NEW DATA ITEMS

2021

Name--Birth Surname

Data Items: 2232

Collection Recommendations:

SEER: Required

NPCR: Required

Description

Last name (surname) of patient at birth, regardless of gender or marital status.
Other alternate names should be recorded in the data item, Name--Alias [2280].

Rationale

This can be used to link reports on a person whose surname might be different on different documents. It is also useful when using a Spanish surname algorithm to categorize ethnicity.

Codes

The field should be left blank if the birth surname is not known or not applicable. Since a value in this field may be used by linkage software or other computer algorithms, only legitimate surnames are allowable, and any variation of "unknown" or "not applicable" is not allowable.

Note: This data item was introduced to be a gender-neutral birth-surname data item, analogous to Name--Maiden [2390]. It is to have been populated in the 2021 conversion by values in [2390]. The original (Name--Maiden) data item had been supported by CoC until January 1, 2003.

AJCC TNM Post Therapy Clinical (yc)

Data Items: 1062, 1063, 1064, 1065, 1066, 1067, 1068

Collection Recommendations:
CoC: Required
SEER: Collected from CoC-accredited hospitals
NPCR: Required when available*

- AJCC TNM Post Therapy Clinical (yc) T
- AJCC TNM Post Therapy Clinical (yc) T (suffix)
- AJCC TNM Post Therapy Clinical (yc) N
- AJCC TNM Post Therapy Clinical (yc) N (suffix)
- AJCC TNM Post Therapy Clinical (yc) M
- AJCC TNM Post Therapy Clinical (yc) Stage Group
- Grade Post Therapy Clin (yc)*

- The AJCC Post Therapy Clin (yc) stage classification has been added. The yc staging will be used for cases receiving neoadjuvant therapy with the planned surgery cancelled for various reasons. The yc TNM data items go into effect with cases diagnosed January 1, 2021 forward.

- These data items have the same valid value lists as the corresponding Post Therapy Path (yp) data items for each site. The notes associated with the lookups indicate when they should be left blank.

- These data items can be found in STORE v2 and are applicable for cases diagnosed January 1, 2021 forward.

Neoadjuvant Data Items

Data Items: 1632, 1633, 1634

Collection Recommendations:
SEER: Required

There are three new neoadjuvant data items.

- Neoadjuvant Therapy [1632]
- Neoadjuvant Therapy-Clinical Response [1633]
- Neoadjuvant Therapy-Treatment Effect [1634]

These data items can be found in the SEER Program and Coding Manual and are applicable for cases diagnosed January 1, 2021 forward only. (These fields must be blank for cases diagnosed prior to 2021).

Neoadjuvant Therapy

Data item: #1632
SEER Manual: Pages 222-226

Effective for cases diagnosed 01/01/2021 or later.

Records whether the patient had neoadjuvant therapy prior to planned definitive surgical resection of the primary site.

This data item provides information related to the quality of care and describes whether a patient had neoadjuvant therapy.

Neoadjuvant therapy: Systemic treatment (chemotherapy, endocrine/hormone therapy, targeted therapy, immunotherapy, or biological therapy) and/or radiation therapy given prior to surgical resection to improve outcomes. May also be called pre-surgical treatment or preoperative treatment.

Coding Guidelines

- Use this data item to record whether neoadjuvant therapy was administered.
- This data item captures a full course of neoadjuvant therapy (generally 4-6 months) or a limited exposure to systemic therapy prior to surgical resection
- Treatment must follow the recommended guidelines for the type and duration of treatment for that primary site and/or histology
- The length of a full course of treatment may vary depending on the primary site and/or histology
  - For example, some sites only require 2-3 months of neoadjuvant therapy
  - Refer to NCCN guidelines for further information on what is a full course of neoadjuvant therapy
- A physician's statement that a patient has completed neoadjuvant therapy must be used for this data item

Code	Description
0	No neoadjuvant therapy, no treatment before surgery, surgical resection not part of first course of treatment plan Autopsy only
1	Neoadjuvant therapy completed according to treatment plan and guidelines
2	Neoadjuvant therapy started, but not completed OR unknown if completed
3	Limited systemic exposure when the intent was not neoadjuvant; treatment did not meet the definition of neoadjuvant therapy
9	Unknown if neoadjuvant therapy performed Death certificate only (DCO)

Coding Instructions

Assign Code 0

- **When neoadjuvant therapy or tumor-directed treatment prior to surgical resection is not part of treatment plan**
- **When surgical resection is not part of planned first course of treatment**

  Example: Patient with unresectable lung cancer (no surgical resection planned), chemotherapy and radiation planned.

