Site-Specific Data Item (SSDI) Manual

Effective with Cases Diagnosed 1/1/2018 and Forward

published April 2018

DRAFT

Editors: Jennifer Ruhl, MSHCA, RHIT, CCS, CTR, NCI SEER
Jim Hofferkamp, CTR, NAACCR
Elizabeth Ward, PhD, Consultant to NAACCR

Suggested Citation: Ruhl J, Ward E, Hofferkamp J, et al. (February 2018). Site-Specific Data Item (SSDI) Manual. NAACCR, Springfield, IL 62704-4194

Funding for this project was made possible in part by a contract with Federal funds from the National Cancer Institute, National Institutes of Health and Department of Health & Human Services under Contract number HHSN261201400004I / HHSN26100002. Additionally, funding for this project was made possible in part by a cooperative agreement with Federal funds from the Centers for Disease Control and Prevention Cooperative Agreement number 5NU58DP004917. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NCI and CDC. The NAACCR Board of Directors adopted these standards in February 2018.

NAACCR gratefully acknowledges the dedicated work of the NAACCR *Site-Specific Data Item (SSDI) Taskforce.*

- Jennifer Ruhl, MSHCA, RHIT, CCS, CTR (NCI SEER) (co-chair)
- Elizabeth Ward, PhD, Consultant to NAACCR (co-chair)
- Mary Brant, BS, CTR (California Cancer Registry)
- Iris Chilton, CHIM, CTR (Alberta, Canada)
- Elaine Collins, RHIA, CTR (contractor for SEER)
- Michelle Esterly, RHIA, CTR (Booz Allen Hamilton under contract to CDC NPCR)
- Donna Gress, RHIT, CTR (AJCC)
- Donna M. Hansen, CTR (California Cancer Registry)
- Lori Havener, CTR (NAACCR)
- Jim Hofferkamp, CTR (NAACCR)
- Annette Hurlbut, RHIT, CTR (Elekta)
- Sandy Jones (NPCR)
- Tricia Kulmacz (NAACCR)
- Jenna Mazreku, CTR (California Cancer Registry)
- Laura Meyer-Vega (AJCC)
- Richard Moldwin, M.D., Ph.D (College of American Pathologists)
- Serban Negoita, MD, DrPH, CPH, CTR; National Cancer Institute, Bethesda, MD
- Nicola Schussler, BS (IMS)
- Marilyn Scocozza, CTR (California Cancer Registry)
- Jennifer E. Seiffert, MLIS, CTR, (CyberData Technologies, Inc., under contract to CDC's NPCR)
- Kathleen Thoburn (CoC)

NAACCR would also like to acknowledge the assistance provided by the members of the NAACCR *Uniform Data Standards (UDS) workgroup*.

- Suzanne Schwartz, MS, CTR (New Jersey State Cancer Registry) (co-chair)
- Jeanette Jackson-Thompson (Missouri Cancer Registry) (co-chair)
- Nicole Aagaard, MPH, CTR (RMCDS/Univ of Utah)
- Margaret (Peggy) Adamo, BS, AAS, RHIT, CTR (NCI SEER)
- Sally Bushhouse, DVM, MPH, PhD (Minnesota)
- Angela Costantini, BA, CTR (Cincinnati Children's Hospital Medical Center)
- Dan Curran, MS, CTR (C/NET Solutions of the Public Health Institute)
- Kimberly DeWolfe
- Lynda Douglas, CTR (CDC NPCR)
- Michelle Esterly, RHIA, CTR (Booz Allen Hamilton under contract to CDC NPCR)
- Sandra Gamber, CTR, CCS-P (ELEKTA)
- Donna M. Hansen, CTR (California Cancer Registry)
- Lori Havener, CTR (NAACCR)
- Megsys C. Herna
- Jim Hofferkamp, CTR (NAACCR)

DRAFT

- Theresa Juster, MPH (New York State Cancer Registry)
- Amy Kahn, MS, CTR (New York State Cancer Registry)
- Mary Jane King, MPH, CTR (Cancer Care Ontario)
- Lori Koch, BA, CCRP, CTR (Illinois State Cancer Registry)
- Gemma Lee (Cancer Care Ontario)
- Mary Lewis, CTR (CDC-NPCR)
- Sarah Manson
- Cheryl Moody, CTR (California Cancer Registry)
- Linda Mulvihill
- David K. O'Brien, PhD, GISP (Alaska Cancer Registry)
- Heather Stuart-Panko
- Pam Parrish, CTR (Illinois State Cancer Registry)
- Steven Peace, BS, CTR (Florida Cancer Data System)
- Lynn Ries, MS (RiesSearch, LLC-contractor to NCI SEER Program)
- Nancy Rold, BA, CTR (Missouri Cancer Registry)
- Winny Roshala, BA, CTR (SEER Greater California Registry)
- Kathleen Thoburn
- Monica Thornton
- Joanne S Turner, CHIM, CTR (Nova Scotia Cancer Care Program)

DRAFT

Special Acknowledgements

Carolyn Callaghan, CTR and Tiffany Janes, CTR from the *SEER*Educate* program for their thorough review of the SSDIs and contributing greatly to their development.

The AJCC Expert Panels provided critical support in clarifying concepts from the *AJCC Cancer Staging Manual, Eighth Edition*.

Starting with this release, the SSDI taskforce has included representation from the College of American Pathologists (CAP). CAP participation has allowed us to harmonize data elements between AJCC, NAACCR and the CAP Cancer Protocols (CCPs), and electronic Cancer Checklists (eCCs). Since the terminology on many pathology reports is guided by the latest CPPs and eCCs, the new CAP-consistent language in many of the SSDI value sets and notes will ease the burden of coding current pathology terminology into exact matches with NAACCR value sets. This is part of a broader effort to work towards improving interoperability between EHR data sets and NAACCR SSDIs.

The following individuals contributed to the document support and web development.

- Suzanne Adams, CTR (IMS)
- Dustin Dennison, M.MIS (Information Technology Administrator, NAACCR)
- Chuck May (IMS)
- Peter Kim (NPCR)
- Joe Rogers (NPCR)
- Nicola Schussler, BS (IMS)

DRAFT

Table of Contents

Introduction 13
General Definitions and Format of SSDI Codes 16
General Rules for Entering Lab Values and Other Measurements 17
Source Documents 18
Histologic Examination 21
Schema Discriminators 22
Schema Discriminator 1 23
Schema Discriminator 2 24
Schema Discriminator 3 25
SSDIs Required for Stage 26
SSDIs used for EOD Derived Stage Group 27
Schema ID 28
Schema ID Table 29
HEAD AND NECK 37
Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck 38
Schema Discriminator 1: Occult Head and Neck Lymph Nodes 38
Extranodal Extension Head and Neck Clinical 40
Extranodal Extension Head and Neck Pathological 43
Head and Neck Regional Lymph Nodes (Levels I-VII, Other) 46
LN Head and Neck Levels I-III 48
LN Head and Neck Levels IV-V 50
LN Head and Neck Levels VI-VII 52
LN Head and Neck Other 54
LN Size 56
Lip and Oral Cavity 58
Extranodal Extension Head and Neck Clinical 58
Extranodal Extension Head and Neck Pathological 61
LN Size 64
Major Salivary Glands 66
Nasopharynx 67
Schema Discriminator 1: Nasopharynx/Pharyngeal Tonsil 67
Oropharynx 69

DRAFT

Schema Discriminator 2: Oropharyngeal p16 69
Oropharynx 70
Hypopharynx 71
Nasal Cavity and Paranasal Sinuses 72
Larynx 73
Mucosal Melanoma of the Head and Neck 74
Cutaneous Squamous Cell Carcinoma of the Head and Neck 75
High Risk Histologic Features 75
GASTROINTESTINAL TRACT (UPPER AND LOWER) 78
Esophagus and Esophagogastric Junction 79
Schema Discriminator 1: EsophagusGEJunction (EGJ)/Stomach 79
Schema Discriminator 2: Histology Discriminator for 8020/3 81
Esophagus and EGJ Tumor Epicenter 82
Stomach 84
Appendix 85
Colon and Rectum 86
CEA Pretreatment Lab Value and Interpretation 86
CEA Pretreatment Lab Value 87
CEA Pretreatment Interpretation 89
Circumferential Resection Margin (CRM) 91
KRAS 94
Microsatellite Instability (MSI) 96
Perineural Invasion 98
Tumor Deposits 100
HEPATOBILIARY SYSTEM 102
Liver 103
Alpha-Fetoprotein (AFP) Pretreatment Lab Value and Interpretation (Liver) 103
AFP Pretreatment Lab Value 104
AFP Pretreatment Interpretation 105
Model for End-Stage Liver Disease (MELD) Score 106
Bilirubin Pretreatment Total Lab Value 109
Bilirubin Pretreatment Unit of Measure 111
Creatinine Pretreatment Lab Value 112

DRAFT

Creatinine Pretreatment Unit of Measure 114
International Normalized Ratio 115
Intrahepatic Bile Ducts 116
Fibrosis Score 116
Primary Sclerosing Cholangitis 118
Tumor Growth Pattern 120
Gallbladder (including Cystic Duct) 122
Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct 122
Perihilar Bile Ducts 124
Distal Bile Duct 125
THORAX 126
Lung 127
Separate Tumor Nodules 127
Visceral and Parietal Pleural Invasion 130
Pleura (Malignant Mesothelioma) 133
Pleural Effusion 133
BONE ..... **Error! Bookmark not defined.**
Percent Necrosis Post Neoadjuvant 135
SOFT TISSUE SARCOMAS 137
Soft Tissue 138
Bone Invasion 139
Gastrointestinal Stromal Tumor (GIST) 141
Schema Discriminator 1: Primary Peritoneum Tumor 141
KIT Gene Immunohistochemistry 142
SKIN 144
Merkel Cell Carcinoma 145
Extranodal Extension Clin (non-Head and Neck) 145
Extranodal Extension Path (non-Head and Neck) 147
LN Isolated Tumor Cells (ITC) 149
Profound Immune Suppression 151
Melanoma Skin 153
Breslow Tumor Thickness 153
Ulceration 156

DRAFT

Mitotic Rate Melanoma 158
LDH Pretreatment Lab Value 160
LDH Pretreatment Level 162
LDH Upper Limits of Normal 163
BREAST 165
Estrogen Receptor and Progesterone Receptor 166
Estrogen Receptor Percent Positive or Range 168
Estrogen Receptor Summary 170
Estrogen Receptor Total Allred Score 172
Progesterone Receptor Percent Positive or Range 173
Progesterone Receptor Summary 175
Progesterone Receptor Total Allred Score 177
HER2 179
HER2 IHC Summary 182
HER2 ISH Summary 184
HER2 Overall Summary 186
HER2 ISH Single Probe Copy Number 188
HER2 ISH Dual Probe Copy Number 190
HER2 ISH Dual Probe Ratio 192
Multigene Signature Method and Results 194
Multigene Signature Method 196
Multigene Signature Results 198
Oncotype Dx Tests 200
Oncotype Dx Recurrence Score-DCIS 202
Oncotype Dx Risk Level-DCIS 203
Oncotype Dx Recurrence Score-Invasive 204
Oncotype Dx Risk Level-Invasive 205
Ki-67 206
LN Positive Axillary Level I-II 207
Response to Neoadjuvant Therapy 209
FEMALE REPRODUCTIVE ORGANS 211
FIGO 212
Lymph Node Assessment Methods and Status for Regional and Distant Lymph Nodes in GYN sites . 215
Vulva 216

DRAFT

FIGO: Vulva 216
LN Assessment Method Femoral-Inguinal 217
LN Assessment Method Para-Aortic 218
LN Assessment Method Pelvic 219
LN Status Femoral-Inguinal, Para-Aortic, Pelvic 220
LN Laterality 222
Vagina 225
FIGO: Vagina 224
LN Distant Assessment Method 226
LN Distant: Mediastinal, Scalene 227
Cervix 229
FIGO: Cervix 228
Corpus Carcinoma and Carcinosarcoma 229
FIGO: Corpus Carcinoma and Carcinosarcoma 230
Number of Positive and Examined Para-Aortic and Pelvic Nodes 231
Number of Positive Para-Aortic Nodes 232
Number of Examined Para-Aortic Nodes 234
Number of Positive Pelvic Nodes 236
Number of Examined Pelvic Nodes 238
Peritoneal Cytology 240
Corpus Adenosarcoma 242
FIGO Stage (Adenosarcoma) 242
Corpus Sarcoma 244
FIGO Stage (Sarcoma) 244
Corpus Sarcoma 245
Ovary, Fallopian Tube, and Peritoneal Carcinoma 246
FIGO: Ovary, Fallopian Tube, and Peritoneal Carcinoma 246
CA-125 Pretreatment Interpretation 247
Residual Tumor Volume Post Cytoreduction 249
Gestational Trophoblastic Neoplasms (Placenta) 252
FIGO: Gestational Trophoblastic Tumors (Placenta) 252
Gestational Trophoblastic Prognostic Scoring Index 253
MALE GENITAL ORGANS 255

DRAFT

Penis 256
Extranodal Extension Clin (non-Head and Neck) 256
Extranodal Extension Path (non-Head and Neck) 258
Prostate 260
PSA (Prostatic Specific Antigen) Lab Value 260
Gleason Patterns and Scores 263
Gleason Patterns Clinical 266
Gleason Score Clinical 269
Gleason Patterns Pathological 271
Gleason Score Pathological 274
Gleason Tertiary Pattern 276
Number of Cores Positive and Examined 277
Number of Cores Positive 278
Number of Cores Examined 280
Testis 282
Testis Serum Markers and S Category 282
Alpha-fetoprotein (AFP) (Testis) 283
AFP Pre-Orchiectomy Lab Value 285
AFP Pre-Orchiectomy Range 286
AFP Post-Orchiectomy Lab Value 288
AFP Post-Orchiectomy Range 290
Human Chorionic Gonadotropin (hCG) (Testis) 292
hCG Pre-Orchiectomy Lab Value 294
hCG Pre-Orchiectomy Range 295
hCG Post-Orchiectomy Lab Value 297
hCG Post-Orchiectomy Range 299
Lactate Dehydrogenase (LDH) (Testis) 301
LDH Pre-Orchiectomy Range 303
LDH Post-Orchiectomy Range 305
S Category Clinical 307
S Category Pathological 309
URINARY TRACT 311
Kidney 312
Invasion Beyond Capsule 312

DRAFT

Ipsilateral Adrenal Gland Involvement 314
Major Vein Involvement 316
Sarcomatoid Features 318
Urethra 320
Schema Discriminator 1: Urethra/Prostatic Urethra 320
OPHTHALMIC SITES 321
Eyelid Carcinoma 322
Perineural Invasion 322
Conjunctival Melanoma 324
Uveal Melanoma 325
Schema Discriminator 1: Melanoma Ciliary Body/Melanoma Iris 325
Chromosome 3 Status 326
Chromosome 8q Status 328
Extravascular Matrix Patterns 330
Measured Basal Diameter 332
Measured Thickness 334
Microvascular Density 336
Mitotic Count Uveal Melanoma 338
Retinoblastoma 340
Heritable Trait 340
Lacrimal Gland 342
Schema Discriminator 1: Lacrimal Gland/Sac 342
Adenoid Cystic Basaloid Pattern 343
CENTRAL NERVOUS SYSTEM 346
Brain and Other Central Nervous System 347
Brain Molecular Markers 347
Loss of Heterozygosity: Chromosome 1p and Chromosome 19q (CNS) 349
Chromosome 1p: Loss of Heterozygosity (LOH) 350
Chromosome 19q: Loss of Heterozygosity (LOH) 352
Methylation of O6-Methylguanine-Methyltransferase 354
ENDOCRINE SYSTEM 356
Thyroid (including Medullary) 357
Schema Discriminator 1: Thyroid Gland/Thyroglossal Duct 357

DRAFT

HEMATOLOGIC MALIGNANCIES 358
Lymphomas (Adult and Pediatric Hodgkin and Non-Hodgkin Lymphomas) 359
Schema Discriminator 1 (Histology Discriminator for 9591/3) 359
B Symptoms 360
HIV Status 362
NCCN International Prognostic Index (IPI) 364
Rai Classification (CLL/SLL [9823/3 only) 366
Adenopathy 367
Anemia 369
Lymphocytosis 371
Organomegaly 373
Thrombocytopenia 375
Primary Cutaneous Lymphomas 377
Peripheral Blood Involvement 377
Plasma Cell Myeloma and Plasma Cell Disorders 380
Schema Discriminator 1: Plasma Cell Myeloma Terminology 380
RISS Stage (Plasma Cell Myeloma) 382
High Risk Cytogenetics 383
LDH Pretreatment Level 384
Serum Albumin Pretreatment Level 385
Serum Beta-2 Microglobulin Pretreatment Level 386
Leukemia 387
JAK 2 387
ILL-DEFINED OTHER 389
ALPHABETICAL INDEX 390

DRAFT

Introduction

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

The NAACCR Site-Specific Data Item Taskforce

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

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

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

What is a SSDI?

A "SSDI'" is a site-specific data item. "Site" in this instance is based on the primary site, the AJCC chapter, Summary Stage chapter and the EOD schema. SSDIs were preceded by CS SSFs, which were first introduced in 2004 with CSv1, and went through major revisions in 2010 with **Collaborative Stage v2 (CSv2)**. CS SSFs were discontinued as of 12/31/2017.

SSDIs have their own data item name and number and can be collected for as many sites/chapters/schemas as needed.

DRAFT

Each Site-Specific Data Item (SSDI) applies only to selected schemas. SSDI fields should be blank for schemas where they do not apply.

How SSDI's are associated with relevant site/histologies and schemas

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

Process of Developing the SSDIs

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

- First: schema discriminators. These are data items needed to determine the correct SSDIs, AJCC chapter, EOD schema, or Summary Stage schema
- Second: data items required to assign stage
- Third: data items currently required by at least one standard setter and listed as registry collection data items in at least one AJCC 8th edition chapter
- Last: certain data items required by standard setters and not necessarily stage related. These comprise a small percentage of the data items

CS SSFs discontinued in CSv0204 were not reviewed for 2018 data collection. New registry data collection items listed in the AJCC 8th edition were not reviewed, unless they are required for staging.

Number of SSDIs compared to CS SSFs

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

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

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

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

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

DRAFT

General Definitions and Format of SSDI Codes

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

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

Examples:

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

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

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

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

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

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

DRAFT

General Rules for Entering Lab Values and Other Measurements

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

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

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

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

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

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

Check coding instructions for special rules for rounding numbers. AJCC sometimes provides test- and site-specific rounding rules that are of clinical significance. In the absence of a special rule, round 0-4 down and 5-9 up.

Examples for a 6-Character Lab Value	
Value in Record	Data Item Coded as
0.0	0.0
0	0.0
0.1	0.1
1.14	1.1
1.15	1.2
11.0	11.0
11.1	11.1
11	11.0
111.1	111.1
1111.1	1111.1

DRAFT

Source Documents

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

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

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

Important Notes

The following information is intended as a guide to help the registrar locate the test in the medical record and to identify which lab test results should be coded.

Timing for Recording Laboratory Tests. Unless instructions for a specific laboratory test state otherwise, record only tests results obtained:

- before any cancer-directed treatment is given, and
- no earlier than approximately three months before diagnosis

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

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

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

- ***Example 1:*** Physician summarizes breast cancer workup by saying "HER2 IHC was positive at 3+. Registrar would code interpretation as positive
- ***Example 2:*** Physician statement: "He was found to have a PSA of 4.5." The medical record indicates that the biopsy results were positive and the physician stages the case as T1c (tumor identified by needle biopsy, e.g., because of elevated PSA). Registrar may code PSA Interpretation as elevated because it resulted in the needle biopsies that were staged as T1c

- ***Note:*** If the pathologist uses the term "indeterminate," code as borderline; undetermined if positive or negative if that code exists in the data item. If a code for borderline or undetermined does not exist, code as unknown

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

- ***Example 3:*** Medical record laboratory report shows ovarian cancer patient's CA-125 as 69 (normal range < 35 U/ml). Registrar may infer that CA-125 is elevated

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

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

- ***Example 4:*** Physician reports that Alpha Fetoprotein (AFP) collected in the office for a patient suspected to have primary liver cancer was 750 but does not interpret this value. Background information in the manual indicates a high normal would be > 500 but hepatocellular carcinoma values are > 1000. Registrar should code AFP Interpretation as unknown
- ***Example 5:*** Physician reports a CEA of 450 for a colon cancer without interpreting it. Background information in the manual indicates a high normal would be 5 ng/ml. Registrar may code CEA as elevated

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

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

http://www.amamanualofstyle.com/oso/public/jama/si_conversion_table.html.

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

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

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

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

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

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

Table I-2-1a. Measurement Prefixes

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

Table I-2-1b. Unit Abbreviations

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

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

Femtomole	fmol
Microgram	ugr, mcg, mgr
Milliliter	ml

DRAFT

Histologic Examination

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

Also referred to as “microscopic confirmation.”

DRAFT

Schema Discriminators

Introduced in Collaborative Stage version 2 (CSv2), schema discriminators are used when primary site and/or histology are not sufficient to identify the correct AJCC staging algorithm. Due to the complexity of some of the 8th edition chapters, more than one schema discriminator may be needed to define the correct schema. Three SSDI's (Data Item #'s 3926, 3927 and 3928) are available to collect the information needed to define schema, although most chapters that require a schema discriminator need only one.

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

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

DRAFT

Schema Discriminator 1

Item Length: 1
NAACCR Item #: 3926
NAACCR Alternate Name: None

Description

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

Rationale

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

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

The following are Schema Discriminator 1

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

DRAFT

Schema Discriminator 2

Item Length: 1
NAACCR Item #: 3927
NAACCR Alternate Name: None

Description

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

Rationale

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

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

The following are Schema Discriminator 2

- Schema Discriminator 2: Histology Discriminator for 8020/3
- Schema Discriminator 2: Oropharyngeal p16

DRAFT

Schema Discriminator 3

Item Length: 1
NAACCR Item #: 3928
NAACCR Alternate Name: None

Description

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

Rationale

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

For 2018, there are no defined Schema Discriminators 3's.

DRAFT

SSDIs Required for Stage

In addition to T, N, M or EOD fields (primary tumor, regional nodes, and mets), there are SSDIs that are needed to either assign an AJCC 8th edition stage or derive the EOD Derived Stage Group.

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

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

AJCC Chapter	NAACCR Data Item #	NAACCR Data Item Name	EOD Schema(s)
16: Esophagus (Squamous cell only)	3829	Esophagus and EGJ Tumor Epicenter	Esophagus (including GE junction) Squamous
48: Breast	3827	Estrogen Receptor Summary	Breast
	3915	Progesterone Receptor Summary	
	3855	HER2 Overall Summary	
	3904	Oncotype Dx Recurrence Score-Invasive	
56: Gestational Trophoblastic Tumors (Placenta)	3837	Gestational Trophoblastic Prognostic Scoring Index	Placenta
58: Prostate	3920	PSA (Prostatic Specific Antigen) Lab Value	Prostate
59: Testis	3923	S Category Clinical	Testis
	3924	S Category Pathological	
68: Retinoblastoma	3856	Heritable Trait	Retinoblastoma
79: Non-Hodgkin Lymphoma: CLL/SLL	3804	Adenopathy (Rai Classification: CLL/SLL)	Lymphoma (CLL/SLL)
	3811	Anemia (Rai Classification: CLL/SLL)	
	3885	Lymphocytosis (Rai Classification: CLL/SLL)	
	3907	Organomegaly (Rai Classification: CLL/SLL)	
	3933	Thrombocytopenia (Rai Classification: CLL/SLL)	
81: Primary Cutaneous Lymphomas: Mycosis Fungoides	3910	Peripheral Blood Involvement	Mycosis Fungoides
82: Plasma Cell Myeloma and Plasma Cell Disorders	3857	High Risk Cytogenetics	Plasma Cell Myeloma
	3869	LDH Pretreatment Level	
	3930	Serum Albumin Pretreatment Level	
	3931	Serum Beta-2 Microglobulin Pretreatment Level	

DRAFT

SSDIs used for EOD Derived Stage Group

In addition to the SSDIs required for AJCC 8th edition stage, the following SSDIs are used for the EOD Derived Stage group. These SSDIs are only required for those registries that are collecting EOD, but may be collected by others.

Applicable AJCC Chapter	NAACCR Data Item #	NAACCR Data Item Name	EOD Schema(s)
10: HPV-Mediated (p16+) Oropharyngeal Cancer	3883	LN Size	Oropharynx p16+
47: Melanoma Skin	3869	LDH Pretreatment Lab Value	Melanoma Skin
48: Breast	3882	LN Positive Axillary Level I-II	Breast
53: Corpus Uteri-Carcinoma and Carcinosarcoma	3911	Peritoneal Cytology	Corpus Carcinoma and Carcinosarcoma
54: Corpus Uteri-Sarcoma	3911	Peritoneal Cytology	Corpus Adenosarcoma and Corpus Sarcoma
67: Uveal Melanoma	3887	Measured Basal Diameter	Melanoma Choroid and Ciliary Body; Melanoma Iris
	3888	Measured Thickness	

DRAFT

Schema ID

Item Length: 5
NAACCR Item #: 3800
NAACCR Alternate Name: None

Description

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

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

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

Rationale

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

Definition

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

DRAFT

Schema ID Table

Schema ID#/Description	AJCC #/Chapter	SSDI #/Description
00060: Cervical Lymph Nodes and Unknown Primary	**6**: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck	**3926:** Schema Discriminator 1: Occult Head and Neck Lymph Nodes (Primary site C760 only) **3831**: Extranodal Extension Head and Neck Clinical **3832**: Extranodal Extension Head and Neck Pathological **3876**: LN Head and Neck Levels I-III **3877**: LN Head and Neck Levels IV-V **3878**: LN Head and Neck Levels VI-VII **3879**: LN Head and Neck Other **3883**: LN Size
00071: Lip **00072:** Tongue Anterior **00073:** Gum **00074:** Floor of Mouth **00075:** Palate Hard **00076:** Buccal Mucosa **00077:** Mouth Other	**7:** Lip and Oral Cavity	**3831**: Extranodal Extension Head and Neck Clinical **3832**: Extranodal Extension Head and Neck Pathological **3883**: LN Size
00080: Major Salivary Glands	**8:** Major Salivary Glands	**3831**: Extranodal Extension Head and Neck Clinical **3832**: Extranodal Extension Head and Neck Pathological **3883**: LN Size
00090: Nasopharynx	**9**: Nasopharynx	**3831**: Extranodal Extension Head and Neck Clinical **3832**: Extranodal Extension Head and Neck Pathological **3883**: LN Size **3926**: Schema Discriminator 1 (Nasopharynx/PharyngealTonsil)
00100: Oropharynx HPV-Mediated (p16+)	**10**: HPV-Mediated (p16+) Oropharyngeal Cancer (See Oropharynx)	**3831**: Extranodal Extension Head and Neck Clinical **3832**: Extranodal Extension Head and Neck Pathological **3883**: LN Size **3926**: Schema Discriminator 1 (Nasopharynx/PharyngealTonsil) **3927**: Schema Discriminator 2 (Oropharyngeal p16)
00111: Oropharynx (p16-)	**11:** Oropharynx (p16-) and Hypopharynx (See Oropharynx)	**3831**: Extranodal Extension Head and Neck Clinical **3832**: Extranodal Extension Head and Neck Pathological **3883**: LN Size **3926**: Schema Discriminator 1 (Nasopharynx/PharyngealTonsil) **3927**: Schema Discriminator 2 (Oropharyngeal p16)
00112: Hypopharynx	**11**: Oropharynx (p16-) and Hypopharynx (See Hypopharynx)	**3831**: Extranodal Extension Head and Neck Clinical **3832**: Extranodal Extension Head and Neck Pathological **3883**: LN Size
00118: Pharynx Other	No AJCC Chapter	No SSDIs defined for this Schema ID
00119: Middle Ear	No AJCC Chapter	No SSDIs defined for this Schema ID

DRAFT

Schema ID#/Description	AJCC #/Chapter	SSDI #/Description
00121: Maxillary Sinus **00122**: Nasal Cavity and Ethmoid Sinus	**12:** Nasal Cavity and Paranasal Sinuses	**3831**: Extranodal Extension Head and Neck Clinical **3832**: Extranodal Extension Head and Neck Pathological **3883**: LN Size
00128: Sinus Other	No AJCC Chapter	No SSDIs defined for this Schema ID
00130: Larynx Other **00131**: Larynx Supraglottic **00132**: Larynx Glottic **00133**: Larynx Subglottic	**13**: Larynx	**3831**: Extranodal Extension Head and Neck Clinical **3832**: Extranodal Extension Head and Neck Pathological **3883**: LN Size
00140: Melanoma Head and Neck	**14**: Mucosal Melanoma of the Head and Neck	**3831**: Extranodal Extension Head and Neck Clinical **3832**: Extranodal Extension Head and Neck Pathological **3876**: LN Head and Neck Levels I-III **3877**: LN Head and Neck Levels IV-V **3878**: LN Head and Neck Levels VI-VII **3879**: LN Head and Neck Other **3883**: LN Size
00150: Cutaneous Squamous Cell Carcinoma of the Head and Neck	**15**: Cutaneous Squamous Cell Carcinoma of the Head and Neck	**3858**: High Risk Histologic Features **3883**: LN Size **3909**: Perineural Invasion
00161: Esophagus and Esophagus GE Junction (Squamous)	**16**: Esophagus and Esophagogastric Junction	**3926**: Schema Discriminator 1 (EsophagusGEJunction (EGJ)/Stomach) (primary site C160) **3927**: Schema Discriminator 2 (Histology Discriminator for 8020/3) **3829**: Esophagus and EGJ Tumor Epicenter
00169: Esophagus and Esophagus GE Junction (Adenocarcinoma and Other)	**16**: Esophagus and Esophagogastric Junction	**3926**: Schema Discriminator 1 (EsophagusGEJunction (EGJ)/Stomach) (primary site C160) **3927**: Schema Discriminator 2 (Histology Discriminator for 8020/3)
00170: Stomach	**17:** Stomach	**3926**: Schema Discriminator 1 (EsophagusGEJunction (EGJ)/Stomach) (primary site C160)
00180: Small Intestine	**18:** Small Intestine	No SSDIs defined for this Schema ID
00190: Appendix	**19**: Appendix Carcinoma	**3819**: CEA Pretreatment Interpretation **3820**: CEA Pretreatment Lab Value
00200: Colon and Rectum	**20:** Colon and Rectum	**3819**: CEA Pretreatment Interpretation **3820**: CEA Pretreatment Lab Value **3823**: Circumferential Resection Margin (CRM) **3866**: KRAS **3890**: Microsatellite Instability (MSI) **3909**: Perineural Invasion **3934**: Tumor Deposits
00210: Anus	**21**: Anus	No SSDIs defined for this Schema ID
00220: Liver	**22**: Liver	**3809**: AFP Pretreatment Interpretation **3810**: AFP Pretreatment Lab Value

DRAFT

Schema ID#/Description	AJCC #/Chapter	SSDI #/Description
		3813: Bilirubin Pretreatment Total Lab Value **3814**: Bilirubin Pretreatment Unit of Measure **3824**: Creatinine Pretreatment Lab Value **3825**: Creatinine Pretreatment Unit of Measure **3835**: Fibrosis Score **3860**: International Normalized Ratio
00230: Intrahepatic Bile Duct	**23**: Intrahepatic Bile Ducts	**3835**: Fibrosis Score **3917**: Primary Sclerosing Cholangitis **3935**: Tumor Growth Pattern
00241: Gallbladder **00242**: Cystic Duct	**24**: Gallbladder (including Cystic Duct)	**3926**: Schema Discriminator 1 (BileDuctsDistal/BileDuctsPerihilar/ CysticDuct)
00250: Bile Duct Perihilar	**25**: Perihilar Bile Ducts	**3926**: Schema Discriminator 1 (BileDuctsDistal/BileDuctsPerihilar/ CysticDuct) **3917**: Primary Sclerosing Cholangitis
00260: Bile Duct Distal	**26**: Distal Bile Duct	**3926**: Schema Discriminator 1 (BileDuctsDistal/BileDuctsPerihilar/ CysticDuct)
00270: Ampulla of Vater	**27**: Ampulla of Vater	No SSDIs defined for this Schema ID
00278: Biliary Other	No AJCC Chapter	No SSDIs defined for this Schema ID
00280: Pancreas	**28**: Exocrine Pancreas	No SSDIs defined for this Schema ID
00288: Digestive Other	No AJCC Chapter	No SSDIs defined for this Schema ID
00290: NET Stomach	**29**: Neuroendocrine Tumors of the Stomach	No SSDIs defined for this Schema ID
00301: NET Duodenum **00302**: NET Ampulla of Vater	**30**: Neuroendocrine Tumors of the Duodenum and Ampulla of Vater	No SSDIs defined for this Schema ID
00310: NET Jejunum and Ileum	**31**: Neuroendocrine Tumors of the Jejunum and Ileum	No SSDIs defined for this Schema ID
00320: NET Appendix	**32**: Neuroendocrine Tumors of the Appendix	No SSDIs defined for this Schema ID
00330: NET Colon and Rectum	**33**: Neuroendocrine Tumors of the Colon and Rectum	No SSDIs defined for this Schema ID
00340: NET Pancreas	**34**: Neuroendocrine Tumors of the Pancreas	No SSDIs defined for this Schema ID
00350: Thymus	**35**: Thymus	No SSDIs defined for this Schema ID
00358: Trachea	No AJCC Chapter	No SSDIs defined for this Schema ID
00360: Lung	**36**: Lung	**3929**: Separate Tumor Nodules **3937**: Visceral and Parietal Pleural Invasion
00370: Pleural Mesothelioma	**37**: Malignant Mesothelioma	**3913**: Pleural Effusion
00378: Respiratory Other	No AJCC Chapter	No SSDIs defined for this Schema ID
00381: Bone Appendicular Skeleton **00382**: Bone Spine **00383**: Bone Pelvis	**38**: BONE	**3908**: Percent Necrosis Post Neoadjuvant
00400: Soft Tissues Head and Neck	**40**: Soft Tissue Sarcoma of the Head and Neck	**3915**: Bone Invasion

DRAFT

Schema ID#/Description	AJCC #/Chapter	SSDI #/Description
	See Soft Tissue	
00410: Soft Tissues Trunk and Extremities	**41**: Soft Tissue Sarcoma of the Trunk and Extremities See Soft Tissue	**3915**: Bone Invasion
00421: Soft Tissues Abdomen and Thoracic (excluding Heart, Mediastinum, Pleura) **00422**: Heart, Mediastinum, Pleura	**42**: Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs See Soft Tissue	**3915**: Bone Invasion
00430: GIST	**43**: Gastrointestinal Stromal Tumor (GIST)	**3926**: Schema Discriminator 1 (Primary Peritoneum Tumor) **3865**: KIT Gene Immunohistochemistry
00440: Soft Tissues Retroperitoneum	**44**: Soft Tissue Sarcoma of the Retroperitoneum See Soft Tissue	**3815**: Bone Invasion
00450: Soft Tissue Other **00458**: Kaposi Sarcoma	**45**: Soft Tissue Sarcoma-Unusual Sites and Histologies See Soft Tissue	**3926**: Schema Discriminator 1 (Occult Head and Neck Lymph Nodes) (Primary site C760 only) **3815**: Bone Invasion
00460: Merkel Cell Skin	**46**: Merkel Cell Carcinoma	**3830**: Extranodal Extension Clin (non-Head and Neck) **3831**: Extranodal Extension Path (non-Head and Neck) **3880**: LN Isolated Tumor Cells (ITC) **3893**: Mitotic Rate Melanoma **3918**: Profound Immune Suppression
00470: Melanoma Skin	**47**: Melanoma Skin	**3817**: Breslow Tumor Thickness **3936**: Ulceration **3932**: LDH Pretreatment Lab Value **3869**: LDH Pretreatment Level **3870**: LDH Upper Limits of Normal
00478: Skin (except Eyelid)	No AJCC Chapter	No SSDIs defined for this Schema ID
00480: Breast	**48**:BREAST	**3826**: Estrogen Receptor Percent Positive or Range **3827**: Estrogen Receptor Summary **3828**: Estrogen Receptor Total Allred Score **3914**: Progesterone Receptor Percent Positive or Range **3915**: Progesterone Receptor Summary **3916**: Progesterone Total Allred Score **3850**: HER2 IHC Summary **3854**: HER2 ISH Summary **3855**: HER2 Overall Summary **3853**: HER2 ISH Single Probe Copy Number **3851**: HER2 ISH Dual Probe Copy Number **3852**: HER2 ISH Dual Probe Ratio **3894**: Multigene Signature Method **3895**: Multigene Signature Results

DRAFT

Schema ID#/Description	AJCC #/Chapter	SSDI #/Description
		3903: Oncotype Dx Recurrence Score-DCIS **3905**: Oncotype Dx Risk Level-DCIS **3904**: Oncotype Dx Recurrence Score-Invasive **3906**: Oncotype Dx Risk Level-Invasive **3863**: Ki-67 **3882**: LN Positive Axillary Level I-II **3922**: Response to Neoadjuvant Therapy
00500: Vulva	**50**:Vulva	**3836**: FIGO Stage (Vulva) **3871**: LN Assessment Method Femoral-Inguinal **3872**: LN Assessment Method Para-aortic **3873**: LN Assessment Method Pelvic **3884**: LN Status Femoral-Inguinal, Para-aortic, Pelvic **3881**: LN Laterality
00510: Vagina	**51**: Vagina	**3836**: FIGO Stage (Vagina) **3871**: LN Assessment Method Femoral-Inguinal **3872**: LN Assessment Method Para-aortic **3873**: LN Assessment Method Pelvic **3884**: LN Status Femoral-Inguinal, Para-aortic, Pelvic **3874:** LN Distant Assessment Method **3875**: LN Distant: Mediastinal, Scalene
00520: Cervix	**52:** Cervix Uteri	**3836**: FIGO Stage (Cervix) **3871**: LN Assessment Method Femoral-Inguinal **3872**: LN Assessment Method Para-aortic **3873**: LN Assessment Method Pelvic **3884**: LN Status Femoral-Inguinal, Para-aortic, Pelvic **3874:** LN Distant Assessment Method **3875**: LN Distant: Mediastinal, Scalene
00530: Corpus Carcinoma and Carcinosarcoma	**53:**Corpus Uteri-Carcinoma and Carcinosarcoma	**3836**: FIGO Stage (Corpus Carcinoma and Carcinosarcoma) **3901:** Number of Positive Para-Aortic Nodes **3899**: Number of Examined Para-Aortic Nodes **3902:** Number of Positive Pelvic Nodes **3900**: Number of Examined Pelvic Nodes **3911**: Peritoneal Cytology
00541: Corpus Sarcoma **00542**: Corpus Adenosarcoma	**54:** Corpus Uteri-Sarcoma	**3836**: FIGO Stage (Corpus Sarcoma) **3836**: FIGO Stage (Corpus Adenosarcoma) **3901:** Number of Positive Para-Aortic Nodes **3899**: Number of Examined Para-Aortic Nodes **3902:** Number of Positive Pelvic Nodes **3900**: Number of Examined Pelvic Nodes **3911**: Peritoneal Cytology
00551: Ovary **00552:** Primary Peritoneal Carcinoma **00553:** Fallopian Tube	**55:** Ovary, Fallopian Tube, and Peritoneal Carcinoma	**3836:** FIGO Stage (Ovary, Fallopian Tube and Primary Peritoneal Carcinomas) **3818**: CA-125 Pretreatment Interpretation **3921**: Residual Tumor Volume Post Cytoreduction

DRAFT

Schema ID#/Description	AJCC #/Chapter	SSDI #/Description
00558: Adnexa Uterine Other	No AJCC Chapter	No SSDIs defined for this Schema ID
00559: Genital Female Other	No AJCC Chapter	No SSDIs defined for this Schema ID
00560: Placenta	**56**: Gestational Trophoblastic Neoplasms (Placenta)	**3836**: FIGO Stage (Gestational Trophoblastic Tumors) **3837**: Gestational Trophoblastic Prognostic Scoring Index
00570: Penis	**57:** Penis	**3830:** Extranodal Extension Clin (non-Head and Neck) **3833**: Extranodal Extension Path (non-Head and Neck)
00580: Prostate	**58:** Prostate	**3838:** Gleason Patterns Clinical **3840**: Gleason Score Clinical **3839**: Gleason Patterns Pathological **3841**: Gleason Score Pathological **3842**: Gleason Tertiary Pattern **3898**: Number of Cores Positive **3897**: Number of Cores Examined **3920:** PSA (Prostatic Specific Antigen) Lab Value
00590: Testis	**59:** Testis	**3807:** AFP Pre-Orchiectomy Lab Value **3808**: AFP Pre-Orchiectomy Range **3805**: AFP Post-Orchiectomy Lab Value **3806**: AFP Post-Orchiectomy Range **3848**: hCG Pre-Orchiectomy Lab Value **3849:** hCG Pre-Orchiectomy Range **3846**: hCG Post-Orchiectomy Lab Value **3847**: hCG Post-Orchiectomy Range **3868:** LDH Pre-Orchiectomy Range **3867**: LDH Post-Orchiectomy Range **3923**: S Category Clinical **3924**: S Category Pathological
00598: Genital Male Other	No AJCC Chapter	No SSDIs defined for this Schema ID
00600: Kidney-Parenchyma	**60**: Kidney	**3864**: Invasion Beyond Capsule **3861**: Ipsilateral Adrenal Gland Involvement **3886**: Major Vein Involvement **3925**: Sarcomatoid Features
00610: Kidney Renal Pelvis	**61:** Kidney Renal Pelvis	No SSDIs defined for this Schema ID
00620: Bladder	**62:** Bladder	No SSDIs defined for this Schema ID
00631: Urethra **00633**: Urethra Prostatic	**63:** Urethra	**3926**: Schema Discriminator 1 (Urethra/Prostatic Urethra)
00638: Urinary Other	No AJCC Chapter	No SSDIs defined for this Schema ID
00640: Skin Eyelid	**64**: Eyelid Carcinoma	**3909**: Perineural Invasion
00650: Conjunctiva	**65:** Conjunctival Carcinoma	No SSDIs defined for this Schema ID

DRAFT

Schema ID#/Description	AJCC #/Chapter	SSDI #/Description
00660: Melanoma Conjunctiva	**66:** Conjunctival Melanoma	**3888**: Measured Thickness
00671: Melanoma Iris **00672**: Melanoma Choroid and Ciliary Body	**67:** Uveal Melanoma	**3926:** Schema Discriminator 1 (Melanoma Ciliary Body/Melanoma Iris) **3821**: Chromosome 3 Status **3822**: Chromosome 8q Status **3834**: Extravascular Matrix Pattern **3887**: Measured Basal Diameter **3888**: Measured Thickness **3891**: Microvascular Density **3892**: Mitotic Count Uveal Melanoma
00680: Retinoblastomas	**68:** Retinoblastoma	**3856:** Heritable Trait
00690: Lacrimal Gland	**69:** Lacrimal Gland Carcinoma	**3926:** Schema Discriminator 1 (Lacrimal Gland/Lacrimal Sac) **3803**: Adenoid Cystic Basaloid Pattern **3909**: Perineural Invasion
00698: Lacrimal Sac	No AJCC Chapter	**3926:** Schema Discriminator 1 (Lacrimal Gland/Lacrimal Sac)
00700: Orbital Sarcoma	**70**: Orbital Sarcoma	No SSDIs defined for this Schema ID
00710: Lymphoma Ocular Adnexa	**71:** Ocular Adnexal Lymphoma	No SSDIs defined for this Schema ID
00718: Eye Other	No AJCC Chapter	No SSDIs defined for this Schema ID
00721: Brain **00722:** CNS Other	**72**: Brain and Spinal Cord	**3816**: Brain Molecular Markers 3801: Chromosome 1p: Loss of Heterozygosity (LOH) **3802**: Chromosome 19q: Loss of Heterozygosity (LOH) **3889**: Methylation of O6-Methylguanine-Methyltransferase
00723: Intracranial Other	No AJCC Chapter	No SSDIs defined for this Schema ID
00730: Thyroid	**73**: Thyroid-Differentiated and Anaplastic Carcinoma (See Thyroid (including Medullary)	**3926**: Schema Discriminator 1 (Thyroid Gland/Thyroglossal Duct)
00740: Thyroid-Medullary	**74**: Thyroid-Medullary (See Thyroid (including Medullary)	**3926**: Schema Discriminator 1 (Thyroid Gland/Thyroglossal Duct)
00750: Parathyroid	**75**: Parathyroid	No SSDIs defined for this Schema ID
00760: Adrenal Gland	**76**: Adrenal Cortical Carcinoma (See Adrenal Gland)	No SSDIs defined for this Schema ID
00770: NET Adrenal Gland	**77**: Adrenal-Neuroendocrine Tumors (See Adrenal Gland)	No SSDIs defined for this Schema ID
00778: Endocrine Other	No AJCC Chapter	No SSDIs defined for this Schema ID
00790: Lymphoma (excluding CLL/SLL)	**79**: Hodgkin and Non-Hodgkin Lymphomas	**3926**: Schema Discriminator 1 (Histology Discriminator for 9591/3) **3812**: B Symptoms

DRAFT

Schema ID#/Description	AJCC #/Chapter	SSDI #/Description
	80: Pediatric Hodgkin and Non-Hodgkin Lymphomas Lymphomas (Adult and Pediatric Hodgkin and Non-Hodgkin Lymphomas)	**3859**: HIV Status **3896**: NCCN International Prognostic Index (IPI)
00795: Lymphoma (CLL/SLL)	**79**: Hodgkin and Non-Hodgkin Lymphomas **80**: Pediatric Hodgkin and Non-Hodgkin Lymphomas Lymphomas (Adult and Pediatric Hodgkin and Non-Hodgkin Lymphomas)	**3812**: B Symptoms **3859**: HIV Status **3896**: NCCN International Prognostic Index (IPI) **3840:** Adenopathy **3811:** Anemia **3885:** B symptoms **3907:** Organomegaly **3933:** Thrombocytopenia
00811: Mycosis Fungoides	**81:** Primary Cutaneous Lymphomas	**3901:** Peripheral Blood Involvement
00812: Primary Cutaneous Lymphomas (excluding Mycosis Fungoides)		No SSDIs defined for this Schema ID
00821: Plasma Cell Myeloma	**82:** Plasma Cell Myeloma and Plasma Cell Disorders	**3926**: Schema Discriminator 1 (Multiple Myeloma Terminology) **3857**: High Risk Cytogenetics **3869**: LDH Pretreatment Level **3930**: Serum Albumin Pretreatment Level **3931**: Serum Beta-2 Microglobulin Pretreatment Level
00822: Plasma Cell Disorders		No SSDIs defined for this Schema ID
00830: HemeRetic	**83:** Leukemia	**3926**: Schema Discriminator 1 (Histology Discriminator for 9591/3) **3862**: JAK2
99999: Ill-Defined Other	No AJCC Chapter	**3926:** Schema Discriminator 1 (Occult Head and Neck Lymph Nodes) **(Primary site C760 only)**

DRAFT

HEAD AND NECK

DRAFT

Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck

Schema Discriminator 1: Occult Head and Neck Lymph Nodes

Item Length: 1
NAACCR Item #: 3926
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 6: Cervical Lymph Nodes and Unknown Primary

Definition

In AJCC 8th edition, a new chapter was introduced for situations when there are positive cervical nodes (head and neck nodes), however, the primary tumor is not known (occult tumor) and the primary tumor is presumed to be from the head and neck region (primary sites C00-C14, C30-32). This chapter does NOT apply to those cases where the primary site is known or suspected.

To develop a software algorithm that can be used to send the registrar to the right chapter/schema, this schema discriminator was developed.

To get to this schema discriminator, the registrar will assign C760 (head and neck, NOS) when there is a suspected head and neck tumor yet the primary site is not known. The schema discriminator will then be brought up.

Note: Previous instructions were to code these types of cases to C148.

Coding Instructions and Codes

Note 1: This schema discriminator is used to discriminate between head and neck tumors with unknown primary site coded as C760. Some situations require that a more specific primary site be assigned.

- **Chapter 6: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck**
  Occult head and neck tumor with cervical metastasis in level II/III lymph nodes without a p16 immunostain or with negative results and without an Epstein-Barr virus (EBV) encoded small RNAs (EBER) by *in situ* hybridization performed or with negative results are staged using Chapter 6
- **Chapter 9: Nasopharynx**
  Occult head and neck tumors with cervical metastasis in level II/III lymph nodes that is positive for Epstein–Barr virus (EBV+) encoded small RNAs (EBER) identified by *in situ* hybridization are staged using Chapter 9. Assign primary site C119; do NOT code this discriminator
- **Chapter 10: HPV-Mediated (p16+) Oropharyngeal Cancer**
  Occult head and neck tumors with cervical metastasis in level II/III lymph nodes, p16 positive with histology consistent with HPV-mediated oropharyngeal carcinoma (OPC), should be staged using Chapter 10. Assign primary site C109; do NOT code this discriminator
- **Ill Defined, Other (Summary Stage only)**
  If the tumor is not occult or does not have cervical metastasis in level II/III lymph nodes, it is not included in Chapter 6 and will be classified as Ill Defined, Other for Summary Staging

Note 2: Assign this data item based on physician statement or from lab tests performed at diagnosis (pre-treatment).

Note 3: If the code determined by available lab tests differs from the physician statement, the physician's statement takes precedence.

Code	Description	AJCC Disease ID
0	Not Occult	EOD/SS schema (Ill Defined, Other)
1	Occult, Negative cervical nodes (regional head and neck nodes)	EOD/SS schema (Ill Defined, Other)
2	Not tested for EBV or p16 in head and neck regional nodes (EBV and p16 both unknown)	6: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck
3	Unknown EBV, p16 negative in head and neck regional nodes	6: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck
4	Unknown p16, EBV negative in head and neck regional nodes	6: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck
5	Negative for both EBV and p16 in head and neck regional nodes	6: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck
<Blank>	Not C760, discriminator does not apply Positive p16 in head and neck regional nodes, EBV unknown or negative **Assign primary site as C109** Positive EBV in head and neck regional nodes, p16 positive, negative or unknown **Assign primary site as C119**	Various 10: HPV-Mediated (p16+) Oropharyngeal Cancer - (C109) 9: Nasopharynx (C119)

Return back to Schema ID Table

DRAFT

Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck

Extranodal Extension Head and Neck Clinical

Item Length: 1
NAACCR Item #: 3831
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 6: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck
- Chapter 7: Lip and Oral Cavity
- Chapter 8: Major Salivary Glands
- Chapter 9: Nasopharynx
- Chapter 10: HPV-Mediated (p16+) Oropharyngeal Cancer
- Chapter 11: Oropharynx (p16-) and Hypopharynx
- Chapter 12: Nasal Cavity and Paranasal Sinuses
- Chapter 13: Larynx
- Chapter 14: Mucosal Melanoma of the Head and Neck

Description

Extranodal extension is defined as "the extension of a nodal metastasis through the lymph node capsule into adjacent tissue" and is a prognostic factor for most head and neck tumors. This data item pertains to clinical extension.

Rationale

Extranodal Extension Head and Neck Clinical is a Registry Data Collection Variable in AJCC. It was previously collected as Head and Neck SSF# 8 (Common SSF).

