## Site-Specific Data Item (SSDI) Manual

Effective with Cases Diagnosed 1/1/2018 and Forward

Published October 2022

Version 3.0

Editors: Jennifer Ruhl, MSHCA, RHIT, CCS, CTR, NCI SEER Jim Hofferkamp, CTR, NAACCR

Suggested Citation: Ruhl J, Hofferkamp J, et al. (October 2022). 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 2020-2022 NAACCR *Site-Specific Data Item (SSDI)* Work Group.

- Jennifer Ruhl, MSHCA, RHIT, CCS, CTR (NCI SEER) (chair)
- Melissa Alvarado (NPCR)
- Mary Brant, BS, CTR (California Cancer Registry)
- Sheila Fukumura, CTR (Manitoba Cancer Registry)
- Daisy Gray (Kentucky Cancer Registry)
- Donna Gress, RHIT, CTR (AJCC)
- Donna M. Hansen, CTR (California Cancer Registry)
- Jim Hofferkamp, CTR (NAACCR)
- Mei-Chin Hsieh, PhD (Louisiana Cancer Registry)
- Annette Hurlbut, RHIT, CTR (Elekta)
- Suzanne Kessler, MSM, RHIT, CTR (American College of Surgeons)
- Richard Moldwin, M.D., Ph.D (College of American Pathologists)
- Serban Negoita, MD, DrPH, CPH, CTR (NCI SEER)
- Lisa Pareti, BS, RHIT, CTR (Louisiana Cancer Registry)
- Loria Pollack, MD, MPH (Centers for Disease Control and Prevention)
- Nicola Schussler, BS (IMS)
- Aleisha Williams, MBA, CTR (AJCC)
- Janine Smith, BS, CTR (California Cancer Registry)

#### Special Acknowledgements

Carolyn Callaghan, CTR and Tiffany Janes, CTR from the *SEER\*Educate* program, and to Denise Harrison, CTR (Trainer, Educatory) for their continued contribution to the SSDI Work Group

The AJCC Expert Panels for their continued critical support in clarifying concepts from the AJCC Cancer Staging Manual, Eighth Edition and AJCC Cancer Staging System Version 9.

The College of American Pathologists (CAP) for their continued support with a CAP representative on the SSDI Work Group and the recent participation by the CAP Cancer Committee to deal with specific issues. CAP participation allows 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 document support and web development.

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

## **Table of Contents**

Organization of the SSDI Manual and Suggestions for How to Use it	13
Introduction	15
Timing for collection of SSDIs	17
Consult Reports	18
General Definitions and Format of SSDI Codes	19
Source Documents	20
General Rules for Entering Laboratory Values and Other Measurements	21
Rules for Recording Laboratory Values	24
Rules for Recording Tests Based on Solid Tissue	28
Histologic Examination	30
Schema Discriminators	31
3926: Schema Discriminator 1	32
3927: Schema Discriminator 2	33
3928: Schema Discriminator 3	34
SSDIs Required for Stage	35
SSDIs used for EOD Derived Stage Group	36
3800: Schema ID (2018+)	37
Schema ID Table	38
HEAD AND NECK	48
00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)	49
3926: Schema Discriminator 1: Occult Head and Neck Lymph Nodes	49
3831: Extranodal Extension Head and Neck Clinical	53
3832: Extranodal Extension Head and Neck Pathological	56
3876-3879: Head and Neck Regional Lymph Nodes (Levels I-VII, Other)	59
3876: LN Head and Neck Levels I-III	61
3877: LN Head and Neck Levels IV-V	63
3878: LN Head and Neck Levels VI-VII	65
3879: LN Head and Neck Other	67
3883: LN Size	69
00071: Lip (2018+)	71
00072: Tongue Anterior (2018+)	71
00073: Gum (2018+)	71
00074: Floor of Mouth (2018+)	71

	00075: Palate Hard (2018+)	71
	00076: Buccal Mucosa (2018+)	72
	00077: Mouth Other (2018+)	72
	00080: Major Salivary Glands (2018+)	72
	00090: Nasopharynx (2018+)	72
	3926: Schema Discriminator 1: Nasopharynx/Pharyngeal Tonsil	73
	00100: Oropharynx HPV-Mediated (p16+) (2018+)	74
	3927: Schema Discriminator 2: Oropharyngeal p16	75
	00111: Oropharynx (p16-) (2018+)	76
	00112: Hypopharynx (2018+)	77
	00121: Maxillary Sinus (2018+)	77
	00122: Nasal Cavity and Ethmoid Sinuses (2018+)	77
	00130: Larynx Other (2018+)	77
	00131: Larynx Supraglottic (2018+)	77
	00132: Larynx Glottic (2018+)	77
	00133: Larynx SubGlottic (2018+)	78
	00140: Mucosal Melanoma of the Head and Neck (2018+)	78
	00150: Cutaneous Carcinoma of the Head and Neck (2018+)	78
	00150: Cutaneous Carcinoma of the Head and Neck (2018+)         3858: High Risk Histologic Features	
G		79
G	3858: High Risk Histologic Features	79 81
G	3858: High Risk Histologic Features GASTROINTESTINAL TRACT (UPPER AND LOWER)	79 81 <b>82</b>
G	3858: High Risk Histologic Features GASTROINTESTINAL TRACT (UPPER AND LOWER) 00161: Esophagus (including GE junction) Squamous (2018+)	79 81 <b>82</b> 82
G	3858: High Risk Histologic Features GASTROINTESTINAL TRACT (UPPER AND LOWER) <b>00161: Esophagus (including GE junction) Squamous (2018+)</b> 	79 81 <b>82</b> 82 85
G	3858: High Risk Histologic Features GASTROINTESTINAL TRACT (UPPER AND LOWER) 00161: Esophagus (including GE junction) Squamous (2018+) 3926: Schema Discriminator 1: EsophagusGEJunction (EGJ)/Stomach 3927: Schema Discriminator 2: Histology Discriminator for 8020/3	79 81 <b> 82</b> 85 86
G	3858: High Risk Histologic Features GASTROINTESTINAL TRACT (UPPER AND LOWER) 00161: Esophagus (including GE junction) Squamous (2018+) 3926: Schema Discriminator 1: EsophagusGEJunction (EGJ)/Stomach	79 81 82 85 86 88
G	3858: High Risk Histologic Features GASTROINTESTINAL TRACT (UPPER AND LOWER) 00161: Esophagus (including GE junction) Squamous (2018+) 3926: Schema Discriminator 1: EsophagusGEJunction (EGJ)/Stomach 3927: Schema Discriminator 2: Histology Discriminator for 8020/3 3829: Esophagus and EGJ Tumor Epicenter 3855: HER2 Overall Summary	79 81 82 85 86 88 <b> 90</b>
G	3858: High Risk Histologic Features GASTROINTESTINAL TRACT (UPPER AND LOWER) 00161: Esophagus (including GE junction) Squamous (2018+)	79 81 82 85 86 88 90 90
G	3858: High Risk Histologic Features GASTROINTESTINAL TRACT (UPPER AND LOWER) 00161: Esophagus (including GE junction) Squamous (2018+) 3926: Schema Discriminator 1: EsophagusGEJunction (EGJ)/Stomach 3927: Schema Discriminator 2: Histology Discriminator for 8020/3 3829: Esophagus and EGJ Tumor Epicenter 3855: HER2 Overall Summary 00169: Esophagus (including GE junction) (excluding Squamous) (2018+) 00170: Stomach (2018+)	79 81 82 85 86 88 90 90 90
G	3858: High Risk Histologic Features GASTROINTESTINAL TRACT (UPPER AND LOWER) 00161: Esophagus (including GE junction) Squamous (2018+) 3926: Schema Discriminator 1: EsophagusGEJunction (EGJ)/Stomach 3927: Schema Discriminator 2: Histology Discriminator for 8020/3 3829: Esophagus and EGJ Tumor Epicenter 3855: HER2 Overall Summary 00169: Esophagus (including GE junction) (excluding Squamous) (2018+) 00170: Stomach (2018+) 00190: Appendix (2018-2022)	79 81 82 85 86 90 90 90 90
G	3858: High Risk Histologic Features	79 81 82 85 86 90 90 90 91
G	3858: High Risk Histologic Features	79 81 82 85 86 90 90 90 91 93
G	3858: High Risk Histologic Features	79 81 82 85 86 90 90 91 93 93

3823: Circumferential Resection Margin (CRM)	98
3866: KRAS	
3890: Microsatellite Instability (MSI)	104
3909: Perineural Invasion	107
3934: Tumor Deposits	109
3940: BRAF Mutational Analysis	111
3941: NRAS Mutational Analysis	113
09210: Anus (2023+)	116
3956: p16	116
HEPATOBILIARY SYSTEM	117
00220: Liver (2018+)	
3809, 3810: Alpha-Fetoprotein (AFP) Pretreatment Lab Value and Interpretation (Liver).	118
3810: AFP Pretreatment Lab Value	119
3809: AFP Pretreatment Interpretation	120
3813-3814, 3824-3825, 3860: Model for End-Stage Liver Disease (MELD) Score	121
3813: Bilirubin Pretreatment Total Lab Value	124
3814: Bilirubin Pretreatment Unit of Measure	126
3824: Creatinine Pretreatment Lab Value	127
3825: Creatinine Pretreatment Unit of Measure	129
3860: International Normalized Ratio	130
3835: Fibrosis Score	131
002300: Bile Ducts Intrahepat (2018+)	133
3917: Primary Sclerosing Cholangitis	134
3935: Tumor Growth Pattern	136
00242: Cystic Duct (2018+)	138
3926: Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct	138
00250: Bile Ducts Perhilar (2018+)	140
00260: Bile Duct Distal (2018+)	140
00280: Pancreas (2018+)	141
3942: CA 19-9 PreTx Lab Value	141
00290: NET Stomach (2018+)	143
3863: Ki-67	143
00301: NET Duodenum (2018+)	145
00302: NET Ampulla of Vater (2018+)	145
00310: NET Jejunum and Ileum (2018+)	145

00320: NET Appendix (2018+)	145
00330: NET Colon and Rectum (2018+)	145
00340: NET Pancreas (2018+)	145
THORAX	146
00360: Lung (2018+)	147
3929: Separate Tumor Nodules	147
3937: Visceral and Parietal Pleural Invasion	
3938: ALK Rearrangement	
3939: EGFR Mutational Analysis	
00370: Pleura Mesothelioma (2018+)	157
3913: Pleural Effusion	157
BONE	
00381: Bone Appendicular Skeleton (2018+)	160
3908: Percent Necrosis Post Neoadjuvant	
00382: Bone Spine (2018+)	162
00383: Bone Pelvis (2018+)	162
SOFT TISSUE SARCOMA	163
00400: Soft Tissue Head and Neck (2018+)	164
3815: Bone Invasion	
00410: Soft Tissue Trunk and Extremities (2018+)	166
3927: Schema Discriminator 2: Soft Tissue Sarcoma (C473, C475, C493-C495)	
00421: Soft Tissue Abdomen and Thoracic (2018+)	171
00422: Heart, Mediastinum and Pleura (2018+)	171
00430: GIST (2018+)	172
3926: Schema Discriminator 1: Primary Peritoneum Tumor	172
3865: KIT Gene Immunohistochemistry	173
00440: Retroperitoneum (2018+)	175
00458: Soft Tissue Rare (2018+)	175
00459: Soft Tissue Other (2018+)	175
SKIN	
00460: Merkel Cell Carcinoma (2018+)	177
3830: Extranodal Extension Clin (non-Head and Neck)	
3833: Extranodal Extension Path (non-Head and Neck)	179
3880: LN Isolated Tumor Cells (ITC)	

3918: Profound Immune Suppression	
00470: Melanoma Skin (2018+)	185
3817: Breslow Tumor Thickness	
3936: Ulceration	
3893: Mitotic Rate Melanoma	
3932: LDH Lab Value	
3869: LDH Level	
3870: LDH Upper Limits of Normal	
3961: Clinical Margin Width	
BREAST	
00480: Breast (2018+)	200
Estrogen Receptor and Progesterone Receptor	
3827: Estrogen Receptor Summary	202
3826: Estrogen Receptor Percent Positive or Range	
3828: Estrogen Receptor Total Allred Score	206
3915: Progesterone Receptor Summary	
3914: Progesterone Receptor Percent Positive or Range	210
3916: Progesterone Receptor Total Allred Score	212
HER2	214
3850: HER2 IHC Summary	217
3854: HER2 ISH Summary	219
3855: HER2 Overall Summary	221
3853: HER2 ISH Single Probe Copy Number	223
3851: HER2 ISH Dual Probe Copy Number	225
3852: HER2 ISH Dual Probe Ratio	227
Multigene Signature Method and Results	229
3894: Multigene Signature Method	231
3895: Multigene Signature Results	233
Oncotype Dx Tests	235
3903: Oncotype Dx Recurrence Score-DCIS	237
3905: Oncotype Dx Risk Level-DCIS	238
3904: Oncotype Dx Recurrence Score-Invasive	
3906: Oncotype Dx Risk Level-Invasive	241
3863: Ki-67	242
3882: LN Positive Axillary Level I-II	244

3922: Response to Neoadjuvant Therapy	247
FEMALE REPRODUCTIVE ORGANS	249
3836: FIGO	250
Lymph Node Assessment Methods & Status for Regional & Distant Lymph Nodes in GYN Site	es 253
00500: Vulva (2018+)	254
3836: FIGO: Vulva	254
3959: LN Status: Femoral-Inguinal	255
3871: LN Assessment Method Femoral-Inguinal	257
3957: LN Status: Pelvic	259
3873: LN Assessment Method Pelvic	261
3881: LN Laterality	263
00510: Vagina (2018+)	265
3836: FIGO: Vagina	265
3959: LN Status: Femoral-Inguinal	266
3871: LN Assessment Method Femoral-Inguinal	268
3958: LN Status: Para-Aortic	270
3872: LN Assessment Method Para-Aortic	272
3957: LN Status: Pelvic	274
3873: LN Assessment Method Pelvic	276
3875: LN Distant: Mediastinal, Scalene	278
3874: LN Distant Assessment Method	279
00520: Cervix (2018-2020)	280
3836: FIGO: Cervix	281
09520: Cervix (2021+)	283
3956: p16	284
00528: Cervix Sarcoma	285
00530: Corpus Carcinoma and Carcinosarcoma (2018+)	286
3836: FIGO: Corpus Carcinoma and Carcinosarcoma	286
3899-3902: Number of Positive and Examined Para-Aortic and Pelvic Nodes	288
3901: Number of Positive Para-Aortic Nodes	289
3899: Number of Examined Para-Aortic Nodes	291
3902: Number of Positive Pelvic Nodes	293
3900: Number of Examined Pelvic Nodes	295
3911: Peritoneal Cytology	297
00541: Corpus Sarcoma (2018+)	299

	3836: FIGO Stage (Sarcoma)	
(	00542: Corpus Adenosarcoma (2018+)	301
	3836: FIGO Stage (Adenosarcoma)	
(	00551: Ovary (2018+)	303
	3836: FIGO: Ovary, Fallopian Tube, and Peritoneal Carcinoma	
	3818: CA-125 Pretreatment Interpretation	
	3921: Residual Tumor Volume Post Cytoreduction	
(	00552: Primary Peritoneal Carcinoma (2018+)	309
(	00553: Fallopian Tube (2018+)	310
(	00560: Placenta (2018+)	311
	3836: FIGO: Gestational Trophoblastic Tumors (Placenta)	
	3837: Gestational Trophoblastic Prognostic Scoring Index	
MA	ALE GENITAL ORGANS	
(	00570: Penis (2018+)	315
(	00580: Prostate (2018+)	316
	3920: PSA (Prostatic Specific Antigen) Lab Value	
	Gleason Patterns and Scores	
	3838: Gleason Patterns Clinical	
	3840: Gleason Score Clinical	
	3839: Gleason Patterns Pathological	
	3841: Gleason Score Pathological	
	3842: Gleason Tertiary Pattern	
	Number of Cores Positive and Examined	
	3898: Number of Cores Positive	334
	3897: Number of Cores Examined	
(	00590: Testis (2018+)	
	Testis Serum Markers and S Category	
	Alpha-fetoprotein (AFP) (Testis)	
	3807: AFP Pre-Orchiectomy Lab Value	
	3808: AFP Pre-Orchiectomy Range	
	3805: AFP Post-Orchiectomy Lab Value	
	3806: AFP Post-Orchiectomy Range	347
	Human Chorionic Gonadotropin (hCG) (Testis)	
	3848: hCG Pre-Orchiectomy Lab Value	351
	3849: hCG Pre-Orchiectomy Range	

	3846: hCG Post-Orchiectomy Lab Value	353
	3847: hCG Post-Orchiectomy Range	355
	Lactate Dehydrogenase (LDH) (Testis)	357
	3868: LDH Pre-Orchiectomy Range	359
	3867: LDH Post-Orchiectomy Range	360
	3923: S Category Clinical	362
	3924: S Category Pathological	364
URI	NARY TRACT	366
0	0600: Kidney Parenchyma (2018+)	367
	3864: Invasion Beyond Capsule	367
	3886: Major Vein Involvement	369
	3861: Ipsilateral Adrenal Gland Involvement	371
	3925: Sarcomatoid Features	373
0	0631: Urethra (2018+)	375
	3926: Schema Discriminator 1: Urethra/Prostatic Urethra	375
0	0633: Urethra-Prostatic (2018+)	376
OPł	ITHALMIC SITES	377
0	0640: Skin Eyelid (2018+)	378
	3909: Perineural Invasion	378
0	0660: Melanoma Conjunctiva (2018+)	380
0	0671: Melanoma Iris (2018+)	381
	3926: Schema Discriminator 1: Melanoma Ciliary Body/Melanoma Iris	381
	3821: Chromosome 3 Status	382
	3822: Chromosome 8q Status	384
	3834: Extravascular Matrix Patterns	386
	3887: Measured Basal Diameter	388
	3888: Measured Thickness	390
	3891: Microvascular Density	392
	3892: Mitotic Count Uveal Melanoma	394
0	0672: Melanoma Choiroid and Ciliary Body (2018+)	396
0	0680: Retinoblastoma (2018+)	397
	3856: Heritable Trait	397
0	0690: Lacrimal Gland (2018+)	399
	3926: Schema Discriminator 1: Lacrimal Gland/Sac	400
	3803: Adenoid Cystic Basaloid Pattern	401

00698: Lacrimal Sac (2018+)	403
CENTRAL NERVOUS SYSTEM	
00721: Brain (2018-2022)	405
3816: Brain Molecular Markers	
3801, 3802: Loss of Heterozygosity: Chromosome 1p and Chromosome 19q (CNS)	
3801: Chromosome 1p: Loss of Heterozygosity (LOH)	
3802: Chromosome 19q: Loss of Heterozygosity (LOH)	410
3889: Methylation of O6-Methylguanine-Methyltransferase	
09721: Brain (2023+)	414
00722: CNS Other (2018-2022)	415
09722: CNS Other (2023+)	416
09724: Medulloblastoma (2023+)	417
ENDOCRINE SYSTEM	
00730: Thyroid (2018+)	419
3926: Schema Discriminator 1: Thyroid Gland/Thyroglossal Duct	
00740: Thyroid Medullary (2018+)	420
HEMATOLOGIC MALIGNANCIES	
00790: Lymphoma (excluding CLL/SLL) (2018+)	422
3926: Schema Discriminator 1: Histology Discriminator for 9591/3	
3812: B Symptoms	
3859: HIV Status	
3896: NCCN International Prognostic Index (IPI)	
00795: Lymphoma-CLL/SLL (2018+)	429
Rai Classification	
3885: Lymphocytosis	
3804: Adenopathy	434
3907: Organomegaly	
3811: Anemia	
3933: Thrombocytopenia	
3955: Derived Rai stage	
00811: Mycosis Fungoides (2018+)	443
3910: Peripheral Blood Involvement	
00821: Plasma Cell Myeloma (2018+)	446
RISS Stage (Plasma Cell Myeloma)	
3926: Schema Discriminator 1: Plasma Cell Myeloma Terminology	

3931: Serum Beta-2 Microglobulin Pretreatment Level	
3930: Serum Albumin Pretreatment Level	
3857: High Risk Cytogenetics	450
3869: LDH Level	451
00830: HemeRetic (2018+)	452
3862: JAK 2	453
99999: Ill-Defined Other (2018+)	455
ALPHABETICAL INDEX	

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

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

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

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

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

#### For each SSDI, the SSDI Manual includes:

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

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

## Appendix A

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

## Appendix B

Appendix B is an excel spreadsheet which lists all of the CSv2 site specific factors by CS Schema, their current status (based on CoC), primary site, and (where applicable), the NAACCR v18 Data Item # and Name.

#### Appendix C

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

## Introduction

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

## The NAACCR Site-Specific Data Item Taskforce

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

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 Staging System, Summary Stage chapter and the EOD schema. SSDIs were preceded by CS SSFs, which were first introduced in 2004 with CSv1, and went through major revisions in 2010 with **Collaborative Stage v2** (CSv2). CS SSFs were discontinued as of 12/31/2017.

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

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

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

## How SSDIs are associated with relevant site/histologies and schemas

In **Collaborative Stage v2 (CSv2),** 153 Schemas were defined based on site/histology and used to assign applicable site-specific factors (SSFs) and staging algorithms. For 2018, Schema ID [3800] is used to link all combinations of sites and histologies (using additional information from schema discriminators if needed) with the appropriate stage data collection systems and SSDIs. AJCC ID [995] is used to link AJCC staging eligible sites/histologies (using additional information from schema discriminators if needed) with the appropriate Stage data collection systems and SSDIs. AJCC ID [995] is used to link AJCC staging eligible sites/histologies (using additional information from schema discriminators if needed) with the appropriate AJCC Staging System and staging algorithm. Schema ID and AJCC ID will be derived by registry software based on site and histology codes entered by the registrar. Refer to **Appendix A** for a complete listing of schemas IDs and 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 Staging System, EOD schema, or Summary Stage schema
- Second: data items required to assign stage
- Third: data items currently required by at least one standard setter and listed as registry collection data items in at least one AJCC Staging System
- Last: certain data items required by standard setters and not necessarily 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 Staging System was not reviewed, unless they are required for staging.