- **When patient did not have neoadjuvant therapy based on the sequence of treatment**

  Example: Patient diagnosed with breast cancer via needle core biopsy, had surgical resection, and then had adjuvant chemotherapy/radiation.

- **For autopsy only cases**

- **For cases for which neoadjuvant therapy is not a part of standard treatment. *(List of primary sites and schemas listed in the SEER Manual)***

- Primary Sites: C420, C421, C423, C424, C809
- Schemas:
- 00830 HemeRetic
- 99999 Ill-Defined Other
- 00790: Lymphoma
- 00795: Lymphoma (CLL/SLL)
- 00811: Mycosis Fungoides
- 00822: Plasma Cell Disorders
- 00822: Plasma Cell Myeloma
- 00812: Primary Cutaneous Lymphomas (excluding MF and SS)

Assign Code 1

- **For any tumor-directed therapy meeting the definition of neoadjuvant therapy**
  - Occurring prior to an intended or performed definitive surgical resection, **AND**
  - Documented as neoadjuvant treatment by a treating physician or part of the patient's documented treatment regimen/protocol.
- **When the patient completed the full course of neoadjuvant therapy with or without *(the completion of the)* planned surgical resection.**
  - **Example 1:** Patient diagnosed with rectal cancer via biopsy. Patient received 6 cycles of chemotherapy with concurrent radiation and then had surgical resection.
  - **Example 2:** Patient diagnosed with rectal cancer, 6 cycles of chemotherapy and radiation recommended. After completion of neoadjuvant therapy, re-evaluation of tumor burden done, and no evidence of cancer found. The planned surgical resection was not performed.
  - **Example 3:** Patient diagnosed with pancreatic cancer; 6 cycles of chemotherapy recommended. During last cycle, patient developed heart issues due to the chemotherapy. Planned surgical resection not performed due to risk factors and patient placed on hospice.
  - **Example 4:** Patient completed neoadjuvant therapy, surgery recommended, but patient refused any further treatment or patient died prior to surgical resection.
  - **Example 5:** Patient had a full course of neoadjuvant therapy, surgical resection recommended, unknown if performed.

Assign Code 2

- **When any tumor-directed therapy (excluding surgical resection) meeting the definition of neoadjuvant therapy whose intent was neoadjuvant, was begun and the patient did not complete the full course of neoadjuvant therapy.**
    - **Example:** Patient diagnosed with advanced breast cancer; 6 cycles of chemotherapy, followed by surgical resection recommended. After 4th cycle of chemotherapy, patient's tumor was noted to be growing despite the chemotherapy and planned surgical resection not performed (neoadjuvant therapy failed)

Assign Code 3

- **When any tumor-directed therapy (excluding surgical resection) not documented as neoadjuvant in the treatment plan and not meeting treatment guideline recommendations for neoadjuvant therapy was given.**

- **When patient receives some therapy prior to surgical resection, but not enough to qualify for a full course of neoadjuvant therapy.**
  - **Example1:** Patient diagnosed with prostate cancer. Patient received one shot of Lupron followed by prostatectomy 2 weeks later.
  - **Example2:** Patient diagnosed with breast cancer. Due to scheduling, patient not able to have surgical resection for 3 weeks, patient given Tamoxifen, followed by mastectomy with sentinel lymph node biopsy.

Assign Code 9 when:

- **It is unknown whether neoadjuvant therapy was administered.**
    - Planned, but unknown if given
    - Death certificate only (DCO)

Note1: Code 9 (unknown) should be used rarely.

Note2: Use code 0 when it is clear that the patient did not have neoadjuvant therapy based on the sequence of diagnosis and treatment.