Definition

The presence of extranodal extension (ENE) from regional lymph nodes is an important prognostic factor in some cancers because these patients are rarely cured without some type of systemic chemotherapy or radiation. Extranodal extension is defined as metastatic tumor growing from within the lymph node outward through the lymph node capsule and into surrounding connective tissues.

This data item for ENE detected clinically.

Coding guidelines

- Code 0 when there are positive nodes clinically, but ENE not identified/not present.
- Code 1 when there are positive nodes clinically, ENE is identified by physical exam or imaging
- Code 2 when there are positive nodes clinically, ENE is identified by biopsy (microscopically confirmed)
- Code 7 when nodes are clinically negative (cN0)
- Code 9 when
    - No information in the medical record

- Positive nodes clinically, not evaluated (assessed) for ENE
- Positive nodes clinically, unknown if evaluated (assessed) for ENE
- Lymph nodes not evaluated (assessed) clinically
- Unknown if lymph nodes evaluated (assessed) clinically

Additional Information

- **Source documents:** pathology report, imaging reports, physical exam
- **Other names:** ENE, extracapsular extension, ECE

Coding Instructions and Codes

Note 1: Physician statement of extranodal extension (ENE) clinically or physician clinical stage indicating the absence or presence of ENE can be used to code this data item when no other information is available. Physical exam alone is sufficient to determine Clinical ENE.

Note 2: The assessment of ENE must be based on evidence acquired prior to definitive surgery of the primary site, chemotherapy, radiation or other type of treatment, i.e., the clinical timeframe for staging.

- The assessment for ENE **in addition to physical examination** may include imaging, biopsy of the regional lymph node, and/or biopsy of tissues surrounding the regional lymph node.
- Imaging **alone** is not enough to determine or exclude ENE.

Note 3: Be aware that the rules for coding ENE for head and neck sites compared to non-head and neck sites are different.

Note 4: Code 0 when lymph nodes are determined to be positive and physical examination does not indicate any signs of extranodal extension.

Note 5: Code 1 when

- ENE is unquestionable as determined by physical examination
  - Clinical ENE is described in the AJCC 8th edition as "Unambiguous evidence of gross ENE on clinical examination (e.g., invasion of skin, infiltration of musculature, tethering to adjacent structures, or cranial nerve, brachial plexus, sympathetic trunk, or phrenic nerve invasion with dysfunction)"
- The terms 'fixed' or 'matted' are used to describe lymph nodes
- Lymph node biopsy (e.g., FNA, core, incisional, excisional, sentinel node) confirms ENE.
- Other terms for ENE include: 'extranodal spread', 'extracapsular extension', or 'extracapsular spread'.

Note 6: Code 9 when physical exam is not available AND at least one of the following

- No additional information
- Statement of lymph node involvement with no information on ENE
- Lymph node biopsy (e.g., FNA, core, incisional, excisional, sentinel node) performed and is negative for ENE

Code	Description
0	Regional lymph nodes involved, ENE not present/not identified during diagnostic workup
1	Regional lymph nodes involved, ENE present/identified during diagnostic workup, based on physical exam WITH or WITHOUT imaging

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

Return back to Schema ID Table

DRAFT

Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck

Extranodal Extension Head and Neck Pathological

Item Length: 1
NAACCR Item #: 3832
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 6: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck
- Chapter 7: Lip and Oral Cavity
- Chapter 8: Major Salivary Glands
- Chapter 9: Nasopharynx
- Chapter 10: HPV-Mediated (p16+) Oropharyngeal Cancer
- Chapter 11: Oropharynx (p16-) and Hypopharynx
- Chapter 12: Nasal Cavity and Paranasal Sinuses
- Chapter 13: Larynx
- Chapter 14: Mucosal Melanoma of the Head and Neck

Description

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

Rationale

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

Definition

The presence of extranodal extension (ENE) from regional lymph nodes is an important prognostic factor in some cancers because these patients are rarely cured without some type of systemic chemotherapy or radiation. Extranodal extension is defined as metastatic tumor growing from within the lymph node outward through the lymph node capsule and into surrounding connective tissues.

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

Coding guidelines

- Code 0.0 when there are positive nodes pathologically, but ENE not identified/not present.
- Code the actual size of the ENE in the range 0.1-9.9 mm
- Code X.1 when actual size of the ENE is 10 mm or greater
- Code X.2 when stated to be microscopic [ENE (mi)]
- Code X.3 when stated to be major [ENE (ma)]
- Code X.4 when size not documented, unknown whether microscopic (mi) or major (ma)
- Code X.7 when nodes are surgically resected and they are negative (pN0)

- Code X.9 when
    - No information in the medical record
    - Positive nodes pathologically, not evaluated (assessed) for ENE
    - Positive nodes pathologically, unknown if evaluated (assessed) for ENE
    - Lymph nodes not evaluated (assessed) pathologically (no surgical resection of lymph nodes)
    - Unknown if lymph nodes evaluated pathologically (assessed)

Additional Information

- **Source documents:** pathology report from surgical resection
- **Other names:** ENE, extracapsular extension, ECE

Coding Instructions and Codes

Note 1: Physician statement of extranodal extension (ENE) pathologically during a lymph node dissection or physician pathological stage indicating the absence or presence of ENE can be used to code this data item when no other information is available.

Note 2: Code the status of ENE assessed on histopathological examination of surgically resected involved regional lymph node(s). Do not code ENE from a lymph node biopsy (FNA, core, incisional, excisional, sentinel). Do not code ENE for any distant lymph nodes.

Note 3: Be aware that the rules for coding ENE for head and neck sites compared to non-head and neck sites are different.

Note 4: Definitions of ENE subtypes and rules:
- Microscopic ENE [ENE (mi)] is defined as less than or equal to 2 mm.
- Major ENE [ENE (ma)] is defined as greater than 2 mm.
- Both ENE (mi) and ENE (ma) qualify as ENE (+) for definition of pN.

Note 5: The measurement of ENE is the distance from the lymph node capsule in millimeters (mm).

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

Code	Description
	Pathological assessment of lymph nodes not done, or unknown if done

Return back to Schema ID Table

DRAFT

Head and Neck Regional Lymph Nodes (Levels I-VII, Other)

For head and neck sites, regional lymph node information is coded in several different data items.

- LN Head and Neck Levels I-III [NAACCR Data Item # 3876]
- LN Head and Neck Levels IV-V [NAACCR Data Item # 3877]
- LN Head and Neck Levels VI-VII [NAACCR Data Item # 3878]
- LN Head and Neck Other [NAACCR Data Item # 3879]

The Head and Neck Levels are defined as

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

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

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

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

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

- Middle deep cervical, mid-jugular

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

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

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

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

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

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

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

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

Other head and neck lymph nodes:

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

Coding guidelines

Example 1: A carcinoma of the base of tongue involves bilateral submandibular nodes and left upper, mid-, and lower jugular nodes, the largest measuring 4 cm. There is no extracapsular extension. These are level I, II, III, and IV lymph nodes according to AJCC definitions.

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

Example 2: Patient diagnosed elsewhere with carcinoma of oropharynx with cervical lymph node involvement. No other information available. All Head and Neck Level data items are coded to 0 since there is no specific information about the levels.

- Levels I-III: Code 0
- Levels IV-V: Code 0
- Levels VI-VII: Code 0
- Head and Neck, Other: Code 0

Coding NOS

Note: When the only information available is “Regional nodes, NOS” or “Cervical nodes, NOS” or “Internal jugular nodes, NOS” or “Lymph nodes, NOS,” code 0. In other words, if regional nodes are known to be positive but the level(s) of nodes involved is unknown, code 0.

Coding a Node That Overlaps Two Levels

Note: If a lymph node is described as involving two levels, code both levels.

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

DRAFT

Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck

LN Head and Neck Levels I-III

Item Length: 1
NAACCR Item #: 3876
NAACCR Alternate Name: Lymph Nodes Head and Neck Levels I-III
AJCC 8th Edition Chapter(s):

- Chapter 6: Cervical Lymph Nodes and Unknown Primary Tumors of Head and Neck
- Chapter 14: Mucosal Melanoma of the Head and Neck

Description

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

Rationale

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

Definition

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

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

See Head and Neck Regional Lymph Nodes (Levels I-VII, Other) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of Levels I-III lymph node involvement can be used to code this data item when no other information is available.

Note 2: Head and Neck Lymph Node Involvement is coded in the following data items

- LN Head and Neck Levels I-III [NAACCR Data Item # 3876]
- LN Head and Neck Levels IV-V [NAACCR Data Item # 3877]
- LN Head and Neck Levels VI-VII [NAACCR Data Item # 3878]
- LN Head and Neck Other [NAACCR Data Item # 3879]

Note 3: Code the presence or absence of lymph node involvement for Levels I-III.

For more information on Levels I-III lymph nodes, see AJCC 8th edition, Chapter 5: *Staging Head and Neck Cancers*, Table 5.1

Note 4: Pathological information takes priority over clinical.

Note 5: If involved regional node levels are documented as a range, or if the involved nodes overlap multiple levels, code all levels specified.

Note 6: If information is available on some nodes, but the others are unknown, code what is known.

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

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

Return back to Schema ID Table

DRAFT

Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck

LN Head and Neck Levels IV-V

Item Length: 1
NAACCR Item #: 3877
NAACCR Alternate Name: Lymph Nodes Head and Neck Levels IV-V
AJCC 8th Edition Chapter(s):

- Chapter 6: Cervical Lymph Nodes and Unknown Primary Tumors of Head and Neck
- Chapter 14: Mucosal Melanoma of the Head and Neck

Description

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

Rationale

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

Definition

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

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

See Head and Neck Regional Lymph Nodes (Levels I-VII, Other) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of Levels IV-V lymph node involvement can be used to code this data item when no other information is available.

Note 2: Head and Neck Lymph Node Involvement is coded in the following data items

- LN Head and Neck Levels I-III [NAACCR Data Item # 3876]
- LN Head and Neck Levels IV-V [NAACCR Data Item # 3877]
- LN Head and Neck Levels VI-VII [NAACCR Data Item # 3878]
- LN Head and Neck Other [NAACCR Data Item # 3879]

Note 3: Code the presence or absence of lymph node involvement for Levels IV-V

For more information on Levels IV-V lymph nodes, see AJCC 8th edition, Chapter 5: *Staging Head and Neck Cancers*, Table 5.1

Note 4: Pathological information takes priority over clinical.

Note 5: If involved regional node levels are documented as a range, and/or if the involved nodes overlap multiple levels, code all levels specified.

Note 6: If information is available on some nodes, but the others are unknown, code what is known.

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

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

Return back to Schema ID Table

DRAFT

Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck

LN Head and Neck Levels VI-VII

Item Length: 1
NAACCR Item #: 3878
NAACCR Alternate Name: Lymph Nodes Head and Neck Levels VI-VII
AJCC 8th Edition Chapter(s):

- Chapter 6: Cervical Lymph Nodes and Unknown Primary Tumors of Head and Neck
- Chapter 14: Mucosal Melanoma of the Head and Neck

Description

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

Rationale

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

Definition

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

- **Note 1**: This data item was previously collected for all head and neck sites. It is now only clinically relevant for unknown head and neck primaries with positive cervical (head and neck) lymph nodes and mucosal melanomas of the head and neck.
- **Note 2**: In **Collaborative Stage v2 (CSv2),** Facial Lymph Nodes were collected with Levels VI-VII. They have now been moved to the "other" group.

See Head and Neck Regional Lymph Nodes (Levels I-VII, Other) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of Levels VI-VII lymph node involvement can be used to code this data item when no other information is available.

Note 2: Head and Neck Lymph Node Involvement is coded in the following data items

- LN Head and Neck Levels I-III [NAACCR Data Item # 3876]
- LN Head and Neck Levels IV-V [NAACCR Data Item # 3877]
- LN Head and Neck Levels VI-VII [NAACCR Data Item # 3878]
- LN Head and Neck Other [NAACCR Data Item # 3879]

Note 3: Code the presence or absence of lymph node involvement for Levels VI-VII

For more information on Levels VI-VII lymph nodes, see AJCC 8th edition, Chapter 5: *Staging Head and Neck Cancers*, Table 5.1

Note 4: Pathological information takes priority over clinical.

Note 5: If involved regional node levels are documented as a range, or if the involved nodes overlap multiple levels, code all levels specified.

Note 6: If information is available on some nodes, but the others are unknown, code what is known.

> ***Example***: Multiple lymph nodes involved, level VI documented, but the other levels not mentioned. Code 1 to indicate level VI involvement.

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

Return back to Schema ID Table

DRAFT

Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck

LN Head and Neck Other

Item Length: 1
NAACCR Item #: 3879
NAACCR Alternate Name: Lymph Nodes Head and Neck Other
AJCC 8th Edition Chapter(s):

- Chapter 6: Cervical Lymph Nodes and Unknown Primary Tumors of Head and Neck
- Chapter 14: Mucosal Melanoma of the Head and Neck

Description

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

Rationale

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

Definition

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

- **Note 1**: This data item was previously collected for all head and neck sites. It is now only clinically relevant for unknown head and neck primaries with positive cervical (head and neck) lymph nodes and mucosal melanomas of the head and neck.
- **Note 2**: **In Collaborative Stage v2 (CSv2),** Facial Lymph Nodes were collected with Levels VI-VII. They are now collected with the "other" lymph nodes.

See Head and Neck Regional Lymph Nodes (Levels I-VII, Other) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of other head and neck lymph node involvement can be used to code this data item when no other information is available.

Note 2: Head and Neck Lymph Node Involvement is coded in the following data items

- LN Head and Neck Levels I-III [NAACCR Data Item # 3876]
- LN Head and Neck Levels IV-V [NAACCR Data Item # 3877]
- LN Head and Neck Levels VI-VII [NAACCR Data Item # 3878]
- LN Head and Neck Other [NAACCR Data Item # 3879]

Note 3: Code the presence or absence of lymph node involvement for the "other" group.

For more information on the other head and neck lymph nodes, see AJCC 8th edition, Chapter 5: *Staging Head and Neck Cancers*, Table 5.1

Note 4: Pathological information takes priority over clinical.

Note 5: If involved regional node levels are documented as a range, and/or if the involved nodes overlap multiple levels, code 7.

Note 6: If information is available on some nodes, but the others are unknown, code what is known.

- ***Example***: Multiple lymph nodes involved, preauricular documented, but the other levels not mentioned. Code 4 to indicate preauricular involvement.

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

Return back to Schema ID Table

DRAFT

Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck

LN Size

Item Length: 4
NAACCR Item #: 3883
NAACCR Alternate Name: Lymph Nodes Size
AJCC 8th Edition Chapter(s):

- Chapter 6: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck
- Chapter 7: Lip and Oral Cavity
- Chapter 8: Major Salivary Glands
- Chapter 9: Nasopharynx
- Chapter 10: HPV-Mediated (p16+) Oropharyngeal Cancer
- Chapter 11: Oropharynx (p16-) and Hypopharynx
- Chapter 12: Nasal Cavity and Paranasal Sinuses
- Chapter 13: Larynx
- Chapter 14: Mucosal Melanoma of the Head and Neck
- Chapter 15: Cutaneous Squamous Cell Carcinoma of Head and Neck

Description

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

Rationale

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

Definition

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

Coding guidelines

Code the largest diameter of any involved regional lymph nodes for head and neck (cervical lymph nodes). The measurement can be pathological, if available, or clinical.

- Code 0.0 when no regional lymph nodes are involved
- Code XX.1 for 100 millimeters (10 cm) or greater
- Code XX.2 for microscopic focus or foci only and no size of focus given
- Code XX.3 for lymph node met less than 1 cm (10 mm)
- Code XX.9 when
    - Positive lymph nodes but size not stated
    - No information about regional lymph nodes
    - Lymph nodes not assessed or unknown if assessed

DRAFT

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

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

Coding Instructions and Codes

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

Note 2: If the same largest involved node (or same level) is examined both clinically and pathologically, record the size of the node from the pathology report, even if it is smaller.

> ***Example***: Clinical evaluation shows 1.5 cm (15 mm) Level II lymph node, pathological examination shows Level II 1.3 cm (13 mm). Code 13.0.

Note 3: If the largest involved node is not examined pathologically, use the clinical node size.

Note 4: Do not code the size of any distant nodes.

Code	Description
0.0	No involved regional nodes
0.1-99.9	0.1 – 99.9 millimeters (mm) (Exact size of lymph node to nearest tenth of a mm)
XX.1	100 millimeters (mm) or greater
XX.2	Microscopic focus or foci only and no size of focus given
XX.3	Described as "less than 1 centimeter (cm)"
XX.4	Described as "at least” 2 cm
XX.5	Described as "at least” 3 cm
XX.6	Described as "at least” 4 cm
XX.7	Described as greater than 5 cm
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error)
XX.9	Not documented in medical record Regional lymph node(s) involved, size not stated Lymph Nodes Size not assessed, or unknown if assessed

Return back to Schema ID Table

DRAFT

Lip and Oral Cavity

Extranodal Extension Head and Neck Clinical

Item Length: 1
NAACCR Item #: 3831
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 6: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck
- Chapter 7: Lip and Oral Cavity
- Chapter 8: Major Salivary Glands
- Chapter 9: Nasopharynx
- Chapter 10: HPV-Mediated (p16+) Oropharyngeal Cancer
- Chapter 11: Oropharynx (p16-) and Hypopharynx
- Chapter 12: Nasal Cavity and Paranasal Sinuses
- Chapter 13: Larynx
- Chapter 14: Mucosal Melanoma of the Head and Neck

Description

Extranodal extension is defined as "the extension of a nodal metastasis through the lymph node capsule into adjacent tissue" and is a prognostic factor for most head and neck tumors. This data item pertains to clinical extension.

Rationale

Extranodal Extension Head and Neck Clinical is a Registry Data Collection Variable in AJCC. It was previously collected as Head and Neck SSF# 8 (Common SSF).

Definition

The presence of extranodal extension (ENE) from regional lymph nodes is an important prognostic factor in some cancers because these patients are rarely cured without some type of systemic chemotherapy or radiation. Extranodal extension is defined as metastatic tumor growing from within the lymph node outward through the lymph node capsule and into surrounding connective tissues.

This data item for ENE detected clinically.

Coding guidelines

- Code 0 when there are positive nodes clinically, but ENE not identified/not present.
- Code 1 when there are positive nodes clinically, ENE is identified by physical exam or imaging
- Code 2 when there are positive nodes clinically, ENE is identified by biopsy (microscopically confirmed)
- Code 7 when nodes are clinically negative (cN0)
- Code 9 when
    - No information in the medical record

- Positive nodes clinically, not evaluated (assessed) for ENE
- Positive nodes clinically, unknown if evaluated (assessed) for ENE
- Lymph nodes not evaluated (assessed) clinically
- Unknown if lymph nodes evaluated (assessed) clinically

Additional Information

- **Source documents:** pathology report, imaging reports, physical exam
- **Other names:** ENE, extracapsular extension, ECE

Coding Instructions and Codes

Note 1: Physician statement of extranodal extension (ENE) clinically or physician clinical stage indicating the absence or presence of ENE can be used to code this data item when no other information is available. Physical exam alone is sufficient to determine Clinical ENE.

Note 2: The assessment of ENE must be based on evidence acquired prior to definitive surgery of the primary site, chemotherapy, radiation or other type of treatment, i.e., the clinical timeframe for staging.

- The assessment for ENE **in addition to physical examination** may include imaging, biopsy of the regional lymph node, and/or biopsy of tissues surrounding the regional lymph node.
- Imaging **alone** is not enough to determine or exclude ENE.

Note 3: Be aware that the rules for coding ENE for head and neck sites compared to non-head and neck sites are different.

Note 4: Code 0 when lymph nodes are determined to be positive and physical examination does not indicate any signs of extranodal extension.

Note 5: Code 1 when

- ENE is unquestionable as determined by physical examination
  - Clinical ENE is described in the AJCC 8th edition as "Unambiguous evidence of gross ENE on clinical examination (e.g., invasion of skin, infiltration of musculature, tethering to adjacent structures, or cranial nerve, brachial plexus, sympathetic trunk, or phrenic nerve invasion with dysfunction)"
- The terms 'fixed' or 'matted' are used to describe lymph nodes
- Lymph node biopsy (e.g., FNA, core, incisional, excisional, sentinel node) confirms ENE.
- Other terms for ENE include: 'extranodal spread', 'extracapsular extension', or 'extracapsular spread'.

Note 6: Code 9 when physical exam is not available AND at least one of the following

- No additional information
- Statement of lymph node involvement with no information on ENE
- Lymph node biopsy (e.g., FNA, core, incisional, excisional, sentinel node) performed and is negative for ENE

Code	Description
0	Regional lymph nodes involved, ENE not present/not identified during diagnostic workup
1	Regional lymph nodes involved, ENE present/identified during diagnostic workup, based on physical exam WITH or WITHOUT imaging

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

Return back to Schema ID Table

DRAFT

Lip and Oral Cavity

Extranodal Extension Head and Neck Pathological

Item Length: 1
NAACCR Item #: 3832
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 6: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck
- Chapter 7: Lip and Oral Cavity
- Chapter 8: Major Salivary Glands
- Chapter 9: Nasopharynx
- Chapter 10: HPV-Mediated (p16+) Oropharyngeal Cancer
- Chapter 11: Oropharynx (p16-) and Hypopharynx
- Chapter 12: Nasal Cavity and Paranasal Sinuses
- Chapter 13: Larynx
- Chapter 14: Mucosal Melanoma of the Head and Neck

Description

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

Rationale

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

Definition

The presence of extranodal extension (ENE) from regional lymph nodes is an important prognostic factor in some cancers because these patients are rarely cured without some type of systemic chemotherapy or radiation. Extranodal extension is defined as metastatic tumor growing from within the lymph node outward through the lymph node capsule and into surrounding connective tissues.

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

Coding guidelines

- Code 0.0 when there are positive nodes pathologically, but ENE not identified/not present.
- Code the actual size of the ENE in the range 0.1-9.9 mm
- Code X.1 when actual size of the ENE is 10 mm or greater
- Code X.2 when stated to be microscopic [ENE (mi)]
- Code X.3 when stated to be major [ENE (ma)]
- Code X.4 when size not documented, unknown whether microscopic (mi) or major (ma)
- Code X.7 when nodes are surgically resected and they are negative (pN0)

- Code X.9 when
    - No information in the medical record
    - Positive nodes pathologically, not evaluated (assessed) for ENE
    - Positive nodes pathologically, unknown if evaluated (assessed) for ENE
    - Lymph nodes not evaluated (assessed) pathologically (no surgical resection of lymph nodes)
    - Unknown if lymph nodes evaluated pathologically (assessed)

Additional Information

- **Source documents:** pathology report from surgical resection
- **Other names:** ENE, extracapsular extension, ECE

Coding Instructions and Codes

Note 1: Physician statement of extranodal extension (ENE) pathologically during a lymph node dissection or physician pathological stage indicating the absence or presence of ENE can be used to code this data item when no other information is available.

Note 2: Code the status of ENE assessed on histopathological examination of surgically resected involved regional lymph node(s). Do not code ENE from a lymph node biopsy (FNA, core, incisional, excisional, sentinel). Do not code ENE for any distant lymph nodes.

Note 3: Be aware that the rules for coding ENE for head and neck sites compared to non-head and neck sites are different.

Note 4: Definitions of ENE subtypes and rules:
- Microscopic ENE [ENE (mi)] is defined as less than or equal to 2 mm.
- Major ENE [ENE (ma)] is defined as greater than 2 mm.
- Both ENE (mi) and ENE (ma) qualify as ENE (+) for definition of pN.

Note 5: The measurement of ENE is the distance from the lymph node capsule in millimeters (mm).

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

Code	Description
	Pathological assessment of lymph nodes not done, or unknown if done

Return back to Schema ID Table

DRAFT

Lip and Oral Cavity

LN Size

Item Length: 4
NAACCR Item #: 3883
NAACCR Alternate Name: Lymph Nodes Size
AJCC 8th Edition Chapter(s):

- Chapter 6: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck
- Chapter 7: Lip and Oral Cavity
- Chapter 8: Major Salivary Glands
- Chapter 9: Nasopharynx
- Chapter 10: HPV-Mediated (p16+) Oropharyngeal Cancer
- Chapter 11: Oropharynx (p16-) and Hypopharynx
- Chapter 12: Nasal Cavity and Paranasal Sinuses
- Chapter 13: Larynx
- Chapter 14: Mucosal Melanoma of the Head and Neck
- Chapter 15: Cutaneous Squamous Cell Carcinoma of Head and Neck

Description

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

Rationale

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

Definition

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

Coding guidelines

Code the largest diameter of any involved regional lymph nodes for head and neck (cervical lymph nodes). The measurement can be pathological, if available, or clinical.

- Code 0.0 when no regional lymph nodes are involved
- Code XX.1 for 100 millimeters (10 cm) or greater
- Code XX.2 for microscopic focus or foci only and no size of focus given
- Code XX.3 for lymph node met less than 1 cm (10 mm)
- Code XX.9 when
    - Positive lymph nodes but size not stated
    - No information about regional lymph nodes
    - Lymph nodes not assessed or unknown if assessed

DRAFT

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

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

Coding Instructions and Codes

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

Note 2: If the same largest involved node (or same level) is examined both clinically and pathologically, record the size of the node from the pathology report, even if it is smaller.

> ***Example***: Clinical evaluation shows 1.5 cm (15 mm) Level II lymph node, pathological examination shows Level II 1.3 cm (13 mm). Code 13.0.

Note 3: If the largest involved node is not examined pathologically, use the clinical node size.

Note 4: Do not code the size of any distant nodes.

Code	Description
0.0	No involved regional nodes
0.1-99.9	0.1 – 99.9 millimeters (mm) (Exact size of lymph node to nearest tenth of a mm)
XX.1	100 millimeters (mm) or greater
XX.2	Microscopic focus or foci only and no size of focus given
XX.3	Described as "less than 1 centimeter (cm)"
XX.4	Described as "at least” 2 cm
XX.5	Described as "at least” 3 cm
XX.6	Described as "at least” 4 cm
XX.7	Described as greater than 5 cm
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error)
XX.9	Not documented in medical record Regional lymph node(s) involved, size not stated Lymph Nodes Size not assessed, or unknown if assessed

Return back to Schema ID Table

DRAFT

Major Salivary Glands

See Lip and Oral Cavity for the following data items

- Extranodal Extension Head and Neck Clinical
- Extranodal Extension Head and Neck Pathological
- LN Size

Return back to Schema ID Table

DRAFT

Nasopharynx

Schema Discriminator 1: Nasopharynx/Pharyngeal Tonsil

Item Length: 1
NAACCR Item #: 3926
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 10: HPV Mediated Oropharynx p16+
- Chapter 11: Oropharynx (p16-) and Hypopharynx

Definition

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

Coding Instructions and Codes

Note: A schema discriminator is used to discriminate for primary site C111: Posterior wall of nasopharynx. Code the specific site in which the tumor arose.

- **Chapter 9: Nasopharynx (see code 1)**
  Used to stage for the following primary site descriptions: posterior wall of nasopharynx (NOS)
- **Chapter 10 or 11: HPV-Mediated (p16+) Oropharyngeal Cancer or Oropharynx (p16-) (see code 2)**
  Oropharynx chapters are used for the following primary site descriptions. An additional schema discriminator will be used to distinguish between Chapter 10 and 11
  - Adenoid
  - Pharyngeal tonsil

Code	Description	AJCC Disease ID
1	Posterior wall of nasopharynx, NOS	9: Nasopharynx
2	Adenoid Pharyngeal tonsil	Schema discriminator 2: Oropharyngeal p16
Blank	Primary Site is NOT C111, Discriminator is not necessary	

Return back to Schema ID Table

DRAFT

Nasopharynx

See Lip and Oral Cavity for the following data items

- Extranodal Extension Head and Neck Clinical
- Extranodal Extension Head and Neck Pathological
- LN Size

Return back to Schema ID Table

DRAFT

Oropharynx

See Schema Discriminator 1: Nasopharynx/Pharyngeal Tonsil for the following data item

- **Schema Discriminator 1 (Nasopharynx/PharyngealTonsil)**

Schema Discriminator 2: Oropharyngeal p16

Item Length: 1
NAACCR Item #: 3927
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 10: HPV Mediated Oropharynx p16+
- Chapter 11: Oropharynx (p16-) and Hypopharynx

Definition

Staging for oropharyngeal cancers changed in the AJCC 8th edition. Chapter 10 is now for p16+ tumors, while Chapter 11 is for p16- negative tumors or where the p16 is not assessed or unknown. A schema discriminator is necessary to determine the p16 status so that the appropriate chapter/schema is used.

Coding Instructions and Codes

Note 1: A schema discriminator is used to discriminate between oropharyngeal tumors that are p16 positive and oropharyngeal tumors that are p16 negative OR p16 status unknown.

Note 2: Only the HPV p16+ test can be used for this chapter. If another HPV test is done, code 9.

- **Chapter 10: HPV-Mediated (p16+) Oropharyngeal Cancer (see code 2)**
  Used to stage for the following: p16 (+) (positive)
- **Chapter 11: Oropharynx (p16-) and Hypopharynx**
  Used to stage for the following:
  - p16 expression of weak intensity or limited distribution (see code 1)
  - p16 without an immunostain performed (see code 9)

Code	Description	AJCC Disease ID
1	p16 Negative; Nonreactive	11.1: Oropharynx (p16-)
2	p16 Positive; HPV Positive; Diffuse, Strong reactivity	10: HPV-Mediated (p16+) Oropharyngeal Cancer
9	Not tested for p16; Unknown	11.1: Oropharynx (p16-)

Return back to Schema ID Table

DRAFT

Oropharynx

See Lip and Oral Cavity for the following data items

- Extranodal Extension Head and Neck Clinical
- Extranodal Extension Head and Neck Pathological
- LN Size

Return back to Schema ID Table

DRAFT

Hypopharynx

See Lip and Oral Cavity for the following data items

- Extranodal Extension Head and Neck Clinical
- Extranodal Extension Head and Neck Pathological
- LN Size

Return back to Schema ID Table

DRAFT

Nasal Cavity and Paranasal Sinuses

See Lip and Oral Cavity for the following data items

- Extranodal Extension Head and Neck Clinical
- Extranodal Extension Head and Neck Pathological
- LN Size

Return back to Schema ID Table

DRAFT

Larynx

See Lip and Oral Cavity for the following data items

- Extranodal Extension Head and Neck Clinical
- Extranodal Extension Head and Neck Pathological
- LN Size

Return back to Schema ID Table

DRAFT

Mucosal Melanoma of the Head and Neck

See Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck for the following data items

- Extranodal Extension Head and Neck Clinical
- Extranodal Extension Head and Neck Pathological
- LN Head and Neck Levels I-III
- LN Head and Neck Levels IV-V
- LN Head and Neck Levels VI-VII
- LN Head and Neck Other
- LN Size

Return back to Schema ID Table

DRAFT

Cutaneous Squamous Cell Carcinoma of the Head and Neck

High Risk Histologic Features

Item Length: 1
1NAACCR Item #: 3858
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 15, Cutaneous Squamous Cell Carcinoma of the Head and Neck

Description

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

Rationale

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

Definition

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

*In **Collaborative Stage v2 (CSv2**), which was based on AJCC 7th edition, the number of high risk features impacted the assignment of T. This is no longer the case. The type of high risk feature is now recorded instead of the number.*

Coding guidelines

Record the presence of high-risk features

- Code 1 for desmoplasia
- Code 2 for poor differentiation (grade 3)
- Code 3 for sarcomatoid differentiation (features)
- Code 4 for undifferentiated (grade 4)
- Code 5 when more than one feature is present
- Code 6 when high risk features are present, but it is not specified which one
- Code 9 when
    - Not documented in medical record
    - High risk features not evaluated (assessed)
    - Unknown if high-risk features evaluated (assessed)

Additional Information

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

- **Other names:** high risk histologic features, high risk tumor features

Coding Instructions and Codes

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

Note 2: High risk histologic features include
- Desmoplasia
- Poor differentiation (grade 3)
- Sarcomatoid differentiation (features)
- Undifferentiated (grade 4)

Note 3: Code 5 if more than one high risk histologic feature is present.

Note 4: Record the presence of high risk histologic features as documented in the medical record.

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

Return back to Schema ID Table

DRAFT

Cutaneous Squamous Cell Carcinoma of the Head and Neck

See Lip and Oral Cavity for the following data item

- LN Size

See Colon and Rectum for the following data item

- Perineural Invasion

DRAFT

GASTROINTESTINAL TRACT (UPPER AND LOWER)

DRAFT

Esophagus and Esophagogastric Junction

Schema Discriminator 1: EsophagusGEJunction (EGJ)/Stomach

Item Length: 1
NAACCR Item #: 3926
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

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

Definition

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

Note: This is different from AJCC 7th edition (CSv2) where the measurement was 5 cm.

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

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

Coding Notes and Instructions

Note: When primary site code is C160, the cancer will be staged using either the stomach cancer schema or the esophagus schema depending on the distance of the tumor's epicenter into the proximal stomach and whether the esophagogastric junction is involved.

Assign the code that best reflects EGJ involvement and the distance of the tumor's epicenter into the proximal stomach.

Chapter 16: Esophagus and Esophagogastric Junction (see code 2)
- Tumor involving the EGJ with epicenter less than 2 cm into proximal stomach

Chapter 17: Stomach (see codes 0, 3, and 9)
- No involvement of the EGJ or unknown if involvement of the EGJ AND epicenter at any distance

Code	Description	AJCC Disease ID
0	NO involvement of esophagus or gastroesophageal junction AND epicenter at ANY DISTANCE into the proximal stomach (including distance unknown)	17: Stomach
2	INVOLVEMENT of esophagus or esophagogastric junction (EGJ) AND epicenter LESS THAN OR EQUAL TO 2 cm into the proximal stomach	16 Esophagus 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	17: Stomach
9	UNKNOWN involvement of esophagus or gastroesophageal junction AND epicenter at ANY DISTANCE into the proximal stomach (including distance unknown)	17: Stomach

Return back to Schema ID Table

DRAFT

Esophagus and Esophagogastric Junction

Schema Discriminator 2: Histology Discriminator for 8020/3

Item Length: 1
NAACCR Item #: 3927
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 16: Esophagus and Esophagogastric Junction

Definition

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

Coding Instructions and Codes

Note: A schema discriminator is used to discriminate for histology 8020/3: Undifferentiated carcinoma to determine which Stage Group table to use.

- **8020/3: Undifferentiated carcinoma with squamous component (see code 1)**
  - Use the Squamous Cell Carcinoma Stage Group Table
- **8020/3: Undifferentiated carcinoma with glandular component (see code 2)**
  - Use the Adenocarcinoma Stage Group Table
- **8020/3: Undifferentiated carcinoma, NOS (no mention of squamous or glandular component) (see code 3)**
  - Use the Squamous Cell Carcinoma Stage Group Table

Code	Description	AJCC Disease ID
1	Undifferentiated carcinoma with squamous component	16.1: Esophagus and Esophagogastric Junction: Squamous Cell Carcinoma
2	Undifferentiated carcinoma with glandular component	16.2: Esophagus and Esophagogastric Junction: Adenocarcinoma
9	Undifferentiated carcinoma, NOS	16.1: Esophagus and Esophagogastric Junction: Squamous Cell Carcinoma

Return back to Schema ID Table

DRAFT

Esophagus and Esophagogastric Junction

Esophagus and EGJ Tumor Epicenter

Item Length: 1
NAACCR Item #: 3829
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 16, Esophagus and Esophagus GE Junction

Required for Staging: AJCC 8th edition and EOD, for Squamous Cell Carcinomas only

Description

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

Rationale

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

Coding Instructions and Codes

Note 1: This data item is used for pathological staging for squamous cell carcinoma of the esophagus and esophagogastric junction. If information is available for clinical staging, record it.

Note 2: Location is defined by the position of the **epicenter** of the tumor in the esophagus.

Information is most likely to be obtained from pathological exam, scopes, operative notes or CT scans. The epicenter of the lesion is used to describe location.

> ***Example***: If the lesion was from 15-21 cm, this is a 6-cm lesion with **epicenter at 18 cm**. It is the midpoint.

Note 3: Clinician or pathologist statement of epicenter being the upper, middle, or lower takes priority over any individual results or measurements. If no statement of epicenter is provided indicating upper, middle, or lower is provided, the following measurements may be used.

- 15-24 cm from incisors = upper
- 25-29 cm from incisors = middle
- 30-40/45 cm from incisors = lower

Note 4: Additional information about the epicenter may be found in Chapter 16, *Esophagus and Esophagogastric Junction*, Table 16.1 and Figure 16.1.

Note 5: The ascertainment of the epicenter of the tumor is for staging purposes and is separate from the assignment of the ICD-O-3 topography code. If you have an overlapping tumor (C158), do not recode the topography based on the epicenter.

DRAFT

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

Return back to Schema ID Table

DRAFT

Stomach

See Esophagus and Esophagogastric Junction for

- Schema Discriminator 1: EsophagusGEJunction (EGJ)/Stomach

Return back to Schema ID Table

DRAFT

Appendix

See Colon and Rectum **for**

- CEA Pretreatment Lab Value
- CEA Pretreatment Interpretation

Return back to Schema ID Table

DRAFT

Colon and Rectum

CEA Pretreatment Lab Value and Interpretation

Definition

A protein molecule found in many different cells of the body but associated with certain tumors and with the developing fetus. CEA is used as a tumor marker especially for gastrointestinal cancers, as colorectal cancer is the most frequent cause for an increased/elevated CEA. CEA is also elevated by biliary obstruction, alcoholic hepatitis, and heavy smoking. CEA level is most frequently tested on blood serum, but it may be tested in body fluids and/or biopsy tissue. An abnormally high CEA level prior to tumor resection is expected to fall following successful removal of the cancer. An increasing value indicates possible recurrence.

There are 2 data items that record information on CEA. These data items should be coded from the same test

- CEA Pretreatment Lab Value [NAACCR Data Item #3820]
- CEA Pretreatment Interpretation [NAACCR Data Item #3819]

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	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
Test ordered, results not in chart	XXXX.7	7
Not documented in medical record CEA test not done Unknown if CEA test done	XXXX.9	9

Additional Information

- **Other names:** Carcinoembryonic antigen
- **Source documents:** clinical laboratory report, sometimes pathology or cytology report; H&P, operative report; consultant report; discharge summary
- **Normal reference range:**
  - Nonsmoker: < 2.5 ng/ml (SI: < 2.5 mg/L) SI Conversion: 1 mg/L = 1 ng/ml.
  - Smoker: < 5 ng/ml (SI: < 5 mg/L) SI Conversion: 1 mg/mL = 1 mg/L

DRAFT

Colon and Rectum

CEA Pretreatment Lab Value

Item Length: 6
NAACCR Item #: 3820
NAACCR Alternate Name: CEA (Carcinoembryonic Antigen) Pretreatment Lab Value
AJCC 8th Edition Chapter(s):

- Chapter 19: Appendix
- Chapter 20: Colon and Rectum

Description

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

Rationale

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

See CEA Pretreatment Lab Value and Interpretation **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of CEA (Carcinoembryonic Antigen) Pretreatment Lab Value can be used to code this data item when no other information is available.

Note 2: Record the lab value of the highest CEA test result documented in the medical record **prior to treatment or polypectomy.** The lab value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: CEA is a tumor marker that has value in the management of certain malignancies.

Note 4: Record to the nearest tenth in nanograms/milliliter (ng/ml) the highest CEA lab value documented in the medical record **prior to treatment or polypectomy**.

- ***Example***: Code a pretreatment CEA of 7 ng/ml as 7.0.

Note 5: For an uncertain value, record the stated closest value.

- ***Example:*** Code a value stated as "less than 0.5 ng/ml" as 0.5.

Note 6: Record 0.1 when the lab results are stated as less than 0.1 ng/ml with no exact value.

Note 7: The same laboratory test should be used to record information in CEA Pretreatment Interpretation [NAACCR Data Item #3819].

Code	Description
0.0	0.0 nanograms/milliliter (ng/m) exactly

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

Return back to Schema ID Table

DRAFT

Colon and Rectum

CEA Pretreatment Interpretation

Item Length: 1
NAACCR Item #: 3819
NAACCR Alternate Name: CEA (Carcinoembryonic Antigen) Pretreatment Interpretation
AJCC 8th Edition Chapter(s):

- Chapter 19: Appendix
- Chapter 20: Colon and Rectum

Description

CEA (Carcinoembryonic Antigen) Pretreatment Interpretation refers to the interpretation of the CEA value prior to treatment. CEA is a glycoprotein that is produced by adenocarcinomas from all sites as well as many squamous cell carcinomas of the lung and other sites. CEA may be measured in blood, plasma or serum. CEA is a prognostic marker for adenocarcinomas of the appendix, colon and rectum and is used to monitor response to treatment.

Rationale

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

See CEA Pretreatment Lab Value and Interpretation **for additional information.**

for additional information.

Coding Instructions and Codes

Note 1: Physician statement of CEA (Carcinoembryonic Antigen) Pretreatment Interpretation can be used to code this data item when no other information is available.

Note 2: Record the interpretation of the highest CEA test result documented in the medical record **prior to treatment or a polypectomy.**

Note 3: Code 9 if there is no statement that the CEA is positive/elevated, negative/normal, and the lab value with its normal range (from which you can determine interpretation), is not documented.

Note 4: The same laboratory test should be used to record information in CEA Pretreatment Lab Value NAACCR Data Item #3820].

Code	Description
0	CEA negative/normal; within normal limits
1	CEA positive/elevated
2	Borderline
3	Undetermined if positive or negative (normal values not available) AND no MD interpretation
7	Test ordered, results not in chart

Code	Description
8	Not applicable: Information not collected for this case (If this data item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record CEA (Carcinoembryonic Antigen) Pretreatment Interpretation not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Colon and Rectum

Circumferential Resection Margin (CRM)

Item Length: 4
NAACCR Item #: 3823
NAACCR Alternate Name: Circumferential or Radial Resection Margin (CRM)
AJCC 8th Edition Chapter(s): Chapter 20, Colon and Rectum

Description

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

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.

Coding guidelines

- Code 0.0 is for positive margins
- Codes 0.1-99.9 is for coding the exact measurement in millimeters of the negative margin
- Code XX.0 for margins described as greater than 100 mm
- Code XX.1 when the margin is stated as clear, but the distance is not available
- Codes XX.2-XX.6 is for when the pathology uses “at least” categories
- Code XX.7 when there is no surgical resection of the primary site
- Code XX.9 when
    - Not documented in the medical record
    - CRM is not evaluated (assessed)
    - Unknown if CRM is evaluated (assessed)

Additional Information

- **Source documents:** pathology report
- **For further information, refer to the** Colon and Rectum **cancer protocol published by the College of American Pathologists for AJCC 8th edition, published October 2017.**

Coding Instructions and Codes

Note 1: Physician statement of Circumferential or Radial Resection Margin can be used to code this data item when no other information is available.

Note 2: Tumor involvement of the circumferential resection margin or radial resection margin appears to be a strong prognostic factor for local or systemic recurrences and survival after surgery.

Note 3: The CRM may also be referred to as the circumferential radial margin or mesenteric margin.

Note 4: According to the AJCC 8th edition, "the CRM is the distance in millimeters between the deepest point of tumor invasion in the primary cancer and the margin of resection in the retroperitoneum or mesentery."

Note 5: Record in Millimeters (mm) to the nearest tenth the distance between the leading edge of the tumor and the nearest edge of surgically dissected margin as recorded in the pathology report.

Examples
If the CRM is 2 mm, code 2.0
If the CRM is 2.78 mm, code 2.8

Note 6: If the margin is involved (positive), code 0.0. If the margin is described as less than 1 mm with no more specific measurement, Code 0.0; margins of 0-1 mm are recorded by the pathologist as involved.

Note 7: If the value is recorded in Centimeters, multiply by 10 to get the value in Millimeters (mm).

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

Note 8: Code XX.9 (CRM not mentioned) if the pathology report describes only distal and proximal margins, or margins, NOS.

- Only specific statements about the CRM are collected in this data item.

Note 9: An exact measurement takes precedence over codes beginning with XX.

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

Code	Description
	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

Return back to Schema ID Table

DRAFT

Colon and Rectum

KRAS

Item Length: 1
NAACCR Item #: 3866
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 20, Colon and Rectum

Description

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

Rationale

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

Definition

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

According to the Colon and Rectum Biomarker Reporting "The presence of a KRAS mutation has been shown to be associated with lack of clinical response to therapies targeted at EGFR, such as cetuximab and panitumumab. While clinical guidelines for KRAS mutational analysis are evolving, current provisional recommendations from the American Society of Clinical Oncology are that all patients with stage IV colorectal carcinoma who are candidates for anti-EGFR antibody therapy should have their tumor tested for KRAS mutations. Anti-EGFR antibody therapy is not recommended for patients whose tumors show mutations in KRAS codon 12, 13, or 61, but data on codon 146 are currently insufficient."

Additional Information

- **Source documents:** pathology report or clinical laboratory report, Colon and Rectum Biomarker Reporting **cancer protocol**
- **Other names:** K-Ras, K-ras, Ki-Ras
- **For further information, refer to the** Colon and Rectum Biomarker Reporting **cancer protocol published by the College of American Pathologists for AJCC 8th edition, published October 2017.**

Coding Instructions and Codes

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

Note 2: KRAS 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 KRAS gene mutations are often present in colorectal cancer.

Note 3: KRAS analysis is commonly done for patients with metastatic disease.

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

Code	Description
0	Normal (wild type) Negative for mutations
1	Abnormal (mutated) in codon(s) 12, 13 and/or 61
2	Abnormal (mutated) in codon 146 only
3	Abnormal (mutated), but not in codon(s) 12, 13, 61, or 146
4	Abnormal (mutated), NOS, codon(s) not specified
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record KRAS not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Colon and Rectum

Microsatellite Instability (MSI)

Item Length: 1
NAACCR Item #: 3890
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 20, Colon and Rectum

Description

Microsatellite Instability (MSI) is a form of genetic instability manifested by changes in the length of repeated single- to six-nucleotide sequences (known as DNA microsatellite sequences). High MSI, found in about 15% of colorectal carcinomas, is an adverse prognostic factor for colorectal carcinomas and predicts poor response to 5-FU chemotherapy (although the addition of oxaliplatin in FOLFOX regimens negates the adverse effects (page 266 AJCC manual)). High MSI is a hallmark of hereditary nonpolyposis colorectal carcinoma, also known as Lynch syndrome.

Rationale

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

Definition

Describes cancer cells that have a greater than normal number of genetic markers called microsatellites. Microsatellites are short, repeated, sequences of DNA. Cancer cells that have large numbers of microsatellites may have defects in the ability to correct mistakes that occur when DNA is copied in the cell. Microsatellite instability is found most often in colorectal cancer, other types of gastrointestinal cancer, and endometrial cancer. It may also be found in cancers of the breast, prostate, bladder, and thyroid. Knowing whether cancer is microsatellite instability high may help plan the best treatment.

Additional Information

- **Other names**: MSI-H

For further information, refer to the Colon and Rectum Biomarker Reporting **cancer protocol published by the College of American Pathologists for AJCC 8th edition, published October 2017**

Coding Instructions and Codes

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

Note 2: The microsatellite instability (MSI) test is a genetic test performed on tumor tissue to look for differences in length of certain non-functioning sections of DNA. The differences are caused by problems with the genes that normally repair DNA. A high-positive MSI (MSI-H) result may indicate that the gene repair problem is related to the development of the cancer, and that the patient may have hereditary nonpolyposis colorectal cancer (HNPCC) (also known as Lynch syndrome.) A low-positive or stable MSI

result (stable meaning that there are no differences in the lengths) means it is unlikely that the cancer is related to a hereditary condition.

Note 3: Testing for MSI may be done by immunology or genetic testing. Some laboratories only test for MSI via immunology such as Mismatch Repair (MMR) Protein. Results from immunology will only provide you with positive or negative results and will not specify whether the MSI is low or high.

If the testing was done via immunology, code 9. Only genetic testing results will specify whether the MSI is low or high.

Note 4: In Canada, the following terms are often used

- MMR normal (code 0)
- MMR abnormal (code 2)

Note 5: If both tests are done and one or both are positive, code 2.

Note 6: If all tests done are negative, code 0.

Code	Description
0	Microsatellite instability (MSI) stable; microsatellite stable (MSS); negative, NOS AND/OR Mismatch repair (MMR) intact, no loss of nuclear expression of MMR proteins
1	MSI unstable low (MSI-L)
2	MSI unstable high (MSI-H) AND/OR MMR-D (loss of nuclear expression of one or more MMR proteins, MMR protein deficient)
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record MSI-indeterminate Microsatellite instability not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Colon and Rectum

Perineural Invasion

Item Length: 1
NAACCR Item #: 3909
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 15: Cutaneous Squamous Cell Carcinoma of Head and Neck
- Chapter 20: Colon and Rectum
- Chapter 64: Eyelid Carcinoma
- Chapter 69: Lacrimal Gland

Description

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

Rationale

Perineural Invasion is a Registry Data Collection Variable in AJCC. It was previously collected as Colon and Rectum CS SSF# 8 and Lacrimal Gland CS SSF# 4.

Definition

Perineural invasion is infiltration of nerves in the area of the lesion by tumor cells or spread of tumor along the nerve pathway. The presence of perineural invasion has been shown in several studies to be an indicator of poor patient prognosis. Where positive findings like perineural invasion are expected to be included in pathology reports, negative results can be assumed if they are not specifically addressed.

Code whether perineural invasion is present based on the description in the pathology report.

Additional Information

- **Source documents:** pathology report
- **Other names:** PNI, neurotropism
- **For further information, refer to the** Colon and Rectum **cancer protocol published by the College of American Pathologists for AJCC 8th edition, published October 2017.**

Change from Collaborative Stage v2 (CSv2): *In* ***CSv2****, if pathology report was available and there was no mention of perineural invasion, the registrar could assume that it was negative and code appropriately. Per the SSDI as of 2018, this assumption cannot be made. There must be a statement that perineural invasion is not present/negative to assign "negative." (Code 0)*

Coding Instructions and Codes

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

Note 2: Code the presence or absence of perineural invasion by the primary tumor as documented in the pathology report.

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

Return back to Schema ID Table

DRAFT

Colon and Rectum

Tumor Deposits

Item Length: 2
NAACCR Item #: 3934
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 20, Colon and Rectum

Description

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

Rationale

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

Definition

Tumor deposits are separate nodules or deposits of malignant cells in perirectal or pericolic fat without evidence of residual lymph node tissue. If present, tumor deposits may be found within the primary lymphatic drainage area of the tumor. They are different from direct extension from the primary tumor and may be the result of lymphovascular invasion with extravascular extension, a totally replaced lymph node, or discontinuous spread. Nodules of tumor outside the primary lymphatic drainage area of the tumor are distant metastasis.

Coding guidelines

Record whether tumor deposits are present or absent.

- Code 00 when the pathology report states that there are no tumor deposits
- Code the number of tumor deposits reported in the pathology report. Do not count involved lymph nodes in this field, only tumor deposits
- Code X1 for 100 or more tumor deposits
- Code X2 if tumor deposits are mentioned but a number is not reported
- Code X9 when
    - Not documented in medical record
    - No surgical resection done
    - Pathology report not available
    - Tumor deposits not evaluated (not assessed)
    - Unknown if Tumor Deposits evaluated (assessed)

Additional Information

- **Source documents:** pathology reports, Colon and Rectum cancer protocol

- **Other names:** discontinuous extramural extension, malignant tumor foci, malignant peritumoral deposits, satellite nodule
- **Change from Collaborative Stage v2 (CSv2):** In **CSv2**, if pathology report was available and there was no mention of tumor deposits, the registrar could assume there were no tumor deposits and code none. For the SSDI, this assumption cannot be made. There must be a statement that there are no tumor deposits to code 00.