Number of SSDIs compared to CS SSFs

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

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

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

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

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

## **Timing for collection of SSDIs**

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

*Note*: Active surveillance is first course of treatment.

## **Consult Reports**

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

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

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

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

• Record ER and PR as negative

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

• Record Grade 2 and ER 80% intermediate

## **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.")

## Death Certificate Only (DCOs) cases

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

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

## **Source Documents**

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

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

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

## **General Rules for Entering Laboratory Values and Other Measurements**

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

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

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

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

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

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

#### Examples for a 6-Character Lab Value

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

#### **Rounding Rules**

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

The general rounding rules are:

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

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

- HER2 ISH Single Probe Copy Number
- HER2 ISH Dual Probe Copy Number
- HER2 ISH Dual Probe Ratio

#### Examples

- Breslow's measurement 4.32 mm
  - Since the last digit is 2, round down and record 4.3
- CEA lab value 18.35
  - Since the last digit is 5, round up and record 18.4
- HER2 ISH Dual Probe Copy Number 6.78
  - Per note 8: If the test results are presented to the hundredth decimal, ignore the hundredth decimal. Do NOT round. Record 6.7
  - This also applies to HER2 ISH Single Probe Copy Number and HER2 ISH Dual Probe Ratio
- *Note*: ER (and PR) percent positive do not have decimal points in the data items, so anything with a decimal point will have to be rounded.
  - *Example*: 78.6. Since the last digit is 6, round up and record 079 (79%)
  - Note: For ER and PR percent positive, if a value is documented as 99.5% to 99.9%, round up to 100% (code 100)

#### Recording values when "less than" or "greater than" are used

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

#### SSDIs with decimals in their code structures

Example 1: PSA stated as < (less than) 5. Record 4.9</li>Example 2: hCG lab value resulting findings of < (less than) 1. Record 0.9</li>Example 3: Ki-67 reported as > (greater than) 20%. Record 20.1

#### SSDIs without decimals in their code structure:

Example 1: ER Percent Positive stated as < (less than) 60%. Record 059 (59%)</li>Example 2: PR Percent Positive stated as > (greater than) 75%. Record 076 (76%)Example 3: ER Percent Positive < (less than) 50%. Record 049 (49%)</li>

## **Rules for Recording Laboratory Values**

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

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

Follow the below guidelines for recording laboratory values:

- All laboratory values must be done no earlier than approximately three months before diagnosis
- Only record test results obtained before any cancer-directed treatment is given (neoadjuvant therapy or surgical), unless instructions for a specific laboratory test state otherwise
- Record the highest laboratory value if multiple laboratory tests results are available, unless instructions for a specific laboratory test state otherwise

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

Schema	SSDI#	SSDI	SSDI Specific Coding Rules
Colon and Rectum	3820	CEA Pretreatment Lab Value	Yes
Colon and Rectum	3819	CEA Pretreatment Interpretation	Yes
Liver	3810	AFP Pretreatment Lab Value	
Liver	3809	AFP Pretreatment Interpretation	
Liver	3813	Bilirubin Pretreatment Total Lab Value	
Liver	3814	Bilirubin Pretreatment Unit of Measure	
Liver	3820	Creatinine Pretreatment Total Lab Value	
Liver	3825	Creatinine Pretreatment Unit of Measure	
Liver	3860	International Normalized Ratio for Prothrombin Time	
Lymphoma (CLL/SLL)	3811	Anemia	
Lymphoma (CLL/SLL)	3933	Thrombocytopenia	
Mycosis Fungoides	3910	Peripheral Blood Involvement	
Ovary, Fallopian Tube,	3818	CA-125 Pretreatment Interpretation	
Primary Peritoneal			
Carcinoma			
Melanoma Skin	3932	LDH Lab Value	Yes
Melanoma Skin	3869	LDH Level	Yes
Melanoma Skin	3870	LDH Upper Limits of Normal	Yes
Pancreas	3942	CA 19-9 PreTx Lab Value	
Plasma Cell Myeloma	3930	Serum Albumin Pretreatment Level	
Plasma Cell Myeloma	3931	Serum Beta-2 Microglobulin Pretreatment Level	
Plasma Cell Myeloma	3932	LDH Lab Value	
Prostate	3920	PSA Lab Value (See SSDI specific instructions)	Yes
Testis	3807	AFP Pre-Orchiectomy Lab Value	Yes
Testis	3808	AFP Pre-Orchiectomy Range	Yes
Testis	3805	AFP Post-Orchiectomy Lab Value	Yes
Testis	3806	AFP Post-Orchiectomy Range	Yes
Testis	3848	hCG Pre-Orchiectomy Lab Value	Yes
Testis	3849	hCG Pre-Orchiectomy Range	Yes
Testis	3846	hCG Post-Orchiectomy Lab Value	Yes
Testis	3847	hCG Post-Orchiectomy Range	Yes

Schema	SSDI#	SSDI	SSDI Specific Coding Rules
Testis	3868	LDH Pre-Orchiectomy Range	Yes
Testis	3867	LDH Post-Orchiectomy Range	Yes

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

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

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

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

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

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

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

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

- **Example 3:** Physician reports that Alpha Fetoprotein (AFP) collected in the office for a patient suspected to have primary liver cancer was 750 but does not interpret this value. Background information in the manual indicates a high normal would be > 500 but hepatocellular carcinoma values are > 1000. Registrar should code AFP Interpretation as unknown
- **Example 4:** Physician reports a CEA of 450 for a colon cancer without interpreting it. Background information in the manual indicates a high normal would be 5 ng/ml. Registrar may code CEA as elevated

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

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

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

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

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

Note: Micrograms ( $\mu$ g) 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-	М
1000	Kilo-	k
10	Deka-	da
1 (baseline)		
1/10	Deci-	d
1/100	Centi-	с
1/1000	Milli-	m
One millionth	Micro-	m, u, or mc
One billionth	Nano-	n
One trillionth	Pico-	р
One quadrillionth	Femto	f

Table I-2-1b. Unit Abbreviations

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

## Table I-2-1c. Examples

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

## **Rules for Recording Tests Based on Solid Tissue**

## **Priority Order for SSDIs**

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

General Rules versus SSDI specific rules

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

Schema	SSDI#	SSDI	SSDI Specific Coding Rules
Bile Ducts Intrahepatic	3935	Tumor Growth Pattern	
Bile Ducts Intrahepatic	3835	Fibrosis Score	
Liver			
Bile Ducts Intrahepatic,	3917	Primary Sclerosing Cholangitis	
Bile Ducts Perihilar			
Bone	3908	Percent Necrosis Post Neoadjuvant	Yes
Brain, CNS	3816	Brain Molecular Markers	
Brain, CNS	3801	Chromosome 1p: Loss of Heterozygosity	
Brain, CNS	3802	Chromosome 19q: Loss of Heterozygosity	
Brain, CNS	3889	Methylation of O6-Methylguanine-Methyltransferase (MGMT)	
Breast	3827	Estrogen Receptor Summary	Yes
Breast	3826	Estrogen Receptor Percent Positive or Range	Yes
Breast	3828	Estrogen Receptor Total Allred Score	Yes
Breast	3882	LN Positive Axillary Level I-II	Yes
Breast	3915	Progesterone Receptor Summary	Yes
Breast	3914	Progesterone Receptor Percent Positive or Range	Yes
Breast	3916	Progesterone Receptor Total Allred Score	Yes
Breast	3855	HER2 Overall Summary	Yes
Breast	3894	Multigene Signature Method	
Breast	3895	Multigene Signature Results	
Breast	3903	Oncotype Dx Recurrence Score-DCIS	
Breast	3905	Oncotype Dx Risk Level-DCIS	
Breast	3904	Oncotype Dx Recurrence Score-Invasive	
Breast	3906	Oncotype Dx Risk Level Invasive	
Breast	3863	Ki-67	Yes
Colon and Rectum	3823	Circumferential Resection Margin	Yes
Colon and Rectum	3866	KRAS	
Colon and Rectum	3890	Microsatellite Instability (MSI)	
Colon and Rectum	3909	Perineural Invasion	Yes
Colon and Rectum	3934	Tumor Deposits	Yes
Colon and Rectum	3940	BRAF Mutational Analysis	
Colon and Rectum	3941	NRAS Mutational Analysis	

Schema	SSDI#	SSDI	SSDI Specific
			Coding Rules
Cutaneous Carcinoma	3858	High Risk Histologic Features	
Skin			
Cutaneous Carcinoma	3909	Perineural Invasion	Yes
Skin			
Esophagus (both	3855	HER2 Overall Summary	
schemas)			
GIST	3865	KIT Gene Immunochemistry	
HemeRetic	3862	JAK2	
Kidney	3864	Invasion Beyond Capsule	Yes
Kidney	3886	Major Vein Involvement	Yes
Kidney	3861	Ipsilateral Adrenal Gland Involvement	Yes
Kidney	3925	Sarcomatoid Features	
Lacrimal Gland	3803	Adenoid Cystic Basaloid Pattern	
Lacrimal Gland	3903	Perineural Invasion	Yes
Lung	3938	ALK Rearrangement	
Lung	3939	EGFR Mutational Analysis	
Lung	3937	Visceral and Parietal Pleural Invasion	
Melanoma Choroid and	3821	Chromosome 3 status	
Ciliary Body; Iris			
Melanoma Choroid and	3821	Chromosome 8q status	
Ciliary Body; Iris			
Melanoma Choroid and	3834	Extravascular Matrix Patterns	
Ciliary Body; Iris			
Melanoma Choroid and	3887	Measured Basal Diameter	
Ciliary Body; Iris			
Melanoma Choroid and	3888	Measured Thickness	
Ciliary Body; Iris			
Melanoma Choroid and	3891	Microvascular Density	
Ciliary Body; Iris			
Melanoma Choroid and	3892	Mitotic Count Uveal Melanoma	
Ciliary Body; Iris			
Melanoma Skin	3817	Breslow Tumor Thickness	Yes
Melanoma Skin	3936	Ulceration	Yes
Melanoma Skin	3893	Mitotic Rate Melanoma	
NET Schemas	3863	Ki-67	Yes
Plasma Cell Myeloma	3857	High Risk Cytogenetics	
Prostate	3838	Gleason Patterns Clinical	Yes
Prostate	3840	Gleason Score Clinical	Yes
Prostate	3839	Gleason Patterns Pathological	Yes
Prostate	3841	Gleason Score Pathological	Yes
Prostate	3898	Number of Cores Positive	Yes
Prostate	3897	Number of Cores Examined	Yes
Retinoblastoma	3856	Heritable Trait	
Stomach	3855	HER2 Overall Summary	

## **Histologic Examination**

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

Also referred to as "microscopic confirmation."

## **Schema Discriminators**

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

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

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

## 3926: Schema Discriminator 1

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

#### **Description**

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

#### **Rationale**

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

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

#### The following are Schema Discriminator 1

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

## 3927: Schema Discriminator 2

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

#### **Description**

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

#### **Rationale**

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

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

#### The following are Schema Discriminator 2

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

## 3928: Schema Discriminator 3

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

#### **Description**

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

#### <u>Rationale</u>

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

#### There are currently no defined Schema Discriminators 3s.

## **SSDIs Required for Stage**

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

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

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

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

## SSDIs used for EOD Derived Stage Group

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

SSDI#/Description	Schema ID#/Description
<u>3883: LN Size</u>	00100: Oropharynx HPV-Mediated (p16+)
<u>3869: LDH Level</u>	00470: Melanoma Skin
3882: LN Positive Axillary Level I-II	00480: Breast
<u>3911: Peritoneal Cytology</u>	00530: Corpus Carcinoma and Carcinosarcoma
<u>3911: Peritoneal Cytology</u>	00541: Corpus Sarcoma
<u>3911: Peritoneal Cytology</u>	00542: Corpus Adenosarcoma
3887: Measured Basal Diameter	00671: Melanoma Iris
3887: Measured Basal Diameter	00672: Melanoma Choroid and Ciliary Body
3888: Measured Thickness	00671: Melanoma Iris
3888: Measured Thickness	00672: Melanoma Choroid and Ciliary Body

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

# **Description**

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

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

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

# **Rationale**

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

# **Definition**

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

Schema ID#/Description	SSDI #/Description	Years Applicable
00060: Cervical Lymph Nodes	<b>3926:</b> Schema Discriminator 1: Occult Head and Neck	2018+
and Unknown Primary Tumors	Lymph Nodes (primary site C760)	
of the Head and Neck (2018+)	3831: Extranodal Extension Head and Neck Clinical	2018+
	3832: Extranodal Extension Head and Neck	2018+
	Pathological	
	3876: LN Head and Neck Levels I-III	2018+
	3877: LN Head and Neck Levels IV-V	2018+
	3878: LN Head and Neck Levels VI-VII	2018+
	3879: LN Head and Neck Other	2018+
	3883: LN Size	2018+
00071: Lip (2018+)	<b>3831</b> : Extranodal Extension Head and Neck Clinical	2018+
	<b>3832</b> : Extranodal Extension Head and Neck	2018+
	Pathological	
	<b>3883</b> : LN Size	2018+
00072: Tongue Anterior	<b>3831</b> : Extranodal Extension Head and Neck Clinical	2018+
(2018+)	<b>3832</b> : Extranodal Extension Head and Neck	2018+
<u></u>	Pathological	
	<b>3883</b> : LN Size	2018+
00073: Gum (2018+)	3831: Extranodal Extension Head and Neck Clinical	2018+
<u>00075. Gum (20101)</u>	3832: Extranodal Extension Head and Neck	2018+
	Pathological	20101
	<b>3883</b> : LN Size	2018+
00074: Floor of Mouth (2018+)	<b>3831</b> : Extranodal Extension Head and Neck Clinical	2018+
00074. FIOU OF WOULH (2018+)	<b>3832</b> : Extranodal Extension Head and Neck	2018+
		2010+
	Pathological <b>3883</b> : LN Size	2019
00075, Delete Hard (2018)	<b>3831</b> : Extranodal Extension Head and Neck Clinical	2018+
00075: Palate Hard (2018+)		2018+ 2018+
	3832: Extranodal Extension Head and Neck	2018+
	Pathological	2010
00076 D	3883: LN Size	2018+
00076: Buccal Mucosa (2018+)	<b>3831</b> : Extranodal Extension Head and Neck Clinical	2018+
	<b>3832</b> : Extranodal Extension Head and Neck	2018+
	Pathological	
	3883: LN Size	2018+
00077: Mouth Other (2018+)	<b>3831</b> : Extranodal Extension Head and Neck Clinical	2018+
	<b>3832</b> : Extranodal Extension Head and Neck	2018+
	Pathological	
	3883: LN Size	2018+
00080: Major Salivary Glands	<b>3831</b> : Extranodal Extension Head and Neck Clinical	2018+
<u>(2018+)</u>	<b>3832</b> : Extranodal Extension Head and Neck	2018+
	Pathological	
	3883: LN Size	2018+
<u>00090: Nasopharynx (2018+)</u>	<b>3926</b> : Schema Discriminator 1:	2018+
	Nasopharynx/PharyngealTonsil	
	3831: Extranodal Extension Head and Neck Clinical	2018+
	3832: Extranodal Extension Head and Neck	2018+
	Pathological	
	3883: LN Size	2018+

Schema ID#/Description	SSDI #/Description	Years Applicable
00100: Oropharynx HPV-	<b>3926</b> : Schema Discriminator 1: 20	
Mediated (p16+)	Nasopharynx/PharyngealTonsil	
	<b>3927</b> : Schema Discriminator 2: Oropharyngeal p16	2018+
	3831: Extranodal Extension Head and Neck Clinical	2018+
	3832: Extranodal Extension Head and Neck	2018+
	Pathological	
	3883: LN Size	2018+
<u>00111: Oropharynx (p16-)</u>	<b>3926</b> : Schema Discriminator 1:	2018+
<u>(2018+)</u>	Nasopharynx/PharyngealTonsil	
	<b>3927</b> : Schema Discriminator 2: Oropharyngeal p16	2018+
	3831: Extranodal Extension Head and Neck Clinical	2018+
	3832: Extranodal Extension Head and Neck	2018+
	Pathological	
	3883: LN Size	2018+
00112: Hypopharynx (2018+)	3831: Extranodal Extension Head and Neck Clinical	2018+
	3832: Extranodal Extension Head and Neck	2018+
	Pathological	
	3883: LN Size	2018+
00118: Pharynx Other (2018+)	No SSDIs defined for this Schema ID	NA
00119: Middle Ear (2018+)	No SSDIs defined for this Schema ID	NA
00121: Maxillary Sinus (2018+)	3831: Extranodal Extension Head and Neck Clinical	2018+
<u> </u>	<b>3832</b> : Extranodal Extension Head and Neck	2018+
	Pathological	
	<b>3883</b> : LN Size	2018+
00122: Nasal Cavity and	<b>3831</b> : Extranodal Extension Head and Neck Clinical	2018+
Ethmoid Sinuses (2018+)	<b>3832</b> : Extranodal Extension Head and Neck	2018+
	Pathological	2010
	<b>3883</b> : LN Size	2018+
00128: Sinus Other (2018+)	No SSDIs defined for this Schema ID	NA
00130: Larynx Other (2018+)	3831: Extranodal Extension Head and Neck Clinical	2018+
	<b>3832</b> : Extranodal Extension Head and Neck	2018+
	Pathological	20101
	<b>3883</b> : LN Size	2018+
00131: Larynx Supraglottic	3831: Extranodal Extension Head and Neck Clinical	2018+
(2018+)	<b>3832</b> : Extranodal Extension Head and Neck	2018+
(2018+)	Pathological	2010+
	<b>3883</b> : LN Size	2018+
00122. Longer Clottic (2018.)	<b>3831</b> : Extranodal Extension Head and Neck Clinical	
00132: Larynx Glottic (2018+)	<b>3831</b> : Extranodal Extension Head and Neck Clinical <b>3832</b> : Extranodal Extension Head and Neck	2018+
		2018+
	Pathological	2010.
	3883: LN Size	2018+
00133: Larynx SubGlottic	<b>3831</b> : Extranodal Extension Head and Neck Clinical	2018+
<u>(2018+)</u>	<b>3832</b> : Extranodal Extension Head and Neck	2018+
	Pathological	
	3883: LN Size	2018+

Schema ID#/Description	SSDI #/Description	Years Applicable
00140: Mucosal Melanoma of	3831: Extranodal Extension Head and Neck Clinical 201	
the Head and Neck (2018+)	<b>3832</b> : Extranodal Extension Head and Neck	2018+
	Pathological	2018+
	3876: LN Head and Neck Levels I-III	2018+
	3877: LN Head and Neck Levels IV-V	2018+
	3878: LN Head and Neck Levels VI-VII	2018+
	3879: LN Head and Neck Other	
	<b>3883</b> : LN Size	2018+
00150: Cutaneous Carcinoma	3858: High Risk Histologic Features	2018+
of the Head and Neck (2018+)	3883: LN Size	2018+
	<b>3909</b> : Perineural Invasion	2018+
00161: Esophagus (including	<b>3926</b> : Schema Discriminator 1: EsophagusGE Junction	2018+
GE junction) Squamous	(EGJ)/Stomach) (primary site C160)	
(2018+)	<b>3927</b> : Schema Discriminator 2: Histology	2018+
	Discriminator for 8020/3	
	3829: Esophagus and EGJ Tumor Epicenter	2018+
	3855: HER2 Overall Summary	2021+
00169: Esophagus (including	<b>3926</b> : Schema Discriminator 1: EsophagusGE Junction	2018+
GE junction) (excluding	(EGJ)/Stomach) (primary site C160)	
<u>Squamous) (2018+)</u>	<b>3927</b> : Schema Discriminator 2: Histology	2018+
	Discriminator for 8020/3	
	3855: HER2 Overall Summary	2021+
00170: Stomach (2018+)	<b>3926</b> : Schema Discriminator 1: EsophagusGE Junction	2018+
	(EGJ)/Stomach) (primary site C160)	
	3855: HER2 Overall Summary	2021+
00180: Small Intestine (2018+)	No SSDIs defined for this Schema ID	NA
00190: Appendix (2018-2022)	3819: CEA Pretreatment Interpretation	2018-2022
	3820: CEA Pretreatment Lab Value	2018-2022
09190: Appendix (2023+)	3819: CEA Pretreatment Interpretation	2023+
	<b>3820</b> : CEA Pretreatment Lab Value	2023+
	<b>3960:</b> Histology Subtype	2023+
00200: Colon and Rectum	3819: CEA Pretreatment Interpretation	2018+
(2018+)	<b>3820</b> : CEA Pretreatment Lab Value	2018+
	<b>3823</b> : Circumferential Resection Margin (CRM)	2018+
	3866: KRAS	2018+
	3890: Microsatellite Instability (MSI)	2018+
	<b>3909</b> : Perineural Invasion	2018+
	<b>3934</b> : Tumor Deposits	2018+
	3940: BRAF Mutational Analysis	2021+
	3941: NRAS Mutational Analysis	2021+
00210: Anus (2018-2022)	No SSDIs defined for this Schema ID	NA
<u>09210: Anus (2023+)</u>	<b>3956:</b> p 16	2023+
<u>00220: Liver (2018+)</u>	<b>3809</b> : AFP Pretreatment Interpretation	2018+
	<b>3810</b> : AFP Pretreatment Lab Value	2018+
	3813: Bilirubin Pretreatment Total Lab Value	2018+
	3814: Bilirubin Pretreatment Unit of Measure	2018+
	<b>3824</b> : Creatinine Pretreatment Lab Value	2018+
	<b>3825</b> : Creatinine Pretreatment Unit of Measure	2018+
	3835: Fibrosis Score	2018+

