SSDI

New Data Items
2021

What's New

7 new SSDIs

- HER2 Overall Summary (3855): Esophagus and Stomach
- Ki-67 (3863): NET Schemas
- ALK Rearrangement (3938): Lung
- EGFR Mutation Analysis (3939): Lung
- BRAF Mutation Analysis (3940): Colon and Rectum
- NRSA Mutation Analysis (3941): Colon and Rectum
- CA 19-9 Pre Tx Lab Value (3942): Pancreas

1 new Schema Discriminator 2

- Soft Tissue Sarcomas (3927)

NEW SSDIs

HER2 Overall Summary (3855):

AJCC 8th Edition Chapter(s):

- Chapter 16: Esophagus and Esophagogastric Junction
- Chapter 17: Stomach

Schemas:

- Esophagus
- Esophagus Squamous
- Stomach

Applies for cases diagnosed 2021+ only

Description:

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

Rationale:

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.

Note 1: Physician statement of HER2 Overall Summary can be used to code this data item when no other information is available.

Note 2: HER2 may be recorded for all histologies; however, it is primarily performed for adenocarcinomas. If information is not available, code 9.

Note 3: 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 4: If neoadjuvant therapy is given, record the results 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
9	Not documented in medical record Cannot be determined (indeterminate) HER2 Overall Summary status not assessed or unknown if assessed

Ki-67 (3863):

AJCC 8th Edition Chapter(s):

- Chapter 29: Stomach, Neuroendocrine
- Chapter 30: Duodenum and Ampulla of Vater, Neuroendocrine
- Chapter 31: Jejunum and Ileum, Neuroendocrine
- Chapter 32: Appendix, Neuroendocrine
- Chapter 33: Colon and Rectum, Neuroendocrine
- Chapter 34: Pancreas, Neuroendocrine

Schemas:

- NET Ampulla of Vater
- NET Colon and Rectum
- NET Duodenum
- NET Jejunum and Ileum
- NET Pancreas
- NET Stomach

Applies for cases diagnosed 2021+ only

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 is a Registry Data Collection Variable in AJCC. 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.

Note 1: Physician statement of Ki-67 (MIB-1), also referred to as the "Proliferative Index" 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: 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

Note 4: If neoadjuvant therapy is given, record the results 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

Note 5: A specific value (0.0-100.0) takes priority over XXX.4, XXX.5 or XXX.6. Only use these values when that is the only information available.

- XXX.4, XXX.5 and XXX.6 were added since they are listed on the CAP protocol

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 patient record Ki-67 (MIB-1) not assessed or unknown if assessed

ALK Rearrangement (3938)

AJCC 8th Edition Chapter(s):

- Chapter 36: Lung

Schema:

- Lung

Applies for cases diagnosed 2021+ only

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.

Rationale

ALK rearrangement is recommended by treatment guidelines for patients with advanced lung cancer as a prognostic marker and factor in determining appropriate therapy.

Coding Instructions and Codes

Note 1: Physician statement of ALK rearrangement for non-small cell carcinoma can be used to code this data item when no other information is available.

Note 2: 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 3: 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

Note 4: If ALK Rearrangement is positive and there is no mention of the specific rearrangement, code 4.

Note 5: If neoadjuvant therapy is given, 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

Note 6: 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

EGFR Mutational Analysis (3939)

AJCC 8th Edition Chapter(s):

- Chapter 36: Lung

Schema:

- Lung

Applies for cases diagnosed 2021+ only

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.

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.

Coding Instructions and Codes

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

Note 2: 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 3: The most common EGFR mutations are

- Exon 18 Gly719
- Exon 19 deletion
- Exon 20 insertion
- Exon 20 Thr790Met
- Exon 21 Leu858Arg

Note 4: If EGFR is positive and there is no mention of the mutated codon, or the mutated codon is not specified, code 4.

Note 5: If neoadjuvant therapy is given, 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

Note 6: Code 9 when:

- Insufficient amount of tissue available to perform test
- No microscopic confirmation of tumor
- EGFR 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

BRAF Mutation Analysis (3940)

AJCC 8th Edition Chapter(s):

- Chapter 20, Colon and Rectum

Schemas:

- Colon
- Rectum

Applies for cases diagnosed 2021+ only

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

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.

Coding Instructions and Codes

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

Note 2: 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 3: BRAF 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 BRAF gene mutations are often present in colorectal cancer. The most common BRAF mutations is

- BRAF V600E (c.1799T>A) mutation

Note 4: The most common testing methods for BRAF are

- Direct Sanger sequencing
- High-resolution melting analysis
- Pyrosequencing
- Real-time PCR

Note 5: Results from nodal or metastatic tissue may be used for BRAF.

Note 6: If BRAF is positive and there is no mention of the mutated codon, or the mutated codon is not specified, code 4.