Coding Instructions and Codes

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

Note 2: Tumor deposits are defined as one or more satellite peritumoral nodules in the pericolorectal adipose tissue of a primary carcinoma without histologic evidence of residual lymph node in the nodule."

Tumor deposits may represent discontinuous spread, venous invasion with extravascular spread, or a totally replaced lymph node

Note 3: Record the number of Tumor Deposits whether or not there are positive lymph nodes.

Note 4: Code X9 if surgical resection of the primary site is performed, the pathology report is available, and tumor deposits are not mentioned.

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

Return back to Schema ID Table

DRAFT

HEPATOBILIARY SYSTEM

DRAFT

Liver

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

- AFP Pretreatment Lab Value [NAACCR Data Item #3810]
- AFP Pretreatment Interpretation [NAACCR Data Item #3809]

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

DRAFT

Liver

AFP Pretreatment Lab Value

Item Length: 6
NAACCR Item #: 3810
NAACCR Alternate Name: AFP (Alpha Fetoprotein) Pretreatment Lab Value
AJCC 8th Edition Chapter(s): Chapter 22, Liver

Description

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

Rationale

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

See Alpha-Fetoprotein (AFP) Pretreatment Lab Value and Interpretation (Liver) for additional information

Coding Instructions and Codes

Note 1: Physician statement of AFP (Alpha Fetoprotein) Pretreatment Lab Value can be used to code this data item when no other information is available.

Note 2: Record the lab value of the highest AFP test result documented in the medical record **prior to treatment.** The lab value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: A lab value expressed in micrograms per liter (ug/L) is equivalent to the same value expressed in ng/ml.

Note 4: The same laboratory test should be used to record information in AFP Pretreatment Interpretation [NAACCR Data Item # 3809].

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

Return back to Schema ID Table

DRAFT

Liver

AFP Pretreatment Interpretation

Item Length: 1
NAACCR Item #: 3809
NAACCR Alternate Name: AFP (Alpha Fetoprotein) Pretreatment Interpretation
AJCC 8th Edition Chapter(s): Chapter 22, Liver

Description

AFP (Alpha Fetoprotein) Pretreatment Interpretation, a nonspecific serum protein that generally is elevated in the setting of hepatocellular carcinoma (HCC), is a prognostic factor for liver cancer.

Rationale

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

See Alpha-Fetoprotein (AFP) Pretreatment Lab Value and Interpretation (Liver) for additional information

Coding Instructions and Codes

Note 1: Physician statement of AFP (Alpha Fetoprotein) Pretreatment Interpretation

can be used to code this data item when no other information is available.

Note 2: Record the interpretation of the highest AFP test result documented in the medical record **prior to treatment.**

Note 3: The same laboratory test should be used to record information in AFP Pretreatment Lab Value [NAACCR Data Item # 3810].

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

Return back to Schema ID Table

DRAFT

Model for End-Stage Liver Disease (MELD) Score

The Model for End-stage Liver Disease (MELD) score is used to assess the severity of chronic liver disease, and its original purpose was to help prioritize patients for liver transplant by estimating their risk of dying while waiting for transplant. There are several data items that are defined to record the MELD score.

- Bilirubin Pretreatment Total Lab Value [NAACCR Data Item #3813]
- Bilirubin Pretreatment Unit of Measure [NAACCR Data Item #3814]
- Creatinine Pretreatment Lab Value NAACCR Data Item #3824]
- Creatinine Pretreatment Unit of Measure [NAACCR Data Item #3825]
- International Normalized Ratio [NAACCR Data Item #3860]

Bilirubin Pretreatment Lab Value and Unit of Measure

Bilirubin is produced from the breakdown of hemoglobin (the protein that binds oxygen) in red blood cells. The liver processes bilirubin by excreting it through bile into the intestine. If the liver is damaged, there will be too much bilirubin in the blood, and this can produce jaundice. Elevated bilirubin levels can indicate liver or blood disorders or blockage of bile ducts. Do not code individual conjugate, direct, unconjugated, indirect, or delta values or bilirubin in urine.

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

Coding guidelines

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

Examples	Lab Value Code	Unit of Measure Code
0 ng/ml	0.0	1
23.6 umol/L	23.6	2
127.8 ng/mL	127.8	1
1567 umol/mL	XXX.1	2
638.4	638.4	9
Test ordered, results not in chart	XXXX.7	7
Not documented in medical record Bilirubin test not done Unknown if Bilirubin test done	XXXX.9	9

Additional Information

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

- **Other names:** TBIL. Total bilirubin is a combination of direct (conjugated), indirect (unconjugated), and delta (conjugated bilirubin bound to albumin) bilirubin levels

- **Normal Reference Range:** *0.3-1.5 mg/dL (5-20.5 μmol/L). The normal range may vary slightly from lab* to lab.

    - For Liver, there are 2 data items that record information on Bilirubin. These data items should be coded from the same test
    - Bilirubin Pretreatment Total Lab Value [NAACCR Data Item #3813]
    - Bilirubin Pretreatment Unit of Measure [NAACCR Data item #3814]

Creatinine Pretreatment Lab Value and Unit of Measure

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

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

Coding guidelines

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

Examples	Lab Value Code	Unit of Measure Code
0 ng/ml	0.0	1
0.7 umol/L	0.7	2
25.4 ng/ml	25.4	1
127.6 umol/L	XX.1	2
98.3	98.3	9
Test ordered, results no in chart	XXXX.7	7
Not documented in medical record Creatinine test not done Unknown if Creatinine test done	XXXX.9	9

Additional Information

- **Source documents:** clinical laboratory report (blood serum); value may be part of a metabolic panel
- **Other names:** Serum creatinine, plasma creatinine (PCr), blood creatinine, Creat, Cre, Do not confuse with creatinine clearance or creatine; these are unrelated tests. Do not code urine creatinine or creatinine clearance.
- **Normal Reference Range**
    - Women: 0.5-1.0 mg/dL (45-90 **m**mol/L)
    - Men: 0.7-1.2 mg/dL (60-110 **m**mol/L). Male values are usually higher due to greater muscle mass.
    - Normal value ranges may vary slightly among different laboratories.

International Normalized Ratio (Prothrombin Time)

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

Coding guidelines

- Code the highest INR value in the blood prior to treatment in the range 0.1 to 9.9.
- Code X.1 for an INR of 10.0 or greater.
- Code X.7 if the test was ordered and the results are not in the medical record.
- Code X.9 when
    - there is no information in the medical record about the INR or prothrombin time
    - the test is not done or it's unknown if the test was done

Additional Information

- **Source documents:** clinical laboratory report (blood serum); value may be part of a metabolic or liver function panel; outpatient or ambulatory blood test (finger stick) reported in patient history
- **Other names:** INR
- **Normal ranges:** For a healthy person is 0.9-1.3. A high INR level such as INR=5 indicates that there is a high chance of bleeding. A low level such as INR = 0.5 indicates a high chance of abnormal clotting. Normal values may vary from lab to lab. Record the highest INR value prior to treatment.

DRAFT

Liver

Bilirubin Pretreatment Total Lab Value

Item Length: 5
NAACCR Item #: 3813
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 22, Liver

Description

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

Rationale

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

See Model for End-Stage Liver Disease (MELD) Score **for additional information**

Coding Instructions and Codes

Note 1: Physician statement of Bilirubin Pretreatment Total 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 Bilirubin Total 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: Assay of Bilirubin Pretreatment Total Lab Value includes conjugated (direct) and unconjugated (indirect) bilirubin. Record the **total bilirubin** value for this data item.

Note 4: Record to the nearest tenth of mg/dL or umol/L the highest total bilirubin value prior to treatment.

Note 5: The Model for End-Stage Liver Disease (MELD) is a numerical scale used to determine how urgently a patient with liver disease needs a liver transplant. Results from three routine lab tests are used to calculate the MELD score. Bilirubin, one of the tests, measures how effectively the liver excretes bile.

Note 6: The same laboratory test should be used to record information in Bilirubin Pretreatment Unit of Measure [NAACCR Data Item # 3814].

Code	Description
0.0	0.0 milligram/deciliter (mg/dL) 0.0 micromole/liter (umol/L)

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

Return back to Schema ID Table

DRAFT

Liver

Bilirubin Pretreatment Unit of Measure

Item Length: 1
NAACCR Item #: 3814
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 22, Liver

Description

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

Rationale

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

See Model for End-Stage Liver Disease (MELD) Score **for additional information**

Coding Instructions and Codes

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

Note 2: There are two main methods of describing concentrations: by weight, and by molecular count.

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

Note 3: The same laboratory test should be used to record information in Bilirubin Pretreatment Total Lab Value [NAACCR Data Item # 3813].

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

Return back to Schema ID Table

Liver

Creatinine Pretreatment Lab Value

Item Length: 4
NAACCR Item #: 3824
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 22, Liver

Description

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

Rationale

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

See Model for End-Stage Liver Disease (MELD) Score **for additional information**

Coding Instructions and Code

Note 1: Physician statement of Creatinine 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 Creatinine test result documented in the medical record **prior to treatment.** The lab value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Record the blood or serum creatinine value for this data item. Do not use urine results to code this data item.

Note 4: The Model for End-Stage Liver Disease (MELD) is a numerical scale used to determine how urgently a patient with liver disease needs a liver transplant within the next three months. Results from three routine lab tests are used to calculate the MELD score. Creatinine, one of the tests, measures kidney function; impaired kidney function is often associated with severe liver disease.

Note 5: The same laboratory test should be used to record information in Creatinine Pretreatment Unit of Measure [NAACCR Data Item # 3825].

Code	Description
0.0	0.0 milligram/deciliter (mg/dl) 0.0 micromole/liter (umol/L)
0.1-99.9	0.1-99.9 milligram/deciliter (mg/dl) 0.1-99.9 micromole/liter (umol/L) (Exact value to nearest tenth of mg/dl or umol/L)
XX.1	100 mg/dl or greater 100 umol/L or greater
XX.7	Test ordered, results not in chart

Code	Description
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error.)
XX.9	Not documented in medical record Creatinine Pretreatment Lab Value not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Liver

Creatinine Pretreatment Unit of Measure

Item Length: 1
NAACCR Item #: 3825
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 22, Liver

Description

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

Rationale

Creatinine Pretreatment is a Registry Data Collection Variable in AJCC. Creatinine Pretreatment Unit of Measure is needed to identify the unit in which creatinine is measured and was previously collected as Liver, CS SSF# 5.

See Model for End-Stage Liver Disease (MELD) Score **for additional information**

Coding Instructions and Codes

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

Note 2: There are two main methods of describing concentrations: by weight, and by molecular count.

- Weights are recorded in grams, and molecular counts are recorded in moles.
- Milligrams/deciliter (mg/dL) is the unit of measure commonly used in the United States
- Micromoles/liter (umol/L) is the designated Systeme International (SI) unit of measure commonly used in Canada and Europe.
- 1 mg/dL of creatinine is 88.4 umol/L.

Note 3: The same laboratory test should be used to record information in Creatinine Pretreatment Lab Value [NAACCR Data Item # 3824].

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

Return back to Schema ID Table

Liver

International Normalized Ratio

Item Length: 3
NAACCR Item #: 3860
NAACCR Alternate Name: INR (International Normalized Ratio for Prothrombin Time)
AJCC 8th Edition Chapter(s): Chapter 22, Liver

Description

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

Rationale

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

See Model for End-Stage Liver Disease (MELD) Score **for additional information**

Coding Instructions and Codes

Note 1: Physician statement of the International Normalized Ratio for Prothrombin Time (INR) can be used to code this data item when no other information is available.

Note 2: Record the value of the highest INR test results documented in the medical record **prior to treatment.** The value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: The Model for End-Stage Liver Disease (MELD) is a numerical scale used to determine how urgently a patient with liver disease needs a liver transplant. Results from three routine lab tests are used to calculate the MELD score. International normalized ratio for prothrombin time (INR), one of the tests, measures the liver's ability to make blood clotting factors.

Code	Description
0.0	0.0
0.1	0.1 or less
0.2-9.9	0.2 - 9.9 (Exact ratio to nearest tenth)
X.1	10 or greater
X.7	Test ordered, results not in chart
X.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X.8 may result in an edit error.)
X.9	Not documented in medical record INR (International Normalized Ratio for Prothrombin Time) not assessed or unknown if assessed

Intrahepatic Bile Ducts

Fibrosis Score

Item Length: 1
NAACCR Item #: 3835
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 22: Liver
- Chapter 23: Intrahepatic Bile Ducts

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. The system most commonly used by US pathologists is the Batts-Ludgwig system, other systems include the modified Ishak scoring system and the METAVIR score. The latter is used more widely in Europe than the United States.

The Ishak scoring system uses a 0-6 scale (as noted above and in the codes)

The Batt-s Ludgwig system uses a 0-4 scale, with a score of 3 defined as fibrous septa with architectural distortion but no obvious cirrhosis, and a score of 4 defined as cirrhosis.

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: AJCC 8th edition chapter 22 (Liver) and the CAP protocol for Hepatocellular Carcinoma use the term “fibrosis score.” Chapter 23 (Intrahepatic Bile Ducts) describes it as “nontumoral hepatic parenchymal fibrosis/cirrhosis.” Both AJCC and CAP recommend the Ishak Score system. Ishak uses a scale of 0-6 with 6 indicating cirrhosis. Other pathological scoring systems in use include the Batts-Ludwig system, which uses scores of 0-4, and the METAVIR system which uses scores of F0-F4.

DRAFT

Note 3: FIB-4 is NOT a pathological fibrosis score of 4. It is a scoring method using the patient's age and relevant lab values to calculate a score. The medical record may show something like "FIB-4 = 3.52." Do not code FIB-4 values in this data item.

Note 4: 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 5: If a fibrosis score is stated but the scoring system is not recorded, consult with the physician. If no further information is available assign code 9.

Code	Description
0	Ishak fibrosis score 0-4 No to moderate fibrosis METAVIR score F0-F3 Batt-Ludwig score 0-3
1	Ishak fibrosis score 5-6 Advanced/severe fibrosis METAVIR score F4 Batt-Ludwig score 4 Developing cirrhosis Incomplete cirrhosis Transition to cirrhosis Cirrhosis, probable or definite Cirrhosis, NOS
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

Return back to Schema ID Table

DRAFT

Intrahepatic Bile Ducts

Primary Sclerosing Cholangitis

Item Length: 1
NAACCR Item #: 3917
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 23: Intrahepatic Bile Ducts
- Chapter 25: Perihilar Bile Ducts

Description

Primary sclerosing cholangitis denotes a chronic autoimmune inflammation of the bile ducts that leads to scar formation and narrowing of the ducts over time. It is a prognostic factor for intrahepatic bile duct cancer.

Rationale

Primary Sclerosing Cholangitis is a Registry Data Collection Variable in AJCC. This data item was previously collected for Intrahepatic Bile Duct, SSF# 11.

Definition Primary sclerosing cholangitis is an idiopathic liver disease characterized by inflammation and fibrosis of the entire biliary tree. The chronic inflammation and injury to ducts may lead to cirrhosis and predispose to cholangiocarcinoma at any site in the biliary tree. Patients with primary sclerosing cholangitis are advised to receive neoadjuvant chemoradiation and liver transplantation.

Coding guidelines

Record whether primary sclerosing is absent or present

- Code 0 when there is a statement in the pathology report that primary sclerosing cholangitis is not present
- Code 1 when the pathology report states that primary sclerosing cholangitis is present
- Code 9 when
    - No information in the medical record
    - Pathology report is not available
    - Primary Sclerosing Cholangitis is not evaluated (not assessed)
    - Unknown if Primary Sclerosing Cholangitis is not evaluated (assessed)

Additional Information

- **Source documents:** patient history, pathology report, imaging reports
- **Other names:** PSC, fibrosing cholangitis, chronic obliterative cholangitis, sclerosing cholangitis
- **Change from Collaborative Stage v2 (CSv2):** In **CSv2**, if pathology report was available and there was no mention of primary sclerosing cholangitis, the registrar could assume that it was not present and code appropriately. For the SSDI, this assumption cannot be made. There must be a statement that primary sclerosing cholangitis is not present to code 0.

Coding Instructions and Codes

Note 1: Physician statement of Primary Sclerosing Cholangitis (PSC) can be used to code this data item when no other information is available.

Note 2: PSC is an idiopathic liver disease characterized by inflammation and fibrosis of the entire biliary tree. The chronic inflammation and injury to ducts may lead to cirrhosis and predispose to cholangiocarcinoma at any site in the biliary tree.

Note 3: Code stated diagnosis of PSC either clinically or pathologically as documented in the medical record. This may be by history.

Note 4: Code 9 if there is no mention of primary sclerosing cholangitis (PSC).

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

Return back to Schema ID Table

DRAFT

Intrahepatic Bile Ducts

Tumor Growth Pattern

Item Length: 1
NAACCR Item #: 3935
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 23, Intrahepatic Bile Duct

Description

Tumor Growth Pattern refers to the growth pattern of intrahepatic cholangiocarcinoma.

Rationale

Tumor Growth Pattern is a Registry Data Collection Variable in AJCC. This data item was previously collected for Intrahepatic Bile Duct, SSF# 10.

Definition

There are two types of growth patterns for intrahepatic bile duct carcinomas:

- **Mass-forming** (60% of intrahepatic bile duct cases), which grows outward (radially) from the duct and invades the liver parenchyma in a well-defined mass.
- **Periductal infiltrating type** (20%): spreads along the duct in a diffuse manner that may be associated with poorer prognosis.

Coding guidelines

Record the specific type of tumor growth pattern.

- Code 0 when a radiology, surgery, or pathology report describes the tumor as mass-forming only
- Code 1 when a radiology, surgery, or pathology report describes the tumor as periductal infiltrating only
- Code 2 when a radiology, surgery, or pathology reports mentions both mixed mass forming and periductal infiltrating
- Code 9
    - Not documented in the medical record
    - Tumor growth pattern not evaluated (assessed)
    - Unknown if Tumor Growth Pattern evaluated (assessed)

Additional Information

- **Source documents:** radiology, surgery, or pathology report

Coding Instructions and Codes

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

Note 2: Cholangiocarcinoma may be classified by growth pattern. The tumor growth patterns of intrahepatic cholangiocarcinoma include the mass forming type, the periductal infiltrating type, and a mixed type. The periductal infiltrating type of cholangiocarcinoma demonstrates a diffuse longitudinal growth pattern along the bile duct. Limited analyses suggest that the diffuse periductal infiltrating type is associated with a poor prognosis.

Note 3: Record the presence or absence of an infiltrating periductal component. This information may be obtained from radiology, surgery, or pathology reports.

Code	Description
1	Mass-forming
2	Periductal infiltrating
3	Mixed mass-forming and periductal infiltrating
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Pathology report does not mention tumor growth pattern Cannot be determined by the pathologist Tumor growth pattern not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Gallbladder (including Cystic Duct)

Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct

Item Length: 1
NAACCR Item #: 3926
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 24: Gallbladder (primary site C240 only)
- Chapter 25: Perihilar Bile Ducts
- Chapter 26: Distal Bile Ducts

Definition

Cystic duct, distal bile ducts, and perihilar bile ducts all have the same ICD-O topography code (C240). However, for purposes of stage grouping in the AJCC 8th edition, they each have different chapters for stage. A schema discriminator is necessary to distinguish between these primary sites so that the appropriate chapter/schema is used.

Coding Instructions and Codes

Note: A schema discriminator is used to discriminate for primary site C240 (extrahepatic bile ducts) for the subsite in which the tumor arose.

Chapter 24: Gallbladder (see code 3)
- Per AJCC 8th edition, the gallbladder tapers into the cystic duct

Chapter 25: Perihilar Bile Ducts (see codes 1, 5, 6, 9)
- Per AJCC 8th edition, perihilar (or proximal) cholangiocarcinomas involve the main biliary confluence of the right and left hepatic ducts and comprise 50%-70% of all cases of bile duct carcinoma

Chapter 26: Distal Bile Ducts (see codes 4, 7)
- Per AJCC 8th edition, these tumors have their center located between the confluence of the cystic duct and common hepatic duct and the Ampulla of Vater (excluding ampullary carcinomas)

Code	Description	AJCC Disease ID
1	Perihilar bile duct(s) Proximal extrahepatic bile duct(s) Hepatic duct(s)	25: Perihilar Bile Ducts
3	Cystic bile duct; cystic duct	24: Cystic duct
4	Distal bile duct Common bile duct Common duct, NOS	26: Distal Bile Ducts
5	Diffuse involvement More than one subsite involved, subsite of origin not stated	25: Perihilar Bile Ducts
6	Stated as middle extrahepatic bile duct AND treated with combined hepatic and hilar resection	25: Perihilar Bile Ducts

DRAFT

Code	Description	AJCC Disease ID
7	Stated as middle extrahepatic bile duct AND treated with pancreaticoduodenectomy	26: Distal Bile Ducts
9	Extrahepatic bile ducts, NOS	25: Perihilar Bile Ducts

Return back to Schema ID Table

DRAFT

Perihilar Bile Ducts

See Gallbladder (including Cystic Duct) for

- Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct

See Intrahepatic Bile Ducts for

- Primary Sclerosing Cholangitis

Return back to Schema ID Table

DRAFT

Distal Bile Duct

See Gallbladder (including Cystic Duct) for

- Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct

Return back to Schema ID Table

DRAFT

THORAX

DRAFT

Lung

Separate Tumor Nodules

Item Length: 1
NAACCR Item #: 3929
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 36, Lung

Description

"Separate tumor nodules" refers to what is conceptually a single tumor with intrapulmonary metastasis in the ipsilateral (same) lung. Their presence in the same or different lobes of lung from the primary tumor affects the T and M categories.

Rationale

This data item was previously collected for Lung, SSF# 1 and at least one standard setter is continuing to collect it.

Definition

Separate tumor nodules are defined as intrapulmonary metastasis identified in the same lobe or same lung (ipsilateral) originating from a single lung primary at the time of diagnosis. Biopsy of tumors may or may not be performed. So long as there is a strong suspicion the multiple lesions are of the same histological type by imaging, physician judgement, or microscopically, this meets the criteria of separate tumor nodules representing intrapulmonary metastases. The presence of metastases to extrathoracic sites does not change this distinction.

Coding guidelines

Record the presence of separate tumor nodules within the same ipsilateral lobe and/or different lobes of the same lung which are considered a single primary. The histology of the separate tumors must be the same. Histology may be determined clinically (presumed to be the same based on imaging or physician judgement) or microscopically confirmed.

- Code 0 when
  - SINGLE TUMOR nodule only
  - Separate tumor nodules present with DIFFERENT HISTOLOGIES
- Code 1 when
  - Separate tumor nodules present in the SAME LOBE with the SAME HISTOLOGY
- Code 2 when
  - Separate tumor nodules present in DIFFERENT LOBES of the SAME LUNG (ipsilateral) with the SAME HISTOLOGY.
- Code 3 when
  - Separate tumor nodules present in SAME LOBE AND DIFFERENT LOBES of the SAME LUNG with the SAME HISTOLOGY.

- Code 4 when
    - Separate tumor nodules present in SAME LUNG with the SAME HISTOLOGY and it's UNKNOWN IF they are in the SAME LOBE OR DIFFERENT LOBES.

Additional Information

- **Source documents:** imaging reports and pathology reports

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.

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

Code	Description
	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

Return back to Schema ID Table

DRAFT

Lung

Visceral and Parietal Pleural Invasion

Item Length: 1
NAACCR Item #: 3937
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 36, Lung

Description

Visceral and Parietal Pleural Invasion is defined as invasion beyond the elastic layer or to the surface of the visceral pleura.

Rationale

Visceral and Parietal Pleural Invasion (previously called "pleural/elastic layer invasion (PL)") is a Registry Data Collection Variable for AJCC. This data item was previously collected for Lung, SSF# 2.

Definition

Invasion of one or more layers of the pleura covering the lung (visceral pleura), such as invasion beyond the elastic layer of the pleura. The elastic layer may be identified on hematoxylin and eosin (H&E) stains or by special stains looking for the elastic fibers. An elastic stain is not needed in most cases to assess the pleura for invasion, only in those cases where the distinction between PL0 and PL1 is unclear on H&E sections. Elastic stains may also be helpful in cases where the visceral and parietal pleura are adherent, making it difficult to identify the boundary between the visceral pleural surface and the parietal pleura.

VPI is relevant for peripheral lung tumors. The presence of visceral pleural invasion by tumors smaller than 3 cm changes the T category from pT1 to pT2 and increases the stage from IA to IB in patients with no nodal disease or stage IIA to IIB in patients with peribronchial or hilar nodes. Studies have shown that tumors smaller than 3 cm that penetrate beyond the elastic layer of the visceral pleura behave similarly to similar-size tumors that extend to the visceral pleural surface. Visceral pleural invasion should therefore be considered present not only in tumors that extend to the visceral pleural surface, but also in tumors that penetrate beyond the elastic layer of the visceral pleura. Four to six layers of visceral pleura may be described by the pathologist.

Coding guidelines

Record results of visceral pleural invasion as stated on pathology report. Do not code separate pleural tumor foci or nodules in this field (discontinuous pleural metastasis).

- Code 0 when
  - No evidence of visceral and parietal pleural invasion or described as PL0
  - Tumor does not completely extend through the elastic layer
  - Extends to the elastic layer
- Code 1 when
  - Tumor extends through the elastic layer or described as PL1

    - Invasion beyond the visceral elastic pleura, but limited to the visceral pleura
- Code 2 when
    - Tumor extends to the surface of the visceral pleural or described as PL2
    - Invasion to the surface of the pulmonary (visceral) pleura
- Code 3 when tumor extends to the parietal pleura invasion of parietal pleura (classified as T3) or described as PL3
- Code 4 when
    - Invasion of pleura without specifying visceral or parietal pleura
    - Uncertain whether elastic stain has been performed to identify visceral pleura invasion
- Code 9 when
    - No information in the medical record
    - Only FNA performed
    - Pathology report is not available
    - Visceral and Parietal Pleural Invasion not evaluated (not assessed)
    - Unknown if Visceral and Parietal Pleural Invasion evaluated (assessed)

Additional Information

- **Source documents:** pathology report
- **Other names:** VPI, PL (number)
- For further information, refer to the cancer protocol published by the College of American Pathologists for AJCC 8th edition, published June 2017.
- **Change from Collaborative Stage v2 (CSv2):** In **CSv2**, if pathology report was available and there was no mention of visceral pleural invasion, the registrar could assume that it was negative and code appropriately. For the SSDI, this assumption cannot be made. There must be a statement that visceral pleural invasion is not present to code 0

Coding Instructions and Codes

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

Note 2: *Chapter 36: Lung* of the AJCC Staging Manual 8th edition includes a standardized and precise definition of pleural/elastic layer invasion (PL).

There are four categories:

- PL0: Tumor that is surrounded by lung parenchyma or invades superficially into the pleural connective tissue beneath the elastic layer but falls short of completely traversing the elastic layer of the pleura
- PL1: Tumor that extends through the elastic layer
- PL2: Tumor that extends to the surface of the visceral pleura
- PL3: Tumor that extends to the parietal pleura or chest wall

Categories PL1 and PL2 are considered pleural invasion for staging and are classified as at least a T2. PL3 is classified as at least a T3. PL0 is not considered pleural invasion for TNM staging, and the T category is assigned based on other criteria. Other criteria can also raise the T category for PL1-3 tumors.
When pathologists have difficulty assessing the relationship of the tumor to the elastic layer on routine

hematoxylin and eosin (H and E) stains, they may perform a special elastic stain to make the determination.

Note 3: An FNA is not a histologic specimen and is not adequate to assess pleural layer invasion. If only an FNA is available, code 9.

Note 4: Code 9 if there is microscopic confirmation and there is no mention of visceral 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
1	Invasion of visceral elastic layer Not beyond visceral pleural Stated as PL1
2	Invasion outside surface of the visceral pleura Invasion through outer surface of the visceral pleura Stated as PL2
3	Tumor invades into or through the parietal pleura OR chest wall Stated as PL3
4	Invasion of visceral pleura present, NOS; not stated if PL1 or PL2
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

Return back to Schema ID Table

DRAFT

Pleura (Malignant Pleural Mesothelioma)

Pleural Effusion

Item Length: 1
NAACCR Item #: 3913
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 37, Malignant Pleural Mesothelioma

Description

Pleural effusion is the accumulation of fluid between the parietal pleura (the pleura covering the chest wall and diaphragm) and the visceral pleura (the pleura covering the lungs).

Rationale

Pleural Effusion can be collected by the surveillance community for pleura cancers. Prior to 2018, Pleura SSF #1 was used for Pleural Effusion.

Definition

Pleural effusion is the accumulation of fluid between the two layers of pleura: visceral (covering the lungs) and parietal (lining the chest wall and covering the diaphragm). Pleural effusion is a symptom of mesothelioma that increases the Summary Stage from local or regional direct extension to distant involvement.

Additional Information

- **Source documents:** imaging, pathology and cytology reports
- **Other names:** pleural fluid, thoracentesis

Coding guidelines

Record the absence or presence of pleural effusion. If pleural effusion is present and examined microscopically, record whether the pleural effusion is non-malignant, malignant, or not specified.

- Code 0 when there is no evidence of pleural effusion
- Code 1 when
    - Pleural effusion microscopically confirmed to be non-malignant
    - Pleural effusion is stated to be negative for malignant cells
    - Pleural effusion is seen on imaging but pleural fluid cytology is negative for malignant cells
- Code 2 when
    - Pleural effusion microscopically confirmed to be malignant
    - Pleural effusion is stated to be positive for malignant cells
    - Pleural fluid cytology described as suspicious or suspicious for mesothelioma
- Code 3 when
    - Pleural effusion is reported on imaging but there is no cytology [pleural effusion, NOS]
    - Pleural fluid cytology is described as atypical or atypical mesothelial cells but not specifically as non-malignant or malignant)

DRAFT

- Code 4 when Pleural effusion stated to be present, unknown how confirmed
- Code 9 when
    - Not documented in the medical report
    - Pleural effusion not evaluated (assessed)
    - Unknown if Pleural Effusion evaluated (assessed)

Coding Instructions and Codes

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

Note 2: One of the most common symptoms of mesothelioma is a pleural effusion, or an accumulation of fluid between the parietal pleura (the pleura covering the chest wall and diaphragm) and the visceral pleura (the pleura covering the lungs). Record the absence or presence of pleural effusion and specifically, if present, whether the pleural effusion is non-malignant, malignant, atypical or NOS.

Note 3: If imaging indicates a pleural effusion but pleural fluid cytology is described as negative for malignant cells, assign code 1.

Note 4: If pleural fluid cytology is described as suspicious/suspicious for mesothelioma, assign code 2.

Code	Description
0	Pleural effusion not identified/not present
1	Pleural effusion present, non-malignant (negative)
2	Pleural effusion present, malignant (positive)
3	Pleural effusion, atypical/atypical mesothelial cells
4	Pleural effusion, NOS
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Pleural Effusion not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Bone

Percent Necrosis Post Neoadjuvant

Item Length: 5
NAACCR Item #: 3908
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 38, Bone

Description

Percent Necrosis Post Neoadjuvant is a prognostic factor for bone sarcomas.

Rationale

Percent Necrosis Post Neoadjuvant is a Registry Data Collection Variable for AJCC. It was previously collected as Bone, CS SSF# 3.

Definition

For osteosarcoma and Ewing's sarcoma/PNET, response to neoadjuvant chemotherapy is a prognostic factor. Patients with more than 90% tumor necrosis have a more favorable prognosis than those with less response. The CAP protocol for bone tumor resection provides the pathologist with specific instructions for determining the percentage of tumor necrosis. A separate method (system of Picci) may describe response to treatment in grades: grade I (macroscopic viable tumor), grade II (microscopic viable tumor), or grade III (no viable tumor). Do not code the Picci grade system in this data item.

Record the percentage value of tumor necrosis post neo-adjuvant chemotherapy as stated by the pathologist in the pathology report. Code the value to the nearest whole percent in the range 001 to 100. If the patient has no resection or was not treated with pre-operative chemotherapy, code XXX.9

Additional Information

- **Source documents:** pathology report
- **Other names:** Histologic treatment response, therapy response, chemotherapy effect
- **For further information, refer to the** Bone **cancer protocol published by the College of American Pathologists for AJCC 8th edition, published June 2017.**

Coding instructions and Codes

Note 1: Physician statement of microscopically confirmed Percent Necrosis Post Neoadjuvant Chemotherapy can be used to code this data item if no other documentation is available

Note 2: Record percentage value of the tumor necrosis post neoadjuvant chemotherapy as recorded in the pathology report from resection of the primary tumor.

Note 3: Code XXX.9 if surgical resection of the primary site after neoadjuvant therapy is performed and there is no mention of percent necrosis.

Code	Description
0.0	Tumor necrosis not identified/not present
0.1-100.0	0.1 – 100.0 percent tumor necrosis (Percentage of tumor necrosis to nearest tenth of a percent)
XXX.2	Tumor necrosis present, percent not stated
XXX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XXX.8 will result in an edit error.)
XXX.9	Not documented in medical record No histologic examined of primary site No neoadjuvant therapy No surgical resection of primary site is performed

Return back to Schema ID Table

DRAFT

SOFT TISSUE SARCOMAS

DRAFT

Soft Tissue

See Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck for the following data item:

- Schema Discriminator 1: Occult Head and Neck Lymph Nodes
    - **Primary Site C760 only**

DRAFT

Soft Tissue

Bone Invasion

Item Length: 1
NAACCR Item #: 3815
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 40: Soft Tissue Sarcoma of the Head and Neck
- Chapter 41: Soft Tissue Sarcoma of the Trunk and Extremities
- Chapter 42: Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs
- Chapter 44: Soft Tissue Sarcoma of the Retroperitoneum
- Chapter 45: Soft Tissue Sarcoma - Unusual Histologies and Sites (including Kaposi Sarcoma)

Description

Bone invasion, the presence or absence of bone invasion based on imaging, is a prognostic factor for soft tissue sarcomas.

Rationale

Bone Invasion is a Registry Data Collection Variable in AJCC. This data item was previously collected for Soft Tissue, SSF# 3.

Definition

Direct tumor extension from the primary sarcoma into adjacent bone. This field does not include distant or discontinuous metastases to the skeletal system. Information in this field is based on radiology and other imaging techniques.

Coding guidelines

- Code 0 when there is no evidence of bone invasion on imaging
- Code 1 when there is evidence of bone invasion on imaging
- Code 9 when
    - No information in the medical record
    - Bone invasion not evaluated (assessed)
    - Unknown if bone invasion evaluated (assessed)

Additional Information

- **Source documents:** imaging report

Coding Instructions and Codes

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

DRAFT

Note 2: Record bone invasion as determined by relevant imaging only for the primary tumor. Imaging methodologies include computed tomography (CT) scans and magnetic resonance imaging (MRI).

Note 3: Code 0 if relevant imaging is performed and there is no mention of bone invasion.

Note 4: Code 9 if there is no relevant imaging of the primary site.

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

Return back to Schema ID Table

DRAFT

Gastrointestinal Stromal Tumor (GIST)

Schema Discriminator 1: Primary Peritoneum Tumor

Item Length: 1
NAACCR Item #: 3926
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 43: Gastrointestinal Stromal Tumors

Definition

The GIST chapter includes a schema discriminator for **C481** for location of the primary tumor because all the peritoneum structures are coded to C481, but two separate stage tables are used to derive the TNM values.

Coding Instructions and Codes

Note: Since both omental and peritoneal gastrointestinal stromal tumors (GIST) are coded with the same ICD-O-3 topography code (C481), this data item must be used to identify the appropriate AJCC stage table.

Code	Description	Stage Table
1	Mesentery Mesoappendix Mesocolon Pelvic peritoneum Rectouterine pouch Cul de sac Pouch of Douglas Other specified peritoneal site	Small Intestinal, Esophageal, Colorectal, Mesenteric and Peritoneal GIST
2	Omentum	Gastric and Omental GIST
9	Unknown or no information Not documented in patient record	Small Intestinal, Esophageal, Colorectal, Mesenteric and Peritoneal GIST

Return back to Schema ID Table

DRAFT

Gastrointestinal Stromal Tumor (GIST)

KIT Gene Immunohistochemistry

Item Length: 1
NAACCR Item #: 3865
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 43, Gastrointestinal Tumors

Description

KIT Gene Immunohistochemistry (IHC) is the expression of the KIT gene in tumor tissue specimens based on immunohistochemical (IHC) stains. A positive test is a diagnostic and predictive marker for GIST tumors.

Rationale

KIT Gene Immunohistochemistry (IHC) is a Registry Data Collection Variable in AJCC. This data item was previously collected for GIST schemas in CS (different SSF's).

Definition

KIT is a gene that regulates cell growth and differentiation. Mutations of this gene become oncogenes and cause a gastrointestinal stromal tumor to ignore cellular control signals. About 85-90% of GIST tumors contain oncogenic mutations of the KIT receptor gene. KIT immunohistochemistry is a special immunofluorescent stain that turns mutated cells brown and confirms a diagnosis of GIST. The presence of the KIT gene also indicates that the patient may respond to Gleevec or Sutent.

Additional Information

- **Source documents:** pathology report (special stain)
- **Other names:** CD117, c-kit receptor, KIT receptor tyrosine kinase, or SCFR (stem cell factor receptor)

Coding Instructions and Codes

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

Note 2: KIT Gene Immunohistochemistry (IHC) is the expression of the KIT gene in tumor tissue specimens based on immunohistochemical (IHC) stains. A positive test is a diagnostic and predictive marker for GIST tumors. Do not record secondary or acquired mutations that may have developed because of long-term imatinib treatment.

Note 3: Other names for KIT are CD117 or c-kit.

Code	Description
0	KIT negative/normal; within normal limits
1	KIT positive

Code	Description
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Cannot be determined by pathologist KIT not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

SKIN

DRAFT

Merkel Cell Carcinoma

Extranodal Extension Clin (non-Head and Neck)

Item Length: 1
NAACCR Item #: 3830
NAACCR Alternate Name: Extranodal Extension Clinical (non-Head and Neck)
AJCC 8th Edition Chapter(s):

- Chapter 46: Merkel Cell Skin
- Chapter 57: Penis

Description

Extranodal Extension (ENE) Clinical is defined as "the extension of a nodal metastasis through the lymph node capsule into adjacent tissue" during the diagnostic workup. This data item defines clinical ENE for sites other than Head and Neck**.**

Rationale

Extranodal Extension Clinical (non-Head and Neck) is a Registry Data Collection Variable for AJCC. This data item was previously collected for Penis, SSF# 17.

Definition

The presence of extranodal extension (ENE) from regional lymph nodes is an important prognostic factor in some cancers because these patients are rarely cured without some type of systemic chemotherapy or radiation. Extranodal extension is defined as metastatic tumor growing from within the lymph node outward through the lymph node capsule and into surrounding connective tissues.

This data item is for ENE that is detected clinically.

Coding guidelines

- Code 0 when there are positive nodes clinically, but ENE not identified/not present.
- Code 1 when there are positive nodes clinically, ENE is identified by physical exam or imaging
- Code 2 when there are positive nodes clinically, ENE is identified by biopsy (microscopically confirmed)
- Code 7 when nodes are clinically negative (cN0)
- Code 9 when
    - No information in the medical record
    - Positive nodes clinically, not evaluated (assessed) for ENE
    - Positive nodes clinically, unknown if evaluated (assessed) for ENE
    - Lymph nodes not evaluated (assessed) clinically
    - Unknown if lymph nodes evaluated (assessed) clinically

Additional Information

- **Source documents:** pathology report, imaging reports, physical exam
- **Other names:** ENE, extracapsular extension, ECE

Coding Instructions and Codes

Note 1: Physician statement of Extranodal Extension (ENE) Clinical or physician clinical staging can be used to code this data item when there is no other information available.

Note 2: Extranodal Extension Clinical is defined as "the extension of a nodal metastasis through the lymph node capsule into adjacent tissue" identified during the diagnostic workup. ENE is the preferred terminology. Other names include: extranodal spread, extracapsular extension, or extracapsular spread."

Note 3: Be aware that the rules for coding ENE for head and neck sites compared to non-head and neck sites are different**.**

Note 4: Code the status of extranodal extension assessed during the diagnostic workup for the assignment of the clinical stage for the most involved regional lymph node(s). This is mainly determined by physical examination, and includes statements such as fixed or matted nodes. Imaging may also be used, as well as lymph node biopsies or sentinel node biopsies performed prior to any treatment. Do not code ENE for any distant nodes.

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

Return back to Schema ID Table

DRAFT

Merkel Cell Carcinoma

Extranodal Extension Path (non-Head and Neck)

Item Length: 1
NAACCR Item #: 3833
NAACCR Alternate Name: Extranodal Extension Pathological (non-Head and Neck)
AJCC 8th Edition Chapter(s):

- Chapter 46: Merkel Cell Skin
- Chapter 57: Penis

Description

Extranodal Extension (ENE) Pathological is defined as "the extension of a nodal metastasis through the lymph node capsule into adjacent tissue. This data item defines pathological ENE for sites other than Head and Neck.

Rationale

Extranodal Extension Pathological (non-Head and Neck) is a Registry Data Collection Variable for AJCC. This data item was previously collected for Penis, SSF# 17.

Definition

The presence of extranodal extension (ENE) from regional lymph nodes is an important prognostic factor in some cancers because these patients are rarely cured without some type of systemic chemotherapy or radiation. Extranodal extension is defined as metastatic tumor growing from within the lymph node outward through the lymph node capsule and into surrounding connective tissues.

This data item is for ENE that is detected pathologically.

Coding guidelines

- Code 0 when there are positive nodes pathologically, but ENE not identified/not present
- Code 1 when there are positive nodes pathologically, ENE is identified
- Code 7 when nodes are surgically resected and they are negative (pN0)
- Code 9 when
    - No information in the medical record
    - Positive nodes pathologically, not evaluated (assessed) for ENE
    - Positive nodes pathologically, unknown if evaluated (assessed) for ENE
    - Lymph nodes not evaluated (assessed) pathologically (no surgical resection of lymph nodes)
    - Unknown if lymph nodes evaluated pathologically (assessed)

Additional Information

- **Source documents:** pathology report from surgical resection

- **Other names:** ENE, extracapsular extension, ECE

Coding Instructions and Codes

Note 1: Physician statement of Extranodal Extension (ENE) Pathological or physician pathological staging can be used to code this data item when there is no other information available.

Note 2: Extranodal extension is defined as "the extension of a nodal metastasis through the lymph node capsule into adjacent tissue." ENE is the preferred terminology. Other names include: extranodal spread, extracapsular extension, or extracapsular spread."

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

Note 3: Be aware that the rules for coding ENE for head and neck sites compared to non-head and neck sites are different.

Note 4: Code the status of extranodal extension assessed on the surgical resection specimen for the most involved regional lymph node(s). Do not code ENE for any distant nodes.

Code	Description
0	Regional lymph nodes involved, ENE not present/not identified from surgical resection
1	Regional lymph nodes involved, ENE present/identified from surgical resection
7	No lymph node involvement from surgical resection (pN0)
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error)
9	Not documented in medical record No surgical resection of regional lymph nodes Cannot be determined Pathological assessment of lymph nodes not done, or unknown if done Extranodal Extension Pathological not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Merkel Cell Carcinoma

LN Isolated Tumor Cells (ITC)

Item Length: 1
NAACCR Item #: 3880
NAACCR Alternate Name: Lymph Nodes Isolated Tumor Cells (ITC)
AJCC 8th Edition Chapter(s): Chapter 46, Merkel Cell Carcinoma

Description

Lymph Nodes Isolated Tumor Cells (ITC), the presence of isolated tumor cells in regional lymph node(s) that may be detected by hematoxylin and eosin or by immunohistochemical staining, is a potential prognostic factor for Merkel Cell Carcinoma.

Rationale

Lymph Nodes, Isolated Tumor Cells (ITC) is a Registry Data Collection Variable in AJCC. This data item was previously collected for Merkel Cell Skin, SSF# 18.

Definition

Isolated tumor cells (ITCs) for Merkel cell carcinoma are defined as single tumor cells or small clusters of tumor cells not more than 0.2 mm in greatest dimension. ITCs are usually detected by immunohistochemistry on sentinel lymph node biopsies.

- **Note**: Examples of immunohistochemical staining methods are Cytokeratin 20 (CK20), CAM 5.2, pancytokeratin, and AE1/3. ITCs may be detected by routine H&E stains.

Additional information

- **Source documents:** pathology report

Coding Instructions and Codes

Note 1: Physician statement of Isolated Tumor Cells (ITCs) can be used to code this data item when no other information is available.

Note 2: ITCs include single tumor cells or small clusters, less than or equal to 0.2 mm in greatest dimension, generally without stromal response in the lymph node. These cells usually are found in the subcapsular nodal sinuses but may be seen within the nodal parenchyma.

Note 3: ITCs may be identified in lymph nodes by hematoxylin and eosin staining or by specialized pathological techniques, such as IHC for cytokeratin proteins for carcinomas. Specialized pathology techniques such IHC and molecular techniques are not recommended for routine examination of lymph nodes.

Note 4: Record the status of ITCs as documented by the pathologist.

Code	Description
0	Regional lymph nodes negative for ITCs
1	Regional lymph nodes positive for ITCs (Tumor cell clusters not greater than 0.2 millimeter (mm))
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Cannot be determined by pathologist ITCs not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Merkel Cell Carcinoma

Profound Immune Suppression

Item Length: 1
NAACCR Item #: 3918
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 46, Merkel Cell Carcinoma

Description

Profound Immune Suppression, suppressed immune status that may be associated with HIV/AIDs, solid organ transplant, chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple conditions or other conditions, increases the risk of developing Merkel Cell Carcinoma and is an adverse prognostic factor.

Rationale

Profound Immune Suppression is a Registry Data Collection Variable in AJCC. It was previously collected as Merkel Cell Penis, SSF #22, Merkel Cell Scrotum SSF #22, Merkel Cell Skin, SSF# 22, and Merkel Cell Vulva, SSF #22.

Definition

Profound immune suppression may greatly increase the risk of developing Merkel cell carcinoma. Immune suppression is suppression of the body's immune system and its ability to fight infections and other diseases. Immune suppression may be deliberately induced with drugs, as in preparation for bone marrow or other organ transplantation, to prevent rejection of the donor tissue. It may also result from certain diseases such as Acquired Immune Deficiency Syndrome (AIDS) or lymphoma, and from the use of anti-cancer drugs.

Additional Information

- **Source documents:** patient history, consultation notes, other statement in medical record
- **Other names:** immunosuppression

Coding Instructions and Codes

Note 1: Physician statement of Profound Immune Suppression must be used to code this data item. Do not assume that a patient is immune suppressed just because the patient has one of the conditions listed below in the table. Per AJCC experts, the following terms can also be used to describe "profound immune suppression."

- Immunocompromised
- Immunosuppressed
- Suppressed immune status

Note 2: Per AJCC experts, this data item is limited to the conditions in the table below occurring within two years of the diagnosis of Merkel cell carcinoma.

Note 3: Code 9 if conditions in the table below were not active within 2 years of (or resolved more than 2 years prior to) diagnosis, or if it is unknown when they existed.

Note 4: If more than one condition is documented, code 5. Document the specific conditions in the text field.

Code	Description
0	No immune suppression condition(s) identified/not present
1	Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS)
2	Solid organ transplant recipient
3	Chronic lymphocytic leukemia
4	Non-Hodgkin lymphoma
5	Multiple immune suppression conditions
6	Profound immune suppression present
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Profound immune suppression not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Melanoma Skin

Breslow Tumor Thickness

Item Length: 4
NAACCR Item #: 3817
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 47, Melanoma of the Skin

Description

Breslow Tumor Thickness, the measurement of the thickness of a melanoma as defined by Dr. Alexander Breslow, is a prognostic factor for Melanoma of the Skin

Rationale

Breslow Tumor Thickness is a Registry Data Collection Variable in AJCC. It was previously collected as Melanoma Skin, CS SSF# 1.

Definition

A measure of how deeply a melanoma tumor has grown into the skin. The tumor thickness (depth) is usually measured from the top of the tumor to the deepest tumor cells. If the tumor is ulcerated (the skin is broken), it is measured from the base of the ulcer to the deepest tumor cells. Breslow thickness is used to help determine the stage of cancer. Thicker tumors are linked with lower survival rates.

Coding guidelines

Code a measurement specifically labeled as "thickness" or "depth" or "Breslow depth of invasion" from the pathology report. In the absence of this label, a measurement described as taken from the cut surface of the specimen may be coded. And in the absence of either of these labels, the third dimension in a statement of tumor size can be used to code this field.

Code the greatest measured thickness from any procedure performed on the lesion, whether it is described as a biopsy or an excision. Do not add measurements together from different procedures.

- ***Example:*** A punch biopsy with a thickness of 0.5 mm is followed by a re-excision with a thickness of residual tumor of 0.2 mm. *Code 0.5 mm.*

If the tumor is excised post-neoadjuvant treatment, tumor measurements cannot be compared before and after treatment to determine which would indicate the greater involvement. The same code (XX.9) is used for cases with no surgical procedure of the primary site and cases with surgical procedure of the primary site after neoadjuvant treatment.

Because the thickness table is similar to many other tables that collect a measurement, it is important to identify the correct unit of measurement.

In the range 0.1-99.9, code the actual tumor thickness, tumor depth, or Breslow measurement in **tenths** of millimeters as stated in the pathology report. If the measurement is given in hundredths of

millimeters, use the general rules for rounding to determine the value in tenths of millimeters. This is a four-digit field with a decimal point in the third digit.

- ***Examples**:* Tumor described as 0.5 mm in depth – *code as 0.5*. Lesion 1 mm thick – *code as 1.0*. Breslow 2.5 mm – *code as 2.5*. Thickness of 10 mm (1 cm) – *code as 10.0)*.

Additional Information

- **Source documents:** pathology report
- **Other names:** maximum tumor thickness, Breslow depth of invasion, Breslow thickness, Breslow measurement, Breslow's microstaging

For further information, refer to the Melanoma cancer protocol published by the College of American Pathologists for AJCC 8th edition, published June 2017.

Coding Instructions and Codes

Note 1: Physician statement of Breslow Tumor Thickness can be used to code this data item when no other information is available or the available information is ambiguous.

Note 2: Code Breslow tumor thickness, not size. Record actual measurement in tenths of millimeters from the pathology report. Measurement given in hundredths of millimeters should be rounded to the nearest tenth.

Examples:

0.4 mm – 0.4
1.0 mm- 1.0
2.5 mm – 2.5
2.56 mm- 2.6
11 mm – 11.0
12.35 mm – 12.4 mm

Note 3: Code the greatest measured thickness from any procedure performed on the lesion, whether it is described as a biopsy or an excision.

- For ***example***, if a punch biopsy with a thickness of 1.5 mm is followed by a re-excision with a thickness of residual tumor of 0.2 mm, code 1.5.

Note 4: Do not add measurements together from different procedures (even in the rare circumstance that the pathologist adds the measurements from two specimens).

Note 5: If the pathologist describes the thickness as "at least," use the appropriate A code. An exact measurement takes precedence over A codes.