SSDI #/Description	Years Applicable
3835: Fibrosis Score	2018+
<b>3917</b> : Primary Sclerosing Cholangitis	2018+
3935: Tumor Growth Pattern	2018+
No SSDIs defined for this Schema ID	NA
<b>3926</b> : Schema Discriminator 1:	2018+
BileDuctsDistal/BileDuctsPerihilar/ CysticDuct	
<b>3926</b> : Schema Discriminator 1:	2018+
BileDuctsDistal/BileDuctsPerihilar/ CysticDuct	
<b>3917</b> : Primary Sclerosing Cholangitis	2018+
<b>3926</b> : Schema Discriminator 1:	2018+
BileDuctsDistal/BileDuctsPerihilar/ CysticDuct	
No SSDIs defined for this Schema ID	NA
No SSDIs defined for this Schema ID	NA
<b>3942:</b> CA 19-9 PreTx Lab Value	2021+
No SSDIs defined for this Schema ID	NA
<b>3863:</b> Ki-67	2021+
<b>3863:</b> Ki-67	2021+
<b>3863:</b> Ki-67	2021+
<b>3863:</b> Ki-67	2021+
<b>3863:</b> Ki-67	2021+
<b>3863:</b> Ki-67	2021+
<b>3863:</b> Ki-67	2021+
No SSDIs defined for this Schema ID	NA
No SSDIs defined for this Schema ID	NA
3929: Separate Tumor Nodules	2018+
3937: Visceral and Parietal Pleural Invasion	2018+
3938: ALK Rearrangement	2021+
3939: EGFR Mutational Analysis	2021+
<b>3913</b> : Pleural Effusion	2018+
No SSDIs defined for this Schema ID	NA
3908: Percent Necrosis Post Neoadjuvant	2018+
<b>3908</b> : Percent Necrosis Post Neoadiuvant	2018+
<b>3908</b> : Percent Necrosis Post Neoadjuvant	2018+
3815: Bone Invasion	2018+
3815: Bone Invasion	2018+
<b>3927:</b> Schema Discriminator 2: Soft Tissue Trunk and	2018+
3815: Bone Invasion	2018+
<b>JOLD</b> . DUITE IIIVASIUII	2010.
<b>3927:</b> Schema Discriminator 2: Soft Tissue Trunk and	2018+
	3835: Fibrosis Score3917: Primary Sclerosing Cholangitis3935: Tumor Growth PatternNo SSDIs defined for this Schema ID3926: Schema Discriminator 1:BileDuctsDistal/BileDuctsPerihilar/ CysticDuct3917: Primary Sclerosing Cholangitis3926: Schema Discriminator 1:BileDuctsDistal/BileDuctsPerihilar/ CysticDuct3926: Schema Discriminator 1:BileDuctsDistal/BileDuctsPerihilar/ CysticDuctNo SSDIs defined for this Schema ID3942: CA 19-9 PreTx Lab ValueNo SSDIs defined for this Schema ID3942: CA 19-9 PreTx Lab ValueNo SSDIs defined for this Schema ID3863: Ki-673863: Ki-67<

Schema ID#/Description	SSDI #/Description	Years Applicable
00422: Heart, Mediastinum	3815: Bone Invasion	2018+
and Pleura (2018+)		
<u>00430: GIST (2018+)</u>	<b>3926</b> : Schema Discriminator 1: Primary Peritoneum	2018+
	Tumor	
	3865: KIT Gene Immunohistochemistry	2018+
00440: Retroperitoneum	3815: Bone Invasion	
<u>(2018+)</u>		
00458: Soft Tissue Rare	3815: Bone Invasion	
<u>(2018+)</u>		
00459: Soft Tissue Other	3815: Bone Invasion	
<u>(2018+)</u>	<b>3926:</b> Schema Discriminator 1: Occult Head and Neck	
	Lymph Nodes (primary site C760)	
	<b>3927:</b> Schema Discriminator 2: Soft Tissue Trunk and	
	Extremities/ Soft Tissue Abdomen and Thoracic	
00458: Kaposi Sarcoma	No SSDIs defined for this Schema ID	NA
00460: Merkel Cell Carcinoma	3830: Extranodal Extension Clin (non-Head & Neck)	2018+
<u>(2018+)</u>	3833: Extranodal Extension Path (non-Head & Neck)	2018+
	3880: LN Isolated Tumor Cells (ITC)	2018+
	3918: Profound Immune Suppression	2018+
00470: Melanoma Skin (2018+)	3817: Breslow Tumor Thickness	2018+
	3936: Ulceration	2018+
	3893: Mitotic Rate Melanoma	2018+
	3932: LDH Lab Value	2018+
	3869: LDH Level	2018+
	3870: LDH Upper Limits of Normal	2018+
	<b>3961:</b> Clinical Margin Width	2023+
00478: Skin Other (2018+)	No SSDIs defined for this Schema ID	NA
00480: Breast (2018+)	<b>3826</b> : Estrogen Receptor Percent Positive or Range	2018+
	3827: Estrogen Receptor Summary	2018+
	3828: Estrogen Receptor Total Allred Score	2018-2022
	<b>3914</b> : Progesterone Receptor Percent Positive or	2018+
	Range	
	3915: Progesterone Receptor Summary	2018+
	3916: Progesterone Total Allred Score	2018-2022
	3850: HER2 IHC Summary	2018-2020
	3851: HER2 ISH Dual Probe Copy Number	2018-2020
	3852: HER2 ISH Dual Probe Ratio	2018-2020
	3853: HER2 ISH Single Probe Copy Number	2018-2020
	3854: HER2 ISH Summary	2018-2020
	3855: HER2 Overall Summary	2018+
	3894: Multigene Signature Method	2018+
	3895: Multigene Signature Results	2018+
	<b>3903</b> : Oncotype Dx Recurrence Score-DCIS	2018+
	<b>3904</b> : Oncotype Dx Recurrence Score-Invasive	2018+
	3905: Oncotype Dx Risk Level-DCIS	2018+
	<b>3906</b> : Oncotype Dx Risk Level-Invasive	2018+
	<b>3863</b> : Ki-67	2018+
	3882: LN Positive Axillary Level I-II	2018+
	<b>3922</b> : Response to Neoadjuvant Therapy	2018+

Schema ID#/Description	SSDI #/Description	Years Applicable
<u>00500: Vulva (2018+)</u>	3836: FIGO Stage (Vulva)	2018+
	3959: LN Status: Femoral-Inguinal	2018+
	3871: LN Assessment Method Femoral-Inguinal	2018+
	<b>3957:</b> LN Status: Pelvic	2018+
	3873: LN Assessment Method Pelvic	2018+
	3881: LN Laterality	2018+
00510: Vagina (2018+)	3836: FIGO Stage (Vagina)	2018+
	3959: LN Status: Femoral-Inguinal	2018+
	3871: LN Assessment Method Femoral-Inguinal	2018+
	<b>3958:</b> LN Status: Para-aortic	2018+
	3872: LN Assessment Method Para-aortic	2018+
	3959: LN Status: Pelvic	2018+
	3873: LN Assessment Method Pelvic	2018+
	3874: LN Distant Assessment Method	2018+
	3875: LN Distant: Mediastinal, Scalene	2018+
00520: Cervix (2018-2020)	3836: FIGO Stage (Cervix)	2018-2020
	<b>3871</b> : LN Assessment Method Femoral-Inguinal	2018-2020
	<b>3872</b> : LN Assessment Method Para-aortic	2018-2020
	3873: LN Assessment Method Pelvic	2018-2020
	3874: LN Distant Assessment Method	2018-2020
	3875: LN Distant: Mediastinal, Scalene	2018-2020
09520: Cervix (2021+)	<b>3836</b> : FIGO Stage (Cervix)	2021+
	<b>3958:</b> LN Status Para-aortic	2021+
	3872: LN Assessment Method Para-aortic	2021+
	<b>3957:</b> LN Status Pelvic	2021+
	3873: LN Assessment Method Pelvic	2021+
	3874: LN Distant Assessment Method	2021+
	<b>3875</b> : LN Distant: Mediastinal, Scalene	2021+
	<b>3956:</b> p 16	2021+
00528: Cervix Sarcoma	<b>3836</b> : FIGO Stage (Corpus Sarcoma)	2021+
	<b>3899</b> : Number of Examined Para-Aortic Nodes	2021+
	<b>3900</b> : Number of Examined Pelvic Nodes	2021+
	<b>3901:</b> Number of Positive Para-Aortic Nodes	2021+
	<b>3902:</b> Number of Positive Pelvic Nodes	2021+
	<b>3911</b> : Peritoneal Cytology	2021+
00530: Corpus Carcinoma and	<b>3836</b> : FIGO Stage (Corpus Carcinoma and	2018+
Carcinosarcoma	Carcinosarcoma)	20101
<u>carentosarconta</u>	<b>3899</b> : Number of Examined Para-Aortic Nodes	2018+
	<b>3900</b> : Number of Examined Pelvic Nodes	2018+
	<b>3901:</b> Number of Positive Para-Aortic Nodes	2018+
	<b>3902:</b> Number of Positive Pelvic Nodes	2018+
	<b>3911</b> : Peritoneal Cytology	2018+
00541: Corpus Sarcoma	<b>3836</b> : FIGO Stage (Corpus Sarcoma)	2018+
00041. Corpus Sarcollia	<b>3899</b> : Number of Examined Para-Aortic Nodes	2018+
	<b>3990</b> : Number of Examined Pelvic Nodes	2018+
	<b>3901:</b> Number of Positive Para-Aortic Nodes <b>3902:</b> Number of Positive Pelvic Nodes	2018+
		2018+
	<b>3911</b> : Peritoneal Cytology	2018+

Schema ID#/Description	SSDI #/Description	Years Applicable
00542: Corpus Adenosarcoma	3836: FIGO Stage (Corpus Adenosarcoma)	2018+
	3899: Number of Examined Para-Aortic Nodes	2018+
	3900: Number of Examined Pelvic Nodes	2018+
	<b>3901:</b> Number of Positive Para-Aortic Nodes	2018+
	<b>3902:</b> Number of Positive Pelvic Nodes	2018+
	<b>3911</b> : Peritoneal Cytology	2018+
00551: Ovary (2018+)	3818: CA-125 Pretreatment Interpretation	2018+
	<b>3836:</b> FIGO Stage (Ovary, Fallopian Tube and Primary	2018+
	Peritoneal Carcinomas)	
	<b>3921</b> : Residual Tumor Volume Post Cytoreduction	2018+
00552: Primary Peritoneal	3818: CA-125 Pretreatment Interpretation	2018+
Carcinoma (2018+)	<b>3836:</b> FIGO Stage (Ovary, Fallopian Tube and Primary	2018+
	Peritoneal Carcinomas)	
	<b>3921</b> : Residual Tumor Volume Post Cytoreduction	2018+
00553: Fallopian Tube (2018+)	3818: CA-125 Pretreatment Interpretation	2018+
	3836: FIGO Stage (Ovary, Fallopian Tube and Primary	2018+
	Peritoneal Carcinomas)	
	<b>3921</b> : Residual Tumor Volume Post Cytoreduction	2018+
00558: Adnexa Uterine Other (2018+)	No SSDIs defined for this Schema ID	NA
00559: Genital Female Other (2018+)	No SSDIs defined for this Schema ID	NA
00560: Placenta (2018+)	<b>3836</b> : FIGO Stage (Gestational Trophoblastic Tumors)	2018+
	<b>3837</b> : Gestational Trophoblastic Prognostic Scoring	2018+
	Index	
<u>00570: Penis (2018+)</u>	<b>3830:</b> Extranodal Extension Clin (non-Head and Neck)	2018+
	<b>3833</b> : Extranodal Extension Path (non-Head and	2018+
	Neck)	
00580: Prostate (2018+)	3838: Gleason Patterns Clinical	2018+
	<b>3839</b> : Gleason Patterns Pathological	2018+
	<b>3840</b> : Gleason Score Clinical	2018+
	<b>3841</b> : Gleason Score Pathological	2018+
	<b>3842</b> : Gleason Tertiary Pattern	2018+
	<b>3897</b> : Number of Cores Examined	2018+
	<b>3898</b> : Number of Cores Positive	2018+
	<b>3920:</b> PSA (Prostatic Specific Antigen) Lab Value	2018+
00590: Testis (2018+)	<b>3805</b> : AFP Post-Orchiectomy Lab Value	2018+
	<b>3806</b> : AFP Post-Orchiectomy Range	2018+
	<b>3807:</b> AFP Pre-Orchiectomy Lab Value	2018+
	<b>3808</b> : AFP Pre-Orchiectomy Range	2018+
	<b>3846</b> : hCG Post-Orchiectomy Lab Value	2018+
	<b>3847</b> : hCG Post-Orchiectomy Range	2018+
	<b>3848</b> : hCG Pre-Orchiectomy Lab Value	2018+
	<b>3849:</b> hCG Pre-Orchiectomy Range	2018+
	<b>3867</b> : LDH Post-Orchiectomy Range	2018+
	<b>3868:</b> LDH Pre-Orchiectomy Range	2018+
	<b>3923</b> : S Category Clinical	2018+
	<b>3924:</b> S Category Pathological	2018+
00598: Genital Male Other	No SSDIs defined for this Schema ID	NA
(2018+)		100

Schema ID#/Description	SSDI #/Description	Years Applicable
00600: Kidney Parenchyma	3861: Ipsilateral Adrenal Gland Involvement	2018+
<u>(2018+)</u>	3864: Invasion Beyond Capsule	2018+
	3886: Major Vein Involvement	2018+
	<b>3925</b> : Sarcomatoid Features	2018+
00610: Kidney Renal Pelvis	No SSDIs defined for this Schema ID	NA
(2018+)		
00620: Bladder (2018+)	No SSDIs defined for this Schema ID	NA
00631: Urethra (2018+)	<b>3926</b> : Schema Discriminator 1 (Urethra/Prostatic	2018+
	Urethra)	
00633: Urethra-Prostatic	<b>3926</b> : Schema Discriminator 1 (Urethra/Prostatic	2018+
(2018+)	Urethra)	
00638: Urinary Other (2018+)	No SSDIs defined for this Schema ID	NA
00640: Skin Eyelid (2018+)	<b>3909</b> : Perineural Invasion	2018+
00650: Conjunctiva (2018+)	No SSDIs defined for this Schema ID	NA
00600: Melanoma Conjunctiva	3888: Measured Thickness	2018+
00671: Melanoma Iris (2018+)	<b>3926:</b> Schema Discriminator 1 (Melanoma Ciliary	2018+
	Body/Melanoma Iris)	2010+
	3821: Chromosome 3 Status	2018+
	3822: Chromosome 8q Status	2018+
	3834: Extravascular Matrix Patterns	2018+
	3887: Measured Basal Diameter	2018+
	3888: Measured Thickness	2018+
	3891: Microvascular Density	2018+
	3892: Mitotic Count Uveal Melanoma	2018+
00672: Melanoma Choiroid	<b>3926:</b> Schema Discriminator 1 (Melanoma Ciliary	2018+
and Ciliary Body (2018+)	Body/Melanoma Iris)	
	3821: Chromosome 3 Status	2018+
	3822: Chromosome 8q Status	2018+
	3834: Extravascular Matrix Patterns	2018+
	3887: Measured Basal Diameter	2018+
	3888: Measured Thickness	2018+
	3891: Microvascular Density	2018+
	3892: Mitotic Count Uveal Melanoma	2018+
00680: Retinoblastoma	3856: Heritable Trait	2018+
<u>(2018+)</u>		
00690: Lacrimal Gland (2018+)	<b>3926:</b> Schema Discriminator 1 (Lacrimal	2018+
	Gland/Lacrimal Sac)	
	3803: Adenoid Cystic Basaloid Pattern	2018+
	<b>3909</b> : Perineural Invasion	2018+
00698: Lacrimal Sac (2018+)	<b>3926:</b> Schema Discriminator 1 (Lacrimal	2018+
	Gland/Lacrimal Sac)	
00700: Orbital Sarcoma	No SSDIs defined for this Schema ID	NA
(2018+)		1
(2018+) 00710: Lymphoma Ocular	No SSDIs defined for this Schema ID	NΔ
(2018+) 00710: Lymphoma Ocular Adnexa (2018+)	No SSDIs defined for this Schema ID	NA

Schema ID#/Description	SSDI #/Description	Years Applicable
00721: Brain (2018-2022)	<b>3801</b> : Chromosome 1p: Loss of Heterozygosity (LOH)	2018-2022
	<b>3802</b> : Chromosome 19q: Loss of Heterozygosity	2018-2022
	(LOH)	2018-2022
	3816: Brain Molecular Markers	2018-2022
	3889: Methylation of O6-Methylguanine-	
	Methyltransferase	
<u>09721: Brain (2023+)</u>	<b>3801</b> : Chromosome 1p: Loss of Heterozygosity (LOH)	2023+
	<b>3802</b> : Chromosome 19q: Loss of Heterozygosity	2023+
	(LOH)	2023+
	3816: Brain Molecular Markers	2023+
	<b>3889</b> : Methylation of O6-Methylguanine-	
	Methyltransferase	
00722: CNS Other (2018-2022)	<b>3801</b> : Chromosome 1p: Loss of Heterozygosity (LOH)	2018-2022
	<b>3802</b> : Chromosome 19q: Loss of Heterozygosity	2018-2022
	(LOH)	2018-2022
	3816: Brain Molecular Markers	2018-2022
	3889: Methylation of O6-Methylguanine-	
	Methyltransferase	
09722: CNS Other (2023+)	<b>3801</b> : Chromosome 1p: Loss of Heterozygosity (LOH)	2023+
	<b>3802</b> : Chromosome 19q: Loss of Heterozygosity	2023+
	(LOH)	2023+
	3816: Brain Molecular Markers	2023+
	3889: Methylation of O6-Methylguanine-	
	Methyltransferase	
00723: Intracranial Other	No SSDIs defined for this Schema ID	NA
(2018-2022)		
09723: Intracranial Other (2023+)	No SSDIs defined for this Schema ID	NA
09724: Medulloblastoma	3816: Brain Molecular Markers	2023+
<u>(2023+)</u>		
<u>00730: Thyroid (2018+)</u>	<b>3926</b> : Schema Discriminator 1 (Thyroid	2018+
	Gland/Thyroglossal Duct)	
00740: Thyroid Medullary	<b>3926</b> : Schema Discriminator 1 (Thyroid	2018+
<u>(2018+)</u>	Gland/Thyroglossal Duct)	
00750: Parathyroid (2018+)	No SSDIs defined for this Schema ID	NA
00760: Adrenal Gland (2018+)	No SSDIs defined for this Schema ID	NA
00770: NET Adrenal Gland	No SSDIs defined for this Schema ID	NA
(2018+)		
00778: Endocrine Other	No SSDIs defined for this Schema ID	NA
(2018+)		
00790: Lymphoma (excluding	<b>3926</b> : Schema Discriminator 1 (Histology	2018+
<u>CLL/SLL) (2018+)</u>	Discriminator for 9591/3)	
	3812: B Symptoms	2018+
	3859: HIV Status	2018+
	3896: NCCN International Prognostic Index (IPI)	2018+

Schema ID#/Description	SSDI #/Description	Years Applicable
00795: Lymphoma-CLL/SLL	3812: B Symptoms	2018+
<u>(2018+)</u>	3859: HIV Status	2018+
	3896: NCCN International Prognostic Index (IPI)	2018+
	3804: Adenopathy	2018+
	<b>3811:</b> Anemia	2018+
	3812: B symptoms	2018+
	<b>3859</b> : HIV Status	2018+
	3885: Lymphocytosis	2018+
	3896: NCCN International Prognostic Index (IPI)	2018+
	<b>3907:</b> Organomegaly	2018+
	3933: Thrombocytopenia	2018+
00811: Mycosis Fungoides	<b>3910:</b> Peripheral Blood Involvement	2018+
<u>(2018+)</u>		
00812: Primary Cutaneous	No SSDIs defined for this Schema ID	NA
Lymphomas (excluding		
Mycosis Fungoides) (2018+)		
00821: Plasma Cell Myeloma	<b>3926</b> : Schema Discriminator 1 (Multiple Myeloma	2018+
<u>(2018+)</u>	Terminology)	
	3857: High Risk Cytogenetics	2018+
	3869: LDH Level	2018+
	3930: Serum Albumin Pretreatment Level	2018+
	3931: Serum Beta-2 Microglobulin Pretreatment	2018+
	Level	
00822: Plasma Cell Disorders	No SSDIs defined for this Schema ID	NA
(2018+)		
00830: HemeRetic (2018+)	<b>3926</b> : Schema Discriminator 1 (Histology	2018+
	Discriminator for 9591/3)	
	<b>3862</b> : JAK2	2018+
99999: ILL-DEFINED OTHER	<b>3926:</b> Schema Discriminator 1 (Occult Head and Neck	2018+
<u>(2018+)</u>	Lymph Nodes) (Primary site C760 only)	

# **HEAD AND NECK**

# 3926: Schema Discriminator 1: Occult Head and Neck Lymph Nodes

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

- 00060: Cervical Lymph Nodes and Unknown Primary (2018+)
- 00459: Soft Tissue Other (2018+)
- 99999: Ill-Defined Other (2018+)

# **Definition**

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

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

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

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

- **Note**: If the physician "suspects" or "assigns" a specific head and neck subsite, the registrar is still to assign C760 so that the correct staging information can be abstracted.
  - **Example**: FNA of cervical lymph node metastases shows squamous cell carcinoma, p16 negative. Workup shows no evidence of primary tumor, although physician states this may be a laryngeal primary based on "best guess".
- Even though the primary site is suspected to be larynx, primary site would still be coded to C760. For all head and neck sites, except for oropharynx p16+ and nasopharynx EBV positive, no evidence of primary tumor (T0) does not exist in the individual AJCC chapters or EOD schemas. These cases are collected as unknown head and neck primary (C760), which will have no evidence of primary tumor. This Schema ID was designed specifically to group together these

cases of an occult primary, a tumor that is not identified on physical exam or imaging techniques.