Neoadjuvant Therapy-Clinical Response

Data item: #1633
SEER Manual: Pages 227-230

- Effective for cases diagnosed 01/01/2021 and later.
- Records the clinical outcomes of neoadjuvant therapy prior to planned surgical resection. This data item provides information related to the quality of care and describes the clinical outcomes after neoadjuvant therapy.
- This data item records the clinical outcomes of neoadjuvant therapy as determined by the managing physician (oncologic surgeon, radiation oncologist or medical oncologist).

Coding Guidelines

- Use this data item to record the clinical response (outcomes) to neoadjuvant therapy.
- Neoadjuvant Therapy-Clinical Response is evaluated after primary systemic and/or radiation therapy is completed and prior to surgical resection. It is based on clinical history, physical examination, biopsies, imaging studies, and other diagnostic work up. ***Do not*** use information from the surgical pathology report to code this data item.
- **Code this data item based on the managing/treating physician's interpretation/statement of the response to neoadjuvant therapy, whenever this interpretation/statement is available.**
- **A managing/treating physician statement is required to assign codes 1 – 5.**

Code	Description
0	Neoadjuvant therapy not given
1	Complete clinical response (CR) (per managing/treating physician statement)
2	Partial clinical response (PR) (per managing/treating physician statement)
3	Progressive disease (PD) (per managing/treating physician statement)
4	Stable disease (SD) (per managing/treating physician statement)
5	No response (NR) (per managing/treating physician statement) Not stated as progressive disease (PD) or stable disease (SD)
6	Neoadjuvant therapy done, managing/treating physician interpretation not available, treatment response inferred from imaging, biomarkers, or yc stage
7	Complete clinical response based on biopsy results from a pathology report (per pathologist assessment)
8	Neoadjuvant therapy done, response not documented or unknown
9	Unknown if neoadjuvant therapy performed Death certificate only (DCO)

Coding Instructions

Assign Code 0

- **When neoadjuvant therapy is not administered**
  - Neoadjuvant Therapy data item [NAACCR #1632] coded to 0 or 3
- **When therapy administered does not qualify as neoadjuvant therapy (pre-surgical treatment) because surgical resection not planned.**
  - **Example:** Patient with unresectable lung cancer (no surgical resection planned), chemotherapy and radiation planned. Chemotherapy and radiation do not qualify as neoadjuvant therapy because no surgical resection is planned.
- **When the patient did not have neoadjuvant therapy based on the sequence of diagnosis and treatment.**
  - **Example:** Patient diagnosed with breast cancer via needle core biopsy, had surgical resection followed by chemotherapy and radiation.
- For autopsy only cases
- For the following cases for which neoadjuvant therapy is not a part of standard treatment ***(List of primary sites and schemas listed in the SEER Manual)***

Assign Code 1

- **When the managing/treating physician documents complete (or total) response (CR) based on clinical findings**
  - Note1: CR is defined as the disappearance of all known tumors/lesions and lymph nodes.
  - Note 2: Neoadjuvant Therapy data item [NAACCR #1632] coded to 1 or 2.

Assign Code 2

- **The managing/treating physician documents partial response (PR) based on clinical findings *OR***
  - Note: PR is defined as a decrease in the size/extent of the tumor and/or presence of lymph nodes or metastatic disease.
- **Documented as not being either complete response (CR) or progressive disease (PD)**
  - Note: Neoadjuvant Therapy data item [NAACCR #1632] coded to 1 or 2.

Assign Code 3

- **When the managing/treating physician documents:**
  - Progressive disease (PD) based on clinical findings or
  - "Progression" or that the size/extent of the tumor and/or the presence of lymph nodes or metastatic disease has increased ***OR***
  - There is evidence of new metastasis
    - **Note1:** PD is defined as an increase in the size/extent of the tumor and/or presence of lymph nodes or metastatic disease.
    - **Note 2:** Neoadjuvant Therapy data item [NAACCR #1632] coded to 1 or 2.

Assign Code 4

- **When the managing/treating physician:**
  - Documents no clinical response based on clinical findings due to stable disease (SD) ***OR***
  - States that there is no change in the size/extent of the tumor and/or the presence of lymph nodes or metastatic disease.
    - **Note 1:** SD is defined as no changes in the size/extent of the tumor and/or presence of lymph nodes or metastatic disease.
    - **Note 2:** Neoadjuvant Therapy data item [NAACCR #1632] coded to 1 or 2.