- If the pathologist states "greater than" instead of "at least", code to XX.9, unless it is greater than 9.9 mm (Code AX.0)
- ***Examples***:
  Pathologist states the thickness is "at least 2.0 mm." Code A2.0
  Pathologist states the thickness is "greater than 4 mm." Code XX.9

DRAFT

Code	Description
0.0	No mass/tumor found
0.1-99.9	0.1 - 99.9 millimeters
XX.1	100 millimeters or larger
A0.1-A9.9	Stated as “at least” some measured value of 0.1 to 9.9
AX.0	Stated as greater than 9.9 mm
XX.8	Not applicable: Information not collected for this schema (If this item is required by your standard setter, use of code XX.8 will result in an edit error)
XX.9	Not documented in medical record Microinvasion; microscopic focus or foci only and no depth given Cannot be determined by pathologist In situ melanoma Breslow Tumor Thickness not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Melanoma Skin

Ulceration

Item Length: 1
NAACCR Item #: 3936
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 47, Melanoma of the Skin

Description

Ulceration, the absence of an intact epidermis overlying the primary melanoma based upon histopathological examination, is a prognostic factor for melanoma of the skin.

Rationale

Ulceration is a Registry Data Collection Variable in AJCC. It was previously collected as Melanoma Skin, CS SSF# 2.

Definition

Ulceration is the formation of a break on the skin or on the surface of an organ. An ulcer forms when the surface cells die and are cast off. Ulcers may be associated with cancer and other diseases.

Primary tumor ulceration has been shown to be a dominant independent prognostic factor, and if present, changes the pT stage from T1a to T1b, T2a to T2b, etc., depending on the thickness of the tumor.

- The presence or absence of ulceration must be confirmed on microscopic examination. Melanoma ulceration is defined as the combination of the following features
- Full-thickness epidermal defect (including absence of stratum corneum and basement membrane)
- Evidence of reactive changes (ie, fibrin deposition, neutrophils); and thinning, effacement, or reactive hyperplasia of the surrounding epidermis in the absence of trauma or a recent surgical procedure
- Ulcerated melanomas typically show invasion through the epidermis, whereas nonulcerated melanomas tend to lift the overlying epidermis

Coding guidelines

Record whether ulceration is present or absent

- Code 0 when there is a statement in the pathology report that no ulceration is present
- Code 1 when the pathologist states that ulceration is present
- Code 9 when
    - No information in the medical record
    - Pathology report is not available
    - Ulceration not evaluated (not assessed)
    - Unknown if Ulceration evaluated (assessed)

Additional Information

- **Source documents** pathology report, physical exam, consultant notes, other statement in medical record, CAP Protocol Melanoma of Skin
- **Change from Collaborative Stage v2 (CSv2):** In **CSv2**, if pathology report was available and there was no mention of ulceration, the registrar could assume that it was negative and code appropriately. For the SSDI, this assumption cannot be made. There must be a statement that ulceration is not present to code 0.

Coding Instructions and Codes

Note 1: Physician statement of microscopically confirmed ulceration (e.g., based on biopsy or surgical resection) can be used to code this data item.

Note 2: Ulceration can only be confirmed by microscopic examination. Do not use findings from physical exam.

Note 3: Melanoma ulceration is the absence of an intact epidermis overlying the primary melanoma based upon histopathological examination.

Code	Description
0	Ulceration not identified/not present
1	Ulceration present
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Cannot be determined by the pathologist Pathology report does not mention ulceration Ulceration not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Melanoma Skin

Mitotic Rate Melanoma

Item Length: 2
NAACCR Item #: 3893
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 47, Melanoma of the Skin

Description

Mitotic Rate Melanoma, the number of mitoses per square millimeter based on pathological evaluation, is a prognostic factor for melanoma of the skin.

Rationale

Mitotic Rate Melanoma is a Registry Data Collection Variable in AJCC. It was previously collected as Melanoma Skin, CS SSF# 7.

Definition

Mitotic count is a way of describing the potential aggressiveness of a tumor. For GIST tumors, the count is translated into a mitotic rate that is used with T, N, and M to stage group a case.

Record the number of cells actively dividing as determined by the pathologist. The count will vary according to the type of tumor.

Additional Information

- **Source documents:** pathology report
- **Other names:** mitotic rate, mitotic index (a ratio—do not record this measurement), mitotic activity

Coding Instructions and Codes

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

Note 2: The term "mitotic figures" is the same as mitoses.

Note 3: Record the mitotic rate/count as documented in the pathology report. If there is more than one pathology report for the same melanoma at initial diagnosis and different mitotic counts are documented, code the highest mitotic count from any of the pathology reports.

Code	Description
00	0 mitoses per square millimeter (mm) Mitoses absent No mitoses present
01-99	1 - 99 mitoses/square mm (Exact measurement in mitoses/square mm)

Code	Description
X1	100 mitoses/square mm or more
X2	Stated as "less than 1 mitosis/square mm" Stated as "nonmitogenic"
X3	Stated as "at least 1 mitosis/square mm" Stated as "mitogenic"
X4	Mitotic rate described with denominator other than square millimeter (mm)
X7	Test ordered, results not in chart
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record Mitotic Rate Melanoma not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Melanoma Skin

LDH Pretreatment Lab Value

Item Length: 7
NAACCR Item #: 3932
NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Pretreatment Lab Value
AJCC 8th Edition Chapter(s): Chapter 47, Melanoma of the Skin

Description

LDH Pretreatment Lab Value, measured in serum, is a predictor of treatment response, progression-free survival and overall survival for patients with Stage IV melanoma of the skin.

Rationale

LDH Pretreatment Lab Value is a Registry Data Collection Variable in AJCC. It was previously collected as Melanoma Skin, CS SSF# 5.

Definition

When cells (normal or tumor) are damaged or destroyed, an enzyme called lactate dehydrogenase (LDH) is released into the bloodstream. LDH is an indirect indication of possible tumor burden or damage to an organ, which may be caused by metastatic involvement of liver or lung, or a myocardial infarction. The total LDH should be the test value that is coded, but there are five fractions of LDH that measure tissue specific cellular damage: LD1 and LD2: heart, red blood cells and kidneys; LD3: lung; LD4 and LD5: liver, skin and skeletal muscles. LDH is elevated in 60% of patients with non-seminomatous germ cell tumors of the testis. LDH is not a screening test, nor is it diagnostic of melanoma, ocular adnexal lymphoma, or testicular cancer.

Coding guidelines

- Code 0.0 for a test result of 0 (U/L).
- Code the highest exact LDH lab value prior to treatment in the range 0.1 to 99,999.9
- Code XXXXX.1 for a total LDH lab value of 100,000 or greater.
- Code XXXXX.7 if the test was ordered and the results are not in the medical record.
- Code XXXXX.9 when
    - there is no information in the medical record about the LDH lab value
    - Test is not done or unknown if the test was done

Additional Information

- **Source documents**: clinical laboratory report; may be included in a liver or hepatic panel/profile, a cardiac panel, or a general metabolic panel of tests
- **Other names**: LDH, Lactate dehydrogenase, lactase dehydrogenase, lactic acid dehydrogenase

Coding Instructions and Codes

Note 1: Physician statement of LDH (Lactate Dehydrogenase) 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 serum LDH test results documented in the medical record **prior to treatment** or within 6 weeks of diagnosis**.** Give priority to the first test performed. The lab value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: The same laboratory test should be used to record information in LDH Upper Limits of Normal [NAACCR Data Item # 3870]

Code	Description
0.0	0.0 (U/L)
0.1-99999.9	0.1 – 99,999.9 U/L
XXXXX.1	100,000 U/L or greater
XXXXX.7	Test ordered, results not in chart
XXXXX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XXXXX.8 will result in an edit error.)
XXXXX.9	Not documented in medical record LDH (Lactate Dehydrogenase) Pretreatment Lab Value not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Melanoma Skin

LDH Pretreatment Level

Item Length: 1
NAACCR Item #: 3869
NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Pretreatment Level
AJCC 8th Edition Chapter(s):

- Chapter 47: Melanoma Skin
- Chapter 82: Plasma Cell Myeloma and Plasma Cell Disorders

Description

LDH (Lactate Dehydrogenase) is an enzyme involved in conversion of sugars to energy and present in most cells in the body. Elevated pretreatment LDH is an adverse prognostic factor for plasma cell myeloma and melanoma of the skin.

Rationale

LDH (Lactate Dehydrogenase) Pretreatment Level is a prognostic factor required in AJCC 8th edition for Chapter 83 Plasma Cell Myeloma and Plasma Cell Disorders and Chapter 47 Melanoma Skin. For Plasma Cell Myeloma, LDH is part of the RISS Stage and is new for cases diagnosed 1/1/2018+. For Melanoma Skin, LDH is used to define the M subcategories and was previously collected as Melanoma Skin, SSF #4.

Coding Instructions and Codes

Note 1: Use the reference ranges from your lab to determine if LDH is normal.

Note 2: Record this data item based on a blood test performed at diagnosis (pre-treatment). In the absence of the lab test, a physician's statement of the exact value or interpretation can be used. Use the highest value available.

Note 3: If there is no mention of the LDH, code 9.

Code	Description
0	Normal LDH level Low, below normal
1	Above normal LDH level; High
7	Test ordered, results not in chart
9	Not documented in medical record LDH (Lactate Dehydrogenase) Pretreatment Level not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Melanoma Skin

LDH Upper Limits of Normal

Item Length: 3
NAACCR Item #: 3870
NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Upper Limits of Normal
AJCC 8th Edition Chapter(s): Chapter 47, Melanoma of the Skin

Description

LDH (Lactate Dehydrogenase), an enzyme involved in converting sugars to energy in the body, is elevated in some malignancies. LDH level is a prognostic factor for patients with Stage IV melanoma. This data Item refers to the Upper Limit of Normal in the laboratory test used to interpret the Serum LDH result.

Rationale

LDH (Lactate Dehydrogenase) Upper Limits of Normal is a Registry Data Collection Variable in AJCC. It was previously collected as Melanoma Skin, CS SSF# 6.

Definition

When cells (normal or tumor) are damaged or destroyed, an enzyme called lactate dehydrogenase (LDH) is released into the bloodstream. LDH is an indirect indication of possible tumor burden or damage to an organ, which may be caused by metastatic involvement of liver or lung, or a myocardial infarction. The total LDH should be the test value that is coded, but there are five fractions of LDH that measure tissue specific cellular damage: LD1 and LD2: heart, red blood cells and kidneys; LD3: lung; LD4 and LD5: liver, skin and skeletal muscles. LDH is elevated in 60% of patients with non-seminomatous germ cell tumors of the testis. LDH is not a screening test, nor is it diagnostic of melanoma, ocular adnexal lymphoma, or testicular cancer.

Additional Information

- **Source documents:** clinical laboratory report; may be included in a liver or hepatic panel/profile, a cardiac panel, or a general metabolic panel of tests
- **Other names**: LDH, Lactate dehydrogenase, lactase dehydrogenase, lactic acid dehydrogenase
- ***Normal reference range**:* varies widely by laboratory, patient age, and the units of measurement.
- ***Examples*** of reference range lab values:
    - Lab A Total LDH 71 – 207 U/L
    - Lab B Total LDH 300 – 600 U/L
    - Lab C Total LDH 45 – 90 U/L
    - Lab D Total LDH 150 – 250 U/L

Coding Instructions and Codes

DRAFT

Note 1: Physician statement of LDH (Lactate Dehydrogenase) Upper Limit of Normal can be used to code this data item.

Note 2: Upper limits of normal for LDH vary widely depending on the lab. Common upper limits can be 200, 250, 618, or other values.

Note 3: The same laboratory test should be used to record information LDH Pretreatment Lab Value [NAACCR Data Item # 3869]

Code	Description
001-999	001 - 999 upper limit of normal (Exact upper limit of normal)
XX8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XX8 may result in an edit error.)
XX9	Not documented in medical record LDH Upper Limit not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

BREAST

DRAFT

Breast

Estrogen Receptor and Progesterone Receptor

Definition

Estrogen receptor (ER) positivity and progesterone receptor (PR) positivity are favorable prognostic factors in breast cancer, as well as endometrial carcinoma and meningioma. Positive results predict a favorable response to endocrine (hormonal) therapy. Combined ER and PR positivity is associated with increased response to antiestrogen therapies.

There are a variety of ways to report information on ER and PR results, but there is almost always a summary statement that the result is positive or negative.

The following data items are used to collect ER and PR information

- Estrogen Receptor Percent Positive or Range [NAACCR Data Item #3826]
- Estrogen Receptor Summary [NAACCR Data Item #3827]
- Estrogen Receptor Total Allred Score [NAACCR Data Item #3828]
- Progesterone Receptor Percent Positive or Range [NAACCR Data Item #3914]
- Progesterone Receptor Summary [NAACCR Data Item #3915]
- Progesterone Receptor Total Allred Score [NAACCR Data Item #3916]

Note: Do not use results from the following tests to record ER or PR results

- Oncotype Dx
- MammaPrint
- EndoPredict
- PAM 50 (Prosigna)
- Any other test that records HER2

The two most common ways to report ER and PR results are the percentage of cells with nuclear positivity and the average intensity of staining. Both the PS and IS are based on immunohistochemical staining of tumor cells.

ER and PR status, the percentage of tumor cells with positive nuclear staining, may be reported as a specific number or a range if more than 10%. Intensity refers to degree of nuclear positivity (i.e., pale to dark); average intensity of staining is recorded as weak, moderate or strong.

ER or PR Status
___ Positive
Percentage of cells with nuclear positivity[#]
Specify: ___ %
-OR-
Range (Note A)
___ 1-10% (specify): ____ %[#]
___ 11-20%
___ 21-30%

___ 31-40%
___ 41-50%
___ 51-60%
___ 61-70%
___ 71-80%
___ 81-90%
___ 91-100%
+ Average intensity of staining:
+ ___ Weak
+ ___ Moderate
+ ___ Strong
___ Negative

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, as defined in the following table, and the Intensity Score.

Proportion Score	Positive Cells, %	Intensity	Intensity Score
0	0	None	0
1	<1	Weak	1
2	1 to 10	Intermediate	2
3	11 to 33	Strong	3
4	34 to 66		
5	≥67		

* The Allred score combines the percentage of positive cells and the intensity of the reaction product in most of the carcinoma. The 2 scores are added together for a final score with 8 possible values.

Additional Information

- Breast cancer protocol **published by the College of American Pathologists for AJCC 8th edition, published June 2017.**

DRAFT

Breast

Estrogen Receptor Percent Positive or Range

Item Length: 3
NAACCR Item #: 3826
NAACCR Alternate Name: ER (Estrogen Receptor) Percent Positive or Range
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

Estrogen Receptor Percent Positive or Range is the percent of cells staining estrogen receptor positive by IHC.

Rationale

Estrogen Receptor Percent Positive or Range is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

See Estrogen Receptor and Progesterone Receptor **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of ER (Estrogen 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 ER Summary.

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 XX9.

Code	Description
000	ER negative, or stated as less than 1%
001-100	1-100 percent
R10	Stated as 1-10%
R20	Stated as 11-20%
R30	Stated as 21-30%
R40	Stated as 31-40%
R50	Stated as 41-50%
R60	Stated as 51-60%
R70	Stated as 61-70%
R80	Stated as 71-80%
R90	Stated as 81-90%
R99	Stated as 91-100%
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.)

Code	Description
XX9	Not documented in medical record ER (Estrogen Receptor) Percent Positive or Range not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Breast

Estrogen Receptor Summary

Item Length: 1
NAACCR Item #: 3827
NAACCR Alternate Name: ER (Estrogen Receptor) Summary
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

Estrogen Receptor Summary is a summary of results of the estrogen receptor (ER) assay.

Rationale

This data item is required for prognostic stage grouping in AJCC 8th edition, Chapter 48, *Breast.* It was previously collected as Breast CS SSF # 1.

Coding guidelines

Record the pathologist's interpretation of the assay value from the tumor specimen. Results from the ER assay 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 an ER or PR done as part of a multigene test such as OncotypeDX or MammaPrint.

- Code 0 when the ER is reported as negative or normal
- Code 1 when the ER is reported as positive or elevated
- Code 7 when the ER test was ordered but the results are not available
- Code 9 when the ER is
    - Reported as borderline; undetermined whether positive or negative
    - Cannot be determined by the pathologist (e.g. inadequate specimen)
    - It is unknown whether the ER test was performed
    - The patient has only a clinical diagnosis of breast cancer (no tissue diagnosis)
    - The tumor tissue is completely in situ

See Estrogen Receptor and Progesterone Receptor **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of ER (Estrogen Receptor) Summary status can be used to code this data item when no other information is available.

Note 2: The result of the ER test performed on the primary breast tissue is to be recorded in this data item.

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

Note 4: In cases where ER is reported on more than one breast tumor specimen, record the highest value. If any sample is positive, record as positive.

- ***Exception***: If ER is positive on an in situ specimen and ER is negative on all tested invasive specimens, code ER as negative (code 0).

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 ER results from pre-treatment specimens, report the findings from post-treatment specimens.

Note 6: If the patient is ER positive and node negative, a multigene test such as Oncotype Dx may be performed, in which case another ER test will be performed. The multigene test may include an ER assessment, but do not record the results of ER from the multigene test in this field.

- Record only the results of the test which made the patient eligible to be given the multigene test.

Code	Description
0	ER negative
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

Return back to Schema ID Table

DRAFT

Breast

Estrogen Receptor Total Allred Score

Item Length: 2
NAACCR Item #: 3828
NAACCR Alternate Name: ER (Estrogen Receptor) Total Allred Score
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

Estrogen Receptor Total Allred Score is based on the percentage of cells that stain positive by IHC for estrogen receptor (ER) and the intensity of that staining.

Rationale

Estrogen Receptor Total Allred Score is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

See Estrogen Receptor and Progesterone Receptor **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of ER (Estrogen Receptor) Total Allred Score can be used to code this data item.

Note 2: Code this data item using the same report used to record ER Summary.

Note 3: The Allred system looks at what percentage of cells test positive for hormone receptors, along with how well the receptors show up after staining (this is called "intensity"). This information is then combined to score the sample on a scale from 0 to 8. The higher the score, the more receptors were found and the easier they were to see in the sample.

Note 4: If ER test is performed, but Allred score is not documented, or cannot be calculated, code X9.

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

DRAFT

Breast

Progesterone Receptor Percent Positive or Range

Item Length: 3
NAACCR Item #: 3914
NAACCR Alternate Name: PR (Progesterone Receptor) Percent Positive or Range
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

Progesterone Receptor Percent Positive or Range is the percent of cells staining progesterone receptor positive measured by IHC.

Rationale

Progesterone Receptor Percent Positive or Range is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

See Estrogen Receptor and Progesterone Receptor **for additional information.**

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 PR Summary.

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 XX9.

Code	Description
000	PR negative, or stated as less than 1%
001-100	1-100 percent
R10	Stated as 1-10%
R20	Stated as 11-20%
R30	Stated as 21-30%
R40	Stated as 31-40%
R50	Stated as 41-50%
R60	Stated as 51-60%
R70	Stated as 61-70%
R80	Stated as 71-80%
R90	Stated as 81-90%
R99	Stated as 91-100%
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.)

Code	Description
XX9	Not documented in medical record PR (Progesterone Receptor) Percent Positive or Range not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Breast

Progesterone Receptor Summary

Item Length: 1
NAACCR Item #: 3915
NAACCR Alternate Name: PR (Progesterone Receptor) Summary
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

Progesterone Receptor Summary is a summary of results from the progesterone receptor (PR) assay.

Rationale

This data item is required for prognostic stage grouping in AJCC 8th edition, Chapter 48 *Breast*. It was previously collected as Breast CS SSF # 2.

Coding guidelines

- Code 0 when the PR is reported as negative or normal
- Code 1 when the PR is reported as positive or elevated
- Code 7 when the PR test was ordered but the results are not available
- Code 9 when the PR is
    - Reported as borderline; undetermined whether positive or negative
    - Cannot be determined by the pathologist (e.g. inadequate specimen)
    - It is unknown whether the PR test was performed
    - The patient has only a clinical diagnosis of breast cancer (no tissue diagnosis)
    - The tumor tissue is completely in situ

See Estrogen Receptor and Progesterone Receptor **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of PR (Progesterone Receptor) Summary status can be used to code this data item when no other information is available.

Note 2: The result of the PR test performed on the primary breast tissue is to be recorded in this data item.

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

Note 4: In cases where PR is reported on more than one breast tumor specimen, record the highest value. If any sample is positive, record as positive.

- ***Exception***: If PR is positive on an in situ specimen and PR is negative on all tested invasive specimens, code PR as negative (code 0).

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 PR results from pre-treatment specimens, report the findings from post-treatment specimens.

Note 6: If the patient is PR positive and node negative, a multigene test such as Oncotype Dx may be performed, in which case another PR test will be performed. The multigene test may include a PR assessment, but do not record the results of PR from the multigene test in this field.

- Record only the results of the test which made the patient eligible to be given the multigene test.

Code	Description
0	PR negative
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

Return back to Schema ID Table

DRAFT

Breast

Progesterone Receptor Total Allred Score

Item Length: 2
NAACCR Item #: 3916
NAACCR Alternate Name: PR (Progesterone Receptor) Total Allred Score
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

Progesterone Receptor, Total Allred Score is based on the percentage of cells that stain by IHC for progesterone receptor (PR) and the intensity of that staining.

Rationale

Progesterone Receptor, Total Allred Score is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

See Estrogen Receptor and Progesterone Receptor **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of PR (Progesterone Receptor) Total Allred Score can be used to code this data item.

Note 2: Code this data item using the same report used to record PR Summary.

Note 3: The Allred system looks at what percentage of cells test positive for hormone receptors, along with how well the receptors show up after staining (this is called "intensity"). This information is then combined to score the sample on a scale from 0 to 8. The higher the score, the more receptors were found and the easier they were to see in the sample.

Note 4: If PR test is performed, but Allred score is not documented, or it cannot be calculated, code X9.

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

Code	Description
	PR (Progesterone Receptor) Total Allred Score not assessed, or unknown if assessed

Return back to Schema ID Table

DRAFT

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:

DRAFT

Reporting Results of HER2 Testing by Immunohistochemistry (IHC)

Result	Criteria
Negative (Score 0)	No staining observed *or* Incomplete, faint/barely perceptible membrane staining in ≤10% of invasive tumor cells
Negative (Score 1+)	Incomplete, faint/barely perceptible membrane staining in >10% of invasive tumor cells*
Equivocal (Score 2+) †	Incomplete and/or weak to moderate circumferential membrane staining in >10% of invasive tumor cells *or* Complete, intense, circumferential membrane staining in ≤10% of invasive tumor cells*
Positive (Score 3+)	Complete, intense, circumferential membrane staining in >10% of invasive tumor cells*

If the IHC test is borderline or indeterminate, an ISH test may be performed. The ISH test is a method of testing for overexpression of the HER2 gene that uses fluorescent pieces of DNA that attach only to the HER2 gene copies in cells, which can then be counted under a special microscope. ISH studies determine the presence or absence of gene amplification and methods include fluorescence in situ hybridization (FISH), chromogenic in situ hybridization (CISH), and silver-enhanced in situ hybridization (SISH). Some assays use a single probe to determine the number of HER2 gene copies present (single-probe assays) and others include a chromosome enumeration probe (CEP17) to determine the ratio of HER2 signals to copies of chromosome 17 (dual-probe assays).

Results from single probe and dual probe ISH tests are reported differently and are collected in different data items. For dual probe tests, both HER2/CEP17 ratio and HER2 copy number results are collected in separate data items.

Reporting Results of *HER2* Testing by In Situ Hybridization (single-probe assay)

Result	Criteria
Negative (not amplified)	Average *HER2* copy number <4.0 signals/cell
Equivocal	Average *HER2* copy number ≥4.0 and <6.0 signals/cell†
Positive (amplified)	Average *HER2* copy number ≥6.0 signals/cell†

Reporting Results of *HER2* Testing by In Situ Hybridization (dual-probe assay)

Result	Criteria
Negative (not amplified)	*HER2/CEP17* ratio <2.0 AND average HER2 copy number <4.0 signals/cell
Equivocal	*HER2/CEP17* ratio <2.0 AND average HER2 copy number ≥4.0 but <6.0 signals/cell
Positive (amplified)	*HER2/CEP17* ratio ≥2.0† (regardless of average HER2 copy number) *or* Average HER2 copy number ≥6.0 signals/cell† (regardless of ratio)

Changes from Collaborative Stage v2 (CSv2): In **CSv2**, there were multiple SSFs that collected information on FISH, CISH, or other. In addition, the lab value and the interpretation were collected. For 2018 cases forward, only the interpretation will be recorded. Also, interpretation of all types of ISH tests (FISH, CISH, SISH, single probe, double probe) are to be recorded in the overall ISH data item. If there are multiple tests, record the highest.

Note: HER2 results are to be recorded from IHC or ISH tests only. **Do not use results from the following tests to record HER2 results:**

- Oncotype Dx
- MammaPrint
- EndoPredict
- PAM 50 (Prosigna)
- Any other test that records HER2

DRAFT

Breast

HER2 IHC Summary

Item Length: 1
NAACCR Item #: 3850
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

HER2 IHC Summary is the summary score for HER2 testing by IHC.

Rationale

HER2 IHC Summary is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

See HER2 for additional information.

Coding Instructions and Codes

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

Note 2: The HER2 IHC test performed on the primary breast tissue is to be recorded in this data item.

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

Note 4: In cases where HER2 IHC is reported on more than one breast tumor specimen, record the highest value. If any sample is positive, record as positive.

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 HER2 IHC results from pre-treatment specimens, report the findings from post-treatment specimens.

Note 6: If HER2 IHC is positive on an in situ specimen and HER2 IHC is negative on all tested invasive specimens, code HER2 IHC as negative (code 0).

Note 7: A 2+ (equivocal) finding by IHC should result in additional testing with ISH to determine gene copy number.

Note 8: An immunohistochemistry (IHC) test identifies the protein expressed by the gene (ERBB2), and an in situ hybridization (ISH) test identifies the number of copies of the gene (ERBB2) itself.

Code	Description
0	Negative (Score 0)

Code	Description
1	Negative (Score 1+)
2	Equivocal (Score 2+) Stated as equivocal
3	Positive (Score 3+) Stated as positive
4	Stated as negative, but score not stated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Cannot be determined (indeterminate) HER2 IHC Summary not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Breast

HER2 ISH Summary

Item Length: 1
NAACCR Item #: 3854
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

HER2 in situ hybridization (ISH) Summary is the summary score for results of testing for ERBB2 gene copy number by any ISH method. An immunohistochemistry (IHC) test identifies the protein expressed by the gene (ERBB2), and an ISH test identifies the number of copies of the gene (ERBB2) itself.

Rationale

HER2 ISH Summary is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

See HER2 for additional information.

Coding Instructions and Codes

Note 1: Physician statement of HER2 in situ hybridization (ISH) Summary can be used to code this data item when no other information is available.

Note 2: The HER2 ISH test performed on the primary breast tissue is to be recorded in this data item.

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

Note 4: Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. The same test should be used to code all the HER2 ISH data items.

Note 5: In cases where HER2 ISH is reported on more than one breast tumor specimen, record the highest value. If any sample is positive, record as positive.

Note 6: If neoadjuvant therapy is given, record the assay from tumor specimens prior to neoadjuvant therapy.

If neoadjuvant therapy is given and there are no HER2 ISH results from pre-treatment specimens, report the findings from post-treatment specimens.

Note 7: If HER2 IHC is positive on an in situ specimen and HER2 IHC is negative on all tested invasive specimens, code HER2 IHC as negative (code 0).

Note 8: If HER2 ISH is positive on an in situ specimen and HER2 ISH is negative on all tested invasive specimens, code HER2 as negative (code 0).

Note 9: An immunohistochemistry (IHC) test identifies the protein expressed by the gene (ERBB2), and an ISH test identifies the number of copies of the gene (ERBB2) itself.

Code	Description
0	Negative [not amplified]
2	Equivocal
3	Positive [amplified]
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Results cannot be determined (indeterminate) HER2 ISH Summary not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Breast

HER2 Overall Summary

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

Description

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

Rationale

This data item is required for prognostic stage grouping in AJCC 8th edition, Chapter 48 *Breast*. It was previously collected as Breast, CS SSF # 15.

See HER2 for additional information.

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)
    - The tumor tissue is completely in situ

Coding Instructions and Codes

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

Note 2: The result of the HER2 test performed on the primary breast tissue is to be recorded in this data item.

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

Note 4: In cases where HER2 is reported on more than one breast tumor specimen, record the highest value. If any sample is positive, record as positive.

- ***Exception***: If HER2 is positive on an in situ specimen and HER2 is negative on all tested invasive specimens, code HER2 as negative (code 0).

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 HER2 results from pre-treatment specimens, report the findings from post-treatment specimens.

Note 6: If the patient is HER2 positive and node negative, a multigene test such as Oncotype Dx may be performed, in which case another HER2 test will be performed. Do not record the results of that test in this field.

Record only the results of the test which made the patient eligible to be given the multigene test.

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

Return back to Schema ID Table

DRAFT

Breast

HER2 ISH Single Probe Copy Number

Item Length: 4
NAACCR Item #: 3853
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

HER2 in situ hybridization (ISH) Single Probe Copy Number is the HER2 copy number based on a single probe test.

Rationale

HER2 ISH Single Probe Copy Number is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

See HER2 for additional information.

Coding Instructions and Codes

Note 1: Physician statement of HER2 in situ hybridization (ISH) Single Probe Copy Number can be used to code this data item.

Note 2: A single probe test will report average number or mean signals per cell for HER2. Record the HER2 average number or mean signals per cells in this data item. The average number or mean signals per cell is also called the copy number.

> ***Example***:
>
> SISH RESULTS: FINAL HER 2 IN SITU HYBRIDIZATION INTERPRETATION: POSITIVE (>6 gene copies) HER-2/neu gene amplification.
>
> HER-2/neu SILVER IN SITU HYBRIDIZATION (SISH)
>
> HER-2neu gene (Inform HER2 DNA probe)
>
> Number of tumor cell nuclei counted: 60
>
> Number of Her-2/neu gene copies: 418
>
> Mean HER-2/neu gene copy number: 6.9
>
> Code Single Probe HER2 Copy Number: 6.9
>
> [Note: This is calculated by dividing 418 by 60]

Note 3: Registrars are not to calculate the copy number.

Note 4: Following ASCO-CAP guidelines, a 2+ (equivocal) finding by immunohistochemistry (IHC) should result in additional testing with ISH to determine gene copy number.

Note 5: Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. The same test should be used to code all the HER2 ISH data items.

Note 6: A HER2 ISH test may be called "*ERBB2*." *ERBB2* is the standard symbol for the gene 'erb-b2 receptor tyrosine kinase 2.' An IHC test identifies the protein expressed by the gene, and an ISH test identifies the gene itself.

Note 7: If a HER2 ISH single probe copy number test is done, and the results are between 4 and 6 (equivocal), dual probe tests are recommended.

Note 8: If the test results are presented to the hundredth decimal, ignore the hundredth decimal. Do NOT round.

Example:
Reported as **6.97**, code **6.9**

Code	Description
0.0-99.9	Reported HER2 copy number of 0.0-99.9
XX.1	Reported HER2 copy number of 100 or greater
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error.)
XX.9	Not documented in medical record Cannot be determined (indeterminate) HER2 ISH Single Probe Copy Number not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Breast

HER2 ISH Dual Probe Copy Number

Item Length: 4
NAACCR Item #: 3851
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

HER2 in situ hybridization (ISH) Dual Probe Copy Number is the HER2 copy number based on a dual probe test.

Rationale

HER2 ISH Dual Probe Copy Number is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

See HER2 for additional information.

Coding Instructions and Codes

Note 1: Physician statement of HER2 in situ hybridization (ISH) Dual Probe Copy Number can be used to code this data item.

Note 2: A dual probe test will report average number or mean signals per cell for both HER2 and CEP17, the latter used as a control. Record the HER2 average number or mean signals per cells in this data item. The average number or mean signals per cells is also called the copy number.

> ***Example:***
>
> SISH RESULTS: FINAL HER 2 IN SITU HYBRIDIZATION INTERPRETATION: EQUIVOCAL, INDETERMINATE. HER2 gene copy between 4 & 6 with HER2/CEP17 ratio <2.
>
> HER2/CEP17 RATIO: 4.26 / 3.13 = 1.36
>
> HER-2/neu SILVER IN SITU HYBRIDIZATION (SISH)
>
> HER-2neu gene (Inform HER2 DNA probe)
>
> Number of tumor cell nuclei counted: 120
>
> Number of Her-2/neu gene copies: 511
>
> Mean HER-2/neu gene copy number: 4.26
>
> CEP-17 SILVER IN SITU HYBRIDIZATION (SISH)
>
> CEP-17 (Inform Chromosome 17 probe)

DRAFT

Number of cell nuclei counted: 60

Number of CEP-17 gene copies: 188

Mean CEP-17 gene copies/nucl: 3.13

Code Dual Probe HER2 Copy Number: 4.2

[Note: This is calculated by dividing 511 by 120]

Note 3: Registrars are not to calculate the copy number.

Note 4: Following ASCO-CAP guidelines, a 2+ (equivocal) finding by immunohistochemistry (IHC) should result in additional testing with ISH to determine gene copy number.

Note 5: Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. The same test should be used to code all the HER2 ISH data items.

Note 6: A HER2 ISH test may be called "*ERBB2*." *ERBB2* is the standard symbol for the gene 'erb-b2 receptor tyrosine kinase 2.' An IHC test identifies the protein expressed by the gene, and an ISH test identifies the gene itself.

Note 7: If a HER2 ISH single probe copy number test is done, and the results are between 4 and 6 (equivocal), dual probe tests are recommended.

Note 8: If the test results are presented to the hundredth decimal, ignore the hundredth decimal. Do NOT round.

Example:
Reported as 4.99, code as 4.9

Code	Description
0.0-99.9	Reported HER2 copy number of 0.0-99.9
XX.1	Reported HER2 copy number of 100 or greater
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error.)
XX.9	Not documented in medical record Cannot be determined (indeterminate) HER2 ISH Dual Probe Copy Number not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Breast

HER2 ISH Dual Probe Ratio

Item Length: 4
NAACCR Item #: 3852
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

HER2 ISH Dual Probe Ratio is the summary score for HER2 testing using a dual probe. The test will report results for both HER2 and CEP17, the latter used as a control. The HER2/CEP17 ratio is reported.

Rationale

HER2 ISH Dual Probe Ratio is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

See HER2 for additional information.

Coding Instructions and Codes

Note 1: Physician statement of HER2 in situ hybridization (ISH) Dual Probe Ratio can be used to code this data item.

Note 2: A dual probe test will report results for both HER2 and CEP17, the latter used as a control. The HER2/CEP17 ratio will be reported. Record the ratio in this data item.

> ***Example***:
>
> SISH RESULTS: FINAL HER 2 IN SITU HYBRIDIZATION INTERPRETATION: EQUIVOCAL, INDETERMINATE. HER2 gene copy between 4 & 6 with HER2/CEP17 ratio <2.
>
> HER2/CEP17 RATIO: 4.26 / 3.13 = 1.36
>
> HER-2/neu SILVER IN SITU HYBRIDIZATION (SISH)
>
> HER-2neu gene (Inform HER2 DNA probe)
>
> Number of tumor cell nuclei counted: 120
>
> Number of Her-2/neu gene copies: 511
>
> Mean HER-2/neu gene copy number: 4.26
>
> CEP-17 SILVER IN SITU HYBRIDIZATION (SISH)
>
> CEP-17 (Inform Chromosome 17 probe)
>
> Number of cell nuclei counted: 60

DRAFT

Number of CEP-17 gene copies: 188

Mean CEP-17 gene copies/nucl: 3.13

Code Dual Probe HER2 Copy Number: 4.2

Code Dual Probe Ratio: 1.3

Note 3: Following ASCO-CAP guidelines, a 2+ (equivocal) finding by immunohistochemistry (IHC) should result in additional testing with ISH to determine gene copy number.

Note 4: Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. The same test should be used to code all the HER2 ISH data items.

Note 5: A HER2 ISH test may be called "*ERBB2.*" *ERBB2* is the standard symbol for the gene 'erb-b2 receptor tyrosine kinase 2.' An IHC test identifies the protein expressed by the gene, and an ISH test identifies the gene itself.

Note 6: If the test results are presented to the hundredth decimal, ignore the hundredth decimal. Do NOT round.

Example:
Reported as 1.99, code as 1.9

Code	Description
0.0-99.9	Ratio of 0.0 to 99.9
XX.2	Less than 2.0
XX.3	Greater than or equal to 2.0
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error.)
XX.9	Not documented in medical record Results cannot be determined (indeterminate) HER2 ISH Dual Probe Ratio not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Breast

Multigene Signature Method and Results

Definition

Multigene testing is usually done for node-negative patients to predict risk of recurrence within a specified time period or to predict the likelihood that the patient will respond to specific types of chemotherapy. Multigene testing helps tailor treatment for the woman's specific cancer characteristics. Recent studies indicate that these tests may also be helpful in planning treatment and predicting recurrence in node positive women with small tumors. Some types of tests may be specific to ER positive or negative patients or women in a certain age range. Many different types of genetic testing are available, including IHC-, FISH-, RT-PCR-, and genomic microarray-based multigene predictors.

For the Breast cases, there are 2 data items that record information on Multigene testing.

- Multigene Signature Method [NAACCR Data Item #3894]
- Multigene Signature Results [NAACCR Data Item #3895]

These two fields record the type of multigene signature test that was performed. Both fields should be coded from the same test, which may not be available at the time of diagnosis

- **Note:** In **Collaborative Stage v2 (CSv2),** Oncotype was included in these two data items. Oncotype has now been moved to separate data items. See the "Oncotype Dx" section of this manual for more information**.**

Information is collected on the following tests

- **MammaPrint:** A genomic test that analyzes the activity of certain genes in early-stage breast cancer. Developed to help make treatment decisions based on the cancer's risk of coming back (recurrence) within 10 years after diagnosis.
- **PAM 50 (Prosigna):** PAM50 stands for Prediction Analysis of Microarray 50. It tests a sample of the tumor (removed during a biopsy or surgery) for a group of 50 genes. Along with other factors, the results of the PAM50 (Prosigna) test help predict the chance of metastasis (when cancer spreads to other organs). Prosigna also helps to determine the molecular subtype of breast cancer.
- **Breast Cancer Index:** Analyzes the activity of seven genes to help predict the risk of node-negative, hormone-receptor-positive breast cancer coming back 5 to 10 years after diagnosis. The test can help women and their doctors decide if extending hormonal therapy 5 more years (for a total of 10 years of hormonal therapy) would be beneficial. The Breast Cancer Index reports two scores: how likely the cancer is to recur 5 to 10 years after diagnosis and how likely a woman is to benefit from taking hormonal therapy for a total of 10 years.
- **EndoPredict:** A genomic test for people newly diagnosed with early-stage, estrogen-receptor-positive, HER2-negative breast cancer. May be used to help make treatment decisions based on the cancer's risk of coming back in a part of the body away from the breast (distant metastasis) within 10 years after diagnosis. The EndoPredict test provides a risk score that is either low-risk or high-risk of breast cancer recurring as distant metastasis. Knowing if the cancer has a high or low risk of recurrence can help women and their doctors decide if chemotherapy or other treatments to reduce risk after surgery are needed.

Additional Information

- **Source documents**: specialty reference laboratories (private companies with proprietary testing methods); the actual report may be included in the medical record or may be referenced by the clinician.
- **Other names:** genomic profiling, multigene testing, multigene assay, microarray assay, molecular diagnostics for treatment planning

Return back to Schema ID Table

DRAFT

Breast

Multigene Signature Method

Item Length: 1
NAACCR Item #: 3894
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

Multigene signatures or classifiers are assays of a panel of genes from a tumor specimen, intended to provide a quantitative assessment of the likelihood of response to chemotherapy and to evaluate prognosis or the likelihood of future metastasis. This data item identifies the multigene signature method used. Oncotype Dx is coded elsewhere.

Rationale

Multigene Signature Method is a Registry Data Collection Variable in AJCC. It was previously collected as Breast, CS SSF #22. See also Multigene Signature Results.

See Multigene Signature Method and Results **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of the Multigene Signature Method can be used to code this data item.

Note 2: Multigene signatures or classifiers are assays of a panel of genes from a tumor specimen, intended to provide a quantitative assessment of the likelihood of response to chemotherapy and to evaluate prognosis or the likelihood of future metastasis**.**

Note 3: Code the type of test performed. The same test should be used to record information in Multigene Signature Results [NAACCR Data Item # 3895].

Note 4: Oncotype Dx tests are not recorded in this data item. See the following data items for Oncotype Dx.

- Oncotype Dx Recurrence Score-DCIS [NAACCR Data Item # 3903]
- Oncotype Dx Risk Level-DCIS [NAACCR Data Item # 3905]
- Oncotype Dx Recurrence Score-Invasive [NAACCR Data Item # 3904]
- Oncotype Dx Risk Level-Invasive [NAACCR Data Item # 3906]

Code	Description
1	Mammaprint
2	PAM50 (Prosigna)
3	Breast Cancer Index
4	EndoPredict
5	Test performed, type of test unknown
6	Multiple tests, any tests in codes 1-4
7	Test ordered, results not in chart

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

Return back to Schema ID Table

DRAFT

Breast

Multigene Signature Results

Item Length: 2
NAACCR Item #: 3895
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

Multigene signatures or classifiers are assays of a panel of genes from a tumor specimen, intended to provide a quantitative assessment of the likelihood of response to chemotherapy and to evaluate prognosis or the likelihood of future metastasis. This data item identifies the multigene signature result. Oncotype Dx is coded elsewhere.

Rationale

Multigene Signature Results is a Registry Data Collection Variable in AJCC. It was previously collected as Breast, CS SSF #23. See also Multigene Signature Method.

See Multigene Signature Method and Results **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of the Multigene Signature Results can be used to code this data item.

Note 2: Multigene signatures or classifiers are assays of a panel of genes from a tumor specimen, intended to provide a quantitative assessment of the likelihood of response to chemotherapy and to evaluate prognosis or the likelihood of future metastasis**.**

Note 3: Code the score or risk for the test performed. The same test should be used to record information in Multigene Signature Method [NAACCR Data Item # 3894].

Note 4: Oncotype Dx tests are not recorded in this data item. See the following data items for Oncotype Dx.

- Oncotype Dx Recurrence Score-DCIS [NAACCR Data Item # 3903]
- Oncotype Dx Risk Level-DCIS [NAACCR Data Item # 3905]
- Oncotype Dx Recurrence Score-Invasive [NAACCR Data Item # 3904]
- Oncotype Dx Risk Level-Invasive [NAACCR Data Item # 3906]

Note 5: PAM50 (Prosigna) is a single numeric score of 1-100. If the score is available, record the score. If only the risk level is available, record that.

Note 6: For Mammaprint, EndoPredict, and Breast Cancer Index, only record the risk level.

Code	Description
00-99	Enter actual recurrence score *Note*: Depending on the test, the range of values may be different
X1	Score 100

Code	Description
X2	Low risk
X3	Moderate [intermediate] risk
X4	High risk
X7	Test ordered, results not in chart
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record Multigene Signature Results not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Breast

Oncotype Dx Tests

The recording of Oncotype Dx was previously collected in Multigene Signature Results and Multigene Signature Method in CSv2. Oncotype Dx now has four data items

- Oncotype Dx Recurrence Score-DCIS [NAACCR Data Item # 3903]
- Oncotype Dx Risk Level-DCIS [NAACCR Data Item # 3905]
- Oncotype Dx Recurrence Score-Invasive [NAACCR Data Item # 3904]
- Oncotype Dx Risk Level-Invasive [NAACCR Data Item # 3906]

Oncotype DX DCIS Score

Definition

The Oncotype DX DCIS score is a genomic test that estimates the likelihood of local recurrence (DCIS or invasive) for a patient with DCIS. The results may be used clinically to evaluate benefits of radiation therapy following surgery.

The Oncotype DX DCIS score, a numeric value from 0-100, is coded in NAACCR Data Item #3903.

Oncotype DX DCIS Risk Level, coded in NAACCR Data Item #3905, stratifies the Oncotype DX DCIS Score into three risk levels:

- **Low risk: Recurrence Score lower than 39:** The DCIS has a lower risk of recurrence.
- **Intermediate Risk: Recurrence Score between 39 and 54:** The DCIS has an intermediate risk of recurrence.
- **High risk: Recurrence Score greater than 54:** The DCIS has a higher risk of recurrence.

Additional Information

- **Source documents:** Oncotype Dx DCIS laboratory report, other statements in medical record
- **For further information,** see http://www.oncotypeiq.com/en-US/breast-cancer/patients-and-caregivers/stage-0-dcis/about-the-test

DRAFT

Oncotype DX Breast Recurrence Score

Definition

The Oncotype DX Breast Recurrence Score test (Oncotype DX) test is a genomic test that predicts the risk of distant recurrence and likelihood of benefit chemotherapy for early stage breast cancers. It is required for assigning prognostic stage in AJCC8 for patients with T1-2 N0, M0, ER-positive, HER2 negative breast cancers. Oncotype DX provides a quantitative score, based on a continuous scale from 0-100, with higher scores reflecting higher risk of distant recurrence and higher likelihood of chemotherapy benefit.

The numeric value of the recurrence score is coded in Data Item #3906. When the actual recurrence score is not available, there is an option for coding recurrence scores stated as less than 11 or greater than equal to 11 as this the cut point determined to be clinically relevant for stage group in AJCC8. Oncotype DX Risk Level -Invasive, coded in NAACCR Data Item #3906, stratifies the Oncotype DX recurrence score into three risk levels:

- **Low risk: Recurrence Score result less than 18**: The patient has a lower risk of having a recurrence, assuming 5 years of hormonal therapy is given. Chemotherapy is likely to have little or no benefit.
- **Intermediate Risk: Recurrence Score result between 18 and 30**: The patient has a tumor that is in the middle of the risk spectrum reflecting that biology is continuous and not all patients have a low or a high recurrence risk, assuming 5 years of hormonal therapy is given. The likelihood of distant recurrence and benefit from chemotherapy increases with an increase in the Recurrence Score result.
- **High risk: Recurrence Score result greater than or equal to 31**: The patient has a high risk of distant recurrence, assuming 5 years of hormonal therapy and is likely to benefit from chemotherapy.

Additional Information

- **Source documents:** Oncotype Dx Breast Recurrence Score laboratory report, other statements in medical record
- **For further information,** see http://www.oncotypeiq.com/en-US/breast-cancer/healthcare-professionals/oncotype-dx-breast-recurrence-score/about-the-test

DRAFT

Breast

Oncotype Dx Recurrence Score-DCIS

Item Length: 3
NAACCR Item #: 3903
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

Oncotype Dx Recurrence Score-DCIS is a numeric score of a genomic test to predict the likelihood of distant recurrence of invasive breast cancer based on the assessment of 21 genes.

Rationale

Oncotype Dx Recurrence Score-DCIS is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

See Oncotype Dx Tests **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of Oncotype Dx Recurrence Score-DCIS can be used to code this data item.

Note 2: The Oncotype Dx-DCIS recurrence score is reported as a whole number between 0 and 100.

Note 3: Record only the results of an Oncotype Dx-DCIS recurrence score in this data item. If some other test is used for scoring, assign code XX9.

Note 4: If the only information available is the Oncotype Dx-DCIS Risk Level, assign XX7.

Code	Description
000-100	Enter actual recurrence score between 0 and 100
XX6	Not applicable: invasive case
XX7	Test ordered, results not in chart
XX8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX8 will result in an edit error.)
XX9	Not documented in medical record Oncotype Dx Recurrence Score-DCIS not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Breast

Oncotype Dx Risk Level-DCIS

Item Length: 1
NAACCR Item #: 3905
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

Oncotype Dx Risk Level-DCIS stratifies Oncotype Dx recurrence scores into low, intermediate, and high risk of local recurrence.

Rationale

Oncotype Dx Risk Level-DCIS is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

See Oncotype Dx Tests **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of Oncotype Dx Risk Level-DCIS can be used to code this data item.

Note 2: The Oncotype Dx Risk Level-DCIS test stratifies scores into low, intermediate, and high risk of distant recurrence. If only the score is stated, assign the risk level based on the score.

Note 3: Record only the results of an Oncotype Dx Risk Level-DCIS in this data item. If some other test is used for scoring, assign code 9.

Code	Description
0	Low risk (recurrence score 0-38)
1	Intermediate risk (recurrence score 39-54)
2	High risk (recurrence score greater than or equal to 55)
6	Not applicable: invasive case
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Oncotype Dx Risk Level-DCIS not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Breast

Oncotype Dx Recurrence Score-Invasive

Item Length: 3
NAACCR Item #: 3904
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

Oncotype Dx Recurrence Score-Invasive is a numeric score of a genomic test to predict the likelihood of distant recurrence of invasive breast cancer based on the assessment of 21 genes.

Rationale

Oncotype Dx Recurrence Score-Invasive is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

See Oncotype Dx Tests **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of Oncotype Dx Recurrence Score-Invasive score can be used to code this data item.

Note 2: The Oncotype Dx-Invasive recurrence score is reported as a whole number between 0 and 100. The actual recurrence score takes priority over codes XX4 and XX5.

Note 3: Record only the results of an Oncotype Dx-Invasive recurrence score in this data item. If some other test is used for scoring, assign code XX9.

Note 4: Staging for Breast cancer now depends on the Oncotype-Dx-Invasive recurrence score. Score of less than 11 indicates a pertinent cut off value for staging purposes.

Note 5: If the only information available is the Oncotype Dx-Invasive Risk Level, assign XX7.

Code	Description
000-100	Enter actual recurrence score between 0 and 100
XX4	Stated as less than 11
XX5	Stated as equal to or greater than 11
XX6	Not applicable: in situ case
XX7	Test ordered, results not in chart
XX9	Not documented in medical record Oncotype Dx Recurrence Score-Invasive not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Breast

Oncotype Dx Risk Level-Invasive

Item Length: 1
NAACCR Item #: 3906
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

Oncotype Dx Risk Level-Invasive stratifies Oncotype Dx recurrence scores into low, intermediate, and high risk of distant recurrence.

Rationale

Oncotype Dx Risk Level-Invasive is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

See Oncotype Dx Tests **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of Oncotype Dx Risk Level-Invasive can be used to code this data item.

Note 2: The Oncotype Dx Risk Level-Invasive test stratifies scores into low, intermediate, and high risk of distant recurrence. If only the score is stated, assign the risk level based on the score.

Note 3: Record only the results of an Oncotype Dx Risk Level-Invasive in this data item. If some other test is used for scoring, assign code 9.

Code	Description
0	Low risk (recurrence score 0-17)
1	Intermediate risk (recurrence score 18-30)
2	High risk (recurrence score greater than or equal to 31)
6	Not applicable: DCIS case
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Oncotype Dx Risk Level-Invasive not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Breast

Ki-67

Item Length: 5
NAACCR Item #: 3863
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

Ki-67 (MIB-1) is a marker of cell proliferation. A high value indicates a tumor that is proliferating more rapidly.

Rationale

Ki-67 (MIB-1) is a Registry Data Collection Variable in AJCC. It is a new data item for cases diagnosed 1/1/2018+.