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

# **Coding Guidelines**

This schema discriminator is based on several different criteria

- Positive cervical lymph nodes. This is the overall term used for the head and neck regional lymph nodes, which include Levels I-VII, and other group.
  - For a complete listing of these lymph nodes, see AJCC 8<sup>th</sup> Edition Chapter 5: *Staging Head and Neck Cancer*
  - This same information can be found in the EOD and Summary Stage Manuals
- No evidence of primary tumor and the suspected primary site is in the head and neck. A specific head and neck primary site may be suspected, but if there is no clinical/pathological evidence of the primary tumor, then the case is included in this schema
- Epstein-Barr Virus (EBV): EBV positive cancers are associated with nasopharyngeal cancer.
  - If the EBV (EBER) test is done and is positive, the primary site should be assigned to C119 (nasopharynx, NOS) instead of C760, so that the Nasopharynx staging system can be used. Nasopharynx has a T0, for no evidence of primary tumor
- p16: p16 positive cancers in the head and neck are associated with oropharyngeal cancer. p16 is a surrogate marker for Human Papilloma Virus (HPV).
  - If the p16 test is done and positive (and EBV is negative or unknown), the primary site should be assigned to C109 (oropharynx, NOS) instead of C760, so that the Oropharynx staging system can be used. Oropharynx has a T0, for no evidence of primary tumor.
  - **Note**: p16 is the only test that can be used for this discriminator. If there is another HPV test that is positive, the p16 would still be negative for purposes of this data item.

Code 0: Not occult

- Primary tumor is evident in the head and neck region; however, a specific primary site cannot be identified.
- **Note 1**: If overlapping lesions are evident and the primary site cannot be determined, this would not be a C760, but C148 (overlapping lesions) (Schema ID 00118: Pharynx Other)
- Note 2: For tumors in this category, C760 should be used sparingly. If C760 is assigned, this would be collected in the following schemas: Schema ID 99999: Ill-Defined Other OR Schema ID 00450: Soft Tissue Other (if specified sarcoma)
  - Examples include: Cases with limited information, historical case

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

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

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

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

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

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

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

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

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

• Both EBV and p16 done and reported as negative

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

#### **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.

• 00060: Cervical Lymph Nodes and Unknown Primary

Occult head and neck tumor with cervical metastasis in Levels I-VII, and other group lymph nodes without a p16 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 the AJCC Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck Staging System. Assign primary site C760; code the schema discriminator accordingly.

# • 00090: Nasopharynx

Occult head and neck tumors with cervical metastasis in Levels I-VII, and other group lymph nodes that is positive for Epstein–Barr virus (EBV+) (regardless of p16 status) encoded small RNAs (EBER) identified by in situ hybridization are staged using the AJCC Nasopharynx Staging System. Assign primary site C119; do NOT code this discriminator.

#### • 00100: Oropharynx HPV-Mediated (p16+)

Occult head and neck tumors with cervical metastasis in Levels I-VII, and other group lymph nodes, p16 positive with histology consistent with HPV-mediated oropharyngeal carcinoma (OPC), are staged using the AJCC HPV-Mediated (p16+) Oropharyngeal Cancer Staging System. Assign primary site C109; do NOT code this discriminator

# • 99999: Ill-Defined Other

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

**Note 2**: If there is no evidence of the primary tumor, yet the physician "suspects" a specific head and neck subsite, do not assign that primary site, but code C760 (see exceptions for EBV positive or p16 positive cancers.)

Code	Description	Schema ID #/Description
0	Not Occult	99999: Ill-Defined Other
		00459: Soft Tissue Other (8941/3 only)
1	Occult, Negative cervical nodes (regional head	99999: Ill-Defined Other
	and neck nodes)	00459: Soft Tissue Other (8941/3 only)
2	Not tested for EBV or p16 in head and neck	00060: Cervical Lymph Nodes and
	regional nodes (EBV and p16 both unknown)	Unknown Primary
3	Unknown EBV, p16 negative in head and neck	00060: Cervical Lymph Nodes and
	regional nodes	Unknown Primary
4	Unknown p16, EBV negative in head and neck	00060: Cervical Lymph Nodes and
	regional nodes	Unknown Primary
5	Negative for both EBV and p16 in head and	00060: Cervical Lymph Nodes and
	neck regional nodes	Unknown Primary
<blank></blank>	Not C760, discriminator does not apply	Various
	Positive p16 in head and neck regional nodes, EBV unknown or negative Assign primary site C109	00010: Oropharynx HPV-Mediated (p16+)
	Positive EBV in head and neck regional nodes, p16 positive, negative, or unknown Assign primary site C119	00090: Nasopharynx

# 3831: Extranodal Extension Head and Neck Clinical

Item Length: 1 NAACCR Item #: 3831 XML Parent-NAACCR ID: Tumor-extranodalExtensionHeadNeckClin NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00060: Cervical Lymph Nodes and Unknown Primary (2018+)
- 00071: Lip (2018+)
- 00072: Tongue Anterior (2018+)
- 00073: Gum (2018+)
- 00074: Floor of Mouth (2018+)
- 00075: Palate Hard (2018+)
- 00077: Mouth Other (2018+)
- 00080: Major Salivary Glands (2018+)
- 00090: Nasopharynx (2018+)
- 000100: Oropharynx HPV-Mediated (p16+)
- 00111: Oropharynx (p16-)
- 00112: Hypopharynx (2018+)
- 00121: Ethmoid Sinus (2018+)
- 00122: Nasal Cavity and Ethmoid Sinus (2018+)
- 00130: Larynx Other (2018+)
- 00131: Larynx Supraglottic (2018+)
- 00132: Larynx Glottic (2018+)

# **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 WITH or WITHOUT imaging
- Code 2 when there are positive nodes clinically, ENE is identified by biopsy (microscopically confirmed)
- Code 4 when there are positive nodes clinically, ENE is identified, but not known how identified
- Code 7 when nodes are clinically negative (cN0)
- Code 9 when
  - No information in the medical record
  - o Positive nodes clinically, not evaluated (assessed) for ENE
  - o 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 **clinically 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 Head and Neck Staging System as "Unambiguous evidence of gross ENE on clinical examination (e.g., invasion of skin, infiltration of musculature, tethering to adjacent structures, or cranial nerve, brachial plexus, sympathetic trunk, or phrenic nerve invasion with dysfunction)"
- The terms 'fixed' or 'matted' are used to describe lymph nodes
- 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 or not stated

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
2	Regional lymph nodes involved, ENE present/identified during diagnostic workup, based on microscopic confirmation
4	Regional lymph nodes involved, ENE present/identified, unknown how identified
7	No lymph node involvement during diagnostic workup (cN0)
8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code 8 may result in an edit 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

# 3832: Extranodal Extension Head and Neck Pathological

Item Length: 3 NAACCR Item #: 3832 XML Parent-NAACCR ID: Tumor-extranodalExtensionHeadNeckPath NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00060: Cervical Lymph Nodes and Unknown Primary (2018+)
- 00071: Lip (2018+)
- 00072: Tongue Anterior (2018+)
- 00073: Gum (2018+)
- 00074: Floor of Mouth (2018+)
- 00075: Palate Hard (2018+)
- 00077: Mouth Other (2018+)
- 00080: Major Salivary Glands (2018+)
- 00090: Nasopharynx (2018+)
- 000100: Oropharynx HPV-Mediated (p16+)
- 00111: Oropharynx (p16-)
- 00112: Hypopharynx (2018+)
- 00121: Ethmoid Sinus (2018+)
- 00122: Nasal Cavity and Ethmoid Sinus (2018+)
- 00130: Larynx Other (2018+)
- 00131: Larynx Supraglottic (2018+)
- 00132: Larynx Glottic (2018+)

# **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
  - o 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:** 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 recorded as distant metastatic disease."

**Note 3:** Code the status of ENE assessed on histopathologic examination of **surgically resected** involved regional lymph node(s). Do not code ENE from a lymph node biopsy (FNA, core, incisional, or the absence of ENE from a sentinel). Do not code ENE for any distant lymph nodes. Code the status of ENE based on the following criteria

- Code 0.0
  - Absence of ENE, positive lymph nodes assessed by lymph node dissection
  - 1292: Scope of Regional Lymph Node Surgery must be 3-7
- Codes 0.1-9.9, X.1, X.2, X.3, X.4 as appropriate for
  - Presence of ENE assessed by Sentinel Lymph Node biopsy
  - Presence of ENE assessed by lymph node biopsy
  - o 1292: Scope of Regional Lymph Node Surgery must be 2-7
- Code X.7 as appropriate for
  - Lymph nodes negative for cancer assessed by Sentinel lymph node biopsy or lymph node dissection
  - 1292: Scope of Regional Lymph Node Surgery must be 2-7
- Code X.9
  - Absence of ENE, positive lymph nodes assessed by Sentinel Lymph Node biopsy

- A positive Sentinel Lymph Node biopsy cannot assess the absence of ENE, only the presence of it. This is because there is not enough surrounding tissue in a Sentinel Lymph node biopsy to accurately assess ENE
- If codes 0.1-0.9, X.1-X.7 are used, this indicates that the lymph nodes were surgically resected or a Sentinel Lymph Node biopsy was done and Scope of Regional Lymph Node Surgery [NAACCR Data Item: 1292] must be 2-7

**Note 4:** Be aware that the rules for coding ENE for head and neck sites compared to non-head and neck sites are different.

**Note 5:** 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 6: 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
	Pathological assessment of lymph nodes not done, or unknown if done

# 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

# 3876-3879: 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.

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

# The Head and Neck Levels are defined as

- **1.** 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)
- 2. 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
- **3.** 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
- **4.** 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
- 5. Level V is subdivided into levels VA and VB, which contain the lymph nodes in the posterior triangle bounded by the anterior border of the trapezius muscle posteriorly, the posterior border of the sternocleidomastoid muscle anteriorly, and the clavicle inferiorly. For descriptive purposes, Level V may be further subdivided into upper (VA) and lower (VB) levels corresponding to a plane defined by the inferior border of the cricoid cartilage. Lymph node chains at this level:
  - Posterior cervical, posterior triangle (spinal accessory, transverse cervical [upper, middle, and lower, corresponding to the levels that define upper, middle, and lower jugular nodes]), supraclavicular
- **6.** 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)
- **7.** 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)

- 8. 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 9 since there is no specific information about the levels.
  - Levels I-III: Code 9
  - Levels IV-V: Code 9
  - Levels VI-VII: Code 9
  - Head and Neck, Other: Code 9

# 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 9. In other words, if regional nodes are known to be positive but the level(s) of nodes involved is unknown, code 9.

# 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 II-III because both Level II and Level III are mentioned.

# 3876: LN Head and Neck Levels I-III

Item Length: 1 NAACCR Item #: 3876 XML Parent-NAACCR ID: Tumor-InHeadAndNeckLevels1To3 NAACCR Alternate Name: Lymph Nodes Head and Neck Levels I-III Active years: 2018+ Schemas(s):

- 00060: Cervical Lymph Nodes and Unknown Primary (2018+)
- 00140: Melanoma Head and Neck (2018+)

### **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 <u>3876-3879: Head and Neck Regional Lymph Nodes (Levels I-VII, Other)</u> 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

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

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 8<sup>th</sup> 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

# 3877: LN Head and Neck Levels IV-V

Item Length: 1 NAACCR Item #: 3877 XML Parent-NAACCR ID: Tumor-InHeadAndNeckLevels4To5 NAACCR Alternate Name: Lymph Nodes Head and Neck Levels IV-V Active years: 2018+ Schemas(s):

- 00060: Cervical Lymph Nodes and Unknown Primary (2018+)
- 00140: Melanoma Head and Neck (2018+)

### **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 <u>3876-3879: Head and Neck Regional Lymph Nodes (Levels I-VII, Other)</u> 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

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

**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 8<sup>th</sup> edition, Chapter 5: *Staging Head and Neck Cancers*, Table 5.1

**Note 4:** If lymph nodes are described only as "supraclavicular," try to determine if they are in Level IV (deep to the sternocleidomastoid muscle, in the lower jugular chain) or Level V (in the posterior triangle, inferior to the transverse cervical artery) and code appropriately.

• If the specific level cannot be determined, or is documented as supraclavicular with no further information, code them as Level V nodes

**Note 5:** Pathological information takes priority over clinical.

**Note 6**: If involved regional node levels are documented as a range, and/or if the involved nodes overlap multiple levels, code all levels specified.

Note 7: 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

# 3878: LN Head and Neck Levels VI-VII

Item Length: 1 NAACCR Item #: 3878 XML Parent-NAACCR ID: Tumor-InHeadAndNeckLevels6To7 NAACCR Alternate Name: Lymph Nodes Head and Neck Levels VI-VII Active years: 2018+ Schemas(s):

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

### **Description**

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

### **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 <u>3876-3879: Head and Neck Regional Lymph Nodes (Levels I-VII, Other)</u> 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

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

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 8<sup>th</sup> 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

# 3879: LN Head and Neck Other

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

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

### **Description**

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

### **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 <u>3876-3879: Head and Neck Regional Lymph Nodes (Levels I-VII, Other)</u> 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

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

**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 8<sup>th</sup> 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

# 3883: LN Size

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

- 00060: Cervical Lymph Nodes and Unknown Primary
- 00071: Lip
- 00072: Tongue Anterior
- 00073: Gum
- 00074: Floor of Mouth
- 00075: Palate Hard
- 00076: Buccal Mucosa
- 00077: Mouth Other
- 00080: Major Salivary Glands
- 00090: Nasopharynx
- 00100: Oropharynx HPV-Mediated (p16+)
- 00111: Oropharynx (p16-)
- 00112: Hypopharynx
- 00121: Maxillary Sinus
- 00122: Nasal Cavity and Ethmoid Sinuses
- 00130: Larynx Other
- 00131: Larynx SupraGlottic
- 00132: Larynx Glottic
- 00133: Larynx SubGlottic
- 00140: Melanoma Head and Neck
- 00150: Cutaneous Carcinoma of Head and Neck

# **Description**

Lymph 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)
  - Lymph node described as "subcentimeter)
- 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

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

# Return to <u>Schema ID Table</u>

# 00071: Lip (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00072: Tongue Anterior (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00073: Gum (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00074: Floor of Mouth (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00075: Palate Hard (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00076: Buccal Mucosa (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00077: Mouth Other (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00080: Major Salivary Glands (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00090: Nasopharynx (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 3926: Schema Discriminator 1: Nasopharynx/Pharyngeal Tonsil

Primary site C111 only

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

- 00090: Nasopharynx
- 00100: Oropharynx HPV-Mediated (p16+)
- 00111: Oropharynx (p16-)

## Definition

Nasopharynx and pharyngeal tonsil have the same ICD-O topography code (C111). However, for purposes of stage grouping AJCC 8<sup>th</sup> 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.

- **00090: Nasopharynx (see code 1)** Used to stage for the following primary site description: posterior wall of nasopharynx (NOS)
- 00100 (Oropharynx HPV-Mediated (p16+)) or 00111 (Orpharynx (p16-)) (see code 2) Oropharynx Staging Systems are used for the following primary site descriptions. An additional schema discriminator will be used to distinguish between the AJCC HPV-Mediated (p16+) Oropharyngeal Cancer and Oropharynx (p16-) and Hypopharynx Staging System
  - Adenoid
  - Pharyngeal tonsil

Code	Description	Schema ID #/Description
1	Posterior wall of nasopharynx, NOS	00090: Nasopharynx
2	Adenoid	3927: Schema discriminator 2:
	Pharyngeal tonsil	Oropharyngeal p16
<blank></blank>	Primary Site is NOT C111, Discriminator is not necessary	

# 00100: Oropharynx HPV-Mediated (p16+) (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

See 00090: Nasopharynx (2018+)

• <u>3926: Schema Discriminator 1: Nasopharynx/Pharyngeal Tonsil</u>

# 00100: Oropharynx HPV-Mediated (p16+) (2018+)

# 3927: Schema Discriminator 2: Oropharyngeal p16

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

- 00100: Oropharynx HPV-Mediated (p16+)
- 00111: Oropharynx (p16-)

# **Definition**

Staging for oropharyngeal cancers changed in the AJCC 8<sup>th</sup> 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. If another HPV test is done, code 9.

- 00100: Oropharynx HPV-Mediated (p16+) (see code 2)
  - Used for p16 (+) (positive)
- 00111: Oropharynx (p16-)
  - p16 expression of weak intensity or limited distribution (see code 1)
  - p16 without an immunostain performed (see code 9)

Code	Description	Schema ID#/Description
1	p16 Negative; Nonreactive	00111: Orpharynx (p16-)
2	p16 Positive; HPV Positive; Diffuse, Strong reactivity	00100: Oropharynx HPV-Mediated
		(p16+)
9	Not tested for p16; Unknown	00111: Orpharynx (p16-)

# 00111: Oropharynx (p16-) (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

See 00090: Nasopharynx (2018+)

• <u>3926: Schema Discriminator 1: Nasopharynx/Pharyngeal Tonsil</u>

See 00100: Oropharynx HPV-Mediated (p16+)

• <u>3927: Schema Discriminator 2: Oropharyngeal p16</u>

Return to Schema ID Table

# 00112: Hypopharynx (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00121: Maxillary Sinus (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00122: Nasal Cavity and Ethmoid Sinuses (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00130: Larynx Other (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00131: Larynx Supraglottic (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00132: Larynx Glottic (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00133: Larynx SubGlottic (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3883: LN Size</u>

# 00140: Mucosal Melanoma of the Head and Neck (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

- <u>3831: Extranodal Extension Head and Neck Clinical</u>
- <u>3832: Extranodal Extension Head and Neck Pathological</u>
- <u>3876-3879: Head and Neck Regional Lymph Nodes (Levels I-VII, Other)</u>
  - o <u>3876: LN Head and Neck Levels I-III</u>
  - o <u>3877: LN Head and Neck Levels IV-V</u>
  - o <u>3878: LN Head and Neck Levels VI-VII</u>
  - o <u>3879: LN Head and Neck Other</u>

# 00150: Cutaneous Carcinoma of the Head and Neck (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

• <u>3883: LN Size</u>

See <u>00200: Colon and Rectum</u> for the following data item

• <u>3909: Perineural Invasion</u>

# 00150: Cutaneous Carcinoma of the Head and Neck (2018+)

# 3858: High Risk Histologic Features

Item Length: 1 NAACCR Item #: 3858 XML Parent-NAACCR ID: Tumor-highRiskHistologicFeatures NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00150: Cutaneous Carcinoma of Head and Neck (2018+)

## **Description**

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

# **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 7<sup>th</sup> 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)
  - o 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 the presence or absence of high risk histologic features as documented in the pathology report.

**Note 4:** Code 5 if more than one high risk histologic feature is present.

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

Return to Schema ID Table

# 00161: Esophagus (including GE junction) Squamous (2018+)

# 3926: Schema Discriminator 1: EsophagusGEJunction (EGJ)/Stomach

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

- 00161: Esophagus (including GE junction) Squamous (2018+)
- 00169: Esophagus (including GE junction) (excluding Squamous) (2018+)
- 00170: Stomach (2018+)

# **Definition**

The esophagus chapter of the *AJCC Cancer Staging Manual* 8<sup>th</sup> 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 7<sup>th</sup> 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 system, it is necessary to identify the midpoint or epicenter of the tumor. If the midpoint is at or above the cardia, the tumor is esophageal. If the midpoint of the tumor is within 2 cm distal to the gastroesophageal junction (GEJ) and the lesion extends to or across the GEJ, the case should be coded with the esophagus system. If the midpoint of the tumor is within 2 cm distal to the 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 1:** Under primary site code C160, there are two different structures that are staged differently.

- Esophagogastric junction (Esophagus Schemas)
- Cardia of the Stomach (Stomach schema)

**Note 2:** The gastroesophageal junction (GEJ) (primary site C160) is a poorly defined anatomic area that represents the junction between the distal esophagus and the proximal stomach (cardia). The true anatomic GEJ corresponds to the most proximal aspect of the gastric folds, which represents an endoscopically apparent transition point in most individuals.

**Note 3:** The cardia (also assigned primary site C160) is the **first part of the stomach.** It is the region where the stomach meets the end of the esophageal tube. This region is also referred to as the Z-line or the esophagogastric junction.

**Note 4:** Physician's statement can be used to code this data item when no other information is available.

- **Example:** Patient diagnosed with tumor involving the cardia. No other information available. Physician stages the patient using the Esophagus Staging System/CAP protocol
  - **Answer:** Code 2 based on physician using the Esophagus Staging System

**Note 5:** Tumors with their midpoint (epicenter) in the GE Junction are staged as Esophagus, while tumors with their midpoint (epicenter) in the cardia/stomach are staged using the Stomach Staging System.

• **Note:** The CAP protocol uses "midpoint" instead of "epicenter." This is the pathologist's assessment of the point of tumor origin, regardless of tumor extension into other tissues.

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

Note 1: Use code 2 when

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

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

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

Note 2: Use code 3 when

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

**Note 3:** Use code 9 when there is no documentation regarding EGJ involvement.

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

Return to Schema ID Table

# 00161: Esophagus (including GE junction) Squamous (2018+)

# 3927: Schema Discriminator 2: Histology Discriminator for 8020/3

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

- 00161: Esophagus (including GE junction) Squamous (2018+)
- 00169: Esophagus (including GE junction) (excluding Squamous) (2018+)

# **Definition**

Histology code 8020/3 is defined as "undifferentiated carcinoma." In the AJCC 8<sup>th</sup> 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 AJCC Stage Group table to use.