Assign Code 5

- **When clinical evaluation after neoadjuvant therapy is done and the managing/treating physician documents no response (NR); *and does not indicate:***

    - If the tumor progressed (code 3) or
    - If there was change in the tumor size/extent or
    - If the tumor was stable (see code 4)
        - **Note 1:** No response (NR), NOS is documented by the managing/treating physician based on clinical findings.
        - **Note 2:** Neoadjuvant Therapy data item [NAACCR #1632] coded to 1 or 2.

Assign Code 6

- **When neoadjuvant therapy was completed, there is no statement from the managing/treating physician based on clinical evaluation documented or available, and clinical response is inferred from imaging impression, changes in biomarkers or yc stage.**
    - **Note:** Neoadjuvant Therapy data item [NAACCR #1632] coded to 1.
    - **Example:** Patient completes neoadjuvant therapy and presents to radiology for follow up scan. Per the radiology report, there is significant decrease in the size of the tumor. No documentation can be found from the managing/treating physician regarding the response.

Assign Code 7

- **When a biopsy is done of the primary site, the pathology report states complete response, and there is no statement regarding clinical response from the managing physician.**
    - **Note:** Neoadjuvant Therapy data item [NAACCR #1632] coded as 1.
    - **Example:** Patient completes neoadjuvant therapy for a rectal cancer. Imaging does not identify definitive residual tumor. On endoscopic biopsy, the biopsy of the treated rectal tumor is negative for malignancy.

Assign Code 8

- **When neoadjuvant therapy done, and clinical response is not documented or is unknown.**
    - **Note:** Neoadjuvant Therapy data item [NAACCR #1632] to 1.
    - **Example:** Patient completes neoadjuvant therapy; however, there is no information available regarding the status of the cancer.

Assign Code 9

- **When it is unknown whether neoadjuvant therapy was administered.**
    - Planned, but unknown if given.
    - Death certificate only (DCO)
        - **Note:** Neoadjuvant Therapy data item [NAACCR #1632] coded to 9.

    - **Note1:** Code 9 (unknown) should be used rarely.
    - **Note2:** Use code 0 when it is clear that the patient did not have neoadjuvant therapy based on the sequence of diagnosis and treatment or on standard of care for the diagnosis.

Neoadjuvant Therapy-Treatment Effect

Data item: #1634
SEER Manual: Pages 231

- Effective for cases diagnosed 01/01/2021 or later, ***records the pathologist's statement*** of neoadjuvant treatment effect on the primary tumor or site, with or without lymph nodes and/or distant metastasis, from the ***surgical pathology report***. Whenever treatment effect definitions are recommended by, or available in, the College of American Pathologists (CAP) Cancer Protocols, this data item follows the CAP definitions indicating absent or present effect. When site-specific CAP definitions are not available, use treatment effect codes for All Other Schemas in Appendix C. Site-specific codes are also included in Appendix C of this manual.

This data item provides information related to the quality of care and describes the pathological outcomes after neoadjuvant therapy.

Coding Structure See Appendix C for site-specific codes coding instructions of Neoadjuvant Therapy--Treatment Effect.

- **Specific Treatment Effect Tables Include:**
  - Colon and Rectum, Esophagus, Stomach, Anus, Pancreas
  - Thymus, Heart and Mediastinum, Retroperitoneum, Soft Tissue Abdomen and Thoracic, Soft Tissue Head and Neck, Soft Tissue Other, Soft Tissue Trunk and Extremities
  - Lung
  - Bone Appendicular, Bone Pelvis, Bone Spine
  - Breast
  - Ovary, Fallopian Tube, Primary Peritoneal Carcinoma
  - Prostate

- **All Other Schemas**
  - Schemas not covered by site-specific codes
  - Remaining schemas are based on a General Definition
  - Have no definitions from the CAP protocols
  - General Table

Note: This data item is not the same as AJCC's Post Therapy Path (yp) Pathological Response, which is based on the managing/treating physician's evaluation from the surgical pathology report and clinical evaluation after neoadjuvant therapy. This data item only addresses response based on the surgical pathology report.