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: 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

Return back to Schema ID Table

DRAFT

Breast

LN Positive Axillary Level I-II

Item Length: 2
NAACCR Item #: 3882
NAACCR Alternate Name: Lymph Nodes Positive Axillary Level I-II
AJCC 8th Edition Chapter(s): Chapter 48, Breast

Description

This data item pertains to the number of positive ipsilateral level I and II axillary lymph nodes and intramammary lymph nodes based on pathological information.

Rationale

Lymph Nodes Positive Axillary Level I-II can be collected by the surveillance community for breast cancers. Prior to 2018, Breast SSF#3 was used for Lymph Nodes Positive Axillary Level I-II.

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.

Coding guidelines

- Code 00 when all level I and II axillary lymph nodes are negative on pathological examination
- Code the exact number of lymph nodes in the range 01 to 99 for the exact count of level I and II axillary lymph nodes, or X1 if more than 99 level I and II axillary lymph nodes are positive
- Code X5 if level I and II axillary lymph nodes were positive but the number is not specified
- Code X6 if there was only a positive aspiration of level I or II axillary lymph node(s)
- Code X9 when
    - No axillary nodes were examined
    - Axillary dissection was performed but no axillary lymph nodes were found
    - Clinical diagnosis only (no axillary lymph nodes were removed)

- Unknown whether axillary lymph nodes are positive

Additional information

- **Required for Staging:** EOD only.
- **Source documents** pathology report

Coding Instructions and Codes

Note 1: Physician statement of number of positive ipsilateral Level I-II axillary nodes can be used to code this data item, when no other specific information is available.

Note 2: Include only the number of positive ipsilateral level I and II axillary lymph nodes and intramammary lymph nodes in this field. Intramammary nodes, located within the breast, are not the same as internal mammary nodes, located along the sternum.

Note 3: 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 removed during clinical workup
- If the post-neoadjuvant nodal involvement is more extensive, include only those nodes removed during surgery

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.)

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

Breast

Response to Neoadjuvant Therapy

Item Length: 1
NAACCR Item #: 3922
NAACCR Alternate Name: None
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 items 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
- 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

- **Source documents:** CAP Breast cancer protocol
- **Other names:** treatment effect

Coding Instructions and Codes

Note 1: Clinician statement of Response to Neoadjuvant Therapy ("treatment effect") must be used to code this data item.

Note 2: Review the medical record for a specific statement by a clinician about the response to neoadjuvant therapy. Response is based on pathology report, imaging and clinical findings.

Note 3: Any description of less than "total" or "complete", should be coded as 2, partial response if there is residual tumor on the report.

Code	Description
0	Neoadjuvant therapy not given
1	Stated as complete response (CR)
2	Stated as partial response (PR)
3	Stated as response to treatment, but not noted if complete or partial
4	Stated as no response (NR)
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Response to neoadjuvant therapy not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

FEMALE REPRODUCTIVE ORGANS

DRAFT

FIGO

Item Length: 2
NAACCR Item #: 3836
NAACCR Alternate Name: FIGO Stage
AJCC 8th Edition Chapter(s):

- Chapter 50: Vulva (FIGO: Vulva)
- Chapter 51: Vagina FIGO: Vagina)
- Chapter 52: Cervix Uteri (FIGO: Cervix)
- Chapter 53: Corpus Uteri - Carcinoma and Carcinosarcoma (FIGO: Corpus Carcinoma and Carcinosarcoma)
- Chapter 54: Corpus Sarcoma (FIGO Stage (Adenosarcoma) and FIGO Stage (Sarcoma))
- Chapter 55: Ovary, Fallopian Tube, and Primary Peritoneal Carcinoma (FIGO: Ovary, Fallopian Tube, and Peritoneal Carcinoma)
- Chapter 56: Gestational Trophoblastic Neoplasms (Placenta) (FIGO: Gestational Trophoblastic Tumors (Placenta))

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.

Structure of Codes

For all sites, the structure of the FIGO data items is the same, although not every chapters uses every possible FIGO code and the actual codes used are not the same for all chapters.

Coding guidelines

Code the FIGO stage as stated in the medical record. When lymph node(s) is/are clinically or pathologically positive or metastasis is present, make sure that the FIGO stage reflects the combination of T, N, and M and NOT just the T. If a stage group is stated but it does not specify that it is a FIGO stage, assume that it is a FIGO stage and code it. Do not attempt to code FIGO stage based only on T, N, and M. If you cannot make a determination of stage based on the previous information, code 99

- 01 FIGO Stage I (all chapters)
- 07 FIGO Stage IB2 (cervix only)
- 20 FIGO Stage II (all chapters)
- 34 FIGO Stage IIIA1ii (ovary, fallopian tube, and primary peritoneal carcinoma only)
- 40 FIGO Stage IV (all chapters)
- 99: FIGO Stage unknown, FIGO stage not assessed or unknown if FIGO stage assessed

Additional Information

- **Source documents:** clinician's notes, consultant notes, pathology report, radiation therapy notes

FIGO Stage: Summary of Chapters									
Code	**Description**	**Vulva**	**Vagina**	**Cervix**	**Corpus Sarcoma**	**Corpus Adeno-Sarcoma**	**Corpus Carcinoma**	**Ovary, FT, PPC**	**Placenta**
01	FIGO Stage I	X	X	X	X	X	X	X*	X
02	FIGO Stage IA	X		X	X	X	X	X	
03	FIGO Stage IA1			X					
04	FIGO Stage IA2			X					
05	FIGO Stage IB	X		X	X	X	X	X	
06	FIGO Stage IB1			X					
07	FIGO Stage IB2			X					
08	FIGO Stage IC					X		X	
09	FIGO Stage IC1							X	
10	FIGO Stage IC2							X	
11	FIGO Stage IC3							X	
20	FIGO Stage II	X	X	X	X	X	X	X	X
21	FIGO Stage IIA			X	X	X		X	
22	FIGO Stage IIA1			X				X	
23	FIGO Stage IIA2			X					
24	FIGO Stage IIB			X	X	X			
30	FIGO Stage III	X	X	X	X	X	X	X	X
31	FIGO Stage IIIA	X		X	X	X	X	X	
32	FIGO Stage IIIA1							X	
33	FIGO Stage IIIA1i							X	
34	FIGO Stage IIIA1ii							X	

FIGO Stage: Summary of Chapters									
Code	**Description**	**Vulva**	**Vagina**	**Cervix**	**Corpus Sarcoma**	**Corpus Adeno-Sarcoma**	**Corpus Carcinoma**	**Ovary, FT, PPC**	**Placenta**
35	FIGO Stage IIIA2							X	
36	FIGO Stage IIIB	X		X	X	X	X	X	
37	FIGO Stage IIIC	X			X	X	X	X	
38	FIGO Stage IIIC1					X	X		
39	FIGO Stage IIIC2					X			
40	FIGO Stage IV	X	X	X	X	X	X	X	X
41	FIGO Stage IVA	X	X	X	X	X	X	X	
42	FIGO Stage IVB	X	X	X	X	X	X	X	

Not applicable for Primary Peritoneal Carcinoma

In addition to the codes listed above, the following codes are also applicable to all chapters

97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage unknown, not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Lymph Node Assessment Methods and Status for Regional and Distant Lymph Nodes in GYN sites

Definition

In addition to assigning the N categories for cervix, vagina and vulva cancers, the collection of specific lymph nodes and how they were assessed is important.

- Status refers to positive or negative involvement
- Assessment is the method by which the nodal status was determined

There are 4 data items that collect information on regional lymph nodes. One data item collects the status (positive, negative, unknown) involvement of femoral-inguinal, para-aortic and pelvic lymph nodes. There are 3 assessment data items that collect individual status information on the 3 regional lymph node groups

- LN Assessment Method Femoral-Inguinal [NAACCR Data Item #3871]
- LN Assessment Method Para-Aortic [NAACCR Data Item #38712
- LN Assessment Method Pelvic [NAACCR Data Item #3873]
- LN Status Femoral-Inguinal, Para-Aortic, Pelvic [NAACCR Data Item #3884]

There are 2 data items that collect information on distant lymph nodes. One data item collects the status (positive, negative, unknown) involvement of mediastinal and scalene distant lymph nodes. The other data item collects the assessment method.

- LN Distant Assessment Method [NAACCR Data Item #3874]
- LN Distant: Mediastinal, Scalene [NAACCR Data Item #3875]

For the 2 status fields, the data items have a basic set up

- Code 0 when all lymph nodes are negative
- Multiple codes are available to record single or multiple involvement of lymph nodes
- Code 9 when
    - Not documented in medical record
    - Regional/Distant lymph nodes not evaluated (assessed)
    - Unknown if regional/distant lymph nodes evaluated (assessed)

For the 4 methods fields, the codes are the same

- Code 0 when there is physical exam or imaging only
- Code 1 when there is an incisional biopsy or FNA
- Code 2 when there is an excisional biopsy or lymph node resection
- Code 7 when lymph nodes are assessed, but it is unknown how
- Code 9 when
    - Not documented in medical record
    - Regional/Distant lymph nodes not evaluated (assessed)
    - Unknown if regional/distant lymph nodes evaluated (assessed)

DRAFT

Vulva

FIGO: Vulva

Item Length: 2
NAACCR Item #: 3836
NAACCR Alternate Name: FIGO Stage
AJCC 8th Edition Chapter(s): Chapter 50, Vulva

Note 1: Take the highest Federation Internationale de Gynecologie et d'Obstetrique (FIGO) stage documented in the medical record. Do not attempt to code FIGO stage based only on T, N, and M. If FIGO stage is not documented in the medical record, code 99. FIGO stage is not the same as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

Note 2: If a stage group is stated but it does not specify that it is a FIGO stage, assume that it is a FIGO stage and code it.

Note 3: The FIGO stage definitions do not include Stage 0 (Tis). Code 97 for any case that is in situ (/2).

Code	Description
01	FIGO Stage I
02	FIGO Stage IA
05	FIGO Stage IB
20	FIGO Stage II
30	FIGO Stage III
31	FIGO Stage IIIA
36	FIGO Stage IIIB
37	FIGO Stage IIIC
40	FIGO Stage IV
41	FIGO Stage IVA
42	FIGO Stage IVB
97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage unknown, not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Vulva

LN Assessment Method Femoral-Inguinal

Item Length: 1
NAACCR Item #: 3871
NAACCR Alternate Name: Lymph Nodes Assessment Method Femoral-Inguinal
AJCC 8th Edition Chapter(s):

- Chapter 50: Vulva
- Chapter 51: Vagina

Description

This data item describes the method used to assess involvement of femoral-inguinal lymph nodes associated with certain female genital cancers.

Rationale

Method of assessment of regional nodal status is listed as a Registry Data Collection Variable in the AJCC GYN chapters. This data item was previously collected as Vulva, SSF #15.

See Lymph Node Assessment Methods and Status for Regional and Distant Lymph Nodes in GYN sites **for additional information**

Coding Instructions and Codes

Note 1: Physician statement of femoral-inguinal assessment method can be used to code this data item when no other information is available.

Note 2: Assign the highest applicable code (0-2) in the case of multiple assessments.

Note 3: The assessment results are recorded in LN Assessment Method Femoral-Inguinal [NAACCR Data Item # 3884].

Code	Description
0	Radiography, imaging (Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI), positron emission tomography scan (PET)) Physical exam only
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy Excisional biopsy or resection with microscopic confirmation
7	Regional lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Regional lymph nodes not assessed or unknown if assessed

Vulva

LN Assessment Method Para-Aortic

Item Length: 1
NAACCR Item #: 3872
NAACCR Alternate Name: Lymph Nodes Assessment Method Para-aortic
AJCC 8th Edition Chapter(s):

- Chapter 50: Vulva
- Chapter 51: Vagina

Description

This data item describes the method used to assess involvement of para-aortic lymph nodes associated with certain female genital cancers.

Rationale

Method of assessment of regional nodal status is listed as a Registry Data Collection Variable in the AJCC GYN chapters. This data item was previously collected as Vagina, CS SSF# 5.

See Lymph Node Assessment Methods and Status for Regional and Distant Lymph Nodes in GYN sites **for additional information**

Coding Instructions and Codes

Note 1: Physician statement of para-aortic assessment of nodal status for para-aortic nodes can be used to code this data item when no other information is available.

Note 2: Assign the highest applicable code (0-2) in the case of multiple assessments.

Note 3: The assessment results are recorded in LN Assessment Method Femoral-Inguinal [NAACCR Data Item # 3884].

Code	Description
0	Radiography, imaging (Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI), positron emission tomography scan (PET)) Physical exam only
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy Excisional biopsy or resection with microscopic confirmation
7	Regional lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Regional lymph nodes not assessed or unknown if assessed

Vulva

LN Assessment Method Pelvic

Item Length: 1
NAACCR Item #: 3873
NAACCR Alternate Name: Lymph Nodes Assessment Method Pelvic
AJCC 8th Edition Chapter(s):

- Chapter 50: Vulva
- Chapter 51: Vagina

Description

This data item describes the method used to assess involvement of pelvic lymph nodes associated with certain female genital cancers.

Rationale

Method of assessment of regional nodal status is listed as a Registry Data Collection Variable in the AJCC GYN chapters. This data item was previously collected as Vagina, CS SSF# 3.

See Lymph Node Assessment Methods and Status for Regional and Distant Lymph Nodes in GYN sites **for additional information**

Coding Instructions and Codes

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

Note 2: Assign the highest applicable code (0-2) in the case of multiple assessments.

Note 3: The assessment results are recorded in LN Assessment Method Femoral-Inguinal [NAACCR Data Item # 3884].

Code	Description
0	Radiography, imaging (Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI), positron emission tomography scan (PET)) Physical exam only
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy Excisional biopsy or resection with microscopic confirmation
7	Regional lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Regional lymph nodes not assessed or unknown if assessed

Vulva

LN Status Femoral-Inguinal, Para-Aortic, Pelvic

Item Length: 1
NAACCR Item #: 3884
NAACCR Alternate Name: Lymph Nodes Status: Femoral-Inguinal, Para-aortic and Pelvic
AJCC 8th Edition Chapter(s):

- Chapter 50: Vulva
- Chapter 51: Vagina

Description

This data item describes the status of femoral-inguinal, para-aortic and pelvic lymph nodes associated with certain female genital cancers.

Rationale

Specific regional lymph node involvement is listed as a Registry Data Collection Variable in AJCC. This information was previously collected as Vagina, CS SSF# 2 and CS SSF#4

See Lymph Node Assessment Methods and Status for Regional and Distant Lymph Nodes in GYN sites **for additional information**

Coding Instructions and Codes

Note 1: Physician statement of femoral-inguinal, para-aortic and pelvic nodal status can be used to code this data item when no other information is available.

Note 2: Assign the highest applicable code (1-7) in the case of positive nodes.

Note 3: If a nodal station is in the area being imaged, biopsied, or in the surgical field and there is no mention of involvement, then assume that specific nodal station is negative.

Note 4: If there is no imaging, biopsy, or surgical work up, code 9.

Note 5: The assessment methods are recorded in

- LN Assessment Method Femoral-Inguinal [NAACCR Data Item #3871]
- LN Assessment Method Para-Aortic [NAACCR Data Item #38712
- LN Assessment Method Pelvic [NAACCR Data Item #3873]

Code	Description
0	Negative femoral-inguinal, para-aortic and pelvic lymph nodes
1	Positive femoral-inguinal lymph nodes
2	Positive para-aortic lymph nodes
3	Positive pelvic lymph nodes
4	Positive femoral-inguinal and para-aortic lymph nodes
5	Positive femoral-inguinal and pelvic lymph nodes
6	Positive para-aortic and pelvic lymph nodes

Code	Description
7	Positive para-aortic, pelvic, and femoral-inguinal lymph nodes
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Femoral-Inguinal, Para-Aortic and Pelvic lymph nodes not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Vulva

LN Laterality

Item Length: 1
NAACCR Item #: 3881
NAACCR Alternate Name: Lymph Nodes Laterality
AJCC 8th Edition Chapter(s): Chapter 50, Vulva

Description

This data item describes whether positive regional lymph nodes are unilateral or bilateral.

Rationale

Laterality of regional node metastasis is a Registry Data Collection Variable in AJCC. This data item was previously collected as Vulva, CS SSF# 11.

Definition

This data item records the appropriate description of involved regional lymph nodes, specifically whether they are unilateral or bilateral involvement.

Coding guidelines

- Code the appropriate description of involved regional lymph nodes
- Code 0 when all regional lymph nodes are negative
- Code 1 when
    - all positive regional nodes are ipsilateral
    - involved lymph nodes are described as unilateral
- Code 2 when
    - at least one regional lymph node is involved on each side of the pelvis
    - involvement is described as bilateral or contralateral
- Code 3 when regional lymph node(s) are described as positive but the laterality of the involved nodes is unknown
- Code 9 when
    - Lymph nodes were not examined or assessed
    - there is no information in the medical record about regional lymph node involvement
    - the status of regional lymph nodes is unknown

Additional Information

- **Source documents:** pathology report, imaging, physical exam, other statement in record

Coding Instructions and Codes

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

Code	Description
0	No regional lymph node involvement
1	Unilateral - all positive regional nodes with same laterality OR only one regional node positive
2	Bilateral - positive bilateral regional lymph nodes
3	Laterality unknown - positive regional lymph nodes with unknown laterality
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Lymph node laterality not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Vagina

FIGO: Vagina

Item Length: 2
NAACCR Item #: 3836
NAACCR Alternate Name: FIGO Stage
AJCC 8th Edition Chapter(s): Chapter 51, Vagina

Note 1: Take the highest Federation Internationale de Gynecologie et d'Obstetrique (FIGO) stage documented in the medical record. Do not attempt to code FIGO stage based only on T, N, and M. If FIGO stage is not documented in the medical record, code 99. FIGO stage is not the same as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

Note 2: If a stage group is stated but it does not specify that it is a FIGO stage, assume that it is a FIGO stage and code it.

Note 3: The FIGO stage definitions do not include Stage 0 (Tis). Code 97 for any case that is in situ (/2).

Code	Description
01	FIGO Stage I
20	FIGO Stage II
30	FIGO Stage III
40	FIGO Stage IV
41	FIGO Stage IVA
42	FIGO Stage IVB
97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage unknown, not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Vagina

For the following data items, see Vulva

- LN Assessment Method Femoral-Inguinal
- LN Assessment Method Para-Aortic
- LN Assessment Method Pelvic
- LN Status Femoral-Inguinal, Para-Aortic, Pelvic

Return back to Schema ID Table

DRAFT

Vagina

LN Distant Assessment Method

Item Length: 1
NAACCR Item #: 3874
NAACCR Alternate Name: Lymph Nodes Distant Assessment Method
AJCC 8th Edition Chapter(s):

- Chapter 51: Vagina
- Chapter 52: Cervix

Description

This data item describes the method used to assess involvement of Distant (mediastinal, scalene) nodes associated with certain female genital cancers.

Rationale

Method of assessment of distant nodal status is listed as a Registry Data Collection Variable in the AJCC GYN chapters. This data item was previously collected as Vagina, CS SSF# 7.

See Lymph Node Assessment Methods and Status for Regional and Distant Lymph Nodes in GYN sites **for additional information**

Coding Instructions and Codes

Note 1: Physician statement of Mediastinal and Scalene assessment method can be used to code this data item when no other information is available.

Note 2: Assign the highest applicable code (0-2) in the case of multiple assessments.

Note 3: The assessment results are recorded in LN Distant: Mediastinal, Scalene [NAACCR Data Item # 3875].

Code	Description
0	Radiography, imaging (Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI), positron emission tomography scan (PET)) Physical exam only
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy Excisional biopsy or resection with microscopic confirmation
7	Distant lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Distant lymph nodes not assessed or unknown if assessed

Vagina

LN Distant: Mediastinal, Scalene

Item Length: 1
NAACCR Item #: 3875
NAACCR Alternate Name: Lymph Nodes Distant: Mediastinal, Scalene
AJCC 8th Edition Chapter(s):

- Chapter 51: Vagina
- Chapter 52: Cervix

Description

This data item describes the status of Distant (mediastinal, scalene) nodes associated with certain female genital cancers.

Rationale

Specific distant lymph node involvement is listed as a Registry Data Collection Variable in the AJCC. This data was previously collected as Vagina, CS SSF# 6.

See Lymph Node Assessment Methods and Status for Regional and Distant Lymph Nodes in GYN sites **for additional information**

Coding Instructions and Codes

Note 1: Physician statement of mediastinal and scalene nodal status can be used to code this data item when no other information is available.

Note 2: Assign the highest applicable code (1-3) in the case of positive nodes.

Note 3: If a nodal station is in the area being imaged, biopsied, or in the surgical field and there is no mention of involvement, then assume that specific nodal station is negative.

Note 4: Code 9 is used when there is no relevant nodal information from diagnostic work up, biopsy or surgical resection documented.

Note 5: The assessment method is recorded in LN Distant Assessment Method [NAACCR Data Item # 3874].

Code	Description
0	Negative mediastinal and scalene lymph nodes
1	Positive mediastinal lymph nodes
2	Positive scalene lymph nodes
3	Positive mediastinal and scalene lymph nodes
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Mediastinal and scalene lymph nodes not assessed or unknown if assessed

Cervix

FIGO: Cervix

Item Length: 2
NAACCR Item #: 3836
NAACCR Alternate Name: FIGO Stage
AJCC 8th Edition Chapter(s): Chapter 52: Cervix

Note 1: Take the highest Federation Internationale de Gynecologie et d'Obstetrique (FIGO) stage documented in the medical record. Do not attempt to code FIGO stage based only on T, N, and M. If FIGO stage is not documented in the medical record, code 99. FIGO stage is not the same as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

Note 2: If a stage group is stated but it does not specify that it is a FIGO stage, assume that it is a FIGO stage and code it.

Note 3: The FIGO stage definitions do not include Stage 0 (Tis). Code 97 for any case that is in situ (/2).

Code	Description
01	FIGO Stage I
02	FIGO Stage IA
03	FIGO Stage IA1
04	FIGO Stage IA2
05	FIGO Stage IB
06	FIGO Stage IB1
07	FIGO Stage IB2
20	FIGO Stage II
21	FIGO Stage IIA
22	FIGO Stage IIA1
23	FIGO Stage IIA2
24	FIGO Stage IIB
30	FIGO Stage III
31	FIGO Stage IIIA
36	FIGO Stage IIIB
40	FIGO Stage IV
41	FIGO Stage IVA
42	FIGO Stage IVB
97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage unknown, not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Cervix

For the following data items, see Vulva

- LN Assessment Method Femoral-Inguinal
- LN Assessment Method Para-Aortic
- LN Assessment Method Pelvic
- LN Status Femoral-Inguinal, Para-Aortic, Pelvic

For the following data items, see Vagina

- LN Distant Assessment Method
- LN Distant: Mediastinal, Scalene

Return back to Schema ID Table

DRAFT

Corpus Carcinoma and Carcinosarcoma

FIGO: Corpus Carcinoma and Carcinosarcoma

Item Length: 2
NAACCR Item #: 3836
NAACCR Alternate Name: FIGO Stage
AJCC 8th Edition Chapter(s): Chapter 53, Corpus Uteri-Carcinoma and Carcinosarcoma

Note 1: Take the highest Federation Internationale de Gynecologie et d'Obstetrique (FIGO) stage documented in the medical record. Do not attempt to code FIGO stage based only on T, N, and M. If FIGO stage is not documented in the medical record, code 99. FIGO stage is not the same as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

Note 2: If a stage group is stated but it does not specify that it is a FIGO stage, assume that it is a FIGO stage and code it.

Note 3: The FIGO stage definitions do not include Stage 0 (Tis). Code 97 for any case that is in situ (/2).

Code	Description
01	FIGO Stage I
02	FIGO Stage IA
05	FIGO Stage IB
20	FIGO Stage II
30	FIGO Stage III
31	FIGO Stage IIIA
36	FIGO Stage IIIB
37	FIGO Stage IIIC
38	FIGO Stage IIIC1
39	FIGO Stage IIIC2
40	FIGO Stage IV
41	FIGO Stage IVA
42	FIGO Stage IVB
97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage unknown, not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Corpus Carcinoma and Carcinosarcoma

Number of Positive and Examined Para-Aortic and Pelvic Nodes

Definition

Involvement of regional and distant lymph nodes is an important prognostic factor for cancers of the gynecologic organs. The following list shows the regional and common distant lymph nodes for GYN cancers.

- Common iliac
- External iliac
- Femoral
- Inguinal
- Internal iliac (hypogastric)
- Mediastinal (thoracic cavity)
- Para-Aortic
- Pelvic nodes, NOS
- Scalene (above clavicle)

For the Corpus cases, there are 4 data items that record information on the number of positive and examined para-aortic and pelvic lymph nodes. These data items should be coded from the same procedure

- Number of Positive Para-Aortic Nodes [NAACCR Data Item #3901]
- Number of Examined Para-Aortic Nodes [NAACCR Data Item #3899]
- Number of Positive Pelvic Nodes [NAACCR Data Item #3902]
- Number of Examined Pelvic Nodes [NAACCR Data Item #3900]

Number of nodes positive must ALWAYS be less than or equal to number of nodes examined.

Additional Information

Source documents: pathology report, imaging reports, physical exam, other statements in medical record

Return back to Schema ID Table

DRAFT

Corpus Carcinoma and Carcinosarcoma

Number of Positive Para-Aortic Nodes

Item Length: 2
NAACCR Item #: 3901
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 53: Corpus Uteri-Carcinoma and Carcinosarcoma
- Chapter 54: Corpus Uteri-Sarcoma

Description

Number of Positive Para-Aortic Nodes is the number of positive nodes based on para-aortic nodal dissection.

Rationale

Number of Positive Para-Aortic Nodes is listed as a Registry Data Collection Variable in AJCC. This data item was previously collected as Corpus, CS SSF# 5.

Coding guidelines

- Code 00 for when there are no positive nodes
- Code the exact number of positive nodes 01-99
- Code X1 for 100 or more positive nodes
- Code X2 for positive nodes, but unknown how many
- Code X6 for aspiration or core biopsy of para-aortic node(s) only
- Code X9 when
  - Not documented in the medical record
  - Para-Aortic lymph nodes not evaluated (assessed)
  - Unknown if Para-Aortic lymph nodes evaluated (assessed)

See Number of Positive and Examined Para-Aortic and Pelvic Nodes **for additional information**

Coding Instructions and Codes

Note 1: Physician statement of positive para-aortic nodes can be used to code this data item when no other information is available.

Note 2: Record the number of positive para-aortic lymph nodes documented in the medical record.

Note 3: For this data item, do not include isolated tumor cells (ITCs).

Note 4: Micrometastasis and macrometastasis may be listed separately on the pathology report. Add these two together to get the total number of positive nodes.

Note 5: The number of examined para-aortic nodes is recorded in Number of Examined Para-Aortic Nodes [NAACCR Data Item # 3899].

Code	Description
00	All para-aortic lymph nodes examined negative
01-99	1-99 para-aortic lymph nodes positive (Exact number of nodes positive)
X1	100 or more para-aortic nodes positive
X2	Positive para-aortic nodes identified, number unknown
X6	Positive aspiration or core biopsy of para-aortic lymph node(s)
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record Cannot be determined, indeterminate if positive para-aortic nodes present Para-aortic lymph nodes not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Corpus Carcinoma and Carcinosarcoma

Number of Examined Para-Aortic Nodes

Item Length: 2
NAACCR Item #: 3899
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 53: Corpus Uteri-Carcinoma and Carcinosarcoma
- Chapter 54: Corpus Uteri-Sarcoma

Description

Number of Examined Para-Aortic nodes is the number of nodes examined based on para-aortic nodal dissection.

Rationale

Number of Examined Para-Aortic Nodes is listed as a Registry Data Collection Variable in AJCC. This data item was previously collected as Corpus, CS SSF# 6.

Coding guidelines

- Code 00 for when no nodes are examined
- Code the exact number of examined nodes 01-99
- Code X1 for 100 or more examined nodes
- Code X2 for examined nodes, but unknown how many
- Code X6 for aspiration or core biopsy of para-aortic node(s) only
- Code X9 when
    - Not documented in the medical record
    - Para-Aortic lymph nodes not evaluated (assessed)
    - Unknown if Para-Aortic lymph nodes not evaluated (assessed)

See Number of Positive and Examined Para-Aortic and Pelvic Nodes **for additional information**

Coding Instructions and Codes

Note 1: Physician statement of examined para-aortic nodes can be used to code this data item when no other information is available.

Note 2: Record the number of examined para-aortic lymph nodes documented in the medical record.

Note 3: For this data item, do not include isolated tumor cells (ITCs).

Note 4: The number of positive para-aortic nodes is recorded in Number of Positive Para-Aortic Nodes [NAACCR Data Item # 3901].

Code	Description
00	No para-aortic nodes examined

Code	Description
01-99	1 - 99 para-aortic nodes examined (Exact number of para-aortic lymph nodes examined)
X1	100 or more para-aortic nodes examined
X2	Para-aortic nodes examined, number unknown
X6	No para-aortic lymph nodes removed, but aspiration or core biopsy of para-aortic node(s) only
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record Cannot be determined, indeterminate if examined para-aortic nodes present Para-aortic lymph nodes not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Corpus Carcinoma and Carcinosarcoma

Number of Positive Pelvic Nodes

Item Length: 2
NAACCR Item #: 3902
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 53: Corpus Uteri-Carcinoma and Carcinosarcoma
- Chapter 54: Corpus Uteri-Sarcoma

Description

Number of Positive Pelvic Nodes is the number of positive nodes based on pelvic nodal dissection.

Rationale

Number of Positive Pelvic Nodes is listed as a Registry Data Collection Variable in AJCC. This data item was previously collected as Corpus, CS SSF# 3.

See Number of Positive and Examined Para-Aortic and Pelvic Nodes **for additional information**

Coding guidelines

- Code 00 for when there are no positive nodes
- Code the exact number of positive nodes 01-99
- Code X1 for 100 or more positive nodes
- Code X2 for positive nodes, but unknown how many
- Code X6 for aspiration or core biopsy of pelvic node(s) only
- Code X9 when
    - Not documented in the medical record
    - Pelvic lymph nodes not evaluated (assessed)
    - Unknown if Pelvic lymph nodes evaluated (assessed)

Additional Information

- **Source documents:** pathology report, imaging reports, physical exam, other statements in medical record

Coding Instructions and Codes

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

Note 2: Record the number of positive pelvic lymph nodes documented in the medical record.

Note 3: For this data item, do not include isolated tumor cells (ITCs).

Note 4: Micrometastasis and macrometastasis may be listed separately on the pathology report. Add these two together to get the total number of positive nodes.

DRAFT

Note 5: The number of examined pelvic nodes is recorded in Number of Examined Pelvic Nodes [NAACCR Data Item # 3900].

Code	Description
00	All pelvic nodes examined negative
01-99	1 - 99 pelvic nodes positive (Exact number of nodes positive)
X1	100 or more pelvic nodes positive
X2	Positive pelvic nodes identified, number unknown
X6	Positive aspiration or core biopsy of pelvic lymph node(s)
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record Cannot be determined, indeterminate if positive pelvic nodes present Pelvic lymph nodes not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Corpus Carcinoma and Carcinosarcoma

Number of Examined Pelvic Nodes

Item Length: 2
NAACCR Item #: 3900
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 53: Corpus Uteri-Carcinoma and Carcinosarcoma
- Chapter 54: Corpus Uteri-Sarcoma

Description

Number of Examined Pelvic Nodes is the number of nodes examined based on pelvic nodal dissection.

Rationale

Number of Examined Pelvic Nodes is listed as a Registry Data Collection Variable in AJCC. This data item was previously collected as Corpus, CS SSF# 4.

Coding guidelines

- Code 00 for when no nodes are examined
- Code the exact number of examined nodes 01-99
- Code X1 for 100 or more examined nodes
- Code X2 for nodes examined, but unknown how many
- Code X6 for aspiration or core biopsy of pelvic(s) nodes only
- Code X9 when
    - Not documented in the medical record
    - Pelvic lymph nodes not evaluated (assessed)
    - Unknown if Pelvic lymph nodes not evaluated (assessed)

See Number of Positive and Examined Para-Aortic and Pelvic Nodes **for additional information**

Coding Instructions and Codes

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

Note 2: Record the number of examined pelvic lymph nodes documented in the medical record.

Note 3: For this data item, do not include isolated tumor cells (ITCs).

Note 4: The number of positive pelvic nodes is recorded in Number of Positive Pelvic Nodes [NAACCR Data Item # 3902]

Code	Description
00	No pelvic lymph nodes examined
01-99	1 - 99 pelvic lymph nodes examined (Exact number of pelvic lymph nodes examined)

DRAFT

Code	Description
X1	100 or more pelvic nodes examined
X2	Pelvic nodes examined, number unknown
X6	No pelvic lymph nodes removed, but aspiration or core biopsy of pelvic node(s) only
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record Cannot be determined, indeterminate if examined pelvic nodes present Pelvic lymph nodes not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Corpus Carcinoma and Carcinosarcoma

Peritoneal Cytology

Item Length: 1
NAACCR Item #: 3911
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 53: Corpus-Uteri Carcinoma and Carcinosarcoma
- Chapter 54: Corpus-Uteri Sarcoma

Required for Staging: EOD only (needed for Derived EOD T), for the following schemas:
- Corpus Adenosarcoma
- Corpus Carcinoma and Carcinosarcoma
- Corpus Sarcoma

Description

Peritoneal cytology pertains to the results of cytologic examination for malignant cells performed on fluid that is obtained from the peritoneal cavity.

Rationale

Peritoneal Cytology is listed as a Registry Data Collection Variable in AJCC. This data item was previously collected as Corpus, CS SSF# 2.

Definition

Peritoneal cytology looks for malignant cells in the fluid in the pelvic and peritoneal cavities. Excess natural fluid accumulation is called ascites. If, at laparotomy an analyzable amount of ascites is not present, the surgeon may flood the pelvis and abdomen with saline solution then suction it out and send the fluid for cytologic examination.

Additional Information

- **Source documents:** cytology reports (look for multiple reports), pathology report
- **Other names:** peritoneal washings, peritoneal lavage, possibly paracentesis (if no surgery)

Coding guidelines

- Code 0 when the peritoneal cytology is reported as negative or normal
- Code 1 when the peritoneal cytology test was done and the results were reported as suspicious, undetermined if negative or positive
- Code 2 when the peritoneal cytology is reported as positive
- Code 7 when test was ordered but the results are not in the medical record
- Code 9 when
    - No cytological specimen is available
    - Peritoneal cytology not evaluated (assessed)
    - Unknown if Peritoneal Cytology evaluated (assessed)

DRAFT

Coding Instructions and Codes

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

Note 2: Peritoneal cytology may also be called peritoneal ascitic fluid instead of peritoneal washing or pelvic washing.

Note 3: Cytologic examination for malignant cells may be performed on ascites (fluid that has accumulated in the peritoneal cavity in excess amount) or the fluid (saline) that is introduced into the peritoneal cavity or pelvis, and then removed by suction. The introduction of fluid may be termed peritoneal or pelvic washing or peritoneal lavage.

Code	Description
0	Peritoneal cytology/washing negative for malignancy
1	Peritoneal cytology/washing atypical and/or suspicious
2	Peritoneal cytology/washing malignant (positive for malignancy)
3	Unsatisfactory/nondiagnostic
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record Peritoneal cytology not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Corpus Adenosarcoma

FIGO Stage (Adenosarcoma)

Item Length: 2
NAACCR Item #: 3836
NAACCR Alternate Name: FIGO Stage
AJCC 8th Edition Chapter(s): Chapter 54: Corpus-Uteri Sarcoma

Note 1: Take the highest Federation Internationale de Gynecologie et d'Obstetrique (FIGO) stage documented in the medical record. Do not attempt to code FIGO stage based only on T, N, and M. If FIGO stage is not documented in the medical record, code 99. FIGO stage is not the same as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

Note 2: If a stage group is stated but it does not specify that it is a FIGO stage, assume that it is a FIGO stage and code it.

Note 3: The FIGO stage definitions do not include Stage 0 (Tis). Code 97 for any case that is in situ (/2).

Code	Description
01	FIGO Stage I
02	FIGO Stage IA
05	FIGO Stage IB
08	FIGO Stage IC
20	FIGO Stage II
21	FIGO Stage IIA
24	FIGO Stage IIB
30	FIGO Stage III
31	FIGO Stage IIIA
36	FIGO Stage IIIB
37	FIGO Stage IIIC
40	FIGO Stage IV
41	FIGO Stage IVA
42	FIGO Stage IVB
97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage unknown, not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Corpus Adenosarcoma

For the following data items, see Corpus Carcinoma and Carcinosarcoma

- Number of Positive Para-Aortic Nodes
- Number of Examined Para-Aortic Nodes
- Number of Positive Pelvic Nodes
- Number of Examined Pelvic Nodes
- Peritoneal Cytology

Return back to Schema ID Table

DRAFT

Corpus Sarcoma

FIGO Stage (Sarcoma)

Item Length: 2
NAACCR Item #: 3836
NAACCR Alternate Name: FIGO Stage
AJCC 8th Edition Chapter(s): Chapter 54, Corpus-Uteri Sarcoma

Note 1: Take the highest Federation Internationale de Gynecologie et d'Obstetrique (FIGO) stage documented in the medical record. Do not attempt to code FIGO stage based only on T, N, and M. If FIGO stage is not documented in the medical record, code 99. FIGO stage is not the same as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

Note 2: If a stage group is stated but it does not specify that it is a FIGO stage, assume that it is a FIGO stage and code it.

Note 3: The FIGO stage definitions do not include Stage 0 (Tis). Code 97 for any case that is in situ (/2).

Code	Description
01	FIGO Stage I
02	FIGO Stage IA
05	FIGO Stage IB
20	FIGO Stage II
21	FIGO Stage IIA
24	FIGO Stage IIB
30	FIGO Stage III
31	FIGO Stage IIIA
36	FIGO Stage IIIB
37	FIGO Stage IIIC
40	FIGO Stage IV
41	FIGO Stage IVA
42	FIGO Stage IVB
97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage unknown, not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Corpus Sarcoma

For the following data items, see Corpus Carcinoma and Carcinosarcoma

- Number of Positive Para-Aortic Nodes
- Number of Examined Para-Aortic Nodes
- Number of Positive Pelvic Nodes
- Number of Examined Pelvic Nodes
- Peritoneal Cytology

Return back to Schema ID Table

DRAFT

Ovary, Fallopian Tube, and Peritoneal Carcinoma

FIGO: Ovary, Fallopian Tube, and Peritoneal Carcinoma

Item Length: 2
NAACCR Item #: 3836
NAACCR Alternate Name: FIGO Stage
AJCC 8th Edition Chapter(s): Chapter 55, Ovary, Fallopian Tube, and Peritoneal Carcinoma

Note 1: Take the highest Federation Internationale de Gynecologie et d'Obstetrique (FIGO) stage documented in the medical record. Do not attempt to code FIGO stage based only on T, N, and M. If FIGO stage is not documented in the medical record, code 99. FIGO stage is not the same as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

Note 2: If a stage group is stated but it does not specify that it is a FIGO stage, assume that it is a FIGO stage and code it.

Note 3: The FIGO stage definitions do not include Stage 0 (Tis). Code 97 for any case that is in situ (/2).

Code	Description
01	FIGO Stage I
02	FIGO Stage IA
05	FIGO Stage IB
08	FIGO Stage IC
09	FIGO Stage IC1
10	FIGO Stage IC2
11	FIGO Stage IC3
20	FIGO Stage II
21	FIGO Stage IIA
24	FIGO Stage IIB
30	FIGO Stage III
31	FIGO Stage IIIA
32	FIGO Stage IIIA1
33	FIGO Stage IIIA1i
34	FIGO Stage IIIA1ii
35	FIGO Stage IIIA2
36	FIGO Stage IIIB
37	FIGO Stage IIIC
40	FIGO Stage IV
41	FIGO Stage IVA
42	FIGO Stage IVB
97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage unknown, not assessed or unknown if assessed

DRAFT

Ovary, Fallopian Tube, and Peritoneal Carcinoma

CA-125 Pretreatment Interpretation

Item Length: 1
NAACCR Item #: 3818
NAACCR Alternate Name: CA-125 (Carbohydrate Antigen 125) Pretreatment Interpretation
AJCC 8th Edition Chapter(s): Chapter 55, Ovary, Fallopian Tube, and Primary Peritoneal Carcinoma

Description

Carbohydrate Antigen 125 (CA-125) is a tumor marker that is useful for following the response to therapy in patients with ovarian cancer, who may have elevated levels of this marker.

Rationale

Preoperative CA-125 is a Registry Data Collection Variable listed in AJCC. It was previously collected as Ovary, CS SSF# 1.

Definition

CA-125 is a tumor marker that is not specific to ovarian or primary peritoneal cancer but is useful to monitor for success of treatment and recurrence. Because it can be elevated in many diseases affecting the peritoneal lining of the abdominal and pelvic cavity, it is not a screening test for women who have no history of cancer. Any value over 35 is highly correlated with cancer and about 80% of ovarian cancers show an elevated CA-125. However, a result in the normal range does not rule out cancer. Values up to 65 U/ml may be considered borderline, and values over 200 are unlikely to be due to a benign condition. CA-125 monitors for success of treatment and recurrence. After obtaining a baseline value prior to treatment, a lower result on a subsequent test indicates a response to treatment, and an increasing value indicates possible recurrence.

Coding guidelines

Record the clinician's interpretation of the highest value prior to treatment from a blood or serum test, based on the reference range used by the lab. Do not code the result from thoracentesis or paracentesis fluid.

- Code 0 when the CA-125 is reported as negative or normal.
- Code 1 when the CA-125 is reported as positive or elevated.
- Code 2 when the CA-125 is reported as borderline; undetermined whether positive or negative.
- Code 7 when the CA-125 test was ordered but the results are not in the medical record.
- Code 9 when
    - No information in the medical record
    - CA-125 test not done (not assessed)
    - Unknown if CA-125 test was performed (unknown if assessed)

Additional Information

- **Source documents:** clinical laboratory report (blood or serum test); may be reported in history, clinician or consultant notes or pathology report
- **Other names:** Cancer Antigen 125, CA 125, CA125, Carbohydrate Antigen 125, mucin 16, MUC16
- **Normal reference range**
    - < 35 units per milliliter (U/ml); SI: < 35 kiloUnits/Liter (KU/L).
    - May also be reported as micrograms/milliliter (µg/mL or ug/mL).
    - Normal reference range may vary depending on the laboratory running the test.

Coding Instructions and Codes

Note 1: Physician statement of CA-125 pretreatment interpretation can be used to code this data item when no other information is available.

Note 2: Carbohydrate Antigen 125 (CA-125), also known as cancer antigen 125, mucin 16, or MUC16, is a protein which in humans is encoded by the MUC16 gene. CA-125 is a tumor marker or biomarker that may be elevated in the blood of some patients with ovarian cancer.

Note 3: Record only the blood or serum CA-125 interpretation for this data item. Do not record CA-125 test results based on fluid from the chest or abdominal cavity.

Note 4: Record the CA-125 status prior to treatment.

Note 5: Normal values may vary with patient age and from lab to lab. The typical human reference ranges are 0 to less than or equal 35 units per milliliter (U/mL). This is equivalent to kU/L.

Note 6: Code 9 if there is no statement that the CA-125 is positive/elevated, negative/normal, and the lab value with its normal range (from which you can determine interpretation) is not documented.

Code	Description
0	Negative/normal; within normal limits
1	Positive/elevated
2	Stated as borderline; undetermined whether positive or negative
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error)
9	Not documented in medical record CA-125 not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Ovary, Fallopian Tube, and Peritoneal Carcinoma

Residual Tumor Volume Post Cytoreduction

Item Length: 2
NAACCR Item #: 3921
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 55, Ovary, Fallopian Tube, and Primary Peritoneal Carcinoma

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 chemotherapy. This data item captures two pieces of information about residual tumor: residual tumor volume (amount) and whether the patient had chemotherapy prior to the cytoreductive surgery. Information about residual tumor volume will be in the operative report; information about preoperative (neoadjuvant) chemotherapy will be elsewhere in the medical record or physician notes. Residual tumor less than or greater than 2 cm differentiates T3b/Stage IIIB and T3c/Stage IIC tumors; this data item has a cut point of 1 centimeter.

Additional Information

- **Source documents:** operative report, pathology report; discharge summary, chemotherapy records (inpatient and outpatient), CAP Ovary, Fallopian Tube, Peritoneum cancer protocol.
- **Other names:** debulking, cytoreduction, residual tumor volume

Coding guidelines

Code the size of the largest residual tumor nodule remaining after the primary cytoreduction surgery from the operative report and if chemotherapy was administered preoperatively, increment the code to include that information.

DRAFT

Size of Residual Tumor and Status of Preoperative Chemotherapy CODE	DESCRIPTION		NO NEOADJUVANT CHEMO OR UNKNOWN	NEOADJUVANT CHEMO RECEIVED
00	No gross residual tumor nodules			
10	Residual tumor ≤ 1 cm	**AND**	X	
20	Same as 010	**AND**		X
30	Residual tumor > 1 cm	**AND**	X	
40	Same as 030	**AND**		X
90	Macroscopic residual, size not given	**AND**	X	
91	Same as 90	**AND**		X
92	Procedure described as optimal debulking, size of residual tumor not given	**AND**	X	
93	Same as 92	**AND**		X
98	No cytoreductive surgery performed			
99	Unknown; no information; not documented in record			

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: 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 3: 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 4: Gross residual tumor after primary cytoreductive surgery is a prognostic factor that has been demonstrated in large studies. Whether patients undergo neoadjuvant chemotherapy or primary cytoreduction, 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

DRAFT

Code	Description
00	No gross residual tumor nodules
10	Residual tumor nodule(s) 1 centimeter (cm) or less AND neoadjuvant chemotherapy not given or unknown if given
20	Residual tumor nodule(s) 1 cm or less AND neoadjuvant chemotherapy given (before surgery)
30	Residual tumor nodule(s) greater than 1 cm AND neoadjuvant chemotherapy not given or unknown if given
40	Residual tumor nodule(s) greater than 1 cm AND neoadjuvant chemotherapy given (before surgery)
90	Macroscopic residual tumor, size not stated AND neoadjuvant chemotherapy not given or unknown if given
91	Macroscopic residual tumor nodule(s), size not stated AND neoadjuvant chemotherapy given (before surgery)
92	Procedure described as optimal debulking and size of residual tumor nodule(s) not given AND neoadjuvant chemotherapy not given or unknown if given
93	Procedure described as optimal debulking and size of residual tumor nodule(s) not given AND neoadjuvant chemotherapy given (before surgery)
97	No cytoreductive surgery performed
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

Return back to Schema ID Table

DRAFT

Gestational Trophoblastic Neoplasms (Placenta)

FIGO: Gestational Trophoblastic Tumors (Placenta)

Item Length: 2
NAACCR Item #: 3836
NAACCR Alternate Name: FIGO Stage
AJCC 8th Edition Chapter(s): Chapter 56, Gestational Trophoblastic Tumors

Note 1: Take the highest Federation Internationale de Gynecologie et d'Obstetrique (FIGO) stage documented in the medical record. Do not attempt to code FIGO stage based only on T, N, and M. If FIGO stage is not documented in the medical record, code 99. FIGO stage is not the same as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

Note 2: If a stage group is stated but it does not specify that it is a FIGO stage, assume that it is a FIGO stage and code it.

Note 3: The FIGO stage definitions do not include Stage 0 (Tis). Code 97 for any case that is in situ (/2).

Code	Description
01	FIGO Stage I
20	FIGO Stage II
30	FIGO Stage III
40	FIGO Stage IV
97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record FIGO stage unknown, not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Gestational Trophoblastic Neoplasms (Placenta)

Gestational Trophoblastic Prognostic Scoring Index

Item Length: 2
NAACCR Item #: 3837
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 56, Gestational Trophoblastic Tumors
Required for Staging: AJCC 8th edition and EOD (Placenta schema).

Description

Gestational Trophoblastic Prognostic Scoring Index, a score based on the FIGO-modified World Health Organization (WHO) Prognostic Scoring Index, is used to stratify women with gestational trophoblastic neoplasia in addition to the anatomical stage group. The risk score is appended to the anatomic stage.

Rationale

This data item is required for prognostic stage grouping in AJCC 8th edition, Chapter 56 *Gestational Trophoblastic Neoplasms.* It was previously collected as Placenta, CS SSF # 1.

Definition

The Prognostic Index is a non-anatomic risk factor scoring system that adds a fourth dimension to the stage grouping of gestational trophoblastic tumors (GTT) of the placenta. The score subcategorizes GTTs into low risk or high risk based on a point system. Code the clinician's statement of the total point value for the Prognostic Index in priority over the clinician's statement of risk. Registrars are NOT to calculate the score.

Coding Instructions and Codes

Note 1: This is based on clinician scoring only. The registrar is NOT to calculate the score based on available information.

Note 2: The Prognostic Scoring Index is based on the following components

- Age
- Antecedent Pregnancy
- Interval in Months from Index Pregnancy
- Pretreatment Serum human chorionic gonadotropin (hCG) (IU/ml)
- Largest Tumor Size, Including Uterus
- Sites of Metastases
- Number of Metastases Identified
- Previous Failed Chemotherapy

Note 3: The total score ranges from 00-25.

Note 4: If there is no clinician scoring, or a stated value is greater than 25, code X9.

Code	Description
00-25	Risk factor score

DRAFT

X9	Not documented in medical record Prognostic scoring index not assessed, or unknown if assessed

Return back to Schema ID Table

DRAFT

MALE GENITAL ORGANS

DRAFT

Penis

Extranodal Extension Clin (non-Head and Neck)

Item Length: 1
NAACCR Item #: 3830
NAACCR Alternate Name: Extranodal Extension Clinical (non-Head and Neck)
AJCC 8th Edition Chapter(s):

- Chapter 46: Merkel Cell Skin
- Chapter 57: Penis

Description

Extranodal Extension (ENE) Clinical is defined as "the extension of a nodal metastasis through the lymph node capsule into adjacent tissue" during the diagnostic workup. This data item defines clinical ENE for sites other than Head and Neck**.**

Rationale

Extranodal Extension Clinical (non-Head and Neck) is a Registry Data Collection Variable for AJCC. This data item was previously collected for Penis, SSF# 17.

Definition

The presence of extranodal extension (ENE) from regional lymph nodes is an important prognostic factor in some cancers because these patients are rarely cured without some type of systemic chemotherapy or radiation. Extranodal extension is defined as metastatic tumor growing from within the lymph node outward through the lymph node capsule and into surrounding connective tissues.

This data item is for ENE that is detected clinically.

Coding guidelines

- Code 0 when there are positive nodes clinically, but ENE not identified/not present.
- Code 1 when there are positive nodes clinically, ENE is identified by physical exam or imaging
- Code 2 when there are positive nodes clinically, ENE is identified by biopsy (microscopically confirmed)
- Code 7 when nodes are clinically negative (cN0)
- Code 9 when
    - No information in the medical record
    - Positive nodes clinically, not evaluated (assessed) for ENE
    - Positive nodes clinically, unknown if evaluated (assessed) for ENE
    - Lymph nodes not evaluated (assessed) clinically
    - Unknown if lymph nodes evaluated (assessed) clinically

Additional Information

- **Source documents:** pathology report, imaging reports, physical exam

- **Other names:** ENE, extracapsular extension, ECE

Coding Instructions and Codes

Note 1: Physician statement of Extranodal Extension (ENE) Clinical or physician clinical staging can be used to code this data item when there is no other information available.

