (2018+)

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.

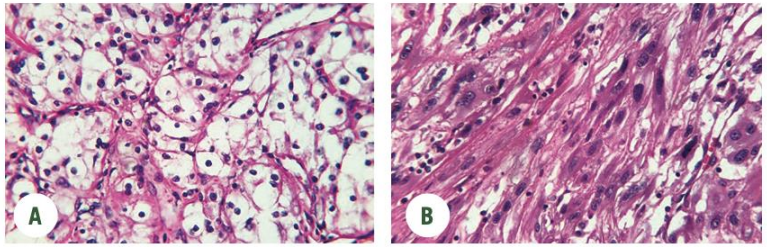


FIGURE 2. **Histopathologic Evaluation of the Renal Mass**

Compact nests and sheets of cells with clear cytoplasm, consistent with clear cell renal cell carcinoma **(A)** pleomorphic and spindle cells with high cellularity and atypia, compatible with sarcomatoid dedifferentiation **(B)**

Coding Instructions and Codes

Note 1: Physician statement of Sarcomatoid Features can be used to code this data item.

Note 2: Sarcomatoid morphology may be manifested by any renal cell carcinoma. The presence of sarcomatoid component in a renal cell carcinoma may be prognostically important.

Note 3: Sarcomatoid features is mostly seen with renal cell carcinoma (all variants); however, if it's seen with other histologies, it can be coded.

Note 4: Record the presence or absence of sarcomatoid features as documented anywhere in the pathology report.

Note 5: Code XX5 when the only information available about Sarcomatoid features is from a metastatic site.

Note 6: Do not use imaging findings to code this data item.

Note 7: Code XX9 if 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

00790: Lymphoma (excluding CLL/SLL) (2018+)

3896: NCCN International Prognostic Index (IPI)

Item Length: 2
NAACCR Item #: 3896
XML Parent-NAACCR ID: Tumor-nccnInternationalPrognosticIndex
NAACCR Alternate Name: None
Active years: 2018+
Schema(s):

- 00790: Lymphoma (excluding CLL/SLL) (2018+)
- 00795: Lymphoma-CLL/SLL (2018+)

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.

Rationale

NCCN International Prognostic Index (IPI) is a Registry Data Collection Variable in AJCC. It was previously collected for Lymphomas, SSF #3.

Definition

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

Additional Information

- **Source documents:** patient history, progress notes, consultant notes, other statements in medical record

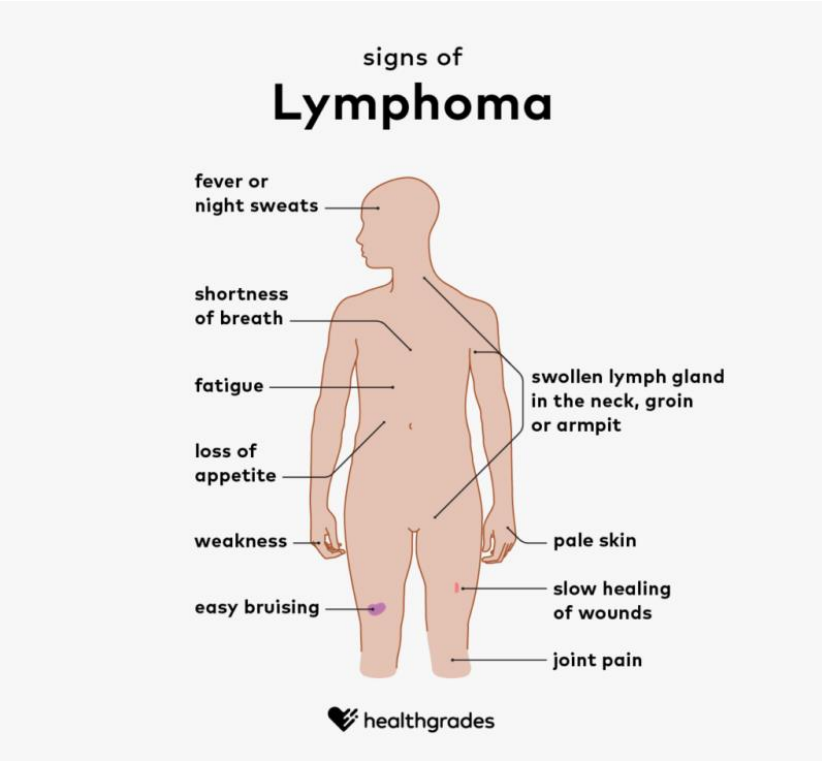
Coding Instructions and Codes

Note 1: 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: A low, intermediate or high risk associated with 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) status not assessed or unknown if assessed

00821: Plasma Cell Myeloma (2018+)

3857: High Risk Cytogenetics

Item Length: 1
NAACCR Item #: 3857
XML Parent-NAACCR ID: Tumor-highRiskCytogenetics
NAACCR Alternate Name: None
Active years: 2018+
Schema(s):

- 00821: Plasma Cell Myeloma (2018+)

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.

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+.

See RISS Stage (Plasma Cell Myeloma) for additional information.

Coding Instructions and Codes

Note 1: Physician statement of presence or absence of high-risk cytogenetics can be used to code this data item.