Code	Description
0	Neoadjuvant therapy not given/no known presurgical therapy
1-4	Site-specific code; type of response
6	Neoadjuvant therapy completed and surgical resection performed, response not documented or unknown
	Cannot be determined
7	Neoadjuvant therapy completed and planned surgical resection not performed
9	Unknown if neoadjuvant therapy performed
	Unknown if planned surgical procedure performed after completion of neoadjuvant therapy
	Death certificate only (DCO)

Code 0: When neoadjuvant therapy is not administered/No known presurgical treatment

Codes 1-4

- These codes are site-specific
- Some of the treatment effect code definitions are schema specific based on definitions from treatment effect sections in the CAP protocols

Code 6: When neoadjuvant therapy was completed, and the response is not documented in the surgical pathology report or is unknown

- Use this code when the surgical pathology report is available, and there is no documented response in the surgical pathology report

- **Code 7: Neoadjuvant therapy completed and planned surgical resection not performed**
  - There are several reasons why surgery may be cancelled
  - Patient completed neoadjuvant therapy and had a complete clinical response, surgical resection is cancelled
  - Patient completed neoadjuvant therapy, had progressive disease or presence of mets after neoadjuvant therapy, surgical resection was cancelled
  - Patient completed neoadjuvant therapy and patient refused surgical resection
- **Code 9: When it is unknown whether neoadjuvant therapy was administered.**
  - Planned, but unknown if given.
  - Death certificate only (DCO)

Example: Breast

Breast

Coding Guidelines: Breast (PDF, 171 KB)

Solid Tumor Rules: Breast (PDF, 1.3 MB)

SURGERY CODES

- Breast - (C500-C509) (PDF, 204 KB)

SITE-SPECIFIC CODES FOR NEOADJUVANT THERAPY TREATMENT EFFECT

- Breast (PDF, 203 KB)
- Thymus, Heart and Mediastinum, Retroperitoneum, Soft Tissue Abdomen and Thoracic, Soft Tissue Head and Neck, Soft Tissue Other, Soft Tissue Trunk and Extremities, GIST (PDF, 206 KB) - Use these codes for sarcomas of the Breast

EOD SCHEMAS

- Breast

Code	Description
0	Neoadjuvant therapy not given/no known presurgical therapy
1	No residual invasive carcinoma present in the breast after presurgical therapy Residual in situ carcinoma only Stated as Complete response (CR)
3	Probable or definite response to presurgical therapy in the invasive carcinoma Stated as Partial response (PR) Stated as minimal or near complete response
4	No definite response to presurgical therapy in the invasive carcinoma Stated as No response (NR) Stated as poor response
6	Neoadjuvant therapy completed and surgical resection performed, response not documented or unknown Cannot be determined
7	Neoadjuvant therapy completed and planned surgical resection not performed
9	Unknown if neoadjuvant therapy performed Unknown if planned surgical procedure performed after completion of neoadjuvant therapy Death Certificate only (DCO)

Coding Instructions

Use the *Neoadjuvant Therapy--Treatment Effect* data item [NAACCR # 1634] to record the findings from the post neoadjuvant therapy **surgical pathology report ONLY** including the Treatment Effect section of the CAP Cancer Protocol if applicable.

1. Assign code **0**
   a. When the patient did not receive neoadjuvant therapy prior to surgical resection
   b. When the treatment administered is not neoadjuvant therapy (pre-surgical treatment) because surgical resection was not planned

      Example: Patient with unresectable breast cancer (no surgical resection planned), chemotherapy and radiation administered.

   c. When it is clear that the patient did not have neoadjuvant therapy based on the sequence of diagnosis and treatment

      Example: Patient diagnosed with breast cancer via needle core biopsy, had surgical resection followed by chemotherapy and radiation.

   d. For autopsy only cases

   Note: *Neoadjuvant Therapy* data item [NAACCR # 1632] coded to 0.
2. Assign code **1** when
   a. A complete (total) pathological response (CR) is documented in the surgical

All Other Schemas (General Table)