Note 2: Extranodal Extension Clinical is defined as "the extension of a nodal metastasis through the lymph node capsule into adjacent tissue" identified during the diagnostic workup. ENE is the preferred terminology. Other names include: extranodal spread, extracapsular extension, or extracapsular spread."

Note 3: Be aware that the rules for coding ENE for head and neck sites compared to non-head and neck sites are different**.**

Note 4: Code the status of extranodal extension assessed during the diagnostic workup for the assignment of the clinical stage for the most involved regional lymph node(s). This is mainly determined by physical examination, and includes statements such as fixed or matted nodes. Imaging may also be used, as well as lymph node biopsies or sentinel node biopsies performed prior to any treatment. Do not code ENE for any distant nodes.

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

Return back to Schema ID Table

DRAFT

Penis

Extranodal Extension Path (non-Head and Neck)

Item Length: 1
NAACCR Item #: 3833
NAACCR Alternate Name: Extranodal Extension Pathological (non-Head and Neck)
AJCC 8th Edition Chapter(s):

- Chapter 46: Merkel Cell Skin
- Chapter 57: Penis

Description

Extranodal Extension (ENE) Pathological is defined as "the extension of a nodal metastasis through the lymph node capsule into adjacent tissue. This data item defines pathological ENE for sites other than Head and Neck.

Rationale

Extranodal Extension Pathological (non-Head and Neck) is a Registry Data Collection Variable for AJCC. This data item was previously collected for Penis, SSF# 17.

Definition

The presence of extranodal extension (ENE) from regional lymph nodes is an important prognostic factor in some cancers because these patients are rarely cured without some type of systemic chemotherapy or radiation. Extranodal extension is defined as metastatic tumor growing from within the lymph node outward through the lymph node capsule and into surrounding connective tissues.

This data item is for ENE that is detected pathologically.

Coding guidelines

- Code 0 when there are positive nodes pathologically, but ENE not identified/not present
- Code 1 when there are positive nodes pathologically, ENE is identified
- Code 7 when nodes are surgically resected and they are negative (pN0)
- Code 9 when
    - No information in the medical record
    - Positive nodes pathologically, not evaluated (assessed) for ENE
    - Positive nodes pathologically, unknown if evaluated (assessed) for ENE
    - Lymph nodes not evaluated (assessed) pathologically (no surgical resection of lymph nodes)
    - Unknown if lymph nodes evaluated pathologically (assessed)

Additional Information

- **Source documents:** pathology report from surgical resection

- **Other names:** ENE, extracapsular extension, ECE

Coding Instructions and Codes

Note 1: Physician statement of Extranodal Extension (ENE) Pathological or physician pathological staging can be used to code this data item when there is no other information available.

Note 2: Extranodal extension is defined as "the extension of a nodal metastasis through the lymph node capsule into adjacent tissue." ENE is the preferred terminology. Other names include: extranodal spread, extracapsular extension, or extracapsular spread."

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

Note 3: Be aware that the rules for coding ENE for head and neck sites compared to non-head and neck sites are different.

Note 4: Code the status of extranodal extension assessed on the surgical resection specimen for the most involved regional lymph node(s). Do not code ENE for any distant nodes.

Code	Description
0	Regional lymph nodes involved, ENE not present/not identified from surgical resection
1	Regional lymph nodes involved, ENE present/identified from surgical resection
7	No lymph node involvement from surgical resection (pN0)
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error)
9	Not documented in medical record No surgical resection of regional lymph nodes Cannot be determined Pathological assessment of lymph nodes not done, or unknown if done Extranodal Extension Pathological not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Prostate

PSA (Prostatic Specific Antigen) Lab Value

Item Length: 5
NAACCR Item #: 3920
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 58, Prostate

Description

PSA (Prostatic Specific Antigen) is a protein produced by cells of the prostate gland and is elevated in patients with prostate cancer. This data item pertains to PSA lab value.

Rationale

This data item is required for prognostic stage grouping in AJCC 8th edition, Chapter 58 *Prostate*. It was previously collected as Prostate, CS SSF #1.

Definition

Serum PSA is the most sensitive tumor marker for monitoring individuals with prostate cancer, including progression of disease and response to therapy. Although originally not intended to be a screening test, this relatively simple blood test has become a very common method of detecting new prostate cancer in its earliest stages. PSA can be totally negative when prostate cancer is found on digital rectal exam. In such cases, PSA will not be helpful in monitoring for recurrence.

- ***Note***: Serum PSA is not the same as free PSA or precursor PSA—do not record values from either of these tests in this field.

Additional Information

- **Source documents:** clinical laboratory report (blood or serum test), history, clinician note, pathology report
- **Other names:** Prostate specific antigen, serum PSA, total PSA

Normal reference range: **varies by age and race of patient.**

- The reference range should be shown on the clinical laboratory report. In general, normal findings are 0 – 4.0 nanograms per milliliter (ng/ml).
- Optimal normal range is 0 – 2.6 ng/ml. Nanograms per milliliter may be reported as micrograms per liter (μg/L or ug/L).

Coding Guidelines

Record the last pre-diagnosis PSA lab value prior to diagnostic biopsy of prostate and initiation of treatment in nanograms per milliliter (ng/ml) in the range 0.1 (.1 ng/ml) to 999.9 (999.9 ng/ml).

- ***Note***: This is a change from CSv2, where the instructions stated to code the highest PSA value within 3 months prior to diagnostic biopsy

Examples	Code	Explanation
PSA 11.56	11.6	PSA documented in tenths, round up
1/5/2018: PSA 5.8 1/29/2018: PSA 5.2 2/22/2018: Biopsy positive for adenocarcinoma	5.2	PSA lab value closest and prior to the diagnostic biopsy
12/19/2017: PSA 44.3 3/11/2018: PSA 42.8 5/1/2018: DRE positive for bilateral palpable nodularity 5/5/2018: Casodex initiated without needle core biopsy	42.8	PSA lab value closest to the initiation of treatment
2/16/2018: PSA 18.6, adjusted PSA value due to patient taking Medication for benign prostatic hypertrophy	18.6	Record the adjusted PSA value ONLY if documented by the clinician in the record. Registrar does not adjust the PSA value due to BPH medication use
1,100 ng/ml	XXX.1	XXXX.1 is defined for values of 1,000 or greater
No PSA done or unknown if done	XXX.9	Definition of unknown

<u>Coding Instructions and Codes</u>

Note 1: Physician statement of prostatic specific antigen (PSA) pre-diagnosis can be used to code this data item when no other information is available.

Note 2: PSA is a prognostic factor required for AJCC staging. It affects the stage group in most cases.

Note 3: Record to the nearest tenth in nanograms/milliliter (ng/ml) the last pre-diagnosis PSA lab value prior to diagnostic biopsy of prostate and treatment. The lab value may be recorded in the lab report, history and physical, or clinical statement in the pathology report, etc.

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

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

For an uncertain value, record the stated closest value. For example, code a value stated as "less than 5.0 ng/ml" as 4.9.

Examples:

PSA of 7.2. Code 7.2
PSA of 10. Code 10.0
PSA of 8.56. Code 8.6
PSA of 110.35. Code 110.4

DRAFT

Note 4: A discrepancy between the PSA documented in the lab report and the PSA documented by the clinician may arise due to the clinician's adjusting the PSA value. Certain medications for benign prostatic hypertrophy (BPH) decrease the PSA.

If there is documentation by a clinician within the medical record of an adjusted PSA value, record the adjusted value.

The registrar does not adjust the PSA value based on BPH medication use.

If there is no documentation by a clinician within the medical record of an adjusted PSA value, record the PSA value provided.

The fact that an adjusted PSA value is being recorded should be documented in the Dx Proc – Lab Tests text field (NAACCR Item # 2550).

Code	Description
0.1	0.1 or less nanograms/milliliter (ng/ml) (Exact value to nearest tenth of ng/ml)
0.2-999.9	0.2 – 999.9 ng/ml (Exact value to nearest tenth of ng/ml)
XXX.1	1,000 ng/ml or greater
XXX.7	Test ordered, results not in chart
XXX.9	Not documented in medical record PSA lab value not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Prostate

Gleason Patterns and Scores

Definition

The Gleason system for grading prostate cancer is the one recommended by the AJCC and College of American Pathologists. The following data items are used to collect information on Gleason.

- Gleason Patterns Clinical [NAACCR Data Item #3838]
- Gleason Score Clinical [NAACCR Data Item #3840]
- Gleason Patterns Pathological [NAACCR Data Item #3839]
- Gleason Score Pathological [NAACCR Data Item #3841]
- Gleason Tertiary Pattern [NAACCR Data Item #3842]

Gleason Patterns

The pathologist determines the Gleason patterns by looking at the prostate tissue under the microscope. The pathologist assigns a grade to the most predominant pattern (largest surface area of involvement, more than 50% of tissue) and a grade for the secondary pattern (second most predominant) based on published Gleason criteria**.** When a patient undergoes radical prostatectomy, the pathologist may look for a third or tertiary pattern in the specimen. When Gleason pattern 5 is present as a tertiary pattern, its presence should be indicated in the pathology report, as a high Gleason pattern appears to be an indicator for worse outcome (shortened time to recurrence). Studies indicate that a Gleason score 7, with tertiary pattern 5, is associated with a worse prognosis than without tertiary pattern 5, and is similar to the prognosis for Gleason score 8 – 10.

- For example, in a specimen where the primary Gleason pattern is 3, the secondary is 4 and there is less than 5% Gleason 5, the report should indicate a Gleason score of 7 (3+4) with tertiary Gleason pattern 5. Gleason grades (patterns) range from 1 (small, uniform gland) to 5 (lack of glands, sheets of cells.)

For the Gleason Patterns data items, there is a long list of codes and definitions in the table, but it may be easier to assign a value if you understand the structure of the code. This is a two-digit field.

- First digit is the Gleason primary pattern value
- Second digit is the Gleason secondary pattern value

Gleason Score

The Gleason score is the sum of the values of the Gleason primary and secondary patterns. A low Gleason score means the cancer tissue is similar to normal prostate tissue and the tumor is less likely to spread; a high Gleason score means the cancer tissue is very different from normal and the tumor is more likely to spread.

Coding guidelines

Clinical Gleason Patterns and Score

Clinical Gleason Pattern and Score: Used to code information on the Gleason pattern from a needle core biopsy or transurethral resection of the prostate (TURP) only. Gleason patterns from prostate tissue on a transurethral resection of the bladder (TURB) specimen can also be used.

If there are multiple needle core biopsies or if both needle core biopsy and TURP are performed, code the patterns and score from the specimen with the highest score.

Examples for Clinical Gleason Patterns and Score

Examples	Pattern Code	Score Code
Gleason 3+3	33	06
Gleason 4+3	43	07
Gleason 4 (Assume a number in the range 2-5 is a primary pattern and code unknown (9) in the second digit)	49	X9
Gleason 7 (Assume a number in the range 6-10 is a score)	X6	07
Gleason 10 (only combination of values that equals 10 is 5+5)	55	10
Needle core biopsy or TURP not done	X7	X7
Gleason not done, or unknown if done	X9	X9

Pathological Gleason Patterns and Score

Used to code information on the Gleason patterns from a prostatectomy or autopsy.

Examples for Pathological Gleason Patterns and Score

Examples	Pattern Code	Score Code
Gleason 3+3	33	06
Gleason 4+3	43	07
Gleason 4 (Assume a number in the range 2-5 is a primary pattern and code unknown (9) in the second digit)	49	X9
Gleason 7 (Assume a number in the range 6-10 is a score)	X6	07
Gleason 10 (only combination of values that equals 10 is 5+5)	55	10
No prostatectomy done	X7	X7
Gleason not done, or unknown if done	X9	X9

Tertiary Gleason Pattern

Used to code information on the Gleason tertiary pattern from a prostatectomy.

Examples for Tertiary Gleason Pattern

Examples	Code
Tertiary pattern 3	30
Tertiary pattern 4	40
No prostatectomy done	X7
Tertiary pattern not done, or unknown if done	X9

<u>Additional Information</u>

DRAFT

- **Clinical**: pathology reports from needle biopsies or transurethral resection of prostate/bladder that contains prostate tissue
    - **Pathological**: pathology report from prostatectomy or autopsy report

Return back to Schema ID Table

DRAFT

Prostate

Gleason Patterns Clinical

Item Length: 2
NAACCR Item #: 3838
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 58, Prostate

Description

Prostate cancers are graded using Gleason score or pattern. This data item represents the Gleason primary and secondary patterns from needle core biopsy or TURP.

Rationale

Gleason Patterns Clinical is a Registry Data Collection Variable for Clinical Stage for AJCC. This data item was previously collected as Prostate, CS SSF# 7.

See Gleason Patterns and Scores **for additional information.**

Coding Instructions and Codes

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

Note 2: Code the Gleason primary and secondary patterns from needle core biopsy or transurethral resection of prostate (TURP) in this field. Gleason primary and secondary patterns provided for any prostate tissue identified from a transurethral resection of a bladder tumor (TURBT) specimen can also be used in this field.

Note 3: Code the Gleason primary and secondary patterns prior to neoadjuvant treatment.

Note 4: Usually prostate cancers are graded using Gleason score or pattern. Gleason grading for prostate primaries is based on a 5-component system (5 histologic patterns). Prostatic cancer generally shows two main histologic patterns. The primary pattern, the pattern occupying greater than 50% of the cancer, is usually indicated by the first number of the Gleason grade, and the secondary pattern is usually indicated by the second number. These two numbers are added together to create a pattern score.

- If there are two numbers, assume that they refer to two patterns (the first number being the primary pattern and the second number the secondary pattern), and sum them to obtain the score.
- If only one number is given and it is less than or equal to 5, assume that it describes a pattern (since scores of 5 or less would reflect Primary or Secondary Pattern Scores of 1 or 2). Code the number as the primary pattern and code the secondary pattern as Unknown.
    - For ***example***, if only one number is given and it is a 3, code “39” for Gleason Patterns and “X9” for Gleason Score.
- If only one number is given and it is greater than 5, assume that it is a score.
    - For ***example***, if only one number is given and it is a 7, code “X6” for Gleason Patterns and “07” for Gleason Score.

- If the pathology report specifies a specific number out of a total of 10, the first number given is the score.
    - For ***example***, if the pathology report says Gleason 7/10, code "07' for Gleason Score and "X6" for Gleason Patterns.

Note 5: If different patterns are documented on multiple needle core biopsies, code the pattern that reflects the highest or most aggressive score regardless if the pathologist provides an overall pattern in a final summary. If different patterns equal the same high score, give priority to the highest primary pattern and then the highest secondary pattern.

- For ***example***, both Gleason 3, 4 and Gleason 4, 3 equal Gleason score 7; code 43. Do not mix patterns from multiple specimens.

Note 6: If needle core biopsy and TURP are both performed, code the pattern that reflects the highest score.

Note 7: Do not infer Gleason Primary and Secondary Pattern from Grade Group (Code X9).

Note 8: The clinical score is recorded in Gleason Score Clinical [NAACCR Data Item # 3840].

Code	Description
11	Primary pattern 1, secondary pattern 1
12	Primary pattern 1, secondary pattern 2
13	Primary pattern 1, secondary pattern 3
14	Primary pattern 1, secondary pattern 4
15	Primary pattern 1, secondary pattern 5
19	Primary pattern 1, secondary pattern unknown
21	Primary pattern 2, secondary pattern 1
22	Primary pattern 2, secondary pattern 2
23	Primary pattern 2, secondary pattern 3
24	Primary pattern 2, secondary pattern 4
25	Primary pattern 2, secondary pattern 5
29	Primary pattern 2, secondary pattern unknown
31	Primary pattern 3, secondary pattern 1
32	Primary pattern 3, secondary pattern 2
33	Primary pattern 3, secondary pattern 3
34	Primary pattern 3, secondary pattern 4
35	Primary pattern 3, secondary pattern 5
39	Primary pattern 3, secondary pattern unknown
41	Primary pattern 4, secondary pattern 1
42	Primary pattern 4, secondary pattern 2
43	Primary pattern 4, secondary pattern 3
44	Primary pattern 4, secondary pattern 4
45	Primary pattern 4, secondary pattern 5
49	Primary pattern 4, secondary pattern unknown
51	Primary pattern 5, secondary pattern 1
52	Primary pattern 5, secondary pattern 2
53	Primary pattern 5, secondary pattern 3
54	Primary pattern 5, secondary pattern 4
55	Primary pattern 5, secondary pattern 5

Code	Description
59	Primary pattern 5, secondary pattern unknown
X6	Primary pattern unknown, secondary pattern unknown
X7	No needle core biopsy/TURP performed
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record Gleason Patterns Clinical not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Prostate

Gleason Score Clinical

Item Length: 2
NAACCR Item #: 3840
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 58, Prostate

Description

This data item records the Gleason score based on adding the values for primary and secondary patterns in Needle Core Biopsy or TURP.

Rationale

Gleason Score Clinical is a Registry Data Collection Variable for AJCC. This data item was previously collected as Prostate, CS SSF# 8.

See Gleason Patterns and Scores **for additional information.**

Coding Instructions and Codes

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

Note 2: Code the Gleason Score Clinical from needle core biopsy or transurethral resection of prostate (TURP) in this field. Gleason primary and secondary patterns provided for any prostate tissue identified from a transurethral resection of a bladder tumor (TURBT) specimen can also be used in this field.

Note 3: Code the Gleason Score prior to neoadjuvant treatment.

Note 4: Usually prostate cancers are graded using Gleason's score or pattern. Gleason's grading for prostate primaries is based on a 5-component system (5 histologic patterns). Prostatic cancer generally shows two main histologic patterns. The primary pattern, the pattern occupying greater than 50% of the cancer, is usually indicated by the first number of the Gleason's grade, and the secondary pattern is usually indicated by the second number. These two numbers are added together to create a pattern score, ranging from 2 to 10.

- If there are two numbers, assume that they refer to two patterns (the first number being the primary pattern and the second number the secondary pattern), and sum them to obtain the score.
- If only one number is given and it is less than or equal to 5, code the total score to X9, unknown or no information.
- If only one number is given and it is greater than 5, assume that it is a score and code as stated.
- If the pathology report specifies a specific number out of a total of 10, the first number given is the score.
    - ***Example***: The pathology report says Gleason's 3/10. The Gleason's score would be 3, and coded as 03.

Note 5: If different scores are documented on multiple needle core biopsies, code the highest or most aggressive score.

Note 6: If needle core biopsy and TURP are both performed, code the highest score.

Note 7: Do not infer the Gleason Score from Grade Group (Code X9).

Note 8: Record the Gleason score based on the addition of the primary and secondary patterns coded in Gleason Patterns Clinical [NAACCR Data Item # 3838].

Code	Description
02	Gleason score 2
03	Gleason score 3
04	Gleason score 4
05	Gleason score 5
06	Gleason score 6
07	Gleason score 7
08	Gleason score 8
09	Gleason score 9
10	Gleason score 10
X7	No needle core biopsy/TURP performed
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record Gleason Score Clinical not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Prostate

Gleason Patterns Pathological

Item Length: 2
NAACCR Item #: 3839
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 58, Prostate

Description

Prostate cancers are graded using Gleason score or pattern. This data item represents the Gleason primary and secondary patterns from prostatectomy or autopsy.

Rationale

Gleason Patterns Pathological is a Registry Data Collection Variable for AJCC. This data item was previously collected as Prostate, CS SSF# 9.

See Gleason Patterns and Scores **for additional information.**

Coding Instructions and Codes

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

Note 2: Code the Gleason primary and secondary patterns from prostatectomy or autopsy only in this field. Unlike Grade Group Pathological, do not include patterns from tissues taken prior to prostatectomy.

Note 3: Usually prostate cancers are graded using Gleason score or pattern. Gleason grading for prostate primaries is based on a 5-component system (5 histologic patterns). Prostatic cancer generally shows two main histologic patterns. The primary pattern, the pattern occupying greater than 50% of the cancer, is usually indicated by the first number of the Gleason grade, and the secondary pattern is usually indicated by the second number. These two numbers are added together to create a pattern score.

- If there are two numbers, assume that they refer to two patterns (the first number being the primary pattern and the second number the secondary pattern), and sum them to obtain the score.
- If only one number is given and it is less than or equal to 5, assume that it describes a pattern (since scores of 5 or less would reflect Primary or Secondary Pattern Scores of 1 or 2). Code the number as the primary pattern and code the secondary pattern as Unknown.
    - For ***example***, if only one number is given and it is a 3, code “39” for Gleason Patterns and “X9” for Gleason Score.
- If only one number is given and it is greater than 5, assume that it is a score.
    - For ***example***, if only one number is given and it is a 7, code “X6” for Gleason Patterns and “07” for Gleason Score.
- If the pathology report specifies a specific number out of a total of 10, the first number given is the score.

- For ***example***, if the pathology report says Gleason 7/10, code "07" for Gleason Score and "X6" for Gleason Patterns.

Note 4: If neoadjuvant therapy was given, code Gleason pathological patterns as X9.

Note 5: Do not infer Gleason Primary and Secondary Pattern from Grade Group (Code X9).

Note 6: If a tertiary pattern is documented on prostatectomy or autopsy, code in Gleason Tertiary Pattern [NAACCR Data Item # 3842].

Note 7: The pathological score is recorded in Gleason Score Pathological [NAACCR Data Item # 3841].

Code	Description
11	Primary pattern 1, secondary pattern 1
12	Primary pattern 1, secondary pattern 2
13	Primary pattern 1, secondary pattern 3
14	Primary pattern 1, secondary pattern 4
15	Primary pattern 1, secondary pattern 5
19	Primary pattern 1, secondary pattern unknown
21	Primary pattern 2, secondary pattern 1
22	Primary pattern 2, secondary pattern 2
23	Primary pattern 2, secondary pattern 3
24	Primary pattern 2, secondary pattern 4
25	Primary pattern 2, secondary pattern 5
29	Primary pattern 2, secondary pattern unknown
31	Primary pattern 3, secondary pattern 1
32	Primary pattern 3, secondary pattern 2
33	Primary pattern 3, secondary pattern 3
34	Primary pattern 3, secondary pattern 4
35	Primary pattern 3, secondary pattern 5
39	Primary pattern 3, secondary pattern unknown
41	Primary pattern 4, secondary pattern 1
42	Primary pattern 4, secondary pattern 2
43	Primary pattern 4, secondary pattern 3
44	Primary pattern 4, secondary pattern 4
45	Primary pattern 4, secondary pattern 5
49	Primary pattern 4, secondary pattern unknown
51	Primary pattern 5, secondary pattern 1
52	Primary pattern 5, secondary pattern 2
53	Primary pattern 5, secondary pattern 3
54	Primary pattern 5, secondary pattern 4
55	Primary pattern 5, secondary pattern 5
59	Primary pattern 5, secondary pattern unknown
X6	Primary pattern unknown, secondary pattern unknown
X7	No prostatectomy/autopsy performed
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record

DRAFT

Code	Description
	Gleason Patterns Pathological not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Prostate

Gleason Score Pathological

Item Length: 2
NAACCR Item #: 3841
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 58, Prostate

Description

This data item records the Gleason score based on adding the values for primary and secondary patterns from prostatectomy or autopsy.

Rationale

Gleason Score Pathological is a Registry Data Collection Variable for AJCC. This data item was previously collected as Prostate, CS SSF# 10.

See Gleason Patterns and Scores **for additional information.**

Coding Instructions and Codes

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

Note 2: Code the Gleason Score Pathological from prostatectomy or autopsy only in this field. Unlike Grade Group Pathological, do not include patterns from tissues taken prior to prostatectomy.

Note 3: Usually prostate cancers are graded using Gleason's score or pattern. Gleason's grading for prostate primaries is based on a 5-component system (5 histologic patterns). Prostatic cancer generally shows two main histologic patterns. The primary pattern, the pattern occupying greater than 50% of the cancer, is usually indicated by the first number of the Gleason's grade, and the secondary pattern is usually indicated by the second number. These two numbers are added together to create a pattern score, ranging from 2 to 10.

- If there are two numbers, assume that they refer to two patterns (the first number being the primary pattern and the second number the secondary pattern), and sum them to obtain the score.
- If only one number is given and it is less than or equal to 5, code the total score to X9, unknown or no information.
- If only one number is given and it is greater than 5, assume that it is a score and code as stated.
- If the pathology report specifies a specific number out of a total of 10, the first number given is the score.
    - ***Example***: The pathology report says Gleason's 3/10. The Gleason's score would be 3, and coded as 03.

Note 4: If neoadjuvant therapy was given, code Gleason pathological score as X9.

Note 5: Do not infer the Gleason Score from Grade Group (Code X9).

DRAFT

Note 6: Record the Gleason score based on the addition of the primary and secondary patterns coded in Gleason Patterns Pathological [NAACCR Data Item # 3839].

Code	Description
02	Gleason score 2
03	Gleason score 3
04	Gleason score 4
05	Gleason score 5
06	Gleason score 6
07	Gleason score 7
08	Gleason score 8
09	Gleason score 9
10	Gleason score 10
X7	No prostatectomy done
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record Gleason Score Pathological not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Prostate

Gleason Tertiary Pattern

Item Length: 2
NAACCR Item #: 3842
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 58, Prostate

Description

Prostate cancers are graded using Gleason score or pattern. This data item represents the tertiary pattern value from prostatectomy or autopsy.

Rationale

Tertiary Gleason pattern on prostatectomy is a Registry Data Collection Variable for AJCC. This data item was previously collected as Prostate, CS SSF# 11.

See Gleason Patterns and Scores **for additional information.**

Coding Instructions and Codes

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

Note 2: If present, a high Gleason Tertiary Pattern appears to be an indication for a worse outcome.

Note 3: Record the tertiary pattern documented on prostatectomy or autopsy only. Record the tertiary pattern prior to neoadjuvant treatment.

- If a tertiary pattern is documented on needle core biopsy or transurethral resection of prostate (TURP), it should be disregarded.
- Do not code the tertiary pattern on prostatectomy or autopsy in Gleason Patterns Pathological.

Note 4: The CAP Prostate Protocol does not include Patterns 1 and 2 for Tertiary Pattern.

Note 5: If neoadjuvant therapy was given, code Gleason patterns as X9.

Code	Description
10	Tertiary pattern 1
20	Tertiary pattern 2
30	Tertiary pattern 3
40	Tertiary pattern 4
50	Tertiary pattern 5
X7	No prostatectomy/autopsy performed
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record Gleason Tertiary Pattern not assessed or unknown if assessed

Prostate

Number of Cores Positive and Examined

Definition

These two data items record the number of positive and examined cores that are microscopically confirmed. A diagnostic procedure, such as a needle core biopsy, can take as many as 20 or more core biopsies to determine the extent of the cancer within the prostate.

Together these two data items can provide researchers with a surrogate estimate of the percentage of the prostate involved by tumor, if that figure is not stated in the pathology report

Number of Cores Positive must ALWAYS be less than or equal to Number of Cores Examined.

For Prostate, there are 2 data items that record information on the number of cores positive and examined. These data items should be coded from the same test.

- Number of Cores Positive [NAACCR Data Item #3898]
- Number of Cores Examined [NAACCR Data Item #3897]

Note: Do not make assumptions about the number of cores positive or examined based on the number of areas biopsied within the prostate (laterality, lobes, apex, base, or mid-prostate). Several cores may be taken from each area.

Additional Information

- **Source documents:** pathology reports from core needle biopsies
- **Other names for procedures:** needle core biopsy, needle biopsy, core biopsy, prostate biopsy, sextant biopsy, transrectal biopsy, ultrasound-guided biopsy, transperineal prostate biopsy, triggered-needle biopsy.

Return back to Schema ID Table

DRAFT

Prostate

Number of Cores Positive

Item Length: 2
NAACCR Item #: 3898
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 58, Prostate

Description

This data item represents the number of positive cores documented in the pathology report from needle biopsy of the prostate gland.

Rationale

Number of Cores Positive is a Registry Data Collection Variable for AJCC. This data item was previously collected as Prostate, CS SSF# 12.

Coding guidelines

- Code 00 for all cores negative
- Code the exact number of positive cores 01-99
- Code X1 for 100 or more positive cores
- Code X6 for positive cores, unknown how many
- Code X9 when
    - Not documented in the medical record
    - Cores not evaluated (assessed)
    - Unknown if Cores evaluated (assessed)

See Number of Cores Positive and Examined **for additional information.**

Coding Instructions and Codes

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

Note 2: Record the number of positive prostate core biopsies from the first prostate core biopsy diagnostic for cancer. If positive cores are identified and the number of positive cores not specifically documented, code X6.

Note 3: If the pathology report contains a summary of the number of cores positive and examined, use the summary provided. If Summary Report is not available and multiple biopsy cores are obtained on the same day, the number of cores examined should be added.

Note 4: Transperineal template-guided saturation biopsy (TTSB) is a stereotactic prostate biopsy technique that typically produces 30 to 80 core biopsies. This is an alternative biopsy technique used for some high-risk patients including men with persistently elevated PSA, those who have atypia on prior prostate biopsies, or men with biopsies showing high grade prostatic intraepithelial neoplasia (PIN).

Note 5: The number of cores examined are recorded in Number of Cores Examined [NAACCR Data Item # 3897].

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

Return back to Schema ID Table

DRAFT

Prostate

Number of Cores Examined

Item Length: 2
NAACCR Item #: 3897
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 58, Prostate

Description

This data item represents the number of cores examined as documented in the pathology report from needle biopsy of the prostate gland.

Rationale

Number of Cores Examined is a Registry Data Collection Variable for AJCC. This data item was previously collected as Prostate, CS SSF# 13.

Coding guidelines

- Code the exact number of examined cores 01-99
- Code X1 for 100 or more examined cores
- Code X6 for examined cores, unknown how many
- Code X9 when
    - Not documented in the medical record
    - Cores not evaluated (assessed)
    - Unknown if Cores evaluated (assessed)

See Number of Cores Positive and Examined **for additional information.**

Coding Instructions and Notes

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

Note 2: Record the number of prostate core biopsies examined from the first prostate core biopsy diagnostic for cancer. If the number of cores examined is not specifically documented, code X6.

Note 3: If the pathology report contains a summary of the number of cores positive and examined, use the summary provided. If Summary Report is not available and multiple biopsy cores are obtained on the same day, the number of cores examined should be added.

Note 4: Transperineal template-guided saturation biopsy (TTSB) is a stereotactic prostate biopsy technique that typically produces 30 to 80 core biopsies. This is an alternative biopsy technique used for some high-risk patients including men with persistently elevated PSA, those who have atypia on prior prostate biopsies, or men with biopsies showing high grade prostatic intraepithelial neoplasia (PIN).

Note 5: The number of cores positive are recorded in Number of Cores Positive [NAACCR Data Item # 3898].

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

Return back to Schema ID Table

DRAFT

Testis

Testis Serum Markers and S Category

In addition to T, N, and M, the S category is collected to stage Testicular cancers. There are three factors that make up the S stage: alpha-fetoprotein (AFP), beta-human chorionic gonadotropin (beta-hCG), and lactase dehydrogenase (LDH). These play an important role as serum tumor markers in the staging and monitoring of germ cell tumors and should be measured prior to removing the involved testicle. For patients with nonseminomas, the degree of tumor-marker elevation after the cancerous testicular has been removed is one of the most significant predictors of prognosis. Serum tumor markers are also very useful for monitoring all stages of nonseminomas and for monitoring metastatic seminomas because elevated marker levels are often the earliest sign of relapse.

There are several data items related to the collection of these variables.

For clinical staging

- AFP Pre-Orchiectomy Lab Value [NAACR Data Item #3807]
- AFP Pre-Orchiectomy Range [NAACR Data Item #3808]
- hCG Pre-Orchiectomy Lab Value [NAACR Data Item #3848]
- hCG Pre-Orchiectomy Range [NAACR Data Item #3849]
- LDH Pre-Orchiectomy Range[NAACR Data Item #3868]
- S Category Clinical [NAACCR Data Item #3923]

For pathological staging

- AFP Post-Orchiectomy Lab Value[NAACR Data Item #3805]
- AFP Post-Orchiectomy Range[NAACR Data Item #3806]
- hCG Post-Orchiectomy Lab Value [NAACR Data Item #3846]
- hCG Post-Orchiectomy Range[NAACR Data Item #3847]
- LDH Post-Orchiectomy Range[NAACR Data Item #3867]
- S Category Pathological[NAACCR Data Item #3924]

In **Collaborative Stage v2 (CSv2**), the "ranges" were used to derive the S category. New data items for AJCC 8th edition is for the assignment of the S category in addition to collecting the individual data items.

Return back to Schema ID Table

DRAFT

Testis

Alpha-fetoprotein (AFP) (Testis)

Definition

Alpha-fetoprotein (AFP) is a protein normally made by immature liver cells in the fetus. In adults, high AFP levels (> 500 ng/ml) in the blood occur only in hepatocellular carcinoma (>1000), liver metastases (from a primary elsewhere), and germ cell tumors of the testes and ovaries. Elevated AFP values are found in non-seminomatous malignancies and mixed tumors of the testis. AFP is used with HCG to identify the specific cell type of testicular cancer. AFP is not secreted by pure seminoma or teratoma. If AFP > 500 ng/ml, the underlying condition is unlikely to be benign. If AFP > 10,000 ng/ml at diagnosis, the patient is likely to have a poor prognosis.

AFP is more useful in monitoring response to therapy than making a diagnosis. The half-life of AFP is 5 to 7 days. After orchiectomy, the AFP should fall to < 25 ng/ml in 25-35 days. If elevated AFP persists, this is an indication of residual tumor.

For Testis, there are 4 data items that record information on AFP for Testis.

- AFP Pre-Orchiectomy Lab Value [NAACR Data Item #3807]
- AFP Pre-Orchiectomy Range [NAACR Data Item #3808]
- AFP Post-Orchiectomy Lab Value [NAACR Data Item #3805]
- AFP Post-Orchiectomy Range[NAACR Data Item #3806]

Coding guidelines

Assign the code for the highest AFP value and corresponding AFP range **prior to orchiectomy**. In the event an orchiectomy is not performed or systemic treatment precedes an orchiectomy, code the highest AFP value and corresponding range prior to any systemic treatment. The AFP Range is a category used to group the lab values into 3 ranges: 1, 2, and 3. The pre-orchiectomy AFP lab value and the pre-orchiectomy AFP range should be from the same test. If the clinician states an S value rather than a lab value, code unknown (code XXXX.9) for the AFP pre-orchiectomy lab value and unknown (code 9) for the AFP pre-orchiectomy range.

Categories used for Pre- and Post-Orchiectomy AFP Range are:

Code	Description
0	Within normal limits
1	Above normal and less than 1,000 nanograms/milliliter (ng/mL)
2	1,000 -10,000 ng/mL
3	Greater than 10,000 ng/mL

Examples for AFP Pre-Orchiectomy and AFP Post-Orchiectomy Lab Value and Range

- *For these examples, the lab's normal reference range for AFP = 0-10 ng/ml*

Examples	Lab Value Code	Range Code
1 ng/ml	1.0	0

Examples	Lab Value Code	Range Code
270 ug/l	270.0 (ng/ml = ug/L)	1
5500 ng/ml	5500.0	2
12,500 ng/ml	12500.0	3
110,000 ng/ml	XXXXX.1	3
Physician states "AFP elevated," but no value documented	XXXXX.9	4
S value stated (no other information available)	XXXXX.9	9
No AFP test done, or unknown if done	XXXXX.9	9

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, Testis cancer protocol **cancer protocol**
- **Other names:** αFP, aFP, Alpha Fetoprotein, Alpha-fetoprotein, α-fetoprotein; fetal alpha globulin
- **Normal Reference Range:** Adult men 0-15 ng/ml (SI: 0-15 µg/L)
- **Measurements:** micrograms/liter (µg/L or ug/L) is equivalent to nanograms per milliliter (ng/ml)

Return back to Schema ID Table

DRAFT

Testis

AFP Pre-Orchiectomy Lab Value

Item Length: 7
NAACCR Item #: 3807
NAACCR Alternate Name: AFP (Alpha Fetoprotein) Pre-Orchiectomy Lab Value
AJCC 8th Edition Chapter(s): Chapter 59, Testis

Description

AFP (Alpha Fetoprotein) Pre-Orchiectomy Lab Value refers to the AFP value measured prior to treatment. AFP is a tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis.

Rationale

AFP (Alpha Fetoprotein) Pre-Orchiectomy Lab Value is a Registry Data Collection Variable in AJCC. It was previously collected as Testis CS SSF# 6.

See Alpha-fetoprotein (AFP) (Testis) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of the AFP (Alpha Fetoprotein) Pre-Orchiectomy Lab Value can be used to code this data item when no other information is available.

Note 2: Record the lab value of the highest AFP test result documented in the medical record **prior to orchiectomy** or prior to any systemic treatment**.** The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: A lab value expressed in micrograms/liter (ug/l) is equivalent to the same value expressed in ng/mL.

Note 4: The same laboratory test should be used to record information in AFP Pre-Orchiectomy Range [NAACCR Data Item #3808].

Code	Description
0.0	0.0 nanograms/milliliter (ng/mL)
0.1-99999.9	0.1 – 99,999.9 ng/mL
XXXXX.1	100,000 ng/mL or greater
XXXXX.7	Test ordered, results not in chart
XXXXX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XXXXX.8 may result in an edit error.)
XXXXX.9	Not documented in medical record AFP (Alpha Fetoprotein) Pre-Orchiectomy Lab Value not assessed or unknown if assessed

Testis

AFP Pre-Orchiectomy Range

Item Length: 1
NAACCR Item #: 3808
NAACCR Alternate Name: AFP (Alpha Fetoprotein) Pre-Orchiectomy Range
AJCC 8th Edition Chapter(s): Chapter 59, Testis

Description

AFP (Alpha Fetoprotein) Pre-Orchiectomy Range identifies the range category of the highest AFP value measured prior to treatment. AFP is a serum tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis.

Rationale

AFP (Alpha Fetoprotein) is a Registry Data Collection Variable in AJCC. AFP (Alpha Fetoprotein) Pre-Orchiectomy Range is used to assign the S Category Clinical and was previously collected as Testis CS SSF# 7.

See Alpha-fetoprotein (AFP) (Testis) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of the AFP (Alpha Fetoprotein) Pre-Orchiectomy Range can be used to code this data item when no other information is available.

Note 2: Record the range of the highest AFP test result documented in the medical record **prior to orchiectomy** or prior to any systemic treatment**.** The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: A lab value expressed in micrograms/liter (ug/L) is equivalent to the same value expressed in nanograms/milliliter (ng/mL).

Note 4: The same laboratory test should be used to record information in AFP Pre-Orchiectomy Lab Value [NAACCR Data Item #3807].

Code	Description
0	Within normal limits
1	Above normal and less than 1,000 nanograms/milliliter (ng/mL)
2	1,000 -10,000 ng/mL
3	Greater than 10,000 ng/mL
4	Pre-Orchiectomy alpha fetoprotein (AFP) stated to be elevated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record

DRAFT

Code	Description
	AFP (Alpha Fetoprotein) Pre-Orchiectomy Range not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Testis

AFP Post-Orchiectomy Lab Value

Item Length: 7
NAACCR Item #: 3805
NAACCR Alternate Name: AFP (Alpha Fetoprotein) Post-Orchiectomy Lab Value
AJCC 8th Edition Chapter(s): Chapter 59, Testis

Description

AFP (Alpha Fetoprotein) Post-Orchiectomy Lab Value refers to the lowest AFP value measured post-orchiectomy. AFP is a serum tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis. The Post-Orchiectomy lab value is used to monitor response to therapy.

Rationale

AFP (Alpha Fetoprotein) Post-Orchiectomy Lab Value is a Registry Data Collection Variable in AJCC. It was previously collected as Testis CS SSF# 12.

See Alpha-fetoprotein (AFP) (Testis) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of the AFP (Alpha Fetoprotein) Post-Orchiectomy Lab Value can be used to code this data item when no other information is available.

Note 2: Record the lab value of the AFP test results documented in the medical record **after orchiectomy** but prior to adjuvant therapy. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: If the initial post-orchiectomy AFP remains elevated, review subsequent tests and record the lowest AFP value (normalization or plateau) prior to adjuvant therapy or before the value rises again.

Note 4: A lab value expressed in micrograms/liter (ug/L) is equivalent to the same value expressed in ng/mL.

Note 5: If the pre-orchiectomy AFP was normal, a post-orchiectomy AFP may not be performed. In this case, code XXXXX.9 should be recorded.

Note 6: If the only information available is a statement of elevated or normal, code XXXXX.9.

Note 7: The same laboratory test should be used to record information in AFP Post-Orchiectomy Range [NAACCR Data Item #3806].

Code	Description
0.0	0.0 nanograms/milliliter (ng/mL)
0.1-99999.9	0.1 – 99,999.9 ng/mL
XXXXX.1	100,000 ng/mL or greater

Code	Description
XXXXX.7	Test ordered, results not in chart
XXXXX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XXXXX.8 may result in an edit error.)
XXXXX.9	Not documented in medical record No orchiectomy performed AFP (Alpha Fetoprotein) Post-Orchiectomy Lab Value not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Testis

AFP Post-Orchiectomy Range

Item Length: 1
NAACCR Item #: 3806
NAACCR Alternate Name: AFP (Alpha Fetoprotein) Post-Orchiectomy Range
AJCC 8th Edition Chapter(s): Chapter 59, Testis

Description

AFP (Alpha Fetoprotein) Post-Orchiectomy Range identifies the range category of the lowest AFP value measured post-orchiectomy. AFP is a serum tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis. The Post-Orchiectomy lab value is used to monitor response to therapy.

Rationale

AFP (Alpha Fetoprotein) Post-Orchiectomy Range is a Registry Data Collection Variable in AJCC. AFP (Alpha Fetoprotein) Post-Orchiectomy Range is used to assign the S Category Pathological and was previously collected as Testis CS SSF# 13.

See Alpha-fetoprotein (AFP) (Testis) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of the AFP (Alpha Fetoprotein) Post-Orchiectomy Range can be used to code this data item when there is no other information available.

Note 2: Record the range of the AFP test as documented in the medical record **after orchiectomy** but prior to adjuvant therapy. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: If the initial post-orchiectomy AFP remains elevated, review subsequent tests and record the lowest AFP value (normalization or plateau) prior to adjuvant therapy or before the value rises again.

Note 4: A lab value expressed in micrograms/liter (ug/L) is equivalent to the same value expressed in nanograms/milliliter (ng/mL).

Note 5: If the pre-orchiectomy AFP was normal, a post-orchiectomy AFP may not be performed. In this case, code 9 should be recorded.

Note 6: The same laboratory test should be used to record information in AFP Post-Orchiectomy Lab Value [NAACCR Data Item #3805].

Code	Description
0	Within normal limits
1	Above normal and less than 1,000 nanograms/milliliter (ng/mL)
2	1,000 -10,000 ng/mL

Code	Description
3	Greater than 10,000 ng/mL
4	Post-Orchiectomy alpha fetoprotein (AFP) stated to be elevated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record No orchiectomy performed AFP (Alpha Fetoprotein) Post-Orchiectomy Range not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Testis

Human Chorionic Gonadotropin (hCG) (Testis)

Definition

Human chorionic gonadotropin (hCG) is a hormone produced by the placenta and some germ cell tumors. Two subunits, alpha and beta, can be measured in blood or serum. The alpha subunit is a non-specific marker for pancreatic and pituitary tumors. Beta-hCG levels are never found in normal healthy men. When the presence of beta-hCG is detected in serum, it always indicates a malignancy. Beta-hCG is secreted by some non- seminomatous germ cell tumors and mixed tumors and is used with AFP to identify the specific cell type of testicular cancer. Beta-hCG is also useful in monitoring response to therapy. After orchiectomy, the hCG should be undetectable within 5 to 8 days. If elevated hCG persists, this is an indication of residual tumor.

For Testis, there are 4 data items that record information on hCG.

- hCG Pre-Orchiectomy Lab Value [NAACR Data Item #3848]
- hCG Pre-Orchiectomy Range [NAACR Data Item #3849]
- hCG Post-Orchiectomy Lab Value [NAACR Data Item #3846]
- hCG Post-Orchiectomy Range [NAACR Data Item #3847]

Coding Guidelines

hCG Pre-Orchiectomy Lab Value and Range

Assign the code for the highest hCG value and corresponding hCG range **prior to orchiectomy**. In the event an orchiectomy is not performed or systemic treatment precedes an orchiectomy, code the highest hCG value and corresponding range prior to any systemic treatment. The hCG Range is a category used to group the lab values into 3 ranges: 1, 2, and 3. The pre-orchiectomy hCG lab value and the pre-orchiectomy hCG range should be from the same test. If the clinician states an S value rather than a lab value, code unknown (code XXXX.9) for the hCG pre-orchiectomy lab value and unknown (code 9) for the hCG pre-orchiectomy range.

hCG Post-Orchiectomy Lab Value and Range

Assign the code for the lowest hCG value and corresponding hCG range **after orchiectomy** but prior to adjuvant treatment. The half-life of human chorionic gonadotropic is 1 to 3 days, but it may take much longer for this tumor marker to return to normal. If the first post-orchiectomy hCG remains elevated, continue reviewing subsequent lab work and record the lowest hCG value (normalization or plateau) prior to adjuvant treatment or before the value rises again. The hCG Range is a category used to group the lab values into 3 ranges: 1, 2, and 3. The post-orchiectomy hCG lab value and the post-orchiectomy hCG range should be from the same test. If the clinician states an S value rather than a lab value, code unknown (code XXXX.9) for the hCG post-orchiectomy lab value and unknown (code 9) for the hCG post-orchiectomy range.

Categories used for Pre- and Post-Orchiectomy hCG Range are:

Code	Description
0	Within normal limits
1	Above normal and less than 5,000 milli-International Units/milliliter (mIU/mL)
2	5,000 - 50,000 mIU/mL
3	Greater than 50,000 mIU/mL

Examples for hCG Pre-Orchiectomy and hCG Post-Orchiectomy Lab Value and Range

- *For these examples, the lab's normal reference range for hCG = 0-5 mIU/mL*

Examples	Lab Value Code	Range Code
2.0 mIU/mL	2.0	0
412 mIU/mL	412.0	1
6213 mIU/mL	6213.0	2
14,724 mIU/mL	14724.0	3
108,325 mIU/mL	XXXXX.1	3
Physician states "hCG elevated," but no value documented	XXXXX.9	4
S value stated (no other information available)	XXXXX.9	9
No AFP test done, or unknown if done	XXXXX.9	9

Additional Information

- **Source documents:** clinical laboratory report (blood or serum test), sometimes in history and physical or clinical statement in pathology report, Testis **cancer protocol**
- **Other names:** Human chorionic gonadotropin, b-hCG, beta subunit HCG, beta hCG, β-hCG
- **Normal Reference Range**
  - < 2 ng/ml (SI: < 2 µg/L or < 2 ug/L) 1 ng/ml of HCG is approximately 5 mIU/ml.
  - < 5 mIU/mL (< 5 IU/L) To record mIU/mL in ng/ml, divide the test result by 5.
- **Measurements**: International Units/liter (IU/L) is equivalent to milli-International Units per milliliter (mIU/ml)

Return back to Schema ID Table

DRAFT

Testis

hCG Pre-Orchiectomy Lab Value

Item Length: 7
NAACCR Item #: 3848
NAACCR Alternate Name: hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Lab Value
AJCC 8th Edition Chapter(s): Chapter 59, Testis

Description

hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Lab Value refers to the hCG value measured prior to treatment. hCG is a serum tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis.

Rationale

hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Lab Value is a Registry Data Collection Variable in AJCC. It was previously collected as Testis CS SSF# 8.

See Human Chorionic Gonadotropin (hCG) (Testis) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of the hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Lab Value can be used to code this data item when no other information is available.

Note 2: Record the lab value of the highest hCG test result documented in the medical record **prior to orchiectomy** or prior to any systemic treatment**.** The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: A lab value expressed in International Units/liter (IU/L) is equivalent to the same value expressed in milli-International Units/milliliter (mIU/mL).

Note 4: The same laboratory test should be used to record information in hCG Pre-Orchiectomy Range [NAACCR Data Item #3849].

Code	Description
0.0	0.0 milli-International Units/milliliter (mIU/mL)
0.1-99999.9	0.1 – 99,999.9 mIU/mL
XXXXX.1	100,000 mIU/mL or greater
XXXXX.7	Test ordered, results not in chart
XXXXX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XXXXX.8 may result in an edit error.)
XXXXX.9	Not documented in medical record hCG (Human Chorionic Gonadotropin) Pre-orchiectomy Lab Value not assessed or unknown if assessed

Testis

hCG Pre-Orchiectomy Range

Item Length: 1
NAACCR Item #: 3849
NAACCR Alternate Name: hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Range
AJCC 8th Edition Chapter(s): Chapter 59, Testis

Description

Human Chorionic Gonadotropin (hCG) Pre-Orchiectomy Range identifies the range category of the highest hCG value measured prior to treatment. hCG is a serum tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis.

Rationale

hCG (Human Chorionic Gonadotropin) is a Registry Data Collection Variable in AJCC. hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Range is used to assign the S Category Clinical and was previously collected as Testis CS SSF# 9.

See Human Chorionic Gonadotropin (hCG) (Testis) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of the hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Range can be used to code this data item when no other information is available.

Note 2: Record the range of the highest hCG test result documented in the medical record **prior to orchiectomy** or prior to any systemic treatment**.** The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: A lab value expressed in International Units/liter (IU/L) is equivalent to the same value expressed in milli-International Units/milliliter (mIU/mL).

Note 4: The same laboratory test should be used to record information in hCG Pre-Orchiectomy Lab Value NAACCR Data Item #3848].

Code	Description
0	Within normal limits
1	Above normal and less than 5,000 milli-International Units/milliliter (mIU/mL)
2	5,000 - 50,000 mIU/mL
3	Greater than 50,000 mIU/mL
4	Pre-orchiectomy human chorionic gonadotropin (hCG) stated to be elevated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record

DRAFT

Code	Description
	hCG pre-orchiectomy range not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Testis

hCG Post-Orchiectomy Lab Value

Item Length: 7
NAACCR Item #: 3846
NAACCR Alternate Name: hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Lab Value
AJCC 8th Edition Chapter(s): Chapter 59, Testis

Description

hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Lab Value refers to the lowest hCG value measured post-orchiectomy. hCG is a serum tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis. The Post-Orchiectomy lab value is used to monitor response to therapy.

Rationale

hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Lab Value is a Registry Data Collection Variable in AJCC. It was previously collected as Testis CS SSF# 14.

See Human Chorionic Gonadotropin (hCG) (Testis) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of the hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Lab Value can be used to code this data item when no other information is available.

Note 2: Record the value of the hCG test as documented in the medical record **after orchiectomy** but prior to adjuvant therapy. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: If the initial post-orchiectomy hCG remains elevated, review subsequent tests and record the lowest hCG value (normalization or plateau) prior to adjuvant therapy or before the value rises again.

Note 4: A lab value expressed in International Units/liter (IU/L) is equivalent to the same value expressed in milli-International Units/milliliter (mIU/mL).

Note 5: If the pre-orchiectomy hCG was normal, a post-orchiectomy hCG may not be performed. In this case, code XXXXX.9 should be recorded.

Note 6: If the only information available is a statement of elevated or normal, code XXXXX.9.

Note 7: The same laboratory test should be used to record information in hCG Post-Orchiectomy Range [NAACCR Data Item #3847].