Note 7: If neoadjuvant therapy is given, record the results 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

Note 8: Code 9 when

- Insufficient amount of tissue available to perform test
- No microscopic confirmation of tumor
- BRAF 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
4	Abnormal (mutated), 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

NRAS Mutational Analysis (3941)

AJCC 8th Edition Chapter(s):

- Chapter 20, Colon and Rectum

Schemas:

- Colon and Rectum

Applies for cases diagnosed 2021+ only

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.

Rationale

NRAS mutational analysis is recommended in clinical guidelines for patients with metastatic colon cancer who are being considered for anti-EGFR therapy.

Coding Instructions and Codes

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

Note 2: 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 3: 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.

Note 4: 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.

- Codon 12
  - Gly12Asp (GGT>GAT)
  - Gly12Val (GGT>GTT)
  - Gly12Cys (GGT>TGT)
  - Gly12Ser (GGT>AGT)
  - Gly12Ala (GGT>GCT)
  - Gly12Arg (GGT>CGT)
  - Codon 12 mutation, not otherwise specified
- Codon 13
  - Codon 13 mutation, not otherwise specified
- Codon 61
  - Gln61Lys (CAA>AAA)
  - Gln61Arg (CAA>CGA)
  - Codon 61 mutation, not otherwise specified

Note 5: Results from nodal or metastatic tissue may be used for NRAS.

Note 6: If NRAS is positive and there is no mention of the mutated codon, or the mutated codon is not specified, code 4.

Note 7: If neoadjuvant therapy is given, record the results 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

Note 8: Code 9 when

- Insufficient amount of tissue available to perform test
- No microscopic confirmation of tumor
- 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

CA 19-9 PreTX Lab Value (3942)

AJCC 8th Edition Chapter(s):

Chapter 28: Exocrine Pancreas

Schema:

Pancreas

Applies for cases diagnosed 2021+ only

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.

Rationale

CA 19-9 Pretreatment Lab Value is a strong predictor of resectability in the absence of metastatic disease.

Coding Instructions and Code

Note 1: 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.

Note 2: Record the lab value of the highest CA 19-9 test results 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: CA 19-9 is a tumor marker that has value in the management of certain malignancies.

Note 4: 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

Note 5: Record 0.1 when the lab results are stated as less than 0.1 U/ml with no exact value.

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.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

SCHEMA DISCRIMINATOR

Schema Discriminator 2
Soft Tissue Sarcomas
(C473-C475, C493-C495)

AJCC 8th Edition Chapter(s):

- Chapter 41: Soft Tissue Sarcoma of the Trunk and Extremities
- Chapter 42: Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs

Applies for cases diagnosed 2021+ only

Definition

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 8th edition Soft Tissue Sarcoma chapters 41 and 42 base the eligible sites as either external structures or internal viscera. . For example:

- C493 axilla is an external site using chapter 41
- C493 axillary artery is an internal site using chapter 42
- 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 chapter 41
  - C475 intrapelvic area of sacrococcygeal region uses chapter 42

Rationale

- To develop a software algorithm that can be used to send the registrar to the correct chapter/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.

Coding Guidelines

Code 1: External Structures

- Provide further details on what is an external structure

Code 2: Internal viscera

- Provide further details on what is an internal (visceral) structure)

Code 8: Not applicable

- Code 8 is automatically assigned during the 2021 software upgrade to cases that have already been abstracted. Review of these cases is not required by registrars; however, registrars may go back and review cases if they choose to. Based on what code is chosen, the Schema may change and all related staging fields (AJCC, EOD) may need to be changed.

Code 9: Not specific enough to determine if external or internal

- Provide further details on what not specific enough to determine.

Coding Instructions and Codes

Note 1: A schema discriminator is used to discriminate for peripheral nerve tumors (C473, C474, C475) and connective tissue tumors (C493, C494, C495) for the subsite in which the tumor arose.

Note 2: Code 1 is used for external structures and is assigned to AJCC 8th edition Chapter 41: 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

Note 3: Code 2 is used for internal structures and is assigned to AJCC 8th edition Chapter 42: 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

Note 4: Code 9 is used for when there is not enough specific information to determine if the structure is external or internal and is assigned to AJCC 8 edition Chapter 45: Soft Tissue Sarcoma of Unusual Sites and Histologies (Schema ID 00450: 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

Code	Description	AJCC Disease ID
1	External structures (sites), NOS Examples of terms include: Peripheral nerves and autonomic nervous system (C47) • Abdomen (C474) ○ Abdominal wall ○ Umbilicus • Pelvis (C475) ○ Buttock ○ Gluteal region ○ Groin ○ Inguinal region ○ Perineum ○ Sacrococcygeal region (stated as external) • Thorax ○ 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	41: Soft Tissue Trunk and Extremities

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	42: Soft Tissue Abdomen and Thoracic Visceral Organs

8	Not applicable: Case abstracted prior to 2021 update	42: Soft Tissue Abdomen and Thoracic Visceral Organs
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	45: Soft Tissue Sarcoma of Unusual Sites and Histologies

Questions?

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