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

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

# 00161: Esophagus and Esophagogastric Junction (2018+)

# 3829: Esophagus and EGJ Tumor Epicenter

Item Length: 1 NAACCR Item #: 3829 XML Parent-NAACCR ID: Tumor-esophagusAndEgjTumorEpicenter NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00161: Esophagus (including GE junction) Squamous (2018+)

Required for Staging: The AJCC Esophagus Staging System 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 8<sup>th</sup> 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.

Note 6: If primary site is C259 (Esophagus, NOS), code 9.

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

Return to Schema ID Table

# 00161: Esophagus (including GE junction) Squamous (2018+)

# 3855: HER2 Overall Summary

Item Length: 1 NAACCR Item #: 3855 XML Parent-NAACCR ID: Tumor-her2OverallSummary NAACCR Alternate Name: None Active years: 2021+ Schema(s):

- 00161: Esophagus (including GE junction) Squamous (2018+)
- 00169: Esophagus (including GE junction) (excluding Squamous) (2018+)
- 00170: Stomach (2018+)

## **Description**

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

## Rationale

This data item is required for prognostic stage grouping in AJCC 8<sup>th</sup> edition, Chapter 48 *Breast*. It was previously collected as Breast, CS SSF # 15. Experts recommend that every invasive breast cancer be tested for the presence of HER2 because anti-HER2 treatments are highly effective for these tumors.

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

# **Coding Instructions and Codes**

Note 1: This SSDI is effective for diagnosis years 2021+.

• For cases diagnosed 2018-2020, leave this SSDI blank

**Note 2:** Physician statement of HER2 Overall Summary can be used to code this data item when no other information is available.

**Note 3:** HER2 may be recorded for all histologies; however, it is primarily performed for adenocarcinomas. If information is not available, code 9.

Note 4: The result of the HER2 test performed on the primary tissue is to be recorded in this data item.

• Use the highest (positive versus negative) when there are multiple results

**Note 5:** 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

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

# 00169: Esophagus (including GE junction) (excluding Squamous) (2018+)

See 00161: Esophagus (including GE junction) Squamous (2018+)

- <u>3926: Schema Discriminator 1: EsophagusGEJunction (EGJ)/Stomach</u>
- <u>3927: Schema Discriminator 2: Histology Discriminator for 8020/3</u>
- <u>3855: HER2 Overall Summary</u>

# 00170: Stomach (2018+)

See 00161: Esophagus (including GE junction) Squamous (2018+)

- <u>3926: Schema Discriminator 1: EsophagusGEJunction (EGJ)/Stomach</u>
- <u>3855: HER2 Overall Summary</u>

# 00190: Appendix (2018-2022)

See 00200: Colon and Rectum (2018+) for

- <u>3819: CEA Pretreatment Interpretation</u>
- <u>3820: CEA Pretreatment Lab Value</u>

# 09190: Appendix (2023+)

See 00200: Colon and Rectum (2018+) for

- <u>3819: CEA Pretreatment Interpretation</u>
- <u>3820: CEA Pretreatment Lab Value</u>

# 09190: Appendix (2023+)

# **3960: Histologic Subtype**

Item Length: 1 NAACCR Item #: 3960 XML Parent-NAACCR ID: histologicSubtype NAACCR Alternate Name: None Active years: 2023+ Schema(s):

• 09190: Appendix (2023+)

# **Definition**

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

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

#### **Coding Instructions and Codes**

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

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

**Note 2:** Use the Solid Tumor Rules to determine histology prior to coding this SSDI.

**Note 3:** Histology 8480/2 or 8480/3 have multiple definitions that are collected in this histology. This data item is used to further identify specific subtypes for histology code 8480/2 or 8480/3.

#### Examples:

- Appendix: Disseminated peritoneal adenomucinous/low grade mucinous carcinoma peritonei. Final diagnosis: Low grade appendiceal mucinous neoplasm
  - a. Code 1: This is a low grade mucinous (appendiceal) carcinoma (8480/3), which is LAMN. The peritoneal adenomucinous/low grade mucinous carcinoma peritonei is describing metastatic disease and not the histology
- 2. Appendix: Low grade (well diff) appendiceal adenocarcinoma
  - a. Code 0: This is an adenocarcinoma (8140/3), the low grade (well diff) is describing the grade and not the histology
- 3. Appendix, appendectomy: Low grade appendiceal mucinous neoplasm (LAMN) with focal high grade mucinous neoplasm.
  - a. Code 1: Based on the Solid Tumor Rules, the "focal" would be ignored and this would be a LAMN.
- 4. Appendectomy: Mucinous adenocarcinoma of the appendix

- a. Code 3: Mucinous adenocarcinoma is the preferred terminology for histology code 8480/3. Since there is no mention of "low grade" or "high grade", this would not be LAMN or HAMN
- 5. Appendix: Mucinous (colloid) adenocarcinoma
  - a. Code 3: Colloid adenocarcinoma is an alternate name for 8480/3

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

# Return to Schema ID Table

# 3819, 3820: 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

- <u>3819: CEA Pretreatment Interpretation</u>
- <u>3820: CEA Pretreatment Lab Value</u>

# **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	0
23.6 ng/ml	23.6	1
127.8 ng/ml	127.8	1
3567 ng/ml	3567.0	1
11,000	XXXX.1	1
Test ordered, results not in chart	XXXX.7	7
Not documented in medical record	XXXX.9	9
CEA test not done		
Unknown if CEA test done		

# 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 ng/L

# 3820: CEA Pretreatment Lab Value

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

- 00190: Appendix (2018-2022)
- 09190: Appendix (2023+)
- 00200: Colon and Rectum (2018+)

## **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 <u>3819, 3820: CEA Pretreatment Lab Value and Interpretation</u> 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:** Record 0.1 when the lab results are stated as less than 0.1 ng/ml with no exact value.

**Note 6:** The same laboratory test should be used to record information in <u>3819: CEA Pretreatment</u> <u>Interpretation</u>.

Code	Description
0.0	0.0 nanograms/milliliter (ng/ml) exactly
0.1-	0.1-9999.9 ng/ml
9999.9	(Exact value to nearest tenth in ng/ml)
XXXX.1	10,000 ng/ml or greater
XXXX.7	Test ordered, results not in chart

Code	Description	
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	

# **3819: CEA Pretreatment Interpretation**

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

- 00190: Appendix (2018-2022)
- 09190: Appendix (2023+)
- 00200: Colon and Rectum (2018+)

## **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 <u>3819, 3820: CEA Pretreatment Lab Value and Interpretation</u> 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 3 when a CEA value was documented in the record, but there is no statement that the CEA is positive/elevated, negative/normal, and the normal range (from which you can determine interpretation), is not documented.

**Note 4:** The same laboratory test should be used to record information in <u>3820: CEA Pretreatment Lab</u> <u>Value</u>.

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

# 00200: Colon and Rectum (2018+)

# 3823: Circumferential Resection Margin (CRM)

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

• 00200: Colon and Rectum (2018+)

## **Description**

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

## **Rationale**

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

## **Definition**

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

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

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

# **Coding guidelines**

- Code 0.0 is for positive margins, or margin is less than 0.1 mm
- 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
- Code XX.2 when the margins cannot be assessed
  - **Note**: **ONLY** when the pathology reports/CAP checklist states that the margin cannot be assessed/evaluated.
- Codes XX.3-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)
  - Checked "Not applicable: Radial or Mesenteric Margin" on CAP Checklist
  - 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 the AJCC Staging System *Colon and Rectum*

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

**Note 3:** The following guidelines were developed for the coding of surgery codes in relation to CRM. These guidelines were confirmed by the CAP Cancer Committee.

- For Colon primaries, surgery of primary site must be coded as 30-80
  - If surgery of primary site is 00-29, then CRM must be coded as XX.7
- For Rectal primaries, surgery of primary site must be coded as 27, 30-80
  - If surgery of primary site is 00-26 or 28, then CRM must be coded as XX.7

**Note 4:** 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 5:** The CRM may be referred to as

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

**Note 6:** 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 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:** If the margin is involved (positive), code 0.0. If the margin is described as less than 0.1 mm with no more specific measurement, Code 0.0; margins of 0-1.0 mm are recorded by the pathologist as involved.

**Note 9:** Code **XX.2** (Margins cannot be assessed) **ONLY** when the pathology reports/CAP checklist states that the margin cannot be assessed/evaluated.

Note 10: An exact measurement takes precedence over codes 0.0 and those beginning with XX.

- Exact measurement takes priority even if the pathologist states the margin is positive.
- **Example**: CRM stated as 0.3 mm in Final Diagnosis and Synoptic states: Circumferential (Radial) Margin Interpreted as involved by invasive carcinoma (tumor less than 1mm from margin).
  - Code the 0.3 mm instead of 0.0 (margin involved with tumor)

Note 11: Code XX.9 when

- Checked "Not applicable: Radial or Mesenteric Margin" on CAP Checklist
- Pathology report describes only distal and proximal margins, or margins, NOS
  - Only specific statements about the CRM are collected in this data item
- CRM not mentioned in the record

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

# 00200: Colon and Rectum (2018+)

# 3866: KRAS

Item Length: 1 NAACCR Item #: 3866 XML Parent-NAACCR ID: Tumor-kras NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00200: Colon and Rectum (2018+)

#### **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).

#### **Additional Information**

- Source documents: pathology report or clinical laboratory report
- 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 the AJCC Staging System *Colon and Rectum*

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

- Codon 12
  - Gly12Asp (GGT>GAT)
    Gly12Val (GGT>GTT)
    Gly12Cys (GGT>TGT)
    Gly12Ser (GGT>AGT)
    Gly12Ala (GGT>GCT)
    Gly12 Arg (GGT>CGT)
    Codon 12 mutation, not otherwise specified
- Codon 13

Gly13Asp (GGC>GAC)
Gly13Arg (GGC>CGC)
Gly13Cys (GGC>TGC)
Gly13Ala (GGC>GCC)
Gly13Val (GGC>GTC)
Codon 13 mutation, not otherwise specified

• Codon 61

oGln61Leu (CAA>CTA)

oGIn61His (CAA>CAC)

oCodon 61 mutation, not otherwise specified

• Codon 146

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

Note 4: KRAS analysis is commonly done for patients with metastatic disease.

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

**Note 6:** Record the results of the KRAS from the initial workup (clinical and pathological workup).

**Note 7:** If KRAS is positive and there is no mention of the mutated codon, or the mutated codon is not specified, code 4.

Note 8: Code 9 when

- Insufficient amount of tissue available to perform test
- No microscopic confirmation of tumor
- KRAS not ordered or not done, or unknown if ordered or done

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

Code	Description
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

# 00200: Colon and Rectum (2018+)

# 3890: Microsatellite Instability (MSI)

Item Length: 1 NAACCR Item #: 3890 XML Parent-NAACCR ID: Tumor-microsatelliteInstability NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00200: Colon and Rectum (2018+)

## **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 the AJCC Staging System *Colon and Rectum*

#### **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 encode proteins that normally repair certain types of DNA damage. A high proportion

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

**Note 3:** MSI may be recorded for all stages; however, it is primarily performed for invasive neoplasms. For non-invasive neoplasms (behavior /2), code to 9 if no information available.

Note 4: Results from nodal or metastatic tissue may be used for Microsatellite instability.

**Note 5:** Testing for MSI may be done by immunology or genetic testing. Only genetic testing results will specify whether the MSI is low or high.

- MSI is looking at instability in informative markers
- MSI results are recorded as
  - MSS (Code 0)
  - Stable (Code 0)
  - Negative (Code 0)
  - Low probability of MSI-H (Code 0)
  - MSS/MSI-L (Code 0)
  - MSI-L (Code 1)
  - Unstable, high (Code 2)
  - Unstable, NOS (no designation of high or low) (Code 2)
  - MSI-H (Code 2)
  - MSI-I (intermediate) (Code 9)

Note 6: Testing for Mismatch Repair (MMR) is usually done by immunohistochemistry (IHC).

- Most common markers are MLH1, MSH2, MSH6, PMS2
- MMR results are recorded as
  - No loss of nuclear expression (code 0)
  - Mismatch repair (MMR) intact (code 0)
  - MMR proficient (pMMR or MMR-P) (code 0)
  - MMR normal (code 0)
  - Loss of nuclear expression (code 2)
  - MMR deficient (dMMR or MMR-D) (code 2)
  - MMR abnormal (code 2)

Note 7: If both tests are done and one or both are positive, code 2.

**Note 8:** 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
	MMR proficient (pMMR or MMR-P)
1	MSI unstable low (MSI-L)
2	MSI unstable high (MSI-H)
	AND/OR

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

# 00200: Colon and Rectum (2018+)

## **3909: Perineural Invasion**

Item Length: 1 NAACCR Item #: 3909 XML Parent-NAACCR ID: Tumor-perineuralInvasion NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00150: Cutaneous Carcinoma of the Head and Neck (2018+)
- 00200: Colon and Rectum (2018+)
- 00640: Skin Eyelid (2018+)
- 00690: Lacrimal Gland (2018+)

## **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. If perineural invasion is not mentioned in the pathology report, do not assume that there is no perineural invasion.

#### 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 the AJCC Staging System *Colon and Rectum*
- 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 <u>statement</u> 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.

**Note 3:** Information on **presence** of perineural invasion can be taken from either a biopsy or resection. Absence of perineural invasion can only be taken from a surgical resection pathology report.

**Note 4:** Code 9 if surgical resection of the primary site is performed and there is no mention of perineural invasion.

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

Return to Schema ID Table

## 00200: Colon and Rectum (2018+)

## **3934: Tumor Deposits**

Item Length: 2 NAACCR Item #: 3934 XML Parent-NAACCR ID: Tumor-tumorDeposits NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00200: Colon and Rectum (2018+)

## **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
  - $\circ \quad \text{Not documented in medical record}$
  - 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 report

- **Other names:** discontinuous extramural extension, malignant tumor foci, malignant peritumoral deposits, satellite nodule
- For further information, refer to the **Colon and Rectum** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Colon and Rectum*
- **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-	01-99 Tumor deposits
99	(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

## 00200: Colon and Rectum (2018+)

## **3940: BRAF Mutational Analysis**

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

• 00200: Colon and Rectum (2018+)

## **Description**

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

## **Rationale**

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

## **Definition**

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

## Additional Information

- Source documents: pathology report or clinical laboratory report
- For further information, refer to the **Colon and Rectum Biomarker Reporting** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Colon and Rectum*

## **Coding Instructions and Codes**

Note 1: This SSDI is effective for diagnosis years 2021+.

• For cases diagnosed 2018-2020, leave this SSDI blank

**Note 2:** Physician statement of BRAF can be used to code this data item when no other information is available.

**Note 3:** BRAF may be recorded for all stages; however, it is primarily performed for patients with metastatic disease. If information is not available, code 9.

**Note 4:** BRAF is a gene which belongs to a class of genes known as oncogenes. When mutated, oncogenes have the potential to cause normal cells to become cancerous. Studies suggest that BRAF gene mutations are often present in colorectal cancer. The most common BRAF mutations is

• BRAF V600E (c.1799T>A) mutation

Note 5: The most common testing methods for BRAF are

- Direct Sanger sequencing
- High-resolution melting analysis
- Pyrosequencing
- PCR, allele-specific hybridization
- Real-time PCR

Note 6: Results from nodal or metastatic tissue may be used for BRAF.

**Note 7:** If BRAF is positive and there is no mention of the mutated codon, or the mutated codon is not specified, code 4.

**Note 8:** If neoadjuvant therapy is given, record the assay from tumor specimens prior to neoadjuvant therapy.

• If neoadjuvant therapy is given and there are no BRAF results from pre-treatment specimens, report the findings from post-treatment specimens

## Note 9: Code 9 when

- Insufficient amount of tissue available to perform test
- No microscopic confirmation of tumor
- BRAF not ordered or not done, or unknown if ordered or done

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

## 00200: Colon and Rectum (2018+)

## **3941: NRAS Mutational Analysis**

Item Length: 1 NAACCR Item #: 3941 XML Parent-NAACCR ID: Tumor-nrasMutationalAnalysis NAACCR Alternate Name: None Active years: 2021+ Schema(s):

• 00200: Colon and Rectum (2018+)

## **Description**

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

## **Rationale**

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

## **Definition**

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

## Additional Information

- Source documents: pathology report or clinical laboratory report
- For further information, refer to the **Colon and Rectum Biomarker Reporting** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Colon and Rectum*

## **Coding Instructions and Codes**

Note 1: This SSDI is effective for diagnosis years 2021+.

• For cases diagnosed 2018-2020, leave this SSDI blank

**Note 2:** Physician statement of NRAS can be used to code this data item when no other information is available.

**Note 3:** NRAS may be recorded for all stages; however, it is primarily performed for patients with metastatic disease. If information is not available, code 9.

**Note 4:** NRAS is a gene which belongs to a class of genes known as oncogenes. When mutated, oncogenes have the potential to cause normal cells to become cancerous. Studies suggest that NRAS gene mutations are often present in colorectal cancer.

**Note 5:** There are 3 NRAS codons that are commonly mutated in colorectal cancers. This SSDI does not record the actual mutation, but instead records the codon or codon group that contains the mutation. If a specific NRAS mutation is reported, its codon may be identified from the following list of common NRAS mutations grouped by codon.

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

**Note 6:** Results from nodal or metastatic tissue may be used for NRAS.

**Note 7:** If NRAS is positive and there is no mention of the mutated codon, or the mutated codon is not specified, code 4.

**Note 8:** If neoadjuvant therapy is given, record the assay from tumor specimens prior to neoadjuvant therapy.

• If neoadjuvant therapy is given and there are no NRAS results from pre-treatment specimens, report the findings from post-treatment specimens

## Note 9: Code 9 when

- Insufficient amount of tissue available to perform test
- No microscopic confirmation of tumor
- NRAS not ordered or not done, or unknown if ordered or done

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

Code	Description
9	Not documented in medical record
	NRAS not assessed or unknown if assessed
<blank></blank>	N/A-Diagnosis year is prior to 2021

## 3956: p16

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

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

## **Description**

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

## **Rationale**

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

## Definition

p16 is a tumor suppressor protein also known as cyclin-dependent kinase inhibitor 2A. The p16 biomarker is overexpressed (produced) in response to HPV. It is therefore a surrogate marker for HPV disease.

#### **Coding Instructions and Codes**

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

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

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

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

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

Code	Description
0	p16 Negative; Nonreactive
1	p16 Positive; Diffuse, Strong reactivity
8	Not applicable: Information not collected for this case
	(If this time is required by your standard setter, use of code 8 will result in an edit error)
9	Not tested for p16; Unknown
<blank></blank>	N/A-Diagnosis year prior to 2023

## Return to <u>Schema ID Table</u>

## HEPATOBILIARY SYSTEM

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

#### **Definition**

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

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

- <u>3809: AFP Pretreatment Interpretation</u>
- <u>3810: AFP Pretreatment Lab Value</u>

## 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

## 3810: AFP Pretreatment Lab Value

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

• 00220: Liver (2018+)

## **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 <u>3809, 3810: Alpha-Fetoprotein (AFP) Pretreatment Lab Value and Interpretation (Liver)</u> 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 <u>3809: AFP Pretreatment</u> <u>Interpretation</u>.

Code	Description
0.0	0.0 nanograms/milliliter (ng/ml); not detected
0.1-	0.1-9999.9 ng/ml
9999.9	(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

## **3809: AFP Pretreatment Interpretation**

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

• 00220: Liver (2018+)

## **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 <u>3809, 3810: Alpha-Fetoprotein (AFP) Pretreatment Lab Value and Interpretation (Liver)</u> 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 <u>3810: AFP Pretreatment Lab</u> <u>Value</u>.

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

## 3813-3814, 3824-3825, 3860: 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.

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

## **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**

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	XXXX.9	9
Bilirubin test not done		
Unknown if Bilirubin test done		

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.

## 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  $\mu$ mol/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 with severe liver disease. Creatinine can be measured in blood serum or urine, but these data items apply to blood levels only. Do not code urine creatinine or creatinine clearance in this field.

There are two methods of describing creatinine levels in the blood, weight in grams (milligrams per deciliter), usually used in the US, and molecular count in moles (micromoles per liter) in Canada. Conversion: 1 mg/dL = 17.1 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	XXXX.9	9
Creatinine test not done		
Unknown if Creatinine test done		

## 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 mmol/L)
  - Men: 0.7-1.2 mg/dL (60-110 mmol/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
  - $\circ$  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.

## 3813: Bilirubin Pretreatment Total Lab Value

Item Length: 5 NAACCR Item #: 3813 XML Parent-NAACCR ID: Tumor-bilirubinPretxTotalLabValue NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00220: Liver (2018+)

## **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 <u>3813-3814</u>, <u>3824-3825</u>, <u>3860</u>: <u>Model for End-Stage Liver Disease (MELD) Score</u> 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 and total bilirubin values. 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 <u>3814: Bilirubin Pretreatment</u> Unit of Measure.

Code	Description
0.0	0.0 milligram/deciliter (mg/dL)
	0.0 micromole/liter (umol/L)
0.1-	0.1-999.9 milligram/deciliter (mg/dL)
999.9	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 to <u>Schema ID Table</u>

## 3814: Bilirubin Pretreatment Unit of Measure

Item Length: 1 NAACCR Item #: 3814 XML Parent-NAACCR ID: Tumor-bilirubinPretxUnitOfMeasure NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00220: Liver (2018+)

## **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 <u>3813-3814, 3824-3825, 3860: Model for End-Stage Liver Disease (MELD) Score</u> 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 <u>3813: Bilirubin Pretreatment</u> <u>Total Lab Value</u>.