Code	Description
0.0	0.0 milli-International Units/milliliter (mIU/mL)
0.1-99999.9	0.1 – 99,999.9 mIU/mL

DRAFT

Code	Description
XXXXX.1	100,000 mIU/mL or greater
XXXXX.7	Test ordered, results not in chart
XXXXX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XXXXX.8 may result in an edit error.)
XXXXX.9	Not documented in medical record No orchiectomy performed hCG (Human Chorionic Gonadotropin) Post-orchiectomy Lab Value not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Testis

hCG Post-Orchiectomy Range

Item Length: 1
NAACCR Item #: 3847
NAACCR Alternate Name: hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Range
AJCC 8th Edition Chapter(s): Chapter 59, Testis

Description

Human Chorionic Gonadotropin (hCG) Post-Orchiectomy Range identifies the range category of the lowest hCG value measured post-orchiectomy. hCG is a serum tumor marker that is often elevated in patients with nonseminomatous germ cell tumors of the testis. The Post-Orchiectomy lab value is used to monitor response to therapy.

Rationale

hCG (Human Chorionic Gonadotropin) is a Registry Data Collection Variable in AJCC. hCG (Human Chorionic Gonadotropin) Post-orchiectomy Range is used to assign the S Category Pathological and was previously collected as Testis CS SSF# 15.

See Human Chorionic Gonadotropin (hCG) (Testis) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of the hCG (Human Chorionic Gonadotropin) Post-orchiectomy Range can be used to code this data item when there is no other information available.

Note 2: Record the range of the hCG test as documented in the medical record **after orchiectomy** but prior to adjuvant therapy. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: If the initial post-orchiectomy hCG remains elevated, review subsequent tests and record the lowest hCG value (normalization or plateau) prior to adjuvant therapy or before the value rises again.

Note 4: A lab value expressed in International Units/liter (IU/L) is equivalent to the same value expressed in milli-International Units/milliliter (mIU/mL).

Note 5: If the pre-orchiectomy hCG was normal, a post-orchiectomy hCG may not be performed. In this case, code 9 should be recorded.

Note 6: The same laboratory test should be used to record information in hCG Post-Orchiectomy Lab Value [NAACCR Data Item #3846].

Code	Description
0	Within normal limits
1	Above normal and less than 5,000 milli-International Units/milliliter (mIU/mL)
2	5,000 - 50,000 mIU/mL

Code	Description
3	Greater than 50,000 mIU/mL
4	Post-orchiectomy human chorionic gonadotropin (hCG) stated to be elevated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record No orchiectomy performed hCG (Human Chorionic Gonadotropin) Post-orchiectomy Range not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Testis

Lactate Dehydrogenase (LDH) (Testis)

Definition

When cells (normal or tumor) are damaged or destroyed, an enzyme called lactate dehydrogenase (LDH) is released into the bloodstream. LDH is an indirect indication of possible tumor burden or damage to an organ, which may be caused by metastatic involvement of liver or lung, or a myocardial infarction. The total LDH should be the test value that is coded, but there are five fractions of LDH that measure tissue specific cellular damage: LD1 and LD2: heart, red blood cells and kidneys; LD3: lung; LD4 and LD5: liver, skin and skeletal muscles. LDH is elevated in 60% of patients with non-seminomatous germ cell tumors of the testis. LDH is not a screening test, nor is it diagnostic of melanoma, ocular adnexal lymphoma, or testicular cancer.

For testis, only the LDH Range is coded. LDH is non-specific for testicular cancer. Although part of the criteria for the S category in the TNM system, LDH is not routinely performed unless the patient has evidence of bulky or distant disease.

For Testis, there are 2 data items that record information on LDH.

- LDH Pre-Orchiectomy Range [NAACR Data Item #3868]
- LDH Post-Orchiectomy Range [NAACR Data Item #3867]

Coding guidelines

LDH Pre-Orchiectomy Range

The LDH Range is a category used to group the lab values into 3 ranges: 1, 2, and 3. Code the range of the highest LDH value prior **to orchiectomy**, based on the reference range used by the lab. In the event an orchiectomy is not performed or systemic treatment precedes an orchiectomy, code the range of the highest LDH value prior to any systemic treatment. If the clinician states an S value rather than a lab value, code unknown (code 9).

LDH Post-Orchiectomy Range

Code the range of the highest LDH **after orchiectomy** but prior to adjuvant treatment. If the first post-orchiectomy LDH remains elevated, continue reviewing subsequent lab work and record the lowest LDH value (normalization or plateau) prior to adjuvant treatment or before the value rises again. If the clinician states an S value rather than a lab value, code unknown (code 9).

Categories used for Pre- and Post-Orchiectomy LDH Range are:

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)

Code	Description
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

<u>Additional Information</u>

- **Source documents:** clinical laboratory report; may be included in a liver or hepatic panel/profile, a cardiac panel, or a general metabolic panel of tests, **cancer protocol**
- **Other names:** LD, Lactate dehydrogenase, lactase dehydrogenase, lactic acid dehydrogenase
- **Normal reference range:** varies widely by laboratory, patient age, and the units of measurement.

Return back to Schema ID Table

DRAFT

Testis

LDH Pre-Orchiectomy Range

Item Length: 1
NAACCR Item #: 3868
NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Pre-Orchiectomy Range
AJCC 8th Edition Chapter(s): Chapter 59, Testis

Description

Lactate Dehydrogenase (LDH) Range identifies the range category of the highest LDH value measured prior to treatment. LDH is a nonspecific marker for testicular cancer that is elevated in some germ cell tumors. This data item refers to the Pre-Orchiectomy range.

Rationale

LDH (Lactate Dehydrogenase) is a Registry Data Collection Variable in AJCC. LDH (Lactate Dehydrogenase) Pre-Orchiectomy Range is used to assign the S Category Clinical and was previously collected as Testis CS SSF# 10.

See Lactate Dehydrogenase (LDH) (Testis) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of the LDH (Lactate Dehydrogenase) Pre-Orchiectomy Range can be used to code this data item when no other information is available.

Note 2: Record the range of the highest LDH test result documented in the medical record **prior to orchiectomy** or prior to any systemic treatment**.** The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: Of the three tumor markers, lactate dehydrogenase (LDH) is the least specific for testicular cancer. The magnitude of LDH elevation directly correlates with Testis tumor burden.

Code	Description
0	Within normal limits
1	Less than 1.5 x N (Less than 1.5 times the upper limit of normal for LDH)
2	1.5 to 10 x N (Between 1.5 and 10 times the upper limit of normal for LDH)
3	Greater than 10 x N (Greater than 10 times the upper limit of normal for LDH)
4	Pre-Orchiectomy lactate dehydrogenase (LDH) range stated to be elevated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record

DRAFT

Code	Description
	LDH (Lactate Dehydrogenase) Pre-Orchiectomy Range not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Testis

LDH Post-Orchiectomy Range

Item Length: 1
NAACCR Item #: 3867
NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Post-Orchiectomy Range
AJCC 8th Edition Chapter(s): Chapter 59, Testis

Description

LDH (Lactate Dehydrogenase) Post-Orchiectomy Range identifies the range category of the lowest LDH value measured post-orchiectomy. LDH is a nonspecific marker for testicular cancer that is elevated in some germ cell tumors. The Post-Orchiectomy lab value is used to monitor response to therapy.

Rationale

LDH (Lactate Dehydrogenase) is a Registry Data Collection Variable in AJCC. LDH (Lactate Dehydrogenase) Post-Orchiectomy Range is used to assign the S Category Pathological and was previously collected as Testis CS SSF# 16.

See Lactate Dehydrogenase (LDH) (Testis) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of the LDH (Lactate Dehydrogenase) Post-Orchiectomy Range can be used to code this data item when there is no other information available.

Note 2: Record the range of the LDH test as documented in the medical record **after orchiectomy** but prior to adjuvant therapy. The lab value may be documented in a lab report, history and physical, or clinical statement in the pathology report.

Note 3: If the initial post-orchiectomy LDH remains elevated, review subsequent tests and record the lowest LDH value (normalization or plateau) prior to adjuvant therapy or before the value rises again.

Note 4: Of the three tumor markers, lactate dehydrogenase (LDH) is the least specific for testicular cancer. The magnitude of LDH elevation directly correlates with Testis tumor burden.

Note 5: If the pre-orchiectomy LDH was normal, a post-orchiectomy LDH may not be performed. In this case, code 9 should be recorded.

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)

DRAFT

Code	Description
4	Post-Orchiectomy lactate dehydrogenase (LDH) range stated to be elevated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record No orchiectomy performed LDH (Lactate Dehydrogenase) Post-Orchiectomy Range not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Testis

S Category Clinical

Item Length: 1
NAACCR Item #: 3923
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 59, Testis

Description

S Category Clinical combines the results of pre-orchiectomy Alpha Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG) and Lactate Dehydrogenase (LDH) into a summary S value.

Rationale

S Category Clinical 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

- **Source documents:** CAP Testis cancer protocol

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-S2. Only one elevated test is needed to assign S3. If any individual test is not available and none of the available tests results meets the S3 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

Code	Description
	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.

Return back to Schema ID Table

DRAFT

Testis

S Category Pathological

Item Length: 1
NAACCR Item #: 3924
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 59, Testis

Description

S Category Pathological combines the results of post-orchiectomy Alpha Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG) and Lactate Dehydrogenase (LDH) into a summary S value.

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

- **Source documents:** CAP Testis cancer protocol

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-S2. Only one elevated test is needed to assign S3. If any individual test is not available and none of the available tests results meets the S3 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

Code	Description
	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 Pathological not assessed or unknown if assessed

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

Return back to Schema ID Table

DRAFT

URINARY TRACT

DRAFT

Kidney

Invasion Beyond Capsule

Item Length: 1
NAACCR Item #: 3864
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 60, Kidney

Description

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

Rationale

Kidney Tumor Extension into specific tissues for Kidney is a Registry Data Collection Variable in AJCC. It was previously collected as Kidney, CS SSF #1.

Definition

This data item collects additional information on the description of tumor spread (invasion beyond capsule) as documented in the pathology report. Do not include clinical findings in this field.

Coding guidelines

- Code 0: There is no invasion beyond capsule
- Code 1: Perinephric fat, which is the layer of fat (adipose tissue) outside the renal capsule but inside Gerota's fascia
- Code 2: Renal sinus, which is the elongated oval indentation in the renal parenchyma occupied by the renal pelvis, renal calyces, blood vessels, nerves, and perisinus fat
- Code 3: Gerota's fascia (Gerota's capsule), which is a fibrous envelope of tissue that surrounds the kidney
- Code 4: Any combination of codes 1-3
- Code 5: Invasion beyond the capsule, NOS
- Code 9 when
    - There is no documentation in the medical record
    - Clinical diagnosis only
    - Evaluation of capsule invasion not done or unknown if done

Additional Information

- **Source documents:** pathology report, CAP Kidney cancer protocol

Change from Collaborative Stage v2 (CSv2): *In **CSv2**, if pathology report was available and there is no mention of invasion beyond capsule, the registrar could assume that it was negative and code appropriately. For the SSDI, this assumption cannot be made. There must be a statement that invasion beyond capsule is not present to code 0.*

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.

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.

Note 4: Record invasion beyond capsule as documented in the pathology report. Assign code 0 if surgical resection of the primary site is performed, the pathology report is available for review, and invasion beyond capsule is not mentioned.

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

Return back to Schema ID Table

DRAFT

Kidney

Ipsilateral Adrenal Gland Involvement

Item Length: 1
NAACCR Item #: 3861
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 60, Kidney

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).

Rationale

Ipsilateral adrenal gland involvement for Kidney is a Registry Data Collection Variable in AJCC. It was previously collected as Kidney, CS SSF #3.

Definition

The adrenal gland is contained within Gerota's fascia and is contiguous with the kidney, but it has its own lymphatic and vascular drainage systems. Involvement of the ipsilateral (same side) adrenal gland by kidney tumor—an adverse prognostic indicator—may be by direct extension (contiguous) or hematogenous (through the bloodstream; discontiguous). Do not include clinical findings in this field.

Coding guidelines

- Code 0: There is no involvement of the ipsilateral adrenal gland
- Code 1: Ipsilateral adrenal gland involved by direct extension (contiguous involvement)
- Code 2: Ipsilateral adrenal gland involved by separate nodule (discontiguous involvement)
- Code 3: Ipsilateral adrenal gland involvement by contiguous and discontiguous involvement
- Code 4: Ipsilateral adrenal gland involvement, unknown if contiguous or discontiguous involvement
- Code 9 when
    - There is no documentation in the medical record
    - Clinical diagnosis only
    - Evaluation of ipsilateral adrenal gland involvement not done or unknown if done

Additional Information

- **Source documents:** pathology report, CAP Kidney cancer protocol
- **Other names:** suprarenal gland; same side (ipsilateral)

Change from Collaborative Stage v2 (CSv2): *In **CSv2**, if pathology report was available and there was no mention of ipsilateral gland involvement, the registrar could assume that it was negative and code appropriately. For the SSDI, this assumption cannot be made. There must be a statement that ipsilateral gland involvement is not present to code 0.*

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.

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

Return back to Schema ID Table

DRAFT

Kidney

Major Vein Involvement

Item Length: 1
NAACCR Item #: 3886
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 60, Kidney

Description

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

Rationale

Involvement of major veins for Kidney is a Registry Data Collection Variable in AJCC. It was previously collected as Kidney, CS SSF #2.

Definition

Involvement of veins from a renal cancer has prognostic implications because tumor cells can more easily disseminate through the bloodstream. This data item records information about the presence and level of involvement of specific major blood vessels. Do not code microscopically identified involvement of small unnamed blood vessels within the kidney; this information is coded in the field Lymph-Vascular Invasion (LVI). The tumor may be described as a thrombus, a cluster of tumor cells presents in the center of the vein but not attached to the wall of the vein. Tumor spread may resemble mud extruding along the inside of a pipe. Direct tumor invasion of the wall of the inferior vena cava is not coded in this field.

Record the code that best describes involvement of the renal vein and/or inferior vena cava (IVC) as described in the pathology report. Do not include clinical findings in this field.

Coding guidelines

- Code 0: There is no involvement of the major veins
- Code 1: Involvement of the renal vein or segmental branches
- Code 2: Involvement of the inferior vena cava (IVC)
- Code 3: Involvement of major veins, but not specified which one (renal vein, segmental branches or inferior vena cava (IVC))
- Code 4: Involvement of more than one vein (any combination of codes 1-3)
- Code 9 when
    - There is no documentation in the medical record
    - Clinical diagnosis only
    - Evaluation of major vein involvement not done or unknown if done

Additional Information

- **Source documents:** pathology report, CAP Kidney cancer protocol

Change from Collaborative Stage v2 (CSv2): *In **CSv2**, if pathology report was available and there was no mention of major vein involvement, the registrar could assume that it was negative and code*

appropriately. For the SSDI, this assumption cannot be made. There must be a statement that major vein involvement is not present to code 0.

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.

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

Return back to Schema ID Table

DRAFT

Kidney

Sarcomatoid Features

Item Length: 3
NAACCR Item #: 3925
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 60, Kidney

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.

Rationale

Sarcomatoid features for Kidney is a Registry Data Collection Variable in AJCC. It was previously collected as Kidney, CS SSF #4.

Definition

The presence of sarcomatoid or spindle cell features in a kidney tumor is a strong adverse prognostic factor. There is a specific ICD-O morphology code for renal cell carcinoma, sarcomatoid or spindle cell (8318/3), but this data item documents any sarcomatoid or spindle cell features in any renal cell cancer.

- **Note**: This data item applies to carcinomas only; rare sarcomas of the kidney should not be coded in this field
- Code the percentage of sarcomatoid features documented anywhere in the pathology report

Coding guidelines

Record whether tumor deposits are present or absent.

- Code 000 when the pathology report states that there are no sarcomatoid features
- Code 001-100 code exact percentage of sarcomatoid features appropriately [1% (001) to 100% (100)]
- Code R01-R05 when only range documented (specific percentage not available)
- Code XX6 when sarcomatoid features present, percentage unknown
- Code XX7 when histology is not renal cell carcinoma
- Code XX9 when
    - Not documented in medical record
    - No surgical resection done
    - Pathology report not available
    - Sarcomatoid features not evaluated (not assessed)
    - Unknown if Sarcomatoid Features evaluated (assessed)

Additional Information

- **Source documents:** pathology report, CAP Kidney cancer protocol

- **Other names:** spindle cell features

Change from Collaborative Stage v2 (CSv2): *In **CSv2**, if pathology report was available and there was no mention of sarcomatoid features, the registrar could assume that they were not present and code appropriately. For the SSDI, this assumption cannot be made. There must be a statement that sarcomatoid features are not present to code 000.*

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

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

Note 5: 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%
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

Return back to Schema ID Table

DRAFT

Urethra

Schema Discriminator 1: Urethra/Prostatic Urethra

Item Length: 1
NAACCR Item #: 3926
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): 63: Urethra

Definition

Urethra (male and female) and prostatic urethra have the same ICD-O topography code (C680). However, for purposes of stage grouping AJCC 8th edition, they each have different definitions for T or primary tumor extension. A schema discriminator is necessary to distinguish between these primary sites so that the appropriate sub(chapter)/schema is used.

Coding Instructions and Codes

Note: A schema discriminator is used to discriminate between urethra (male and female) and prostatic urethra. Code the site in which the tumor arose.

Urethra: Male Penile Urethra and Female Urethra (see code 1)

- Subsites include: Urethra, NOS; Urethral gland, Cowper gland

Urethra: Prostatic Urethra (see code 2)

- Subsites include: Prostatic urethra, Prostatic utricle

Code	Description	AJCC Disease ID
1	Male penile urethra Female urethra Urethral gland Cowper gland Urethra, NOS	63.1 Male Penile and Female Urethra: Urothelial Carcinomas; 63.2 Male Penile and Female Urethra: Squamous Cell Carcinoma and Adenocarcinoma
2	Males only Prostatic urethra Prostatic utricle	63.3 Prostatic Urethra: Urothelial Carcinomas; 63.4 Prostatic Urethra: Squamous Cell Carcinoma and Adenocarcinoma

Return back to Schema ID Table

DRAFT

OPHTHALMIC SITES

DRAFT

Eyelid Carcinoma

Perineural Invasion

Item Length: 1
NAACCR Item #: 3909
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 15: Cutaneous Squamous Cell Carcinoma of Head and Neck
- Chapter 20: Colon and Rectum
- Chapter 64: Eyelid Carcinoma
- Chapter 69: Lacrimal Gland

Description

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

Rationale

Perineural Invasion is a Registry Data Collection Variable in AJCC. It was previously collected as Colon and Rectum CS SSF# 8 and Lacrimal Gland CS SSF# 4.

Definition

Perineural invasion is infiltration of nerves in the area of the lesion by tumor cells or spread of tumor along the nerve pathway. The presence of perineural invasion has been shown in several studies to be an indicator of poor patient prognosis. Where positive findings like perineural invasion are expected to be included in pathology reports, negative results can be assumed if they are not specifically addressed.

Code whether perineural invasion is present based on the description in the pathology report.

Additional Information

- **Source documents:** pathology report
- **Other names:** PNI, neurotropism
- **For further information, refer to the** Colon and Rectum **cancer protocol published by the College of American Pathologists for AJCC 8th edition, published October 2017.**
- **Change from Collaborative Stage v2 (CSv2):** In **CSv2**, if pathology report was available and there was no mention of perineural invasion, the registrar could assume that it was negative and code appropriately. Per the SSDI as of 2018, this assumption cannot be made. There must be a statement that perineural invasion is not present/negative to assign "negative." (Code 0)

Coding Instructions and Codes

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

Note 2: Code the presence or absence of perineural invasion by the primary tumor as documented in the pathology report.

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

Return back to Schema ID Table

DRAFT

Conjunctival Melanoma

- See Measured Thickness in Melanoma Uvea

DRAFT

Uveal Melanoma

Schema Discriminator 1: Melanoma Ciliary Body/Melanoma Iris

Item Length: 1
NAACCR Item #: 3926
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 67: Uveal Melanoma

Definition

Iris and ciliary body have the same ICD-O topography code (C694). However, for purposes of stage grouping AJCC 8th edition, they each have different definitions for T or primary tumor extension. A schema discriminator is necessary to distinguish between these primary sites so that the appropriate sub(chapter)/schema is used.

Coding Instructions and Codes

Note: A schema discriminator is used to discriminate between melanoma tumors with primary site code C694: Ciliary Body/Iris. Code the site in which the tumor arose.

Melanoma Ciliary Body (see code 1)

- Subsites include: Ciliary body, crystalline lens, sclera, uveal tract, intraocular, eyeball

Melanoma Iris (see code 2)

- Subsite includes: Iris

Code	Description	AJCC Disease ID
1	Ciliary Body Crystalline lens Sclera Uveal tract Intraocular Eyeball	67:2 Uvea: Choroidal and Ciliary Body Melanomas
2	Iris	67:1 Uvea: Iris Melanomas

Return back to Schema ID Table

DRAFT

Uveal Melanoma

Chromosome 3 Status

Item Length: 1
NAACCR Item #: 3821
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 67, Uveal Melanoma

Description

Chromosome 3 Status refers to the partial or total loss of Chromosome 3, which is a prognostic factor for uveal melanoma.

Rationale

Chromosome 3 Status is a Registry Data Collection Variable in AJCC. This data item was previously collected as Uveal Melanoma, CS SSF# 5.

Definition

The loss of an entire copy of chromosome 3, which occurs in about half of patients, is the most important indicator of poor prognosis for the uveal melanomas, particularly melanoma of the choroids and ciliary body. A variety of sophisticated tests can be used to determine chromosome 3 status

- Karyotyping
- Fluorescence *in situ* hybridization
- Comparative genomic hybridization
- DNA polymorphism analysis (e.g., single nucleotide polymorphism, microsatellite)
- Multiplex ligation probe amplification
- Monosomy 3 means loss of chromosome 3. Determination of chromosome status may be affected by prior irradiation

Coding guidelines

- Code 0 when there is no loss of chromosome 3, or disomy 3
- Code 1 when there is partial loss of chromosome 3
- Code 2 when there is complete loss of chromosome 3, or monosomy 3
- Code 3 when there is loss of chromosome 3, how much not known
- Code 7 when test done, but test results not available
- Code 9 when
    - No documentation in the medical record
    - Chromosome 3 not evaluated (assessed)
    - Unknown if Chromosome 3 evaluated (assessed)
    - Patients received radiation therapy prior to testing

Additional Information

- **Source documents:** pathology report, CAP Uveal Melanoma cancer protocol, specialty/reference lab report, gene expression profile report, other statement in medical record

- **Other names:** Monosomy 3, loss of chromosome 3, chromosome 3 loss of heterozygosity (LOH), isodisomy 3 (rare)

Coding Instructions and Codes

Note 1: Physician statement of chromosome 3 status can be used to code this data item when no other information is available.

Note 2: Monosomy 3, especially if combined with a frequently coexisting gain in chromosome 8q, is independently associated with metastatic risk. Chromosome 3 and 8 statuses may be determined with karyotyping or fluorescent in situ hybridization (FISH).

Note 3: See also Chromosome 8q Status (NAACCR Data Item #3822)

Code	Description
0	No loss of chromosome 3
1	Partial loss of chromosome 3
2	Complete loss of chromosome 3
3	Loss of chromosome 3, NOS
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Chromosome 3 status not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Uveal Melanoma

Chromosome 8q Status

Item Length: 1
NAACCR Item #: 3822
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 67, Uveal Melanoma

Description

Chromosome 8q Status refers to gain in Chromosome 8q, which is a prognostic factor for uveal melanoma.

Rationale

Chromosome 8q Status is a Registry Data Collection Variable in AJCC. This data item was previously collected as Uveal Melanoma, CS SSF# 7.

Definition

The loss of an entire copy of chromosome 8, which occurs in about half of patients, is the most important indicator of poor prognosis for the uveal melanomas, particularly melanoma of the choroids and ciliary body. A variety of sophisticated tests can be used to determine chromosome 8 status

- Karyotyping;
- Fluorescence *in situ* hybridization;
- Comparative genomic hybridization
- DNA polymorphism analysis (e.g., single nucleotide polymorphism, microsatellite);
- Multiplex ligation probe amplification;
- Monosomy 3 means loss of chromosome 3. Determination of chromosome status may be affected by prior irradiation.

Coding guidelines

- Code 0 when there is no gain in chromosome 8q
- Code 1 when there is gain in chromosome 8q
- Code 7 when test done, but results not available
- Code 9 when
    - No documentation in the medical record
    - Chromosome 8q not evaluated (assessed)
    - Unknown if Chromosome 8q evaluated (assessed)
    - Patients received radiation therapy prior to testing

Additional Information

- **Source documents:** pathology report, CAP Uveal Melanoma cancer protocol specialty/reference lab report, gene expression profile report, other statement in medical record
- **Other names:** 8q duplication, 8q trisomy, duplication 8q, partial trisomy 8q, trisomy 8q,

Coding Instructions and Codes

Note 1: Physician statement of chromosome 8q status can be used to code this data item when no other information is available.

Note 2: Monosomy 3, especially if combined with a frequently coexisting gain in chromosome 8q, is independently associated with metastatic risk. Chromosome 3 and 8 statuses may be determined with karyotyping or fluorescent in situ hybridization.

Note 3: See also Chromosome 3 Status (NAACCR Data Item #3821)

Code	Description
0	No gain in chromosome 8q
1	Gain in chromosome 8q
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Chromosome 8q status not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Uveal Melanoma

Extravascular Matrix Patterns

Item Length: 1
NAACCR Item #: 3834
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 67, Uveal Melanoma

Description

Extravascular Matrix Patterns, the presence of loops and networks in extracellular matrix patterns, is a prognostic factor for uveal melanoma.

Rationale

Extravascular Matrix Patterns is a Registry Data Collection Variable in AJCC 8. This data item was previously collected as Uveal Melanoma, CS SSF #11 and CS SSF# 12. These two data items were combined into one data for cases diagnosed 1/1/2018+.

Definition

The presence of extravascular matrix patterns is an indicator for shorter survival. There are two different types of patterns: loops only, or loops forming networks. The identification of the complex monocirculatory patterns (i.e., loops, networks, arcs with branching, parallel with cross-linking or a combination of these patterns) are done using confocal indocyanine green angiography. The patterns are assessed with light microscopy under a dark green filter after staining with periodic-acid Schiff without counterstain. This determines the presence or absence of each matrix pattern, which appear deep purple against a pink background.

Coding guidelines

- Code 0 when pathology report states loops and networks not found
- Code 1 when pathology reports states networks and/or loops present
- Code 9 when the ER is
    - Pathology report available and there is no mention of extravascular matrix patterns (loops or networks)
    - Extravascular matrix patterns not assessed or unknown if assessed

Additional Information

- **Source documents:** pathology report, CAP Uveal Melanoma cancer protocol confocal indocyanine green angiography report, clinician comment

Coding instructions and Codes

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

Note 2: The presence of certain types of extravascular matrix patterns is independently associated with the risk of metastasis. This is documented conclusively for individual loops and for loops forming networks consisting of at least three back-to-back loops. Absence of both loops and networks is associated with the longer survival and presence of loops forming networks is associated with the shortest survival time.

Code	Description
0	Extravascular matrix patterns not present/not identified
1	Extravascular matrix patterns present/identified
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Extravascular Matrix Patterns not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Uveal Melanoma

Measured Basal Diameter

Item Length: 4
NAACCR Item #: 3887
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 67, Uveal Melanoma

Required for Staging: EOD only (used in the calculation of Derived EOD T)

- Melanoma Choroid and Ciliary Body
- Melanoma Iris

Description

Measured Basal Diameter, the largest basal diameter of a uveal melanoma, is a prognostic indicator for this tumor.

Rationale

Measured Basal Diameter is listed as a Registry Data Collection Variable in AJCC. It was previously collected as Uveal Melanoma, CS SSF# 2.

Definition

The basal diameter is the width (horizontal measurement) of the melanoma at its base (in contact with sclera). This is not the same as the depth of invasion (see NAACCR Data Item #3888-Measured Thickness). Clinical research has shown that as an uveal tumor becomes larger, the risk of hematogenous metastases and death increases. In addition, knowing the size of the melanoma is important for treatment planning.

Per the CAP guidelines for Uveal Melanoma, "in clinical practice, the largest tumor basal diameter may be estimated in optic disc diameters (dd, average: 1 dd = 1.5 mm). Techniques such as ultrasonography and fundus photography are used to provide more accurate measurement. When histopathological measurements are recorded after fixation, tumor diameter and thickness may be underestimated because of tissue shrinkage."

Additional Information

- **Source documents**: high-frequency ultrasonography (ultrasound biomicroscopy) report, pathology report, CAP Uveal Melanoma cancer protocol wide-angle fundus camera measurement, clinician report or other documentation in medical record
- **Other names:** largest tumor diameter (LTD), tumor basal size; do not code tumor basal area (measured in square millimeters)

Coding Instructions and Codes

Note 1: Physician statement of measured basal diameter (not the same as tumor size) can be used to code this data item when no other information is available.

Note 2: Code Measured Basal Diameter of tumor not size. Record actual measurement in millimeters (mm) to nearest tenth from clinical documentation, or from a pathology report if surgery performed.

Code	Description
0.0	No mass/tumor found
0.1-99.9	0.1 – 99.9 millimeters (mm) (Exact measurement to nearest tenth of mm)
XX.0	100 millimeters (mm) or larger
XX.1	Described as "less than 3 mm"
XX.2	Described as “at least” 3 mm
XX.3	Described as “at least” 6 mm
XX.4	Described as “at least” 9 mm
XX.5	Described as “at least” 12 mm
XX.6	Described as “at least” 15 mm
XX.7	Described as “at least” 18 mm
XX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XX.8 may result in an edit error.)
XX.9	Not documented in medical record Cannot be determined by pathologist Measured Basal Diameter not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Uveal Melanoma

Measured Thickness

Item Length: 4
NAACCR Item #: 3888
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 66: Melanoma Conjunctiva
- Chapter 67: Uveal Melanoma

Required for Staging: EOD only (used in the calculation of Derived EOD T)
- Melanoma Choroid and Ciliary Body
- Melanoma Iris

Description

Measured Thickness, or height, the thickness of a uveal melanoma, is a prognostic indicator for this tumor.

Rationale

Measured Thickness is listed as a Registry Data Collection Variable in AJCC. It was previously collected as Uveal Melanoma, CS SSF# 3.

Definition

This data items measures tumor thickness, height or depth (vertical dimension), rather than size (lateral dimension) of basal diameter (horizontal dimension). (For basal diameter, see NAACCR Data Item #3887-Measured Basal Diameter).

The depth of invasion or tumor thickness measurement for melanomas of the choroid, ciliary body, and iris is collected in *tenths* of millimeters as stated in the pathology report for the resected specimen. (This is similar to, but not the same as, Breslow depth of invasion, which is measured in hundredths of millimeters.) Code a measurement specifically labeled as “thickness” “height” or “depth” in the pathology report. In the absence of this label, a measurement described as taken from the cut surface of the specimen can be coded. And in the absence of either of these labels, the third dimension in a statement of tumor size (length x width x depth) can be used by the registrar to code this field.

Per the CAP guidelines for Uveal Melanoma, “in clinical practice, tumor thickness may be estimated in diopters (average: 2.5 diopters = 1 mm). Techniques such as ultrasonography and fundus photography are used to provide more accurate measurement. When histopathological measurements are recorded after fixation, tumor diameter and thickness may be underestimated because of tissue shrinkage.”

Additional Information

DRAFT

- **Source documents:** high-frequency ultrasonography (ultrasound biomicroscopy) report, pathology report, CAP Uveal Melanoma cancer protocol wide-angle fundus camera measurement, clinician report or other documentation in medical record
- **Other names:** maximum tumor thickness, depth of invasion; perpendicular tumor diameter (PTD); tumor height

Coding Instructions and Codes

Note 1: Physician statement of measured thickness, or height, can be used to code this data item when no other information is available.

Note 2: Code Measured Thickness, or height, of tumor, not size. Record actual measurement in millimeters (mm) from clinical documentation, or from a pathology report if surgery performed.

Code	Description
0.0	No mass/tumor found
0.1-99.9	0.1 – 99.9 millimeters (mm) (Exact measurement to nearest tenth of mm)
XX.0	100 millimeters (mm) or larger
XX.1	Described as "less than 3 mm"
XX.2	Described as “at least” 3 mm
XX.3	Described as “at least” 6 mm
XX.4	Described as “at least” 9 mm
XX.5	Described as “at least” 12 mm
XX.6	Described as “greater than” 15 mm
XX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XX.8 may result in an edit error.)
XX.9	Not documented in medical record Cannot be determined Measured Thickness not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Uveal Melanoma

Microvascular Density

Item Length: 2
NAACCR Item #: 3891
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 67, Uveal Melanoma

Description

Microvascular Density, a quantitative measure of tumor vascularity, is a prognostic factor for uveal melanoma.

Rationale

Microvascular Density, is a Registry Data Collection Variable in AJCC. This data item was previously collected as Uveal Melanoma, CS SSF# 13.

Definition

A high density of microvessels, identified immunohistochemically using antibodies for vascular endothelial cells (such as Factor VIII-related antigen, CD34 epitope, etc.), has prognostic significance in a melanoma of the uvea. Higher counts have more unfavorable outcome. To obtain microvascular density, the pathologist, using a microscope with an eyepiece graticule (grid) of approximately 0.3 square mm and X200 magnification, counts microvessels from the most highly vascularized areas ("hot spots") of the tumor, identified by scanning the entire immunostained tumor at lower magnification. Any immunolabeled element, clearly separate from an adjacent one and either totally inside the graticule or touching its top or left border, is counted as a microvessel. In several studies, the range of microvascular density was from 5 to 121 vessels, although this will vary depending on the type of immunostaining and area of graticule used.

Code the microvascular density (number of microvessels) in whole numbers as stated in the pathology report in the code range 001 (1 vessel per 0.3 square millimeters) to 500 (500 vessels per 0.3 square millimeters).

Additional Information

- **Source documents:** pathology report, CAP Uveal Melanoma cancer protocol

Coding Instructions and Codes

Note 1: Physician statement of microvascular density (MVD) can be used to code this data item when no other information is available.

Note 2: MVD is independently associated with metastatic risk. The number of immunopositive elements is labeled with a marker for vascular endothelial cells (e.g., CD34 epitope, CD31 epitope, factor VIII-related antigen) and counted from area of densest vascularization (typical field area, 0.3 mm2 squared). Higher counts are associated with shorter survival.

Note 3: Record the results as expressed on the laboratory test. Record the information based on quartiles for laboratory standards if this is the only expression of results.

Code	Description
00	No vessels involved
01-99	01-99 vessels per 0.3 square millimeter (mm2)
X1	Greater than or equal to 100 vessels per 0.3 square millimeter (mm2)
X2	Lowest quartile for laboratory
X3	Second quartile for laboratory
X4	Third quartile for laboratory
X5	Highest quartile for laboratory
X7	Test ordered, results not in chart
X8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
X9	Not documented in medical record Microvascular Density (MVD) not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Uveal Melanoma

Mitotic Count Uveal Melanoma

Item Length: 4
NAACCR Item #: 3892
NAACCR Alternate Name: Mitotic None
AJCC 8th Edition Chapter(s): Chapter 67, Uveal Melanoma

Description

Mitotic Count Uveal Melanoma, the number of mitoses per 40 high-power fields (HPF) based on pathological evaluation, is a prognostic factor for uveal melanoma.

Rationale

Mitotic Count Uveal Melanoma is listed as a Registry Data Collection Variable in AJCC. It was previously collected as Uveal Melanoma, CS SSF# 9.

Definition

Mitotic count is collected for several different types of cancers. For melanomas of the choroids, ciliary body and iris, the standard measurement is the total number of mitoses per 40 high power fields (HPF at 40 times magnification) per 0.152 square millimeters.

Additional Instructions

- **Source documents:** pathology report, CAP Uveal Melanoma cancer protocol

Coding Instructions and Codes

Note 1: Physician statement of mitotic count for a uveal melanoma can be used to code this data item when no other information is available.

Note 2: The mitotic count, the number of mitoses per 40 high-power fields (HPF), reflects the potential aggressiveness or prognosis of uveal melanomas. This data item presumes the denominator of 40 HPF, so just the numerator (the mitotic count) is coded here.

- For other schemas in which mitotic count is collected, the denominator may vary.

Note 3: An HPF usually has a magnification objective of 40 (a 40x field). As described in the AJCC chapter on uveal melanomas, the typical field area is 0.152 square millimeters (mm2).

Note 4: Record mitotic count to the nearest tenth as documented in the pathology report.

- For ***example***, a mitotic count of 6/40 HPF would be coded 6.0.

Code	Description
0.0	0 mitoses per 40 high-power fields (HPF) Mitoses absent, no mitoses present, no mitotic activity
0.1-99.9	0.1-99.9 mitosis per 40 HPF
XX.1	100 or more mitoses per 40 HPF

Code	Description
XX.2	Stated as low mitotic count or rate with no specific number
XX.3	Stated as high mitotic count or rate with no specific number
XX.4	Mitotic count described with denominator other than 40 HPF
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code XX.8 may result in an edit error.)
XX.9	Not documented in medical record Mitotic Count Uveal Melanoma not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Retinoblastoma

Heritable Trait

Item Length: 1
NAACCR Item #: 3856
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 68, Retinoblastoma

Description

Heritable trait pertains to evidence that a tumor is associated with a heritable mutation. In retinoblastoma, the heritable trait is a germline mutation in the RB1 gene, which is associated with bilateral disease, family history of retinoblastoma, presence of concomitant CNS midline embryonic tumor (commonly in pineal region), or retinoblastoma with an intracranial primitive neuroectodermal tumor (i.e., trilateral retinoblastoma). Children with any of these features may be assigned the H1 status without molecular testing. High quality molecular testing for RB1 mutation is required to determine the presence or absence of RB1 mutation for children without clinical features of a heritable mutation.

Rationale

Heritable trait is required for prognostic stage grouping in AJCC 8th edition, Chapter 68 *Retinoblastoma*. It is a new data item for cases diagnosed 1/1/2018+.

Definition

Heritable disease (trait) is defined by the presence of a germline mutation of the *RB1* gene. This germline mutation may have been inherited from an affected progenitor (25% of cases) or may have occurred in a germ cell before conception or in utero during early embryogenesis in patients with sporadic disease (75% of cases). The presence of positive family history or bilateral or multifocal disease is suggestive of heritable disease.

Heritable retinoblastoma may manifest as unilateral or bilateral disease. The penetrance of the *RB1* mutation (laterality, age at diagnosis, and number of tumors) is probably dependent on concurrent genetic modifiers such as *MDM2* and *MDM4* polymorphisms. All children with bilateral disease and approximately 15% of patients with unilateral disease are presumed to have the heritable form, even though only 25% have an affected parent.

In heritable retinoblastoma, tumors tend to be diagnosed at a younger age than in the nonheritable form of the disease. Unilateral retinoblastoma in children younger than 1 year raises concern for heritable disease, whereas older children with a unilateral tumor are more likely to have the nonheritable form of the disease.

Children with a germline *RB1* mutation may continue to develop new tumors for a few years after diagnosis and treatment; for this reason, they need to be examined frequently. It is common practice for examinations to occur every 2 to 4 months for at least 28 months. The interval between exams is based on the stability of the disease and age of the child (i.e., less frequent visits as the child ages).

Patients with heritable retinoblastoma are also at a greater risk for subsequent neoplasms.

Heritable trait is required for prognostic stage grouping in AJCC 8th edition, Chapter 68 *Retinoblastoma*. It is a new data item for cases diagnosed 1/1/2018+.

Additional Information

- **Source documents:** lab reports (blood), pathology report

Coding Instructions and Codes

Note 1: Physician statement of retinoblastoma heritable trait can be used to code this data item.

Note 2: Code Heritable trait (H) based on the criteria listed in Chapter 68 *Retinoblastoma* "Definition of Heritable Trait (H)."

Note 3: Code 0 (H0) if clinical features do not exist or laboratory germline RB1 test is negative or there is no clinical evidence of mutation. Results may be from blood or tissue testing.

Note 4: Code 0 (H0) if residual (false negative) risk for a mutation is less than 1% or at population risk (0.007%) in a laboratory with demonstrated sensitivity greater than 97%.

Note 5: Code 1 (H1) may be assigned based on positive molecular testing for germline RB1 gene.

Note 6: Code 1 (H1) may be assigned based on clinical evidence of any of the following features even without molecular testing (in particular for children). When discrete clinical evidence of heritable trait is not present, high-quality molecular evidence is mandatory before designating a child as H1 positive.

- Bilateral disease
- Family history of retinoblastoma
- Presence of concomitant CNS midline embryonic tumor (commonly in pineal region)
- Retinoblastoma with an intracranial primitive neuroectodermal tumor (i.e., trilateral retinoblastoma)

Note 7: Variants of unknown significance should be categorized as 9 (HX).

Code	Description
0	H0: Normal RB1 alleles No clinical evidence of mutation
1	H1: RB1 gene mutation OR Clinical evidence of mutation
7	Test ordered, results not in chart
9	HX: Not documented in medical record Test not done, or unknown if done Insufficient evidence of a constitutional RB1 gene mutation

Return back to Schema ID Table

DRAFT

Lacrimal Gland

Schema Discriminator 1: Lacrimal Gland/Sac

Item Length: 1
NAACCR Item #: 3926
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 69: Lacrimal Gland

Definition

The lacrimal (also spelled lachrymal) gland is the only epithelial structure normally present within the orbit. Its composition is the same as epithelial salivary glands and TNM staging parallels that of the major salivary gland classification

Lacrimal gland and lacrimal sac have the same ICD-O topography code (C695). However, for purposes of stage grouping AJCC 8th edition, lacrimal gland is AJCC staged while lacrimal sac is not (Summary Stage only). A schema discriminator is necessary to distinguish between these primary sites so that the appropriate chapter/schema is used.

Coding Instructions and Codes

Note 1: A schema discriminator is used to discriminate between lacrimal gland and lacrimal sac tumors with primary site code C695: Lacrimal Gland. Code the site in which the tumor arose.

Note 2: If the histology is transitional cell carcinoma (8120/3, 8130/3), assign code 2.

Lacrimal Gland (see code 1)
- Subsites include: lacrimal gland

Lacrimal Sac (see code 2)
- Subsites include: lacrimal sac, lacrimal duct (NOS), nasal lacrimal duct

Code	Description	AJCC Disease ID
1	Lacrimal gland	69: Lacrimal Gland Carcinoma
2	Lacrimal sac Lacrimal duct, NOS Nasal lacrimal duct/sac Nasolacrimal duct	n/a (not TNM staged)
9	Lacrimal, NOS	n/a (not TNM staged)

Return back to Schema ID Table

DRAFT

Lacrimal Gland

Adenoid Cystic Basaloid Pattern

Item Length: 5
NAACCR Item #: 3803
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 69, Lacrimal Gland Carcinoma

Description

Adenoid Cystic Basaloid Pattern, the presence of a basaloid pattern on pathological examination, is a prognostic factor for adenoid cystic carcinoma of the lacrimal gland.

Rationale

Adenoid Cystic Basaloid Pattern is a Registry Data Collection Variable in AJCC 8. This data item was previously collected as Lacrimal Gland, CS SSF# 6.

Definition

Adenoid cystic carcinoma (ICD-O-3 morphology code 8200/3) is the most common malignant epithelial tumor of the lacrimal gland. Adenoid cystic carcinoma is a tumor composed of modified myoepithelial and ductal differentiated cells. A genetic alteration (i.e., fusion oncogene MYB-NFIB) is found in the majority of adenoid cystic carcinomas There are three histologic patterns within the adenoid cystic carcinoma group: cribriform, solid and tubular.

Coding guidelines

- Code 0.0 when the pathology report states that basaloid or solid pattern is not present
- Code 0.1-100.0 when the pathology report states the percent of basaloid or solid pattern that is present
- Code XXX.5 when basaloid or solid pattern present but percentage not known;
- Code XXX.9 when
    - Histopathologic pattern not documented in the medical record
    - Histopathologic pattern not evaluated (assessed)
    - Unknown if histopathologic pattern evaluated (assessed)
    - When histologic type other than 8200 and there is no mention of basaloid pattern (see Note 2 under coding instructions)

Additional Information

- **Source documents:** pathology report
- **Other names:** ACC, basaloid type adenoid cystic carcinoma

Coding Instructions and Codes

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

Note 2: This is most commonly found in Adenoid Cystic Carcinoma (8200/3), but can be present in other histologies.

Code	Description
0.0-100.0	0.0 to 100.0 percent basaloid pattern
XXX.5	Basaloid pattern present, percentage not stated
XXX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XXX.8 will result in an edit error.)
XXX.9	Not documented in medical record Adenoid Cystic Basaloid Pattern not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Lacrimal Gland

See Eyelid Carcinoma for the following data item

Return back to Schema ID Table

DRAFT

DRAFT

Brain and Other Central Nervous System

Brain Molecular Markers

Item Length: 2
NAACCR Item #: 3816
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 72, Brain and Spinal Cord

Description

Multiple brain molecular markers have become standard pathology components necessary for diagnosis. This data item captures clinically important brain cancer subtypes identified by molecular markers that are not distinguishable by ICD-O-3 codes.

Rationale

Collection of these clinically important brain cancer subtypes has been recommended by CBTRUS.

Coding Instructions and Codes

Note 1: This data item applies only to ICD-O-3 histology codes: 9400/3, 9401/3, 9440/3, 9450/3, 9451/3, 9471/3 and 9478/3. If a histology is not included in this list, assign, code 85.

Note 2: Physician statement of histologic subtype can be used to code this data item.

Note 3: Only one code is applicable for each tumor.

- IDH mutation status distinguishes between clinically important subtypes within ICD-O-3 9400/3, Diffuse astrocytoma and 9401/3, Anaplastic astrocytoma.
- IDH mutant and 1p/19q co-deletion distinguishes between clinically important subtypes within ICD-O-3 code 9450/3, Oligodendroglioma and 9451/3, Anaplastic Oligodendroglioma.
- IDH-wildtype distinguishes clinically important subtypes within ICD-O-3 9400/3, Diffuse astrocytoma, 9401/3, Anaplastic astrocytoma and 9440/3, Glioblastoma, Epithelioid glioblastoma and Glioblastoma, NOS (note that the new ICD-O-3 code 9445/3 applies to Glioblastoma, IDH-mutant; information regarding this subtype is not collected using this data item).
- SHH-activation and TP53-wildtype distinguishes between clinically important subtypes within ICD-O-3 histology code 9471/3, Medulloblastoma.
- C19MC alteration status distinguishes a clinically important highly aggressive subtype within ICD-O-3 9478/3, Embryonal tumor with multilayered rosettes.

***Examples*:**

1. Biopsy of brain tumor, microscopic confirmation diagnosis: Diffuse Astrocytoma (9400/3). Additional testing done and IDH-mutant is identified. Code 01. Biopsy of brain tumor, microscopic confirmation diagnosis: Anaplastic astrocytoma (9401/3). No further testing or results unknown. Code 99.
2. MRI of brain tumor, clinical diagnosis: glioblastoma. No further workup. Code 99.
3. Biopsy of brain tumor, microscopic confirmation diagnosis: Mixed glioma (9382/3). Code 85.

Code	Description
01	Diffuse astrocytoma, IDH-mutant (9400/3)
02	Diffuse astrocytoma, IDH-wildtype (9400/3)
03	Anaplastic astrocytoma, IDH-mutant (9401/3)
04	Anaplastic astrocytoma, IDH-wildtype (9401/3)
05	Glioblastoma, IDH-wildtype (9440/3)
06	Oligodendroglioma, IDH-mutant and 1 p/19q co-deleted (9450/3)
07	Anaplastic oligodendroglioma, IDH-mutant and 1p/19q co-deleted (9451/3)
08	Medulloblastoma, SHH-activated and TP53-wildtype (9471/3)
09	Embryonal tumor with multilayered rosettes, C19MC-altered (9478/3)
85	Not applicable: Histology not 9400/3, 9401/3, 9440/3, 9450/3, 9451/3, 9471/3, 9478/3
86	Benign or borderline tumor
87	Test ordered, results not in chart
88	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 88 will result in an edit error.)
99	Not documented in patient record No microscopic confirmation Brain molecular markers not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Brain and Other Central Nervous System

Loss of Heterozygosity: Chromosome 1p and Chromosome 19q (CNS)

Definition

These two genetic tests are frequently done at the same time and reported together. Loss of heterozygosity (LOH) in a chromosome means that genetic material normally found in a specific area of a chromosome is missing. In other words, this is damage to the chromosome that results in failure of tumor suppression, which in turn may cause the development or progression of a malignancy. For 1p LOH, the specific chromosomal defect is on the short arm (p) of chromosome 1. For 19q LOH, the specific chromosomal defect is on the long arm (q) of chromosome 19.

Normal cells have two complete copies of each chromosome, a state called heterozygosity. The loss of this section of the chromosome is associated with improved outcome. It can be used to aid diagnosis and to make treatment decisions because sensitivity to chemotherapy agents, such as lomustine, procarbazine, and vincristine, is increased with either 1p or 19q LOH. Special molecular diagnostic (polymerase chain reaction or gene amplification) tests look for missing genetic material. LOH for chromosome 1p and 19q is tested primarily for oligodendroglioma, anaplastic oligodendroglioma, oligoastrocytoma, and anaplastic oligoastrocytoma. It is infrequently tested for other gliomas, such as glioblastoma multiforme.

Coding guidelines

- Code 0 when the 1p/19q is not identified/not present
- Code 1 when the 1p/19q is present
- Code 7 when the 1p/19q test was ordered but the results are not in the medical record
- Code 9 when
    - No documentation in the medical record
    - 1p/19q test not done (not assessed)
    - Unknown if 1p/19q test was performed (unknown if assessed)

Additional Information

- **Other names** allelic loss, gene deletion; 1p/19q fragment analysis

Return back to Schema ID Table

DRAFT

Brain and Other Central Nervous System

Chromosome 1p: Loss of Heterozygosity (LOH)

Item Length: 1
NAACCR Item #: 3801
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 72, Brain and Spinal Cord

Description

Chromosome 1p: Loss of Heterozygosity (LOH) refers to the loss of genetic material normally found on the short arm of one of the patient's two copies of chromosome 1. Codeletion of Chromosome 1p and 19q is a diagnostic, prognostic and predictive marker for gliomas and is strongly associated with the oligodendroglioma phenotype.

Rationale

Chromosome 1p: Loss of Heterozygosity (LOH) is a Registry Data Collection Variable in AJCC. It was previously collected as Brain, CS SSF #5.

See Loss of Heterozygosity: Chromosome 1p and Chromosome 19q (CNS) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of Chromosome 1p deletion/LOH can be used to code this data item.

Note 2: This is a special molecular diagnostic test performed on tumor tissue to identify loss of genetic material normally found on the short arm of one of the patient's two copies of chromosome 1. A normal cell will contain two complete copies of each chromosome, one from each parent, and this normal state is termed heterozygous. Loss of heterozygosity (LOH) is an abnormal state reflecting loss of the whole arm of chromosome 1p following a chromosomal translocation event.

Note 3: Other terms for LOH include whole arm loss, gene deletion and allelic loss.

Note 4: Below is a list of histologies/terms for which the Chromosome 1p test is commonly done. If the test was done, record the results, regardless of the histology.