- **Code 1:** Complete pathological response
  - No viable cancer cells/no residual invasive carcinoma identified
  - Residual in situ carcinoma only
- **Code 2:** Near complete pathological response
  - Single cells or rare small groups of invasive cancer cells
- **Code 3:** Partial or minimal response
  - Residual invasive cancer cells present with evidence of tumor regression, more than single cells or rare small groups of cancer cell
- **Code 4:** Poor or no pathological response
  - Extensive residual cancer with no evident tumor regression

Additional Stage-Related Data Items

Data Items: 3938, 3939, 3940, 3941, 3942
Collection Recommendations:
CoC: Required, site specific; when available
SEER: Required

Site-specific Data Items (SSDIs)

- 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

Note: These Items will be covered in the SSDI Presentation

NCDB COVID-19

Data Items: 3943, 3944, 3945, 3946

Collection Recommendations:
CoC: Required, when available
SEER: Required, when available

NCDB--SARSCoV2--Test

NCDB--SARSCoV2--Pos

NCDB--SARSCoV2--Pos Date

NCDB--COVID19--Tx Impact

NCDB--SARSCOV2--TEST

Description

Data item is designed to track whether patient received a SARS-CoV-2 test or not. Collection based on diagnosis years 2020 and 2021.

Rationale

To evaluate the impact of COVID-19 diagnosis on cancer patients.

Codes:

Code 0: Patient not tested for SARS-CoV-2: facility records support that patient did not undergo pre-admit or in-hospital testing

Code 1: Patient tested for Active SARS-CoV2

Code 9: Unknown if patient tested for SARS-CoV-2/No facility record of preadmit hospital testing of SARS-CoV-2

Note: This item may be left blank.

NCDB--SARSCOV2—POS

Description

Data item is designed to track whether patient received a POSITIVE SARS-CoV-2 test or not. Collection based on diagnosis years 2020 and 2021.

Rationale

To evaluate the impact of COVID-19 diagnosis on cancer patients.

Codes:

Code 0: Patient did not test positive for active SARS-CoV-2: No positive test

Code 1: Patient tested positive for active SARS-CoV-2: test positive on at least one test

Code 9: Unknown if tested; test done, results unknown

Note: This item may be left blank.

NCDB--SARSCOV2--POS DATE

Description

What was the date of the first positive test? Collection based on diagnosis years 2020 and 2021.

Rationale

To evaluate the impact of COVID-19 diagnosis on cancer patients.

Codes:

YYYYMMDD: Date the patient had a positive test for SARS-CoV-2, the virus that causes the 2019 novel coronavirus disease (COVID-19), as documented by a medical provider

Blank: Date of the test is unknown or the date of a positive (diagnostic or serologic) test is unknown for SARS-CoV-2

NCDB--COVID19--TX IMPACT

Description

Was the first course of treatment (diagnosis, staging, treatment or other cancer management events) impacted by hospital availability (limited access to facilities or postponement of non-essential procedures) due to COVID-19 pandemic? (No; First Course Delayed; First Course Altered; First Course Cancelled). Collection based on diagnosis years 2020 and 2021.

Rationale

To evaluate the impact of COVID-19 pandemic on cancer patients.

Codes:

Code 1: Treatment not affected; active surveillance, no change

Code 2: First Course of Treatment timeline delayed

Code 3: First Course of Treatment plan altered

Code 4: Cancelled First Course of Treatment

Code 5: Patient refused treatment due to COVID-19

Code 9: Not known if treatment affected

Note: This item may be left blank.

Derived Data Items

Data Items: 2117, 2118, 2156, 2157, 2158, 2159

Collection Recommendations:
CoC: Derived, Derived when available
SEER: Derived, Derived when available*

Schema ID Version Current

Schema ID Version Original

AJCC API Version Current*

AJCC API Version Original*

AJCC Cancer Surveillance API Version Current*

AJCC Cancer Surveillance API Version Original*

Note: This data item will be generated by registry software. No coding instructions are required.

Resources:

STORE Manual
www.facs.org

SEER Program Coding and Staging Manual
www.seer.cancer.gov/tools/codingmanuals/

NAACCR Dictionary
www.naaccr.org/data-standards-data-dictonary/

Questions?

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