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 to <u>Schema ID Table</u>

## 3824: Creatinine Pretreatment Lab Value

Item Length: 4 NAACCR Item #: 3824 XML Parent-NAACCR ID: Tumor-creatininePretreatmentLabValue NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00220: Liver (2018+)

#### **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 <u>3813-3814</u>, <u>3824-3825</u>, <u>3860</u>: <u>Model for End-Stage Liver Disease (MELD) Score</u> 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 <u>3825: Creatinine Pretreatment</u> <u>Unit of Measure</u>.

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)

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

## 3825: Creatinine Pretreatment Unit of Measure

Item Length: 1 NAACCR Item #: 3825 XML Parent-NAACCR ID: Tumor-creatininePretxUnitOfMeasure NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00220: Liver (2018+)

## **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 <u>3813-3814, 3824-3825, 3860: Model for End-Stage Liver Disease (MELD) Score</u> 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 <u>3824: Creatinine Pretreatment</u> <u>Lab Value</u>.

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 to <u>Schema ID Table</u>

## **3860: International Normalized Ratio**

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

• 00220: Liver (2018+)

## **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 <u>3813-3814</u>, <u>3824-3825</u>, <u>3860</u>: <u>Model for End-Stage Liver Disease</u> (<u>MELD</u>) <u>Score</u> for additional information</u>

## **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-	0.2 - 9.9
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

## 3835: Fibrosis Score

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

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

## **Description**

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

## **Rationale**

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

## Definition

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

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

## Additional Information

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

## **Coding Instructions and Codes**

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

**Note 2:** FIB-4 is NOT a pathological fibrosis score of 4. It is a scoring method using the patient's age and relevant lab values to calculate a score. The medical record may show something like "FIB-4 = 3.52." Do not code FIB-4 values in this data item.

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

**Note 4:** Record the results based on information collected during the initial work-up through the first course surgery, in the absence of neoadjuvant treatment. If multiple histologic assessments of the liver (biopsies or resections) are taken and have conflicting scores, record the highest score.

• Information collected after the start of neoadjuvant treatment or primary systemic or radiation therapy may not be used to code this data item.

**Note 5**: To use codes 0 and 1, you must have a histological (microscopic) confirmation of fibrosis/cirrhosis. Code the absence (code 0) or presence (code 1) of fibrosis as documented in the pathology report.

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

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

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

Code	Description	
0	Any of the following histologically confirmed	
	No to moderate fibrosis	
	Ishak fibrosis score 0-4	
	METAVIR score F0-F3	
	Batt-Ludwig score 0-3	
1	Any of the following histologically confirmed	
	Advanced/severe fibrosis	
	Developing cirrhosis	
	Incomplete cirrhosis	
	Transition to cirrhosis	
	Cirrhosis, probably or definite	
	Cirrhosis, NOS	
	Ishak fibrosis score 5-6	
	METAVIR score F4	
	Batt-Ludwig score 4	
7	Clinical statement of advanced/severe fibrosis or cirrhosis, AND	
	Not histologically confirmed or unknown if histologically confirmed	
8	Not applicable: Information not collected for this case	
	(If this item is required by your standard setter, use of code 8 will result in an edit error.)	
9	Not documented in medical record	
	Stated in medical record that patient does not have advanced cirrhosis/advanced fibrosis, not	
	histologically confirmed or unknown if histologically confirmed	
	Fibrosis score stated but cannot be assigned to codes 0 or 1	
	Fibrosis score stated but scoring system not recorded	
	Fibrosis Score not assessed or unknown if assessed	

002300: Bile Ducts Intrahepat (2018+)

See 00220: Liver (2018+)

• <u>3835: Fibrosis Score</u>

## 00230: Bile Ducts Intrahepatic (2018+)

## **3917: Primary Sclerosing Cholangitis**

Item Length: 1 NAACCR Item #: 3917 XML Parent-NAACCR ID: Tumor-primarySclerosingCholangitis NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00230: Bile Ducts Intrahepatic (2018+)
- 00250: Bile Ducts Perihilar (2018+)

## **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
  - o Primary Sclerosing Cholangitis is not evaluated (not assessed)
  - Unknown if Primary Sclerosing Cholangitis is 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

## 00230: Bile Ducts Intrahepatic (2018+)

## **3935: Tumor Growth Pattern**

Item Length: 1 NAACCR Item #: 3935 XML Parent-NAACCR ID: Tumor-tumorGrowthPattern NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00230: Bile Ducts Intrahepatic (2018+)

#### **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 1 when a radiology, surgery, or pathology report describes the tumor as mass-forming only
- Code 2 when a radiology, surgery, or pathology report describes the tumor as periductal infiltrating only
- Code 3 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
	Radiology and/or pathology report does not mention tumor growth pattern
	Cannot be determined by the pathologist
	Tumor growth pattern not assessed or unknown if assessed

Return to <u>Schema ID Table</u>

## 3926: Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct

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

- 00242: Cystic Duct (2018+)
- 00250: Bile Ducts Perihilar (2018+)
- 00260: Bile Duct Distal (2018+)

## **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 8<sup>th</sup> 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.

#### 00242: Cystic Duct (see code 3)

• Per the AJCC Gallbladder Staging System, the gallbladder tapers into the cystic duct

#### 00250: Bile Ducts Perihilar (see codes 1, 5, 6, 9)

• Per the AJCC Perihilar Bile Ducts Staging System, perihilar (or proximal) cholangiocarcinomas involve the main biliary confluence of the right and left hepatic ducts and comprise 50%-70% of all cases of bile duct carcinoma

#### 00260: Bile Ducts Distal (see codes 4, 7)

• Per the AJCC Distal Bile Duct Staging System, these tumors have their center located between the confluence of the cystic duct and common hepatic duct and the Ampulla of Vater (excluding ampullary carcinomas)

Code	Description	Schema ID#/Description
1	Perihilar bile duct(s)	00250: Bile Ducts Perihilar
	Proximal extrahepatic bile duct(s)	
	Hepatic duct(s)	
3	Cystic bile duct; cystic duct	00242: Cystic Duct
4	Distal bile duct	00260: Bile Duct Distal
	Common bile duct	
	Common duct, NOS	
5	Diffuse involvement	00250: Bile Ducts Perihilar
	More than one subsite involved, subsite of origin not stated	
6	Stated as middle extrahepatic bile duct	00250: Bile Ducts Perihilar
	AND treated with combined hepatic and hilar resection	

Code	Description	Schema ID#/Description
7	Stated as middle extrahepatic bile duct	00260: Bile Duct Distal
	AND treated with pancreaticoduodenectomy	
9	Extrahepatic bile ducts, NOS	00250: Bile Ducts Perihilar

## Return to <u>Schema ID Table</u>

## 00250: Bile Ducts Perhilar (2018+)

See 00242: Cystic Duct (2018+)

• <u>3926: Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct</u>

See 00230: Bile Ducts Intrahepatic

• <u>3917: Primary Sclerosing Cholangitis</u>

## 00260: Bile Duct Distal (2018+)

See 00242: Cystic Duct (2018+)

• <u>3926: Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct</u>

## 3942: CA 19-9 PreTx Lab Value

Item Length: 6 NAACCR Item #: 3942 XML Parent-NAACCR ID: Tumor-ca199PretxLabValue Alternate Name: Carbohydrate Antigen 19-9 Pretreatment Lab Value Active years: 2021+ Schema(s):

• 00280: Pancreas (2018+)

## **Description**

Carbohydrate Antigen (CA) 19-9 Pretreatment Lab Value records the CA 19-9 value prior to treatment. CA 19-9 is a tumor marker that has prognostic significance for pancreatic cancer.

## **Rationale**

CA 19-9 Pretreatment Lab Value is a strong predictor of resectability in the absence of metastatic disease. It is a new data item **for cases diagnosed 1/1/2021+.** 

## **Definition**

CA 19-9 is a sialylated Lewis A blood group antigen that is commonly expressed and shed in pancreatic and hepatobiliary disease and in many malignancies, thus is not tumor specific. Preoperative CA 19-9 levels in pancreatic cancer patients correlate both with AJCC staging and resectability [NCCN Guidelines Version 3.2019 Pancreatic Adenocarcinoma].

## Additional Information

- Source documents: clinical laboratory report
- **Other names:** Carbohydrate Antigen 19-9, Cancer Antigen-GI, CA-GI, Cancer Antigen 19-9 https://labtestsonline.org/tests/cancer-antigen-19-9#

## **Coding Instructions and Code**

Note 1: This SSDI is effective for diagnosis years 2021+.

• For cases diagnosed 2018-2020, leave this SSDI blank

**Note 2:** Physician statement of CA 19-9 (Carbohydrate Antigen 19-9) Pretreatment Lab Value can be used to code this data item when no other information is available.

**Note 3:** Record the lab value of the highest CA 19-9 test result documented in the medical record **prior to treatment**. The lab value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.

Note 4: A known lab value takes priority over codes XXXX.2 and XXXX.3

- The lab value takes priority even if the physician documents the interpretation
- *Example*: Patient noted to have a CA 19-9 of 3,219. Physician notes that the value is elevated.

• Code 3219.0 instead of XXXX.3 (elevated)

**Note 5:** CA 19-9 is a tumor marker that has value in the management of certain malignancies.

**Note 6:** Record to the nearest tenth in Units/milliliter (U/ml), the highest CA 19-9 lab value documented in the medical record prior to treatment.

- Example 1: Code a pretreatment CA 19-9 of 7 U/ml as 7.0
- Example 2: Code a pretreatment CA 19-9 of 1672.3 U/ml as 1672.3

**Note 7:** Record 0.1 when the lab results are stated as less than 0.1 U/ml with no exact value.

Code	Description	
0.0	0.0 Units/milliliter (U/ml) exactly	
0.1-	0.1-9999.9 U/ml	
9999.9	(Exact value to nearest tenth in U/ml)	
XXXX.1	10,000 U/ml or greater	
XXXX.2	Lab value not available, physician states CA 19-9 is negative/normal	
XXXX.3	Lab value not available, physician states CA 19-9 is positive/elevated/high	
XXXX.7	Test ordered, results not in chart	
XXXX.8	Not applicable: Information not collected for this case	
	(If this information is required by your standard setter, use of code XXXX.8 may result in an edit error.)	
XXXX.9	Not documented in medical record	
	CA (Carbohydrate Antigen) 19-9 Pretreatment Lab Value not assessed or unknown if assessed	
<blank></blank>	N/A-Diagnosis year is prior to 2021	

## 00290: NET Stomach (2018+)

## 3863: Ki-67

Item Length: 5 NAACCR Item #: 3863 XML Parent-NAACCR ID: Tumor-ki67 Active years: 2021+ Schema(s):

- 00290: NET Stomach (2018+)
- 00301: NET Duodenum (2018+)
- 00302: NET Ampulla of Vater (2018+)
- 00310: NET Jejunum and Ileum (2018+)
- 00320: NET Appendix (2018+)
- 00330: NET Colon and Rectum (2018+)
- 00340: NET Pancreas (2018+)

## **Description**

Ki-67 (MIB-1) (Proliferative Index) is a marker of cell proliferation. A high value indicates a tumor that is proliferating more rapidly. Codes and coding instructions for this data item are site-specific.

## **Rationale**

Ki-67 (MIB-1) (Proliferative Index) is a Registry Data Collection Variable in AJCC. It was a new data item for breast cases diagnosed 1/1/2018+. It will apply to neuroendocrine tumors (NET) of the gastrointestinal tract (AJCC Chapters 29 – 34) for cases diagnosed 1/1/2021+. High Ki-67 is an adverse prognostic factor and Ki-67 is a component of grade for these tumors. NCCN guidelines recommend that tumor differentiation, mitotic rate and Ki-67 should be recorded in the pathology report for these tumors.

Note 1: This SSDI is effective for diagnosis years 2021+.

• For cases diagnosed 2018-2020, leave this SSDI blank

**Note 2:** Physician statement of Ki-67 (MIB-1), also referred to as the "Proliferative Index" can be used to code this data item.

**Note 3:** Ki-67 is a marker of cell proliferation. A high value indicates a tumor that is proliferating more rapidly.

**Note 4:** Results from nodal or metastatic tissue may not be used.

• If the only information you have have is a Ki-67 from a metastatic site, code to XXX.9

**Note 5:** 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.

- Example 1: Ki-67 reported as 14%. Code 14.0
- *Example 2:* Ki-67 reported as 8.6%. Code 8.6

**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 Ki-67 results from pre-treatment specimens, report the findings from post-treatment specimens

**Note 7:** A specific value (0.0-100.0) takes priority over XXX.4, XXX.5 or XXX.6. Code the exact percentage when provided. When the exact percentage is not given, including ranges or terms such as "less than" or "greater than" use the range value codes XXX.4, XXX.5, XXX.6.

- XXX.4, XXX.5 and XXX.6 were added since they are listed on the CAP protocol
  - *Example 1:* Ki-67 stated as less than 1%. Code XXX.4
  - *Example 2:* Ki-67 stated as 5%-10%. Code XXX.5
  - *Example 3:* Ki-67 stated as greater than 4%. Code XXX.5
  - *Example 4:* Ki-67 stated as greater than 30%. Code XXX.6

Code	Description
0.0-100.0	0.0 to 100.0 percent positive: enter percent positive
XXX.4	Ki-67 stated as less than 3%
XXX.5	Ki-67 stated as 3%-20%
XXX.6	Ki-67 stated as greater than 20%
XXX.7	Test done; actual percentage not stated
XXX.8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code XXX.8 will result in an edit error.)
XXX.9	Not documented in medical record
	Ki-67 (MIB-1) not assessed or unknown if assessed
<blank></blank>	N/A-Diagnosis year is prior to 2021

## Return to <u>Schema ID Table</u>

# 00301: NET Duodenum (2018+)

See 00290: NET Stomach (2018+)

• <u>3863: Ki-67</u>

# 00302: NET Ampulla of Vater (2018+)

See 00290: NET Stomach (2018+)

• <u>3863: Ki-67</u>

00310: NET Jejunum and Ileum (2018+)

See <u>00290: NET Stomach (2018+)</u>

• <u>3863: Ki-67</u>

# 00320: NET Appendix (2018+)

See 00290: NET Stomach (2018+)

• <u>3863: Ki-67</u>

# 00330: NET Colon and Rectum (2018+)

See 00290: NET Stomach (2018+)

• <u>3863: Ki-67</u>

# 00340: NET Pancreas (2018+)

See 00290: NET Stomach (2018+)

• <u>3863: Ki-67</u>

# THORAX

# 00360: Lung (2018+)

# **3929: Separate Tumor Nodules**

Item Length: 1 NAACCR Item #: 3929 XML Parent-NAACCR ID: Tumor-separateTumorNodules NAACCR Alternate Name: None Active years: 2018+ Schema(s):

00360: Lung (2018+)

### 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
  - o SINGLE TUMOR nodule only
  - $\circ$   $\:$  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.

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

**Note 4:** Other situations that display multiple lesions are NOT coded in this item. Assign code 0 if the multiple lesions belong to one of these other situations. Refer to the AJCC Staging System Lung for standardized and precise definitions of the situations which aren't separate tumor nodules. They are

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

**Note 5:** "Synchronous" describes the appearance in time compared to the primary tumor. Do not code this item based solely on the word "synchronous". If separate nodules are described as "metachronous," the nodules may be evidence of progression of disease in which case they would not be coded here.

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

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

**Note 8:** Code 9 if there is no relevant imaging or resection of the primary site.

Code	Description			
0	No separate tumor nodules; single tumor only			
	Separate tumor nodules of same histologic type not identified/not present			
	Intrapulmonary metastasis not identified/not present			
	Multiple nodules described as multiple foci of adenocarcinoma in situ or minimally invasive			
	adenocarcinoma			
	Non-invasive neoplasm (behavior /2)			
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			
	Separate Tumor Nodules not assessed or unknown if assessed			

# 00360: Lung (2018+)

# 3937: Visceral and Parietal Pleural Invasion

Item Length: 1 NAACCR Item #: 3937 XML Parent-NAACCR ID: Tumor-visceralParietalPleuralInvasion NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00360: Lung (2018+)

#### **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 PLO 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 pleural surface, but also 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 PLO
  - o Tumor does not penetrate beyond the elastic layer of the visceral pleura
  - Extends to the elastic layer

- Code 4 when
  - Invasion of pleura without specifying visceral or parietal pleura
  - Uncertain whether elastic stain has been performed to identify visceral pleura invasion
  - Pathology report states PL1 or PL2
- Code 5 when tumor extends to the parietal pleura (classified as T3) or described as PL3
- 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)
  - o Unknown if Visceral and Parietal Pleural Invasion evaluated (assessed)

# Additional Information

- **Source documents:** pathology report
- For further information, refer to the **Lung** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Lung*
- **Other names:** VPI, PL (number)
- 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 and Parietal Pleural Invasion can be used to code this data item when no other information is available.

**Note 2:** A surgical resection must be done to determine if the visceral and/or parietal pleural are involved.

Note 3: Do not use imaging findings to code this data item

# Note 4: Code 9 when

- A FNA only is performed. A FNA is not adequate to assess pleural layer invasion
- Surgical resection of the primary site is performed and there is no mention of visceral and/or parietal pleural invasion

Code	Description		
0	No evidence of visceral pleural invasion identified		
	Tumor does not completely traverse the elastic layer of the pleura		
	Stated as PLO		
	Primary tumor is in situ		
	Non-invasive neoplasm (behavior /2)		
	No evidence of primary tumor		
4	Invasion of visceral pleura present, NOS		
	Stated as PL1 or PL2		
5	Tumor invades into or through the parietal pleura OR chest wall		
	Stated as PL3		

Code	Description
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 to <u>Schema ID Table</u>

# 00360: Lung (2018+)

# 3938: ALK Rearrangement

Item Length: 1 NAACCR Item #: 3938 XML Parent-NAACCR ID: Tumor-alkRearrangement Active years: 2021+ Schema(s):

• 00360: Lung (2018+)

## **Description**

Testing for ALK rearrangement is performed for patients with advanced non-small cell lung cancer (NSCLC) to identify tumors which are sensitive to small-molecule ALK kinase inhibitors.

#### **Rationale**

ALK rearrangement is recommended by treatment guidelines for patients with advanced lung cancer to as a prognostic marker and factor in determining appropriate therapy. It is a new data item **for cases diagnosed 1/1/2021+.** 

#### **Definition**

"ALK positive cancer describes cancer cells that have a change in the structure of the anaplastic lymphoma kinase (ALK) gene or a higher than normal amount of ALK protein on their surface. In normal cells, ALK helps control cell growth. When cancer cells have the changed ALK gene or make too much ALK protein, the cancer cells may grow more quickly. Knowing whether a cancer is ALK positive may help plan treatment for advanced non-small cell cancers in the lung." (NCI Dictionary of Cancer Terms https://www.cancer.gov/publications/dictionaries/cancer-terms)

The presence of the ALK protein predicts a favorable response to therapy with a targeted ALK inhibitor, such as crizotinib or ceritinib (chemotherapy).

# **Additional Information**

- **Source documents:** pathology report or clinical laboratory report, molecular report, immunohistochemistry report
- **Other names:** ALK tyrosine kinase receptor, anaplastic lymphoma kinase, anaplastic lymphoma receptor tyrosine kinase, CD246, CD246 antigen, NBLST3
- For further information, refer to the **Lung Biomarker Reporting** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Lung*

#### **Coding Instructions and Codes**

Note 1: This SSDI is effective for diagnosis years 2021+.

• For cases diagnosed 2018-2020, leave this SSDI blank

**Note 2:** Physician statement of ALK rearrangement for non-small cell carcinoma can be used to code this data item when no other information is available.

• This data item only includes rearrangements. Ignore any amplifications or point mutations

**Note 3:** ALK may be recorded for all histologies and stages; however, it is primarily performed for advanced non-small cell carcinomas. If information is not available, code 9.

**Note 4:** The absence or presence of ALK protein expression determines if the tumor will respond to treatment with a targeted inhibitor. ALK protein expression predicts the ALK rearrangement gene, which are more likely to respond to the targeted inhibitor treatment. The most common ALK rearrangements are

- EML4-ALK
- KIF5B-ALK
- TFG-ALK
- KLC1-ALK

**Note 5:** If ALK Rearrangement is positive and there is no mention of the specific rearrangement, code 4.

**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 ALK results from pre-treatment specimens, report the findings from post-treatment specimens

Note 7: Code 9 when

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

Code	Description
0	Normal
	ALK negative
	Negative for rearrangement, no rearrangement identified, no mutations (somatic)
	identified, not present, not detected
1	Abnormal Rearrangement identified/detected: EML4-ALK, KIF5B-ALK, TFG-ALK, and/or
	KLC1-ALK
2	Rearrangement identified/detected: Other ALK Rearrangement not listed in code 1
4	Rearrangement, NOS
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code 8 may result in an edit
	error.)
9	Not documented in medical record
	ALK Rearrangement not assessed or unknown if assessed
<blank></blank>	N/A-Diagnosis year is prior to 2021

# 00360: Lung (2018+)

# **3939: EGFR Mutational Analysis**

Item Length: 1 NAACCR Item #: 3939 XML Parent-NAACCR ID: Tumor-egfrMutationalAnalysis Active years: 2021+ Schema(s):

• 00360: Lung (2018+)

## **Description**

Epidermal growth factor receptor (EGFR) mutational analysis is performed for patients with advanced non-small cell lung cancer (NSCLC) to identify patients with certain activating mutations in the EGFR gene which are sensitive to tyrosine kinase Inhibitors.