- 9382/3: Oligoastrocytoma (anaplastic, or NOS)
- 9400/3: Diffuse astrocytoma (IDH mutant, IDH wild type, or NOS)
- 9401/3: Anaplastic astrocytoma (IDH mutant, IDH wild type, or NOS)
- 9411/3: Gemistocytic astrocytoma, IDH mutant
- 9424/3: Anaplastic pleomorphic xanthoastrocytoma
- 9430/3: Astroblastoma
- 9440/3: Glioblastoma (epithelioid, IDH wild type, or NOS)
- 9441/3: Giant cell glioblastoma
- 9442/3: Gliosarcoma
- 9445/3: Glioblastoma, IDH mutant
- 9450/3: Oligodendroglioma (IDH mutant and 1p/19q codeleted, or NOS)
- 9451/3: Anaplastic oligodendroglioma (IDH mutant and 1p/19q codeleted, or NOS)

- 9505/3: Anaplastic ganglioglioma
- 9530/3: Anaplastic (malignant) meningioma

Note 5: If the histology is not listed among those for which the Chromosome 1p test is commonly done, and the test result is not readily available, assume it was not done and code 9 for unknown.

Note 6: For brain tumors, tests for LOH of chromosomes 1p and 19q may be performed at the same time and reported on a single report. See also Chromosome 19q: Loss of Heterozygosity (LOH) [NAACCR Data Item #3802]

Code	Description
0	Chromosome 1p deletion/LOH not identified/not present
1	Chromosome 1p deletion/LOH identified/present
6	Benign or borderline tumor
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in patient record Cannot be determined by the pathologist Chromosome 1p deletion/LOH not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Brain and Other Central Nervous System

Chromosome 19q: Loss of Heterozygosity (LOH)

Item Length: 1
NAACCR Item #: 3802
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 72, Brain and Spinal Cord

Description

Chromosome 19q: Loss of Heterozygosity (LOH) refers to the loss of genetic material normally found on the long arm of one of the patient's two copies of chromosome 19. Codeletion of Chromosome 1p and 19q is a diagnostic, prognostic and predictive marker for gliomas and is strongly associated with the oligodendroglioma phenotype.

Rationale

Chromosome 19q: Loss of Heterozygosity (LOH) is a Registry Data Collection Variable in AJCC. It was previously collected as Brain, CS SSF #6.

See Loss of Heterozygosity: Chromosome 1p and Chromosome 19q (CNS) **for additional information.**

Coding Instructions and Codes

Note 1: Physician statement of Chromosome 19q deletion/LOH can be used to code this data item.

Note 2: This is a special molecular diagnostic test performed on tumor tissue to identify loss of genetic material normally found on the long arm of one of the patient's two copies of chromosome 19. A normal cell will contain two complete copies of each chromosome, one from each parent, and this normal state is termed heterozygous. Loss of heterozygosity (LOH) is an abnormal state reflecting loss of the whole arm of chromosome 19q following a chromosomal translocation event.

Note 3: Other terms for LOH include whole arm loss, deletion and allelic loss.

Note 4: Below is a list of histologies/terms for which the Chromosome 19q test is commonly done. If the test was done, record the results, regardless of the histology.

- 9382/3: Oligoastrocytoma (anaplastic, or NOS)
- 9400/3: Diffuse astrocytoma (IDH mutant, IDH wild type, or NOS)
- 9401/3: Anaplastic astrocytoma (IDH mutant, IDH wild type, or NOS)
- 9411/3: Gemistocytic astrocytoma, IDH mutant
- 9424/3: Anaplastic pleomorphic xanthoastrocytoma
- 9430/3: Astroblastoma
- 9440/3: Glioblastoma (epithelioid, IDH wild type, or NOS)
- 9441/3: Giant cell glioblastoma
- 9442/3: Gliosarcoma
- 9445/3: Glioblastoma, IDH mutant
- 9450/3: Oligodendroglioma (IDH mutant and 1p/19q codeleted, or NOS)
- 9451/3: Anaplastic oligodendroglioma (IDH mutant and 1p/19q codeleted, or NOS)

- 9505/3: Anaplastic ganglioglioma
- 9530/3: Anaplastic (malignant) meningioma

Note 5: If the histology is not listed among those for which the Chromosome 1p test is commonly done, and the test result is not readily available, assume it was not done and code 9 for unknown.

Note 6: For brain tumors, tests for LOH of chromosomes 1p and 19q may be performed at the same time and reported on a single report. See also Chromosome 1p: Loss of Heterozygosity (LOH) [NAACCR Data Item #3801].

Code	Description
0	Chromosome 19q deletion/LOH not identified/not present
1	Chromosome 19q deletion/LOH present
6	Benign or borderline tumor
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in patient record Cannot be determined by the pathologist Chromosome 19q: LOH not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Brain and Other Central Nervous System

Methylation of O6-Methylguanine-Methyltransferase

Item Length: 1
NAACCR Item #: 3889
NAACCR Alternate Name: Methylation of O6-Methylguanine-Methyltransferase (MGMT)
AJCC 8th Edition Chapter(s): Chapter 72, Brain and Spinal Cord

Description

O6-Methylguanine-Methyltransferase (MGMT) is an enzyme in cells that repairs DNA. Methylation of the MGMT gene reduces production of the MGMT enzyme and the ability of tumor cells to repair damage caused by chemotherapy. Methylation of MGMT is a prognostic and predictive factor for high grade gliomas.

Rationale

Methylation of O6-Methylguanine-Methyltransferase (MGMT) is a Registry Data Collection Variable in AJCC. It was previously collected as Brain, CS SSF #4.

Definition

O6-Methylguanine-Methyltransferase (MGMT) is an enzyme in cells that repairs DNA. DNA repair is undesirable in tumors, because it may enable them to overcome the DNA damage done by chemotherapy. With methylation, less MGMT enzyme is produced, which may lead to prolonged survival compared to unmethylated MGMT

A patient with increased MGMT methylation is more likely to respond to alkylating agents such as temozolomide (Temodar) and the nitrosoureas, some of the few drugs effective for brain tumors. MGMT methylation is a special (not routine) molecular test done on tumor tissue. It is used primarily for anaplastic oligodendroglioma, anaplastic astrocytoma and glioblastoma multiforme, but can also be done for low grade malignant central nervous system tumors.

Coding guidelines

- Code 0 when the MGMT is not identified/not present
- Code 1 when the MGMT is low
- Code 2 when the MGMT is high
- Code 3 when the MGMT is mentioned, but not stated as low or high
- Code 6 for a benign (/0) or borderline (/1) tumor
- Code 7 when the MGMT test was ordered but the results are not in the medical record.
- Code 9 when
    - No information in the medical record about MGMT
    - MGMT test not done (not assessed)
    - Unknown if MGMT test was performed (unknown if assessed)

Additional Information

- **Source documents:** pathology report, specialty or reference laboratory report
- **Other names:** MGMT promoter methylation, methylation status

Coding Instructions and Codes

Note 1: Physician statement of the methylation status of the MGMT, also termed MGMT promoter, gene can be used to code this data item.

Note 2: O6-Methylguanine-Methyltransferase (MGMT) is an enzyme in cells that repairs DNA. DNA repair is undesirable in tumors, because it may enable them to overcome the DNA damage done by chemotherapy. With methylation, less MGMT enzyme is produced, which may lead to prolonged survival compared to unmethylated MGMT.

Note 3: Below is a list of histologies/terms for which the MGMT test is commonly done. If the test was done, record the results, regardless of the histology.

- 9382/3: Anaplastic oligoastrocytoma, NOS
- 9382/3: Oligoastrocytoma, NOS
- 9400/3: Diffuse astrocytoma (IDH mutant, IDH wild type, NOS)
- 9401/3: Anaplastic astrocytoma (IDH mutant, IDH wild type, NOS)
- 9411/3: Gemistocytic astrocytoma, IDH mutant
- 9424/3: Anaplastic pleomorphic xanthoastrocytoma
- 9440/3: Glioblastoma (epithelioid, IDH wild type, NOS)
- 9441/3: Giant cell glioblastoma
- 9442/3: Gliosarcoma
- 9445/3: Glioblastoma, IDH mutant
- 9450/3: Oligodendroglioma (IDH mutant and 1p/19q codeleted, NOS)
- 9451/3: Anaplastic oligodendroglioma (IDH mutant and 1p/19 codeleted, NOS)
- 9505/3: Anaplastic ganglioglioma
- 9530/3: Anaplastic (malignant)meningioma

Note 4: If the histology is not listed among those for which the MGMT test is commonly done, and the test result is not readily available, assume it was not done and code 9 for unknown.

Code	Description
0	MGMT methylation absent/not present, unmethylated MGMT
1	MGMT methylation present, low level Hypomethylated Partial methylated
2	MGMT methylation present, high level Hypermethylated
3	MGMT Methylation present, level unspecified
6	Benign or borderline tumor
7	Test ordered, 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 patient record Cannot be determined by the pathologist MGMT not assessed or unknown if assessed

ENDOCRINE SYSTEM

DRAFT

Thyroid (including Medullary)

Schema Discriminator 1: Thyroid Gland/Thyroglossal Duct

Item Length: 1
NAACCR Item #: 3926
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 73: Thyroid-Differentiated and Anaplastic
- Chapter 74: Thyroid-Medullary

Definition

Thyroid, NOS and thyroglossal duct have the same ICD-O topography code (C739). However, for purposes of stage grouping AJCC 8th edition, thyroid, NOS is AJCC staged while thyroglossal duct is not (summary stage only). A schema discriminator is necessary to distinguish between these primary sites so that the appropriate chapter/schema is used.

Coding Instructions and Codes

Note: A schema discriminator is used to discriminate between thyroid gland and thyroglossal duct tumors with primary site code C739: Thyroid Gland. Code the site in which the tumor arose.

- **Thyroid gland (see code 1)**
  - Subsites include: Thyroid, NOS
- **Thyroglossal duct (see code 2)**

Code	Description	AJCC Disease ID
1	Thyroid gland Thyroid, NOS	73.1: Thyroid: Differentiated 73.2: Thyroid: Anaplastic 74: Thyroid: Medullary
2	Thyroglossal duct cyst	n/a (not TNM staged)

Return back to Schema ID Table

DRAFT

DRAFT

Lymphomas (Adult and Pediatric Hodgkin and Non-Hodgkin Lymphomas)

Schema Discriminator 1 (Histology Discriminator for 9591/3)

Item Length: 1
NAACCR Item #: 3926
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 79: Hodgkin and Non-Hodgkin Lymphomas
- Chapter 80: Pediatric Hodgkin and Non-Hodgkin Lymphomas
- Chapter 83: Leukemia

Coding Notes and Instructions

Note: A schema discriminator is used to discriminate for histology 9591/3: Non-Hodgkin lymphoma to determine which Stage Group table to use.

- **9591/3: Splenic B-cell lymphoma/leukemia, unclassifiable (see code 1)**
  Abstracted and staged as a leukemia
- **9591/3: Hairy cell leukemia variant (see code 2)**
  Abstracted and staged as a leukemia
- **9591/3**: **Splenic diffuse red pulp small B-cell lymphoma (see code 3)**
  Abstracted and staged as a lymphoma
- **9591/3: Non-Hodgkin lymphoma, NOS (see code 9)**
  Abstracted and staged as a lymphoma

Code	Description	AJCC Disease ID
1	Splenic B-cell lymphoma/leukemia, unclassifiable	83: Leukemia
2	Hairy cell leukemia variant Prolymphocytic variant of hairy cell leukemia	83: Leukemia
3	Splenic diffuse red pulp small B-cell lymphoma Splenic marginal zone lymphoma, diffuse variant Splenic red pulp lymphoma with numerous basophilic villous lymphocytes Splenic lymphoma with villous lymphocytes	79.0: Lymphoma
9	Non-Hodgkin lymphoma, NOS Any other terminology describing NHL	79.0: Lymphoma

Return back to Schema ID Table

DRAFT

Lymphomas (Adult and Pediatric Hodgkin and Non-Hodgkin Lymphomas)

B Symptoms

Item Length: 1
NAACCR Item #: 3812
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 79: Hodgkin and Non-Hodgkin Lymphoma
- Chapter 80: Pediatric Hodgkin and Non-Hodgkin Lymphoma

Description

B symptoms refer to systemic symptoms of fever, night sweats, and weight loss which can be associated with both Hodgkin lymphoma and some non-Hodgkin lymphomas. The presence of B symptoms is a prognostic factor for some lymphomas.

Rationale

B symptoms is a Registry Data Collection Variable in AJCC. This data item was previously collected for Lymphomas, SSF# 2.

The stages of Hodgkin Lymphoma are classified as either A or B according to the absence or presence of defined constitutional symptoms. The stage group suffix for a patient without these systemic symptoms is "A," meaning absence of symptoms or asymptomatic; for example, Stage IIA. The stage group suffix for a patient with any of the symptoms listed below is "B," such as Stage IIIB. The symptoms are carefully defined:

- Fevers: Unexplained fever with temperature above 38 degrees centigrade or 101.5 degrees Fahrenheit.
- Night sweats: Drenching sweats (e.g. those that require change of bedclothes)
- Weight loss: Unexplained weight loss of more than 10% of the usual body weight in the 6 months prior to diagnosis.

Other symptoms, such as chills, pruritic, alcohol-induced pain and fatigue, are not included in the A or B designation but are recorded in the medical record, as the reappearance of these symptoms may be a harbinger of recurrence. The designation A or B is not included in the revised staging of NHL in AJCC8, although clinicians are encouraged to record the presence of these symptoms in the medical record. The presence or absence of B symptoms may be collected in registries for both HL and NHL.

Coding guidelines

- Code 0 when there is no evidence of B symptoms present, per physician or physical exam
- Code 1 when the physician states the patient has B symptoms
- Code 9 when
    - Not documented in the medical record

- B symptoms not evaluated (assessed)
- Unknown if B symptoms evaluated (assessed)

Additional Information

- **Source documents:** patient history, progress notes, consultant notes, other statements in medical record
- **Other names:** B symptoms; Fever: Palestine fever, hyperpyrexia, febrile response; sleep hyperhidrosis, nocturnal hyperhydrosis
- **Note**: This was previously required for staging under the Ann Arbor Staging Classification for Lymphomas. The new Lugano Staging System does not require this for staging.
- **Change from Collaborative Stage v2 (CSv2):** In **CSv2**, if there was no mention of B symptoms, the registrar could assume that they were not present and code appropriately. For the SSDI, this assumption cannot be made. There must be a statement that B symptoms are not present to assign code 0.

Coding Instructions and Codes

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

Note 2: Each stage should be classified as either A or B according to the absence or presence of defined constitutional symptoms, such as

- Fevers: Unexplained fever with temperature above 38 degrees C
- Night sweats: Drenching sweats that require change of bedclothes
- Weight loss: Unexplained weight loss of more than 10% of the usual body weight in the six months prior to diagnosis

Note 3: Pruritus alone does not qualify for B classification, nor does alcohol intolerance, fatigue, or a short, febrile illness associated with suspected infections.

Note 4: Code 9 if there is no mention of B symptoms.

Code	Description
0	No B symptoms (asymptomatic) Classified as "A" by physician when asymptomatic
1	Any B symptom(s) Night sweats (drenching) Unexplained fever (above 38 degrees C) Unexplained weight loss (generally greater than 10% of body weight in the six months before admission) B symptoms, NOS Classified as "B" by physician when symptomatic
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record B symptoms not assessed or unknown if assessed

Lymphomas (Adult and Pediatric Hodgkin and Non-Hodgkin Lymphomas)

HIV Status

Item Length: 1
NAACCR Item #: 3859
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 79: Hodgkin and Non-Hodgkin Lymphoma
- Chapter 80: Pediatric Hodgkin and Non-Hodgkin Lymphoma

Description

HIV status refers to infection with the Human Immunodeficiency Virus which causes Acquired Immune Deficiency Syndrome (AIDS). AIDS is associated with increased risk of developing some lymphomas.

Rationale

HIV status can be collected by the surveillance community for neoplasms (e.g., Kaposi Sarcoma, Lymphomas) that are closely related to HIV/AIDS. Prior to 2018, Lymphoma SSF#1 was used for HIV Status.

Definition

Human immunodeficiency virus (HIV) is the causal agent for acquired immune deficiency syndrome (AIDS). Certain types of cancer are associated with HIV and AIDS, including Hodgkin lymphoma, diffuse large B-cell lymphoma, and primary central nervous system lymphoma. These diseases in patients with HIV or AIDS have different clinical and pathological features from the same diseases when they occur in the general population, such as more extranodal involvement. This data item documents whether the patient has HIV infection or AIDS at the time of diagnosis.

Coding guidelines

Code whether the patient has HIV or AIDS, based on statements in the medical record. Do not assume that the patient is negative for HIV or AIDS unless there is a statement to that effect; code 9 instead.

- Code 0 when there is a statement in the record that
  - HIV or AIDS is not present
  - the patient has been tested and is negative for HIV or AIDS
  - the patient has been tested and is not infected with HIV or AIDS
  - the malignancy is not associated with human immunodeficiency virus (HIV) or autoimmune deficiency syndrome (AIDS)
  - an HIV or AIDS test has been done and is negative
- Code 1 when there is a statement in the record that
  - HIV or AIDS is present
  - the patient is positive for HIV or AIDS
  - the patient is infected with HIV or AIDS

    - the patient has a history of HIV or AIDS
    - an HIV or AIDS test has been done and is positive
- Code 9 when there is no mention of HIV or AIDS status in the medical record.

Additional Information

- **Source documents:** clinical laboratory test, statement in medical record
- **Other names:** HIV type 1, HIV type 2, ARC (AIDS related complex), PWA (person with AIDS), PWARC (person with ARC); older terms for HIV type 1: HTLV-3, LAV

Coding Instructions and Codes

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

Note 2: Acquired Immune Deficiency Syndrome (AIDS) lymphomas are a late manifestation of Human Immunodeficiency Virus (HIV) infection and have unique clinical and pathological features that differ from lymphomas in the general population. They have a preponderance for extranodal involvement, with central nervous system being the most common site.

Note 3: HIV includes types I and II. Older terminology includes Human T Lymphotropic Virus -3 (HTLV-3) and Lymphadenopathy Associated Virus (LAV).

Note 4: Code 9 if there is no mention of HIV/AIDS in the medical record. Do not assume that the patient is HIV negative.

Code	Description
0	Not associated with Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS) HIV negative
1	Associated with HIV/AIDS HIV positive
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record HIV status not assessed or unknown if assessed
X9	Not documented in medical record HIV status not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Lymphomas (Adult and Pediatric Hodgkin and Non-Hodgkin Lymphomas)

NCCN International Prognostic Index (IPI)

Item Length: 2
NAACCR Item #: 3896
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 79: Hodgkin and Non-Hodgkin Lymphoma
- Chapter 80: Pediatric Hodgkin and Non-Hodgkin Lymphoma

Description

The NCCN International Prognostic Index (IPI) (previously only "IPI") is used to define risk groups for specific lymphomas using a 0-5 score range, based on age, stage, number of extranodal sites of involvement, patient's performance status and pretreatment 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: 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.

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)

Code	Description
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.)

Return back to Schema ID Table

DRAFT

Rai Classification (CLL/SLL [9823/3 only)

Definition

The Rai classification system is now used to stage chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) (9823/3) using several different criteria. The stages are based on the absence or presence of the following criteria

- Adenopathy (Rai Classification: CLL/SLL) [NAACCR Data Item #3804]
- Anemia (Rai Classification: CLL/SLL) [NAACCR Data Item #3811]
- Lymphocytosis (Rai Classification: CLL/SLL) [NAACCR Data Item #3885]
- Organomegaly (Rai Classification: CLL/SLL) [NAACCR Data Item #3907]
- Thrombocytopenia (Rai Classification: CLL/SLL) [NAACCR Data Item #3933]

Note: All of these data items are required for Staging for AJCC 8th edition and EOD.

Rai stages

- Stage 0 CLL is characterized by absolute lymphocytosis (>15,000/mm3) without adenopathy, hepatosplenomegaly, anemia, or thrombocytopenia
- Stage I CLL is characterized by absolute lymphocytosis with lymphadenopathy without hepatosplenomegaly, anemia, or thrombocytopenia
- Stage II CLL is characterized by absolute lymphocytosis with either hepatomegaly or splenomegaly with or without lymphadenopathy
- Stage III CLL is characterized by absolute lymphocytosis and anemia (hemoglobin <11 g/dL) with or without lymphadenopathy, hepatomegaly, or splenomegaly
- Stage IV CLL is characterized by absolute lymphocytosis and thrombocytopenia (<100,000/mm3) with or without lymphadenopathy, hepatomegaly, splenomegaly, or anemia

Return back to Schema ID Table

DRAFT

Rai Classification (CLL/SLL [9823/3 only)

Adenopathy

Item Length: 1
NAACCR Item #: 3804
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 79: Hodgkin and Non-Hodgkin Lymphoma
- Chapter 80: Pediatric Hodgkin and Non-Hodgkin Lymphoma

Required for Staging: AJCC 8th edition and EOD

Description

Adenopathy is defined as the presence of lymph nodes > 1.5 cm on physical examination (PE) and is part of the staging criteria for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL).

Rationale

Adenopathy is a prognostic factor required for staging of CLL/SLL in AJCC 8th edition, Chapter 79 *Hodgkin and Non-Hodgkin Lymphomas*. It is a new data item for cases diagnosed 1/1/2018+.

See Rai Classification (CLL/SLL [9823/3]) **for additional information.**

Coding Instructions and Codes

Note 1: For cases diagnosed 1/1/2018 and later, all cases of CLL and SLL will require both the **Lugano classification, which is captured in the AJCC stage group data item**, and the **five components of the modified Rai staging system, which are captured in Site-Specific Data Items (adenopathy, anemia, lymphocytosis, organomegaly, and thrombocytopenia)**

The terms B-cell lymphocytic leukemia/chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are considered different clinical presentations of the same disease, with both terms coded 9823. Traditionally the lymphoma diagnosis was staged with the Ann Arbor staging system and it is now staged with the Lugano classification. In North America, CLL was staged with the Rai system.

Note 2: This data item is determined from physical exam alone, there is only an exception for a CT to evaluate PERIPHERAL nodes in an obese patient where the PE is limited; therefore, do not use non-peripheral adenopathy found on the CT for staging.

- A finding of retroperitoneal or mesenteric adenopathy on CT is not considered in determining adenopathy and does not affect the assigned stage

Note 3: Physician statement of presence or absence of adenopathy can be used to code this data item.

Note 4: Adenopathy is defined as the presence of lymph nodes >1.5 cm on physical examination (PE) and is part of the staging criteria.

Note 5: If there is no mention of adenopathy (present or absent), code 9.

Code	Description
0	Adenopathy not identified/not present No lymph nodes > 1.5 cm
1	Adenopathy present Presence of lymph nodes > 1.5 cm
9	Not documented in medical record Adenopathy not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Rai Classification (CLL/SLL [9823/3 only)

Anemia

Item Length: 1
NAACCR Item #: 3811
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 79: Hodgkin and Non-Hodgkin Lymphoma
- Chapter 80: Pediatric Hodgkin and Non-Hodgkin Lymphoma

Required for Staging: AJCC 8th edition and EOD

Description

Anemia is defined by a deficiency of red blood cells or of hemoglobin in the blood. In staging of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL), anemia is defined as Hgb <11.0 g/dL.

Rationale

Anemia is a prognostic factor required for staging of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL) in AJCC 8th edition, Chapter 79 *Hodgkin and Non-Hodgkin Lymphomas*. It is a new data item for cases diagnosed 1/1/2018+.

See Rai Classification (CLL/SLL [9823/3]) **for additional information.**

Coding Instructions and Codes

Note 1: For cases diagnosed 1/1/2018 and later, all cases of CLL and SLL will require both the **Lugano classification, which is captured in the AJCC stage group data item**, and the **five components of the modified Rai staging system, which are captured in Site-Specific Data Items (adenopathy, anemia, lymphocytosis, organomegaly, and thrombocytopenia)**

The terms B-cell lymphocytic leukemia/chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are considered different clinical presentations of the same disease, with both terms coded 9823. Traditionally the lymphoma diagnosis was staged with the Ann Arbor staging system and it is now staged with the Lugano classification. In North America, CLL was staged with the Rai system.

Note 2: Anemia is defined as Hgb <11.0 g/dL and is part of the staging criteria.

- Use the cut points listed in the table regardless of the lab's reference range
- A lab value expressed in grams per liter (g/L) is 10 times the same value expressed in g/dL; therefore, the cut point of 11.0 g/dL is equivalent to 110 g/L

Note 3: Record this data item based on a blood test (CBC or hematocrit) performed at diagnosis (pre-treatment). In the absence of the lab test, a physician's statement can be used.

Note 4: If the presence/absence of anemia determined by available lab values differs from the physician's statement of anemia, the lab value takes precedence.

Note 5: If there is no mention of anemia, or relevant lab results, code 9.

Code	Description
0	Anemia not present Hgb >=11.0 g/dL
1	Anemia present Hgb <11.0 g/dL
6	Lab value unknown, physician states patient is anemic
7	Test ordered, results not in chart
9	Not documented in medical record Anemia not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Rai Classification (CLL/SLL [9823/3 only)

Lymphocytosis

Item Length: 1
NAACCR Item #: 3885
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 79: Hodgkin and Non-Hodgkin Lymphoma
- Chapter 80: Pediatric Hodgkin and Non-Hodgkin Lymphoma

Required for Staging: AJCC 8th edition and EOD

Description

Lymphocytosis s defined by an excess of lymphocytes in the blood. In staging of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL), lymphocytosis is defined as an absolute lymphocyte count (ALC) > 5,000 cells/µL.

Rationale

Lymphocytosis is a prognostic factor required for staging of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL) in AJCC 8th edition, Chapter 79 *Hodgkin and Non-Hodgkin Lymphomas*. It is a new data item for cases diagnosed 1/1/2018+.

See Rai Classification (CLL/SLL [9823/3]) **for additional information.**

Coding Instructions and Codes

Note 1: For cases diagnosed 1/1/2018 and later, all cases of CLL and SLL will require both the **Lugano classification, which is captured in the AJCC stage group data item**, and the **five components of the modified Rai staging system, which are captured in Site-Specific Data Items (adenopathy, anemia, lymphocytosis, organomegaly, and thrombocytopenia)**

The terms B-cell lymphocytic leukemia/chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are considered different clinical presentations of the same disease, with both terms coded 9823. Traditionally the lymphoma diagnosis was staged with the Ann Arbor staging system and it is now staged with the Lugano classification. In North America, CLL was staged with the Rai system.

Note 2: Lymphocytosis (lymphocyte number) is defined by an absolute lymphocyte count (ALC) > 5,000 cells/µL and is part of the staging criteria.

- Use the cut points listed in the table regardless of the lab's reference range
- For cases that document lymphocyte count in SI (Systeme Internationale) units as any of 10*9/L, 10^9/L, or 10E9/L, the cut point of 5,000 cells/µL is equivalent to (5 cells x 10*9/L), (5 cells X 10^9/L), or (5 cells x10E9/L)

Note 3: Record this data item based on a blood test (CBC and differential) performed at diagnosis (pre-treatment). In the absence of the lab test, a physician's statement can be used.

Note 4: If the presence/absence of lymphocytosis determined by available lab values differs from the physician's statement of lymphocytosis, the lab value takes precedence.

Note 5: If there is no mention of lymphocytosis, or relevant lab results, code 9.

Code	Description
0	Lymphocytosis not present Absolute lymphocyte count <= 5,000 cells/µL
1	Lymphocytosis present Absolute lymphocyte count > 5,000 cells/µL
6	Lab value unknown, physician states lymphocytosis is present
7	Test ordered, results not in chart
9	Not documented in medical record Lymphocytosis not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Rai Classification (CLL/SLL [9823/3 only)

Organomegaly

Item Length: 1
NAACCR Item #: 3907
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 79: Hodgkin and Non-Hodgkin Lymphoma
- Chapter 80: Pediatric Hodgkin and Non-Hodgkin Lymphoma

Required for Staging: AJCC 8th edition and EOD

Description

Organomegaly is defined as presence of enlarged liver and/or spleen on physical examination and is part of the staging criteria for Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL).

Rationale

Organomegaly is a prognostic factor required for staging of CLL/SLL in AJCC 8th edition, Chapter 79 *Hodgkin and Non-Hodgkin Lymphomas*. It is a new data item for cases diagnosed 1/1/2018+.

See Rai Classification (CLL/SLL [9823/3]) **for additional information.**

Coding Instructions and Codes

Note 1: For cases diagnosed 1/1/2018 and later, all cases of CLL and SLL will require both the **Lugano classification, which is captured in the AJCC stage group data item**, and the **five components of the modified Rai staging system, which are captured in Site-Specific Data Items (adenopathy, anemia, lymphocytosis, organomegaly, and thrombocytopenia)**

The terms B-cell lymphocytic leukemia/chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are considered different clinical presentations of the same disease, with both terms coded 9823. Traditionally the lymphoma diagnosis was staged with the Ann Arbor staging system and it is now staged with the Lugano classification. In North America, CLL was staged with the Rai system.

Note 2: Physician statement of presence or absence of organomegaly should be used to code this data item.

Note 3: Organomegaly is defined as presence of enlarged liver and/or spleen on physical examination and is part of the staging criteria.

Note 4: If there is no mention of organomegaly (present or absent), code 9.

Code	Description
0	Organomegaly of liver and/or spleen not present
1	Organomegaly of liver and/or spleen present
9	Not documented in medical record

Code	Description
	Organomegaly not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Rai Classification (CLL/SLL [9823/3 only)

Thrombocytopenia

Item Length: 1
NAACCR Item #: 3933
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s):

- Chapter 79: Hodgkin and Non-Hodgkin Lymphoma
- Chapter 80: Pediatric Hodgkin and Non-Hodgkin Lymphoma

Required for Staging: AJCC 8th edition and EOD

Description

Thrombocytopenia is defined by a deficiency of platelets in the blood. In staging of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL), thrombocytopenia is defined as Platelets (Plt) < 100,000/µL.

Rationale

Thrombocytopenia is a prognostic factor required for staging of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL) in AJCC 8th edition, Chapter 79 *Hodgkin and Non-Hodgkin Lymphomas*. It is a new data item for cases diagnosed 1/1/2018+.

See Rai Classification (CLL/SLL [9823/3]) **for additional information.**

Coding Instructions and Codes

Note 1: For cases diagnosed 1/1/2018 and later, all cases of CLL and SLL will require both the **Lugano classification, which is captured in the AJCC stage group data item**, and the **five components of the modified Rai staging system, which are captured in Site-Specific Data Items (adenopathy, anemia, lymphocytosis, organomegaly, and thrombocytopenia)**

The terms B-cell lymphocytic leukemia/chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are considered different clinical presentations of the same disease, with both terms coded 9823. Traditionally the lymphoma diagnosis was staged with the Ann Arbor staging system and it is now staged with the Lugano classification. In North America, CLL was staged with the Rai system.

Note 2: Thrombocytopenia is defined as platelets (Plt) <100,000/µL. This is part of the Modified Rai Staging System and not included as part of the AJCC Lugano staging.

Use the cut points listed in the table regardless of the lab's reference range

For cases that document platelet count in SI (Systeme Internationale) units as any of 10*9/L, 10^9/L, or 10E9/L, the cut point of 100,000 cells/µL is equivalent to (100 cells x 10*9/L), (11 cells x 10^9/L, or (100 cells x 10E9/L)

Note 3: Record this data item based on a blood test (CBC and differential) performed at diagnosis (pre-treatment). In the absence of the lab test, a physician's statement can be used.

Note 4: If the presence/absence of thrombocytopenia determined by available lab values differs from the physician's statement of thrombocytopenia, the lab value takes precedence.

Note 5: If there is no mention of thrombocytopenia, or the relevant lab tests, code 9.

Code	Description
0	Thrombocytopenia not present Platelets (Plt) >=100,000/µL
1	Thrombocytopenia present Platelets (Plt) < 100,000/µL
6	Lab value unknown, physician states thrombocytopenia is present
7	Test ordered, results not in chart
9	Not documented in medical record Thrombocytopenia not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Primary Cutaneous Lymphomas

Peripheral Blood Involvement

Item Length: 1
NAACCR Item #: 3910
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 81, Primary Cutaneous Lymphoma: MF/SS

Required for Staging: AJCC 8th edition and EOD

Description

Peripheral blood involvement, summarized in "B category", refers to the percentage of peripheral blood lymphocytes that are atypical (Sezary) cells and whether they are "Clone negative" or "Clone positive."

Rationale

Peripheral blood involvement is a prognostic factor required in AJCC 8th edition, Chapter 81 *Primary Cutaneous Lymphomas*, for staging of Mycosis Fungoides and Sezary Syndrome. It was previously collected as Mycosis Fungoides, CS SSF #1.

Definition

Mycosis fungoides is the most common type of primary cutaneous T-cell lymphoma. Sezary syndrome is a more aggressive type of primary cutaneous T-cell lymphoma in which a specific type of malignant T lymphocytes (Sezary cells) are present in the circulating blood. Staging of mycosis fungoides includes analysis of the circulating blood for Sezary cells. This analysis can be done by microscopy or flow cytometry. Results of microscopy are reported as counts of Sezary cells per cubic millimeter or the percentage of Sezary cells as a proportion of total lymphocytes. Flow cytometry looks for specific cell surface markers such as CD26.

Information about peripheral blood involvement and T-cell clonality identified by polymerase chain reaction (PCR) or Southern blot analysis is combined in a "B" category unique to mycosis fungoides staging in the TNM system.

The basic categories are B0 (no significant blood involvement); B1 (low blood tumor burden); and B2 (high blood tumor burden). Any mention of B2 puts the case into Stage IV. B0 and B1 are subcategorized by clonality.

Code a statement of peripheral blood involvement and clonality (if given) as reported by the clinician from tissue and/or blood samples. If the physician does not provide a B rating but counts or percentages of neoplastic cells, flow cytometry test results, and/or clonality test results are performed, use the appropriate code for the amount of blood involvement with "clone unknown."

Additional Information

- **Source documents:** pathology report, clinical laboratory reports of blood analysis (tissue and blood samples)
- **Other names:** Peripheral blood involvement: circulating Sezary cells, T-cell clonality: T-cell receptor (TCR) gene rearrangement, Monoclonal: clone +, clone positive, Polyclonal: clone –, clone negative

Coding Instructions and Codes

Note 1: The categories for peripheral blood involvement (B rating) are
- B0: No significant blood involvement
- B1: Low blood tumor burden
- B2: High blood tumor burden

Note 2: Physician statement of B rating can be used to code this data item.

Note 3: If counts or percentages of neoplastic cells and clonality test results are available, but a B rating is not stated by the physician, the registrar can use the information and assign a B rating and code this data item accordingly. If this information is not available, code 9.

Code	Description	B Map
0	Absence of significant blood involvement 5% or less of peripheral blood lymphocytes are atypical (Sezary) cells Clone unknown Stated as B0	B0
1	Absence of significant blood involvement 5% or less of peripheral blood lymphocytes are atypical (Sezary) cells Clone negative Stated as B0a	B0a
2	Absence of significant blood involvement: 5% or less of peripheral blood lymphocytes are atypical (Sezary) cells Clone positive Stated as B0b	B0b
3	Low blood tumor burden More than 5% of peripheral blood lymphocytes are atypical (Sezary) cells but does not meet the criteria of B2 Clone unknown Stated as B1	B1
4	Low blood tumor burden More than 5% of peripheral blood lymphocytes are atypical (Sezary) cells but does not meet the criteria of B2 Clone negative Stated as B1a	B1a
5	Low blood tumor burden More than 5% of peripheral blood lymphocytes are atypical (Sezary) cells	B1b

Code	Description	B Map
	but does not meet the criteria of B2 Clone positive Stated as B1b	
6	High blood tumor burden Greater than or equal to 1000 Sezary cells per microliter (uL) Clone positive Stated as B2	B2
7	Test ordered, results not in chart	BX
9	Not documented in medical record Peripheral Blood Involvement not assessed or unknown if assessed	BX

Return back to Schema ID Table

DRAFT

Plasma Cell Myeloma and Plasma Cell Disorders

Schema Discriminator 1: Plasma Cell Myeloma Terminology

Item Length: 1
NAACCR Item #: 3926
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 82: Plasma Cell Disorders and Multiple Myeloma

Definition

A variety of descriptive terms refer to early phases of plasma cell myeloma, all of which are coded to 9732, and reportable based on the 2010 Hematopoietic and Lymphoid Neoplasms coding rules. Per AJCC 8th edition, not all terms are applicable for the Revised International Staging System (RISS or R-ISS) stage. This schema discriminators collects the specific terminology used to describe the plasma cell myeloma at the time of diagnosis.

Code the terminology used by the physician to describe the plasma cell myeloma from any documentation in the medical record. If other terminology is used later in the course of the disease to describe more aggressive plasma cell myeloma, do not change the code in the schema discriminator.

Coding Instructions and Codes

Note 1: Several terms are used to characterize plasma cell myeloma at the time of diagnosis. All these terms are reportable according to the new Hematopoietic and Lymphoid Neoplasms rules effective for cases diagnosed January 1, 2010 and later.

Note 2: Select the code based on the terminology specified by the physician in the record. Do not attempt to determine the correct terminology based on the diagnostic criteria in the AJCC 8th table 82.1.

Note 3: Do not change the discriminator code if a term used later indicates progression to a more aggressive disease course.

Note 4: If diagnosis is plasma cell leukemia variant and is diagnosed concomitant with plasma cell myeloma, code 0.

Code	Description	Stage Table
0	Plasma cell myeloma (PCM) Multiple myeloma Myeloma, NOS Non-secretory myeloma Ultra-High-Risk Smoldering MM (SMM)	RISS Stage
1	Smoldering plasma cell myeloma (SPCM) Asymptomatic plasma cell myeloma Early myeloma Evolving myeloma	No RISS Stage
9	Other terminology describing myeloma Unknown terminology used	No RISS Stage

Return back to Schema ID Table

DRAFT

RISS Stage (Plasma Cell Myeloma)

AJCC 8th Edition Chapter(s): Chapter 82, Plasma Cell Myeloma and Plasma Cell Disorders

Definition

The Revised International Staging System (RISS or R-ISS) is now used to stage plasma cell myeloma (9732/3), using several different criteria. The stages are based on the absence or presence of the following criteria:

- High Risk Cytogenetics [NAACCR Data Item #3857]
- LDH Pretreatment Level [NAACCR Data Item #3869]
- Serum Albumin Pretreatment Level [NAACCR Data Item #3930]
- Serum Beta-2 Microglobulin Pretreatment Level NAACCR Data Item #3931]

Required for Staging: AJCC 8th edition and EOD.

The RISS stages are

- **Stage I:** Beta-2-microglobulin <3.5 mg/L and albumin ≥3.5 g/dL
- **Stage II:** Not R-ISS I or III
- **Stage III:** Abnormalities by I-FISH (defined as presence of del (17p) and/or translocation t(4/14) and/or translocation t(14;16)

Additional Information

- **Other names:** R-ISS

Return back to Schema ID Table

DRAFT

RISS Stage (Plasma Cell Myeloma)

High Risk Cytogenetics

Item Length: 1
NAACCR Item #: 3857
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 82, Plasma Cell Myeloma and Plasma Cell Disorders

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.

Code	Description
0	High-risk cytogenetics not identified/not present
1	High-risk cytogenetics present
7	Test ordered, results not in chart
9	Not documented in medical record High Risk Cytogenetics not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

RISS Stage (Plasma Cell Myeloma)

LDH Pretreatment Level

Item Length: 1
NAACCR Item #: 3869
NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Pretreatment Level
AJCC 8th Edition Chapter(s):

- Chapter 47: Melanoma Skin
- Chapter 82, Plasma Cell Myeloma and Plasma Cell Disorders

Description

LDH (Lactate Dehydrogenase) is an enzyme involved in conversion of sugars to energy and present in most cells in the body. Elevated pretreatment LDH is an adverse prognostic factor for plasma cell myeloma and melanoma of the skin.

Rationale

LDH (Lactate Dehydrogenase) Pretreatment Level is a prognostic factor required in AJCC 8th edition for Chapter 83 Plasma Cell Myeloma and Plasma Cell Disorders and Chapter 47 Melanoma Skin. For Plasma Cell Myeloma, LDH is part of the RISS Stage and is new for cases diagnosed 1/1/2018+. For Melanoma Skin, LDH is used to define the M subcategories and was previously collected as Melanoma Skin, SSF #4.

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

Coding Instructions and Codes

Note 1: Use the reference ranges from your lab to determine if LDH is normal.

Note 2: Record this data item based on a blood test performed at diagnosis (pre-treatment). In the absence of the lab test, a physician's statement of the exact value or interpretation can be used. Use the highest value available.

Note 3: If there is no mention of the LDH, code 9.

Code	Description
0	Normal LDH level Low, below normal
1	Above normal LDH level; High
7	Test ordered, results not in chart
9	Not documented in medical record LDH (Lactate Dehydrogenase) Pretreatment Level not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

RISS Stage (Plasma Cell Myeloma)

Serum Albumin Pretreatment Level

Item Length: 1
NAACCR Item #: 3930
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 82, Plasma Cell Myeloma and Plasma Cell Disorders

Description

Albumin is the most abundant protein in human blood plasma. Serum albumin pretreatment level is a prognostic factor for plasma cell myeloma.

Rationale

Serum albumin pretreatment level is a prognostic factor required in AJCC 8th edition, Chapter 82 *Plasma Cell Myeloma and Plasma Cell Disorders*, for the Revised International Staging System (RISS). 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: Elevated serum albumin is defined by ≥3.5 g/dL and is part of the Revised International Staging System (RISS).

Use the cut points listed in the table regardless of the lab's reference range

A lab value expressed in grams per liter (g/L) is 10 times the same value expressed in g/dL; therefore, the cut point of 3.5 g/dL is equivalent to 35 g/L.

Note 2: Record this data item based on a blood test performed at diagnosis (pre-treatment). In the absence of the lab test, a physician's statement of the exact value can be used. Do not use findings from a urine test.

Note 3: If there is no mention of the serum albumin, code 9.

Code	Description
0	Serum albumin <3.5 g/dL
1	Serum albumin ≥3.5 g/dL
7	Test ordered, results not in chart
9	Not documented in medical record Serum Albumin Pretreatment Level not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

RISS Stage (Plasma Cell Myeloma)

Serum Beta-2 Microglobulin Pretreatment Level

Item Length: 1
NAACCR Item #: 3931
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): Chapter 82, Plasma Cell Myeloma and Plasma Cell Disorders

Description

Serum Beta-2 Microglobulin is a protein that is found on the surface of many cells and plentiful on the surface of white blood cells. Increased production or destruction of these cells causes Serum β2 (beta-2) Microglobulin level to increase. Elevated Serum β2 (beta-2) Microglobulin level is a prognostic factor for plasma cell myeloma.

Rationale

Serum Beta-2 Microglobulin Pretreatment Level is a prognostic factor required in AJCC 8th edition, Chapter 82 *Plasma Cell Myeloma and Plasma Cell Disorders*, for staging of plasma cell myeloma. It is a new data item for cases diagnosed 1/1/2018+.

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

Coding Instructions and Codes

Note 1: Serum microglobulin is part of the Revised International Staging (RISS). Use the cut points listed in the table below regardless of the lab's reference range.

Note 2: Record this data item based on a blood test performed at diagnosis (pre-treatment). In the absence of the lab test, a physician's statement of the exact value can be used. Use the highest value available.

Note 3: If there is no mention of the serum beta-2 microglobulin, code 9.

Code	Description
0	β2-microglobulin < 3.5 mg/L
1	β2-microglobulin ≥ 3.5 mg/L < 5.5 mg/L
2	β2-microglobulin ≥ 5.5 mg/L
7	Test ordered, results not in chart
9	Not documented in medical record Serum Beta-2 Microglobulin Pretreatment Level not assessed or unknown if assessed

Return back to Schema ID Table

DRAFT

Leukemia

JAK 2

Item Length: 1
NAACCR Item #: 3862
NAACCR Alternate Name: None
AJCC 8th Edition Chapter(s): HemeRetic Schema (EOD/Summary Stage)

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

Return back to Schema ID Table

DRAFT

ILL-DEFINED OTHER

See Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck for the following data item:

- Schema Discriminator 1: Occult Head and Neck Lymph Nodes
    - **Primary Site C760 only**

Return back to Schema ID Table

DRAFT

ALPHABETICAL INDEX

Adenoid Cystic Basaloid Pattern, 352
Adenopathy (Rai Classification: CLL/SLL), 380
AFP Post-Orchiectomy Lab Value, 294
AFP Post-Orchiectomy Range, 296
AFP Pre-Orchiectomy Lab Value, 291
AFP Pre-Orchiectomy Range, 292
AFP Pretreatment Interpretation, 107
AFP Pretreatment Lab Value, 106
Anemia (Rai Classification: CLL/SLL), 382
B Symptoms, 373
Bilirubin Pretreatment Total Lab Value, 111
Bilirubin Pretreatment Unit of Measure, 113
Bone Invasion, 146
Brain Molecular Markers, 358
Breslow Tumor Thickness, 160
CA-125 Pretreatment Interpretation, 254
CEA Pretreatment Interpretation, 90
CEA Pretreatment Lab Value, 88
Chromosome 19q: Loss of Heterozygosity (LOH), 363
Chromosome 1p: Loss of Heterozygosity (LOH), 361
Chromosome 3 Status, 335
Chromosome 8q Status, 337
Circumferential Resection Margin (CRM), 92
Creatinine Pretreatment Lab Value, 114
Creatinine Pretreatment Unit of Measure, 116
Esophagus and EGJ Tumor Epicenter, 82
Esophagus and Esophagogastric Junction, 79, 81, 82
Estrogen Receptor Percent Positive or Range, 175
Estrogen Receptor Summary, 177
Estrogen Receptor Total Allred Score, 179
Extranodal Extension Clin (non-Head and Neck), 152
Extranodal Extension Head and Neck Clinical, 40, 58
Extranodal Extension Head and Neck Pathological, 43, 61
Extranodal Extension Path (non-Head and Neck), 154
Extravascular Matrix Patterns, 339
Fibrosis Score, 118
FIGO Stage (Adenosarcoma), 249
FIGO Stage (Sarcoma), 251
FIGO: Cervix, 236
FIGO: Corpus Carcinoma and Carcinosarcoma, 237
FIGO: Gestational Trophoblastic Tumors (Placenta), 259
FIGO: Ovary, Fallopian Tube, and Peritoneal Carcinoma, 253
FIGO: Vagina, 232
FIGO: Vulva, 223
Gestational Trophoblastic Prognostic Scoring Index, 260
Gleason Patterns Clinical, 273
Gleason Patterns Pathological, 278
Gleason Score Clinical, 276
Gleason Score Pathological, 280
Gleason Tertiary Pattern, 282
hCG Post-Orchiectomy Lab Value, 303
hCG Post-Orchiectomy Range, 305
hCG Pre-Orchiectomy Lab Value, 300
hCG Pre-Orchiectomy Range, 301
HER2 IHC Summary, 189
HER2 ISH Dual Probe Copy Number, 197
HER2 ISH Dual Probe Ratio, 199
HER2 ISH Single Probe Copy Number, 195
HER2 ISH Summary, 191
HER2 Overall Summary, 193
Heritable Trait, 349
High Risk Cytogenetics, 396
High Risk Histologic Features, 75
HIV Status, 375
International Normalized Ratio, 117
Invasion Beyond Capsule, 318
Ipsilateral Adrenal Gland Involvement, 320
JAK 2, 400
Ki-67, 213
KIT Gene Immunohistochemistry, 149
KRAS, 95
LDH Post-Orchiectomy Range, 311
LDH Pre-Orchiectomy Range, 309
LDH Pretreatment Lab Value, 167
LDH Pretreatment Level, 169
LDH Upper Limits of Normal, 170
LN Assessment Method Femoral-Inguinal, 224
LN Assessment Method Para-Aortic, 225
LN Assessment Method Pelvic, 226
LN Distant Assessment Method, 233
LN Distant: Mediastinal, Scalene, 234
LN Head and Neck Levels I-III, 48
LN Head and Neck Levels IV-V, 50

DRAFT

LN Head and Neck Levels VI-VII, 52
LN Head and Neck Other, 54
LN Isolated Tumor Cells (ITC), 156
LN Laterality, 229
LN Positive Axillary Level I-II, 214
LN Size, 56, 64
LN Status Femoral-Inguinal, Para-Aortic, Pelvic, 227
Lymphocytosis (Rai Classification: CLL/SLL), 384
Major Vein Involvement, 322
Measured Basal Diameter, 341
Measured Thickness, 343
Methylation of O6-Methylguanine-Methyltransferase, 365
Microsatellite Instability (MSI), 97
Microvascular Density, 345
Mitotic Count Uveal Melanoma, 347
Mitotic Rate Melanoma, 165
Multigene Signature Method, 203
Multigene Signature Results, 205
NCCN International Prognostic Index (IPI), 377
Number of Cores Examined, 286
Number of Cores Positive, 284
Number of Examined Para-Aortic Nodes, 241
Number of Examined Pelvic Nodes, 245
Number of Positive Para-Aortic Nodes, 239
Number of Positive Pelvic Nodes, 243
Oncotype Dx Recurrence Score-DCIS, 209
Oncotype Dx Recurrence Score-Invasive, 211
Oncotype Dx Risk Level-DCIS, 210
Oncotype Dx Risk Level-Invasive, 212
Organomegaly (Rai Classification: CLL/SLL), 386
Percent Necrosis Post Neoadjuvant, 142
Perineural Invasion, 99
Peripheral Blood Involvement, 390
Peritoneal Cytology, 247
Pleural Effusion, 139
Primary Sclerosing Cholangitis, 120
Profound Immune Suppression, 158
Progesterone Receptor Percent Positive or Range, 180
Progesterone Receptor Summary, 182
Progesterone Receptor Total Allred Score, 184
PSA (Prostatic Specific Antigen) Lab Value, 267
Residual Tumor Volume Post Cytoreduction, 256
Response to Neoadjuvant Therapy, 216
S Category Clinical, 313
S Category Pathological, 315
Sarcomatoid Features, 324
Schema Discriminator 1 (Histology Discriminator for 9591/3), 372
Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct, 124
Schema Discriminator 1: Lacrimal Gland/Sac, 351
Schema Discriminator 1: Melanoma Ciliary Body/Melanoma Iris, 334
Schema Discriminator 1: Nasopharynx/Pharyngeal Tonsil, 67
Schema Discriminator 1: Occult Head and Neck Lymph Nodes, 38
Schema Discriminator 1: Plasma Cell Myeloma Terminology, 393
Schema Discriminator 1: Primary Peritoneum Tumor, 148
Schema Discriminator 1: Thyroid Gland/Thyroglossal Duct, 368
Schema Discriminator 1: Urethra/Prostatic Urethra, 328
Schema Discriminator 2: Histology Discriminator for 8020/3, 81
Schema Discriminator 2: Oropharyngeal p16, 69
Separate Tumor Nodules, 133
Serum Albumin Pretreatment Level, 398
Serum Beta-2 Microglobulin Pretreatment Level, 399
Thrombocytopenia (Rai Classification: CLL/SLL), 388
Tumor Deposits, 101
Tumor Growth Pattern, 122
Ulceration, 163
Visceral and Parietal Pleural Invasion, 136

DRAFT