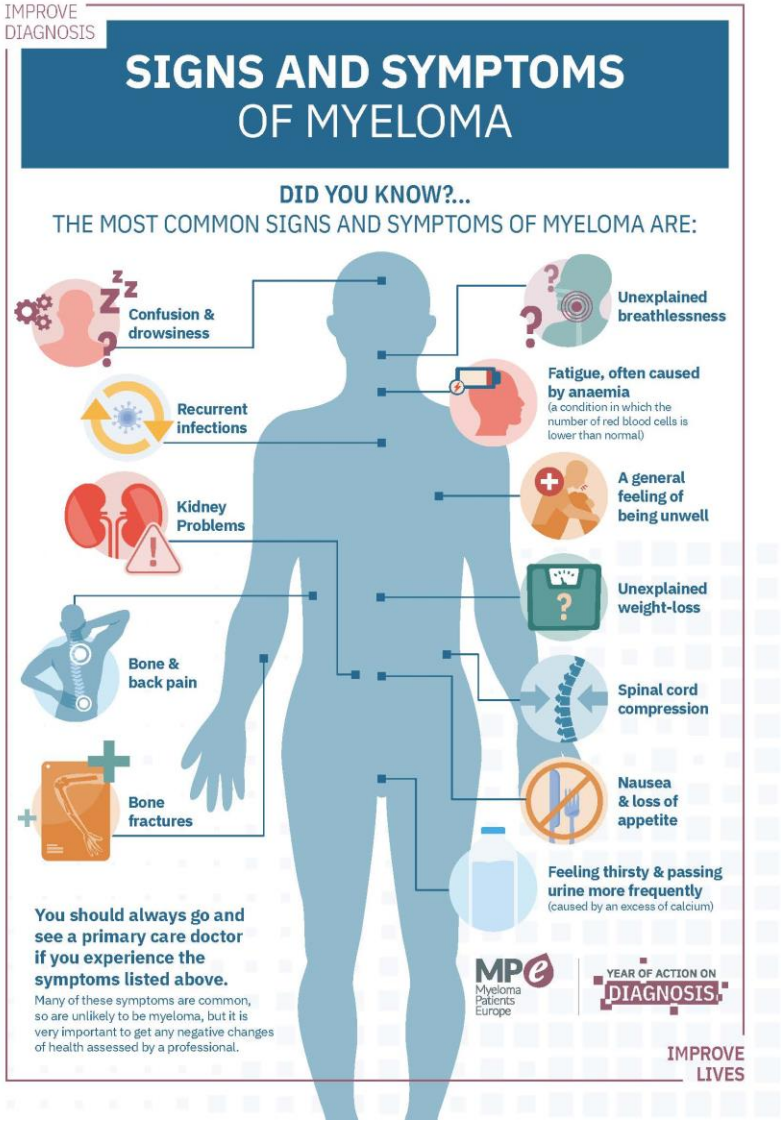
Note 2: Record this data item based on physician statement or FISH test interpretation performed at diagnosis (pre-treatment)

Note 3: 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 4: If there is no mention of high risk cytogenetics, code 9.

Note 5: If Schema Discriminator 1: Plasma Cell Myeloma Terminology is coded to 1 or 9, code 5.

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



00830: HemeRetic (2018+)

3862: JAK 2

Item Length: 1
NAACCR Item #: 3862
XML Parent-NAACCR ID: Tumor-jak2
NAACCR Alternate Name: None
Active years: 2018+
Schema(s):

- 00830: HemeRetic (2018+)

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.

Rationale

JAK2 can be collected by the surveillance community for myeloproliferative neoplasms. Prior to 2018, HemeRetic SSF#1 was used for JAK2.

Definition

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.)

Coding guidelines

Code the result of the JAK2 test as documented in a laboratory test or elsewhere in the medical record. Code this field for any hematopoietic, immunoproliferative, myeloproliferative, or myelodysplastic disease for which JAK2 is tested. For those diseases where JAK2 is not mentioned in the record, or for a HemeRetic schema disease such as leukemia where JAK2 is not normally tested, code as 9.

- Code 0 when the JAK2 test result is stated as negative.
- Code 1 when the JAK2 test was performed and was positive for mutation V617F in exon 14.
- Code 2 when the JAK2 test was performed and was positive for mutation of exon 12.
- Code 3 when the JAK2 test was performed and was positive for another specified mutation.
- Code 4 when the JAK2 test was performed and was positive for more than one mutation.
- Code 7 when there is a statement in the record that the test was ordered but the results are not available.
- Code 9 when
  - There is no information in the medical record about JAK2 testing
  - The results of JAK2 testing are unknown

Additional Information

- **Source documents:** clinical laboratory test (whole blood), reference laboratory test; anatomic pathology (polymerase chain reaction test on bone marrow)
- **Other names:** Janus kinase 2 gene, JAK2 V617F, JAK2 exon 12, JAK2 exon13

Coding Instructions and Codes

Note 1: Physician statement of JAK2 can be used to code this data item when no other information is available.

Note 2: 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.

Note 3: Record JAK2 for any hematopoietic neoplasm. It is most commonly used for the following histologies:

- Polycythemia Vera (9950/3)
- Primary myelofibrosis (9961/3)
- Essential Thrombocytopenia (9962/3)
- Chronic myelomonocytic leukemia (9945/3)

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

THANK YOU!

Questions or if you would like a copy of this presentation, contact:

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