# **Rationale**

EGFR mutational analysis is recommended by treatment guidelines for patients with advanced lung cancer as a prognostic marker and factor in determining appropriate therapy. It is a new data item **for cases diagnosed 1/1/2021+.** 

#### **Definition**

"EGFR (epidermal growth factor receptor) is a protein found on certain types of cells that binds to a substance called epidermal growth factor. The EGFR protein is involved in cell signaling pathways that control cell division and survival. Sometimes, mutations (changes) in the EGFR gene cause EGFR proteins to be made in higher than normal amounts on some types of cancer cells. This causes cancer cells to divide more rapidly." (NCI Dictionary of Cancer Terms https://www.cancer.gov/publications/dictionaries/cancer-terms)

The presence of Exon 20 EGFR activating mutations are associated with a resistance to EGFR tyrosine kinase inhibits, such as erlotinib, afatinib, and gefitinib. There is limited data available on response for some of the other uncommon EGFR mutations (other than Exon 20). (CAP Cancer Protocol).

#### Additional Information

- Source documents: pathology report or clinical laboratory report
- **Other names:** Epidermal growth factor receptor tyrosine kinase inhibitor, ERBB, ERBB1, ErbB1, HER1
- For further information, refer to the Lung Biomarker Reporting cancer protocol published by the College of American Pathologists for the AJCC Staging System Lung

#### **Coding Instructions and Codes**

Note 1: This SSDI is effective for diagnosis years 2021+.

• For cases diagnosed 2018-2020, leave this SSDI blank

**Note 2:** Physician statement of EGFR can be used to code this data item when no other information is available.

**Note 3:** EGFR may be recorded for all histologies and stages; however, it is primarily performed for advanced non-small cell carcinomas. If information is not available, code 9.

Note 4: The most common EGFR mutations are

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

**Note 5:** If EGFR is positive and there is no mention of the mutated codon, or the mutated codon is not specified, code 4.

**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 EGFR results from pre-treatment specimens, report the findings from post-treatment specimens

Note 7: Code 9 when

- Insufficient amount of tissue available to perform test
- No microscopic confirmation of tumor
- EGFR not ordered or not done, or unknown if ordered or done

Code	Description
0	Normal
	EGFR negative, EGFR wild type
	Negative for mutations, no alterations, no mutations (somatic) identified, not present, not
	detected
1	Abnormal (mutated)/detected in exon(s) 18, 19, 20, and/or 21
2	Abnormal (mutated)/detected but not in exon(s) 18, 19, 20, and/or 21
4	Abnormal (mutated)/detected, NOS, exon(s) not specified
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record
	EGFR not assessed or unknown if assessed
<blank></blank>	N/A-Diagnosis year is prior to 2021

# 00370: Pleura Mesothelioma (2018+)

# **3913: Pleural Effusion**

Item Length: 1 NAACCR Item #: 3913 XML Parent-NAACCR ID: Tumor-pleuralEffusion NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00370: Pleural Mesothelioma (2018+)

#### **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
  - o 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
  - o Physician states pleural effusion is positive in the absence of positive cytology
- Code 3 when

- Pleural fluid cytology is described as atypical or atypical mesothelial cells but not specifically as non-malignant or malignant)
- Code 4 when
  - Pleural effusion is reported on imaging, but there is no cytology
  - Pleural effusion is reported on imaging, but there is no physician's statement on whether it is positive
- 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:** 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 2:** A physician's statement of positive (malignant) pleural effusion or a positive cytology confirming a malignant pleural effusion must be used to code this data item.

- Code 2 when
  - There is a positive malignant pleural effusion confirmed by cytology
  - Pleural fluid cytology is described as suspicious/suspicious for mesothelioma
- Code 3 when cytology is described as atypical/atypical mesothelial cells

**Note 3:** The presence of a pleural effusion on imaging alone (i.e., a pleural effusion, NOS) is not equivalent to a malignant pleural effusion.

- Code 1 if imaging indicates a pleural effusion but pleural cytology is described as negative for malignant cells
- Code 4 if imaging indicates a pleural effusion and there is no further information on whether it is positive or negative or cytology not done

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

# Return to <u>Schema ID Table</u>

## BONE

# **3908: Percent Necrosis Post Neoadjuvant**

Item Length: 5 NAACCR Item #: 3908 XML Parent-NAACCR ID: Tumor-percentNecrosisPostNeoadjuvant NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00381: Bone Appendicular Skeleton (2018+)
- 00382: Bone Spine (2018+)
- 00383: Bone Pelvis (2018+)

# **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
- For further information, refer to the **Bone** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Bone*
- Other names: Histologic treatment response, therapy response, chemotherapy effect

# **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
- Surgical resection of the primary site is the initial therapy; therefore, no neoadjuvant therapy was performed

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

# 00382: Bone Spine (2018+)

See 00381: Bone Appendicular Skeleton (2018+)

• <u>3908: Percent Necrosis Post Neoadjuvant</u>

# 00383: Bone Pelvis (2018+)

See 00381: Bone Appendicular Skeleton (2018+)

• <u>3908: Percent Necrosis Post Neoadjuvant</u>

# SOFT TISSUE SARCOMA

# 00400: Soft Tissue Head and Neck (2018+)

# 3815: Bone Invasion

Item Length: 1 NAACCR Item #: 3815 XML Parent-NAACCR ID: Tumor-boneInvasion NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00400: Soft Tissues Head and Neck (2018+)
- 00410: Soft Tissue Trunk and Extremities (2018+)
- 00421: Soft Tissues Abdomen and Thoracic (excluding Heart, Mediastinum, Pleura) (2018+)
- 00422: Heart, Mediastinum, and Pleura (2018+)
- 00440: Retroperitoneum (2018+)
- 00450: Soft Tissue Rare (2018+)
- 00459: Soft Tissue Other (2018+)

#### **Description**

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

#### **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.

**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

# 00410: Soft Tissue Trunk and Extremities (2018+)

See 00400: Soft Tissue Head and Neck (2018+)

• <u>3815: Bone Invasion</u>

# 00410: Soft Tissue Trunk and Extremities (2018+)

# 3927: Schema Discriminator 2: Soft Tissue Sarcoma (C473, C475, C493-C495)

Item Length: 1 NAACCR Item #: 3927 XML Parent-NAACCR ID: Tumor-schemaDiscriminator2 NAACCR Alternate Name: None Active years: 2018+ AJCC 8th Edition Chapter(s):

- 00410: Soft Tissue Trunk and Extremities (2018+)
- 00421: Soft Tissues Abdomen and Thoracic (excluding Heart, Mediastinum, Pleura) (2018+)
- 00459: Soft Tissue Other (2018+)

# **Definition**

The ICD-O-3 assigned topography codes for the peripheral nerve and autonomic nervous systems tumors (C47) and the connective, subcutaneous and other soft tissues (C49) primary sites are based on transverse or horizontal planes. The AJCC Staging System Soft Tissue Sarcoma of the Trunk and Extremities, and Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs base the eligible sites as either external structures or internal viscera. For example

- C493 axilla is an external site using the AJCC Staging System Soft Tissue Sarcoma of the Trunk and Extremities
- C493 axillary artery is an internal site using the AJCC Staging System Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs
- C475 sacrococcygeal region is a large area that may be either external or internal
  - Need to determine the exact area involved to assign the correct chapter
  - C475 external area of sacrococcygeal region uses the AJCC Staging System Soft Tissue Sarcoma of the Trunk and Extremities
  - C475 intrapelvic area of sacrococcygeal region uses the AJCC Staging System Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs To develop a software algorithm that can be used to send the registrar to the correct system/schema, this schema discriminator was developed.

The schema discriminator is based on determining whether the structure involved is part of the external structures or the internal viscera. This is accomplished by

- Terms in ICD-O-3 topography codes sorted appropriately by the physician experts when possible
- Instructions on what to do when terms are not specific enough to be assigned as external structures or internal viscera
  - Without additional information, these may not be staged, for example C475 pelvis
  - With additional information, these may be determined to be external structures or internal viscera
- In addition to the topography codes and terms, there is also an option of "External sites, NOS" and "Internal sites, NOS" for registrars to use to assign the schema discriminator. Registrars may need to use additional information, including physician staging, to choose the appropriate schema discriminator

# **Coding Instructions and Codes**

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

**Note 2:** Code 1 is used for external structures and is assigned to the AJCC Staging System Soft Tissue Sarcoma of the Trunk and Extremities (Schema ID 00410: Soft Tissue Sarcoma of the Trunk and Extremities).

• *Example*: Trapezius muscle (C493) is an external structure, on the outer layer or periphery of the body

**Note 3:** Code 2 is used for internal structures and is assigned to the AJCC Staging System Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs (Schema ID 00421: Soft Tissue Sarcoma of the Abdomen and Thoracic Visceral Organs).

• *Example*: Aorta (C493) is an internal structure, in the inner parts of the body

**Note 4:** Code 8 is only used for cases for 2018-2020 that have already been abstracted prior to the Version 2.0 update (2021 update). It can also be used for 2018-2020 cases that are abstracted after the 2021 updates.

• For cases diagnosed 2021+, code 8 cannot be used

**Note 5:** Code 9 is used for when there is not enough specific information to determine if the structure is external or internal. These cases are collected in Schema ID 00459: Soft Tissue Other.

• *Example*: Chest NOS (C493) does not provide enough information in order to determine if it is either an external structure, on the outer layer or periphery of the body, or an internal structure, in the inner parts of the body

Code	Description	Schema ID#/Description
1	External structures (sites), NOS	00410: Soft Tissue Trunk and Extremities
	Examples of terms include:	
	Peripheral nerves and autonomic nervous system (C47)	
	• Pelvis (C475)	
	<ul> <li>Buttock</li> </ul>	
	<ul> <li>Gluteal region</li> </ul>	
	o Groin	
	<ul> <li>Inguinal region</li> </ul>	
	o Perineum	
	<ul> <li>Sacrococcygeal region (stated as external)</li> </ul>	
	Thorax (C473)	
	o Axilla	
	<ul> <li>Chest wall</li> </ul>	
	<ul> <li>Infraclavicular region</li> </ul>	
	<ul> <li>Scapular region</li> </ul>	
	o Thoracic wall	
	Connective, subcutaneous and other soft tissues (C49)	

Code	Description	Schema ID#/Description
	Abdomen (C494)	
	<ul> <li>Abdominal wall</li> </ul>	
	<ul> <li>Abdominal wall muscle</li> </ul>	
	<ul> <li>Iliopsoas muscle</li> </ul>	
	<ul> <li>Psoas muscle</li> </ul>	
	<ul> <li>Rectus abdominis muscle</li> </ul>	
	<ul> <li>Umbilicus</li> </ul>	
	• Pelvis (C495)	
	o Buttock	
	<ul> <li>Gluteal region</li> </ul>	
	<ul> <li>Gluteus maximus muscle</li> </ul>	
	o Groin	
	<ul> <li>Inguinal region</li> </ul>	
	<ul> <li>Perineum</li> </ul>	
	<ul> <li>Sacrococcygeal region</li> </ul>	
	• Thorax (C493)	
	o Axilla	
	<ul> <li>Chest wall</li> </ul>	
	<ul> <li>Infraclavicular region</li> </ul>	
	<ul> <li>Intracostal muscle</li> </ul>	
	<ul> <li>Latissimus dorsi muscle</li> </ul>	
	<ul> <li>Pectoralis major muscle</li> </ul>	
	<ul> <li>Scapular region</li> </ul>	
	<ul> <li>Thoracic wall</li> </ul>	
	<ul> <li>Trapezius muscle</li> </ul>	
2	Internal structures and viscera (sites), NOS	00421: Soft Tissue Abdomen
-		and Thoracic (excluding Heart,
	Examples of terms include	Mediastinum, Pleura)
	Peripheral nerves and autonomic nervous system (C47)	
	Sacrococcygeal region (intrapelvic)	
	Connective, subcutaneous and other soft tissues (C49)	
	Abdomen (C494)	
	<ul> <li>Abdominal aorta</li> </ul>	
	<ul> <li>Abdominal vena cava</li> </ul>	
	<ul> <li>Celiac artery</li> </ul>	
	<ul> <li>Inferior vena cava</li> </ul>	
	<ul> <li>Mesenteric artery</li> </ul>	
	<ul> <li>Renal artery</li> </ul>	
	<ul> <li>Vena cava</li> </ul>	
	Pelvis (C495)	
	<ul> <li>Iliac artery</li> </ul>	
	<ul> <li>Iliac vein</li> </ul>	
	• Thorax (C493)	
	• Aorta	
	<ul> <li>Adita</li> <li>Axillary artery</li> </ul>	
	<ul> <li>Diaphragm</li> </ul>	
	<ul> <li>Internal mammary artery</li> </ul>	
	<ul> <li>Subclavian artery</li> </ul>	

Code	Description	Schema ID#/Description
	<ul> <li>Superior vena cava</li> </ul>	
	<ul> <li>Thoracic duct</li> </ul>	
8	Not applicable: Diagnosis date 2018-2020	00421: Soft Tissue Abdomen
		and Thoracic (excluding Heart,
		Mediastinum, Pleura)
9	Not specific enough to determine if external or internal	00459: Soft Tissue Other
	Examples of terms include	
	Peripheral nerves and autonomic nervous system (C47)	
	Pelvis (C475)	
	<ul> <li>Lumbosacral plexus</li> </ul>	
	<ul> <li>Sacral nerve</li> </ul>	
	<ul> <li>Sacral plexus</li> </ul>	
	Thorax (C473)	
	<ul> <li>Chest</li> </ul>	
	<ul> <li>Intercostal nerve</li> </ul>	
	Connective, subcutaneous and other soft tissues (C49)	
	• Thorax (C493)	
	<ul> <li>Chest, NOS</li> </ul>	
	o Thorax	

Return to <u>Schema ID Table</u>

# 00421: Soft Tissue Abdomen and Thoracic (2018+)

See 00400: Soft Tissue Head and Neck (2018+)

• <u>3815: Bone Invasion</u>

# See 00410: Soft Tissue Trunk and Extremities (2018+)

• <u>3927: Schema Discriminator 2: Soft Tissue Sarcoma (C473, C475, C493-C495)</u>

00422: Heart, Mediastinum and Pleura (2018+)

See 00400: Soft Tissue Head and Neck (2018+)

• <u>3815: Bone Invasion</u>

# 00430: GIST (2018+)

# 3926: Schema Discriminator 1: Primary Peritoneum Tumor

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

• 00430: GIST (2018+)

#### **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	Small Intestinal, Esophageal,
	Mesoappendix	Colorectal, Mesenteric and
	Mesocolon	Peritoneal GIST
	Pelvic peritoneum	
	Rectouterine pouch	
	Cul de sac	
	Pouch of Douglas	
	Other specified peritoneal site	
2	Omentum	Gastric and Omental GIST
9	Unknown or no information	Small Intestinal, Esophageal,
	Not documented in medical record	Colorectal, Mesenteric and
		Peritoneal GIST

# 00430: GIST (2018+)

# 3865: KIT Gene Immunohistochemistry

Item Length: 1 NAACCR Item #: 3865 XML Parent-NAACCR ID: Tumor-kitGeneImmunohistochemistry NAACCR Alternate Name: None Active years: 2018+ Schema(s): • 00430: GIST (2018+)

#### **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 SSFs).

#### **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.

Note 4: Results from nodal or metastatic tissue may be used for KIT Gene Immunohistochemistry.

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

Return to <u>Schema ID Table</u>

# 00440: Retroperitoneum (2018+)

See 00400: Soft Tissue Head and Neck (2018+)

• <u>3815: Bone Invasion</u>

# 00458: Soft Tissue Rare (2018+)

See 00400: Soft Tissue Head and Neck (2018+)

• <u>3815: Bone Invasion</u>

# 00459: Soft Tissue Other (2018+)

See 00400: Soft Tissue Head and Neck (2018+)

• <u>3815: Bone Invasion</u>

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck (2018+)

• <u>3926: Schema Discriminator 1: Occult Head and Neck Lymph Nodes</u>

See 00410: Soft Tissue Trunk and Extremities (2018+)

• <u>3927: Schema Discriminator 2: Soft Tissue Sarcoma (C473, C475, C493-C495)</u>

# SKIN

# 3830: Extranodal Extension Clin (non-Head and Neck)

Item Length: 1 NAACCR Item #: 3830 XML Parent-NAACCR ID: Tumor-extranodalExtensionClin NAACCR Alternate Name: Extranodal Extension Clinical (non-Head and Neck) Active years: 2018+ Schemas(s):

- 00460: Merkel Cell Skin (2018+)
- 00570: Penis (2018+)

#### **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 WITH or WITHOUT 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 4 when there are positive nodes clinically, ENE is identified, but not known how identified
- Code 9 when
  - No information in the medical record
  - Positive nodes clinically, not evaluated (assessed) for ENE
  - o 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 WITH or WITHOUT imaging
2	Regional lymph nodes involved, ENE present/identified during diagnostic workup, based on microscopic confirmation
4	Regional lymph nodes involved, ENE present/identified, unknown how identified
7	No lymph node involvement during diagnostic workup (cN0) Non-invasive neoplasm (behavior /2)
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error)
9	Not documented in medical record Clinical ENE not assessed or unknown if assessed during diagnostic workup Clinical assessment of lymph nodes not done, or unknown if done

# 3833: Extranodal Extension Path (non-Head and Neck)

Item Length: 1 NAACCR Item #: 3833 XML Parent-NAACCR ID: Tumor-extranodalExtensionPath NAACCR Alternate Name: Extranodal Extension Pathological (non-Head and Neck) Active years: 2018+ Schemas(s):

- 00460: Merkel Cell Skin (2018+)
- 00570: Penis (2018+)

# **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
  - o 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 recorded as 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 lymph nodes. Code the status of ENE based on the following criteria

- Code 0
  - Absence of ENE, positive lymph nodes assessed by lymph node dissection
  - 1292: Scope of Regional Lymph Node Surgery must be 3-7
- Code 1
  - Presence of ENE assessed by Sentinel Lymph Node biopsy
  - Presence of ENE assessed by lymph node dissection
  - 1292: Scope of Regional Lymph Node Surgery must be 2-7
- Code 7
  - Lymph nodes negative for cancer assessed by Sentinel lymph node biopsy or lymph node dissection
  - 1292: Scope of Regional Lymph Node Surgery must be 2-7
- Code 9
  - Absence of ENE, positive lymph nodes assessed by Sentinel Lymph Node biopsy
    - A positive Sentinel Lymph Node biopsy cannot assess the absence of ENE, only the presence of it. This is because there is not enough surrounding tissue in a Sentinel Lymph node biopsy to accurately assess ENE
- If codes 1 or 7 are used, this indicates that the lymph nodes were surgically resected or a Sentinel Lymph Node biopsy was done and Scope of Regional Lymph Node Surgery [NAACCR Data Item: 1292] must be 2-7

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
	Non-invasive neoplasm (behavior /2)
	Cannot be determined
	Pathological assessment of lymph nodes not done, or unknown if done
	Extranodal Extension Pathological not assessed or unknown if assessed

# Return to <u>Schema ID Table</u>

# 00460: Merkel Cell Carcinoma (2018+)

# 3880: LN Isolated Tumor Cells (ITC)

NAACCR Item #: 3880 XML Parent-NAACCR ID: Tumor-InIsolatedTumorCells NAACCR Alternate Name: Lymph Nodes Isolated Tumor Cells (ITC) Active years: 2018+ Schemas(s):

• 00460: Merkel Cell Skin (2018+)

## **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	

# 00460: Merkel Cell Carcinoma (2018+)

## **3918: Profound Immune Suppression**

Item Length: 1 NAACCR Item #: 3918 XML Parent-NAACCR ID: Tumor-profoundImmuneSuppression NAACCR Alternate Name: None Active years: 2018+ Schemas(s):

• 00460: Merkel Cell Skin (2018+)

#### **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.

- For the following conditions, these patients will experience chonic immunosuppression. These are no time limits for these conditions. If a patient has a history (regardless of when diagnosed or treatment status), code as present
  - Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) (Code 1)
  - Solid organ transplant recipient (Code 2)
  - Chronic lymphocytic leukemia (Code 3)

**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 to Schema ID Table

## 00470: Melanoma Skin (2018+)

# **3817: Breslow Tumor Thickness**

Item Length: 4 NAACCR Item #: 3817 XML Parent-NAACCR ID: Tumor-breslowTumorThickness NAACCR Alternate Name: None Active years: 2018+ Schemas(s):

• 00470: Melanoma Skin (2018+)

## **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
- For further information, refer to the **Skin Melanoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Melanoma of the Skin*
- **Other names:** maximum tumor thickness, Breslow depth of invasion, Breslow thickness, Breslow measurement, Breslow's microstaging

# **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:** If there are multiple procedures and the pathologist adds the measurement together to get a final Breslow's depth, the registrar can use this.

• Do not add the measurements together, only the pathologist can do this

**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

Code	Description
0.0	No mass/tumor found
0.1	Greater than 0.0 and less than or equal to 0.1
0.2-99.9	0.2 – 99.9 millimeters
XX.1	100 millimeters or larger
A0.1-	Stated as "at least" some measured value of 0.1 to 9.9
A9.9	
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
	Non-invasive neoplasm (behavior /2)
	Breslow Tumor Thickness not assessed or unknown if assessed

# 00470: Melanoma Skin (2018+)

## 3936: Ulceration

Item Length: 1 NAACCR Item #: 3936 XML Parent-NAACCR ID: Tumor-ulceration NAACCR Alternate Name: None Active years: 2018+ Schemas(s):

• 00470: Melanoma Skin (2018+)

## **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 (i.e., fibrin deposition, neutrophils); and thinning, effacement, or reactive hyperplasia of the surrounding epidermis in the absence of trauma or a recent surgical procedure
- Ulcerated melanomas typically show invasion through the epidermis, whereas nonulcerated melanomas tend to lift the overlying epidermis

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

• It is possible for a patient to present with an ulcerated lesion noted on physical exam, but this is not the same thing as ulceration seen on a microscopic exam

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

- Code 1 if any biopsy (punch, shave, excisional, etc.) or wide excision is positive for ulceration in the presence of an underlying melanoma
- Code 0 is all specimens are negative OR one specimen is negative and the other is unknown
- Ulceration must be caused by an underlying melanoma. Ulceration caused by trauma from a previous procedure should not be coded as positive for this SSDI

**Note 4:** Code 9 if there is microscopic examination and there is no mention of ulceration.

• This instruction **does** apply to non-invasive neoplasms (behavior 2)

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

# 00470: Melanoma Skin (2018+)

## 3893: Mitotic Rate Melanoma

Item Length: 2 NAACCR Item #: 3893 XML Parent-NAACCR ID: Tumor-mitoticRateMelanoma NAACCR Alternate Name: None Active years: 2018+ Schemas(s):

• 00470: Melanoma Skin (2018+)

#### **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. 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
- For further information, refer to the **Skin Melanoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Melanoma of the Skin*
- **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)
X1	100 mitoses/square mm or more
X2	Stated as "less than 1 mitosis/square mm"
	Stated as "nonmitogenic"
X3	Stated as "at least 1 mitosis/square mm"
	Stated as "mitogenic"
X4	Mitotic rate described with denominator other than square millimeter (mm)
X7	Test ordered, results not in chart
X8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record
	Mitotic Rate Melanoma not assessed or unknown if assessed

# 00470: Melanoma Skin (2018+)

# 3932: LDH Lab Value

Item Length: 7 NAACCR Item #: 3932 XML Parent-NAACCR ID: Tumor-IdhPretreatmentLabValue NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Lab Value, LDH (Lactate Dehydrogenase) Lab Value Active years: 2018+ Schemas(s):

• 00470: Melanoma Skin (2018+)

## **Description**

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

## **Rationale**

LDH 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 systemic (chemo, immunotherapy, hormone), radiation therapy or surgery to a metastatic site 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) Lab Value can be used to code this data item when no other information is available.

**Note 2:** LDH is important in melanoma staging in the setting of DISTANT metastasis. LDH level might only be ordered after re-excision/wide excision and/or nodal evaluation indicates a higher risk of distant metastasis. Imaging may then be performed and if distant metastasis are identified, LDH is ordered.

**Note 3:** Record the lab value of the highest serum LDH test results documented in the medical record either before or after surgical resection of the primary tumor with or without regional lymph node dissection. The LDH must be taken prior to systemic (chemo, immunotherapy, hormone), radiation therapy or surgery to a metastatic site. The lab value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.

**Note 4:** The same laboratory test should be used to record information in <u>3869: LDH Level</u> and <u>3870:</u> <u>LDH Upper Limits of Normal</u>.

Code	Description
0.0	0.0 (U/L)
0.1-	0.1 – 99,999.9 U/L
99999.9	
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) Lab Value not assessed or unknown if assessed

Return to Schema ID Table

# 3869: LDH Level

Item Length: 1 NAACCR Item #: 3869 XML Parent-NAACCR ID: Tumor-IdhPretreatmentLevel NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Level, LDH (Lactate Dehydrogenase) Level Active years: 2018+ Schemas(s):

- 00470: Melanoma Skin (2018+)
- 00821: Plasma Cell Myeloma (2018+)

## **Description**

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

## **Rationale**

LDH (Lactate Dehydrogenase) Level is a prognostic factor required in AJCC 8<sup>th</sup> edition for Chapter 82 Plasma Cell Myeloma and Plasma Cell Disorders and Chapter 47 Melanoma Skin. For Plasma Cell Myeloma, LDH is part of the RISS Stage and is new for cases diagnosed 1/1/2018+. For Melanoma Skin, LDH is used to define the M subcategories and was previously collected as Melanoma Skin, SSF #4.

## **Coding Instructions and Codes**

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

**Note 2:** Record the lab value of the highest serum LDH test results documented in the medical record either before or after surgical resection of the primary tumor with or without regional lymph node dissection. The LDH must be taken prior to systemic (chemo, immunotherapy, hormone), radiation therapy or surgery to a metastatic site. The lab value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.

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

**Note 4:** The same laboratory test should be used to record information in <u>3870: LDH Upper Limits of</u> <u>Normal</u> and <u>3932: LDH Lab Value</u>.

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) Level not assessed or unknown if assessed	

## 00470: Melanoma Skin (2018+)

# 3870: LDH Upper Limits of Normal

NAACCR Item #: 3870 XML Parent-NAACCR ID: Tumor-IdhUpperLimitsOfNormal NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Upper Limits of Normal Active years: 2018+ Schemas(s):

• 00470: Melanoma Skin (2018+)

#### **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**

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

**Note 2:** Record the value of the highest serum LDH test results documented in the medical record either before or after surgical resection of the primary tumor with or without regional lymph node dissection. The LDH must be taken prior to systemic (chemo, immunotherapy, hormone), radiation therapy or surgery to a metastatic site. The lab value may be recorded in a lab report, history and physical, or clinical statement in the pathology report.

**Note 3**: Upper limits of normal for LDH vary widely depending on the lab. Common upper limits can be 200, 250, 618, or other values.

**Note 4:** The same laboratory test should be used to record information in <u>3932: LDH Lab Value</u> and <u>3869: LDH Level</u>.

Code	Description	
001-	001 - 999 upper limit of normal	
999	(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 to Schema ID Table

# 00470: Melanoma Skin (2018+)

# **3961: Clinical Margin Width**

Item Length: 4 NAACCR Item #: 3961 XML Parent-NAACCR ID: clinicalMarginWidth NAACCR Alternate Name: None Active years: 2023+ Schemas(s):

• 00470: Melanoma Skin (2018+)

## **Description**

Clinical margin width describes the margins from a wide excision for a melanoma primary. The margin width is measured by the surgeon prior to the procedure. The measurement is taken, in centimeters, from the edge of the lesion or the prior excision scar to the peripheral margin of the specimen.

## **Rationale**

Clinical margin width for wide local excision of a melanoma is based on the original Breslow thickness of the primary tumor, as indicated on the initial biopsy pathology report.

## **Definition**

Per the American College of Surgeons Optimal Resources for Cancer Care-2020 Standards Standard 5.5 Local Excision for Primary Cutaneous Melanoma, the clinical margin width for wide local excision of invasive melanoma should be 1 cm for melanomas <1 mm thick, 1 to 2 cm for invasive melanomas 1 to 2 mm thick, and 2 cm for invasive melanomas >2 mm thick. The clinical margin width for wide local excision of a melanoma in situ should be at least 5 mm.

#### Coding Instructions and Codes

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

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

**Note 2:** "The appropriate [wide local excision] margins are measured from the periphery of any gross residual tumor or the <u>edges of the entire previous biopsy scar (shave or excisional).</u>" *Operative Standards for Cancer Surgery, Volume 2, page 392.* 

**Note 3:** Code the peripheral surgical margins from the operative report from a wide excision

- Do not use the pathology report to code this data item.
- Margins from wide excision-Measured from the edge of the lesion or the prior excision scar to the peripheral margin of the specimen, do not use deep margin
- Do not add margins together
- If multiple wide excisions are performed, code the clinical margin width from the procedure with the largest margin

**Note 4:** Physician statement of clinical margin width can be used to code this data item when no other information is available, or the available information is ambiguous

• Order of priority

- Operative Note
- Physician statement in medical record

**Note 5:** Record stated margin in centimeters. Include decimal point.

Examples:

0.5 cm - 0.5 1 cm- 1.0 .5 cm - 2.5

Code	Description
0.1	Documented as 0.1cm or less (1mm or less)
0.2-9.9	0.2 cm – 9.9 cm
XX.1	10 centimeters or greater
XX.8	Not Applicable. Information not collected for this schema
	(If this information is required by your standard setter, use of code XX.8 may
	result in an edit error)
XX.9	Not documented in medical record
	No Wide Excision performed
	Mohs or similar procedure
	Wide Excision performed, but clinical margin width not documented.
	No surgical resection performed (B000)
	Unknown if procedure performed.
BLANK	N/A-Diagnosis year is prior to 2023.

# Return to Schema ID Table

## 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

- <u>3826: Estrogen Receptor Percent Positive or Range</u>
- <u>3827: Estrogen Receptor Summary</u>
- <u>3828: Estrogen Receptor Total Allred Score</u>
- <u>3914: Progesterone Receptor Percent Positive or Range</u>
- <u>3915: Progesterone Receptor Summary</u>
- <u>3916: Progesterone Receptor Total Allred Score</u>

#### 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<sup>#</sup> Specify: \_\_\_\_ % -OR-Range (Note A) \_\_\_\_ 1-10% (specify): \_\_\_\_ %<sup>#</sup> \_\_\_\_ 11-20% \_\_\_\_ 21-30% \_\_\_\_ 31-40% \_\_\_\_ 31-40% \_\_\_\_ 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 and the Intensity Score, as defined in the tables below.

The Allred score combines the percentage of positive cells (proportion score) and the intensity score of the reaction product in most of the carcinoma. The 2 scores are added together for a final score with 8 possible values (00-08).

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

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

## Additional Information

• For further information, refer to the **Breast** or **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast* 

## 00480: Breast (2018+)

## **3827: Estrogen Receptor Summary**

Item Length: 1 NAACCR Item #: 3827 XML Parent-NAACCR ID: Tumor-estrogenReceptorSummary NAACCR Alternate Name: ER (Estrogen Receptor) Summary Active years: 2018+ Schemas(s):

• 00480: Breast (2018+)

## **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 8<sup>th</sup> 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)
  - $\circ$   $\;$  It is unknown whether the ER test was performed
  - The patient has only a clinical diagnosis of breast cancer (no tissue diagnosis)

## See <u>3826-3827, 3914-3916: Estrogen Receptor and Progesterone Receptor</u> 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 in situ or invasive carcinoma in the primary tumor.

**Note 4:** In cases where there are invasive and in situ components in the primary tumor and ER is done on both, ignore the in situ results.

- If ER is positive on an in situ component and ER is negative on all tested invasive components in the primary tumor, code ER as negative (code 0)
- If in situ and invasive components present and ER only done on the in situ component in the primary tumor, code unknown (code 9)

**Note 5:** In cases where there is a single tumor with multiple biopsies and/or surgical resection with different ER results.

• Use the highest (positive versus negative)

**Note 6:** In cases where there are multiple tumors with different ER results, code the results from the largest tumor size (determined either clinically or pathologically) when multiple tumors are present.

• Do not use specimen size to determine the largest tumor size

**Note 7:** 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 8**: If the patient is ER positive and node negative, a multigene test such as Oncotype Dx may be performed, in which case another ER test will be performed. Do not record the results of that test in this field.

• Record only the results of the test which made the patient eligible to be given the multigene test

Code	Description
0	ER negative (0.0% or less than 1%)
1	ER positive
7	Test ordered, results not in chart
9	Not documented in medical record
	Cannot be determined (indeterminate)
	ER (Estrogen Receptor) Summary status not assessed or unknown if
	assessed

# 3826: Estrogen Receptor Percent Positive or Range

Item Length: 3 NAACCR Item #: 3826 XML Parent-NAACCR ID: Tumor-estrogenReceptorPercntPosOrRange NAACCR Alternate Name: ER (Estrogen Receptor) Percent Positive or Range Active years: 2018+ Schemas(s):

• 00480: Breast (2018+)

## **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 <u>3826-3827, 3914-3916: Estrogen Receptor and Progesterone Receptor</u> for additional information.

## **Coding Instructions and Codes**

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

Note 2: Code this data item using the same report used to record <u>3827: Estrogen Receptor Summary</u>.

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

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

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

**Note 6:** Ranges for the codes in this data item are defined in steps of 10 which correspond to the CAP protocol. If a range in a report is given in steps other than those provided in the codes, code to the range that contains the lowest number of the range in the report.

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

Code	Description	
000	ER negative, or stated as less than 1%	
001-100	1-100 percent	
R10	Stated as 1-10%	
R20	Stated as 11-20%	
R30	Stated as 21-30%	
R40	Stated as 31-40%	
R50	Stated as 41-50%	
R60	Stated as 51-60%	
R70	Stated as 61-70%	

Code	Description	
R80	Stated as 71-80%	
R90	Stated as 81-90%	
R99	Stated as 91-100%	
XX7	Test done, results not in chart	
XX8	Not applicable: Information not collected for this case	
	(If this item is required by your standard setter, use of code XX8 will result in an edit error.)	
XX9	Not documented in medical record	
	ER (Estrogen Receptor) Percent Positive or Range not assessed or unknown if assessed	

# 3828: Estrogen Receptor Total Allred Score

Item Length: 2 NAACCR Item #: 3828 XML Parent-NAACCR ID: Tumor-estrogenReceptorTotalAllredScore NAACCR Alternate Name: ER (Estrogen Receptor) Total Allred Score Active years: 2018-2022 Schemas(s):

• 00480: Breast (2018+)

## **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 <u>3826-3827, 3914-3916: Estrogen Receptor and Progesterone Receptor</u> for additional information.

#### **Coding Instructions and Codes**

**Note 1:** This SSDI is no longer required by any of the standard setters starting with 2023 diagnoses.

• For cases diagnosed 2023+, this SSDI may be left blank

**Note 2:** Physician statement of ER (Estrogen Receptor) Total Allred Score can be used to code this data item.

Note 3: Code this data item using the same report used to record <u>3827: Estrogen Receptor Summary</u>.

**Note 4:** 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.

- The registrar should not calculate the Allred score unless both components are available (proportion score and intensity)
- See the <u>Allred Score for Estrogen and Progesterone Receptor Evaluation</u> section in the SSDI manual for assistance in determining the Allred Score

Note 5: 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	

Code	Description	
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	
<blank></blank>	NA-Diagnosis years is after 2022	

# **3915: Progesterone Receptor Summary**

Item Length: 1 NAACCR Item #: 3915 XML Parent-NAACCR ID: Tumor-progesteroneRecepSummary NAACCR Alternate Name: PR (Progesterone Receptor) Summary Active years: 2018+ Schemas(s):

• 00480: Breast (2018+)

## **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 8<sup>th</sup> 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
  - o Cannot be determined by the pathologist (e.g. inadequate specimen)
  - o It is unknown whether the PR test was performed
  - The patient has only a clinical diagnosis of breast cancer (no tissue diagnosis)

See <u>3826-3827, 3914-3916: Estrogen Receptor and Progesterone Receptor</u> 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 in situ or invasive carcinoma in the primary tumor.

**Note 4:** In cases where there are invasive and in situ components in the primary tumor and PR is done on both, ignore the in situ results.

• If PR is positive on an in situ component and PR is negative on all tested invasive components in the primary tumor, code PR as negative (code 0)

• If in situ and invasive components present and PR only done on the in situ component in the primary tumor, code unknown (code 9)

**Note 5:** In cases where there is a single tumor with multiple biopsies and/or surgical resection with different PR results.

• Use the highest (positive versus negative)

**Note 6:** In cases where there are multiple tumors with different PR results, code the results from the largest tumor size (determined either clinically or pathologically) when multiple tumors are present.

• Do not use specimen size to determine the largest tumor size

**Note 7:** 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 8**: 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. 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	PR negative (0.0% or less than 1%)
1	PR positive
7	Test ordered, results not in chart
9	Not documented in medical record
	Cannot be determined (indeterminate)
	PR (Progesterone Receptor) Summary status not assessed or
	unknown if assessed

Return to Schema ID Table

## 00480: Breast (2018+)

## **3914: Progesterone Receptor Percent Positive or Range**

Item Length: 3 NAACCR Item #: 3914 XML Parent-NAACCR ID: Tumor-progesteroneRecepPrcntPosOrRange NAACCR Alternate Name: PR (Progesterone Receptor) Percent Positive or Range Active years: 2018+ Schemas(s):

• 00480: Breast (2018+)

#### **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 <u>3826-3827, 3914-3916: Estrogen Receptor and Progesterone Receptor</u> 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 <u>3915: Progesterone Receptor</u> <u>Summary</u>.

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

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

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

**Note 6:** Ranges for the codes in this data item are defined in steps of 10 which correspond to the CAP protocol. If a range in a report is given in steps other than those provided in the codes, code to the range that contains the lowest number of the range in the report.

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

Code	Description	
000	PR negative, or stated as less than 1%	
001-100	1-100 percent	
R10	Stated as 1-10%	
R20	Stated as 11-20%	
R30	Stated as 21-30%	
R40	Stated as 31-40%	

Code	Description	
R50	Stated as 41-50%	
R60	Stated as 51-60%	
R70	Stated as 61-70%	
R80	Stated as 71-80%	
R90	Stated as 81-90%	
R99	Stated as 91-100%	
XX7	Test done, results not in chart	
XX8	Not applicable: Information not collected for this case	
	(If this item is required by your standard setter, use of code XX8 will result in an edit	
	error.)	
XX9	Not documented in medical record	
	PR (Progesterone Receptor) Percent Positive or Range not assessed or unknown if	
	assessed	

# Return to Schema ID Table

## 00480: Breast (2018+)

## **3916: Progesterone Receptor Total Allred Score**

Item Length: 2 NAACCR Item #: 3916 XML Parent-NAACCR ID: Tumor-progesteroneRecepTotalAllredScor NAACCR Alternate Name: PR (Progesterone Receptor) Total Allred Score Active years: 2018-2022 Schemas(s):

• 00480: Breast (2018+)

## **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 <u>3826-3827, 3914-3916: Estrogen Receptor and Progesterone Receptor</u> for additional information.

#### **Coding Instructions and Codes**

**Note 1:** This SSDI is no longer required by any of the standard setters starting with 2023 diagnoses.

• For cases diagnosed 2023+, this SSDI may be left blank

**Note 2:** Physician statement of PR (Progesterone Receptor) Total Allred Score can be used to code this data item.

**Note 3:** Code this data item using the same report used to record <u>3915: Progesterone Receptor</u> <u>Summary</u>.

**Note 4:** 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.

- The registrar should not calculate the Allred score unless both components are available (proportion score and intensity)
- See the <u>Allred Score for Estrogen and Progesterone Receptor Evaluation</u> section in the SSDI manual for assistance in determining the Allred Score

Note 5: 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

Code	Description	
04	Total PR Allred score of 4	
05	Total PR Allred score of 5	
06	Total PR Allred score of 6	
07	Total PR Allred score of 7	
08	Total PR Allred score of 8	
X8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code X8 will result in an edit error.)	
X9	Not documented in medical record PR (Progesterone Receptor) Total Allred Score not assessed, or unknown if assessed	
<blank></blank>	NA-Diagnosis years is after 2022	

# 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:

- <u>3850: HER2 IHC Summary</u>
- <u>3851: HER2 ISH Dual Probe Copy Number</u>
- <u>3852: HER2 ISH Dual Probe Ratio</u>
- <u>3853: HER2 ISH Single Probe Copy Number</u>
- <u>3854: HER2 ISH Summary</u>
- <u>3855: HER2 Overall Summary</u>

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:

## 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.

Result	Criteria
Negative (not amplified)	Average HER2 copy number <4.0 signals/cell
Equivocal	Average <i>HER2</i> copy number ≥4.0 and <6.0 signals/cell
Positive (amplified)	Average <i>HER2</i> copy number ≥6.0 signals/cell

# Reporting Results of HER2 Testing by In Situ Hybridization (single-probe assay)

# 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)

**Note:** TP52, SMSCR and RARA are gene genes that are also on chromosome 17. However, they are not close to the centromere, and thus can be used to assess borderline/equivocal fish results (ratios) when the centromeric probe for chromosome 17 (CEP17) performance may be problematic. Although these may be helpful in some cases, they are not the same as the CEP17 result or the ratio determined from CEP17. There should always be a prior CEP17 result when these other results are found in the chart. If one of these tests (TP52, SMSCR, RARA, or others) are used and a dual probe copy number/ratio are documented, record that results in the appropriate data item.

D17Z1 is the CEP17 probe used in the Vysis (Abbot) FISH kit. So, for the HER2 data items, D17Z1 and CEP17 are to be treated as the same thing.

**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

## **Additional Information**

• For further information, refer to the **Breast** or **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast* 

## 3850: HER2 IHC Summary

Item Length: 1 NAACCR Item #: 3850 XML Parent-NAACCR ID: Tumor-her2lhcSummary NAACCR Alternate Name: None Active years: 2018-2020 Schemas(s):

• 00480: Breast (2018+)

## **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 <u>3850-3855: HER2</u> for additional information.

### **Coding Instructions and Codes**

**Note 1:** This SSDI is no longer required by any of the standard setters starting with 2021 diagnoses.

• For cases diagnosed 2021+, this SSDI may be left blank

**Note 2:** Physician statement of HER2 IHC Summary can be used to code this data item when no other information is available.

Note 3: The HER2 IHC test performed on the primary breast tissue is to be recorded in this data item.

**Note 4:** Results from nodal or metastatic tissue may be used, ONLY when there is no evidence of primary tumor.

**Note 5:** In cases where there are invasive and in situ components and HER2 IHC is done on both, ignore the in situ results.

- If HER2 IHC is positive on an in situ component and HER2 IHC is negative on all tested invasive components, code HER2 IHC as negative (code 0)
- If in situ and invasive components present and HER2 IHC only done on the in situ component, code unknown (code 9)

**Note 6:** In cases where there is a single tumor with multiple biopsies and/or surgical resection with different HER2 IHC results.

• Use the highest (positive versus negative)

**Note 7:** In cases where there are multiple tumors with different HER2 IHC results, code the results from the largest tumor size (determined either clinically or pathologically) when multiple tumors are present.

• Do not use specimen size to determine the largest tumor size

**Note 8:** 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 9:** A 2+ (equivocal) finding by IHC should result in additional testing with ISH to determine gene copy number.

**Note 10:** 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.

**Note 11:** HER2 is not routinely done on pure in situ tumors (behavior /2); however, if you have an in situ tumor and there are HER2 results, go ahead and record it. Otherwise code 9.

Code	Description
0	Negative (Score 0)
1	Negative (Score 1+)
2	Equivocal (Score 2+)
	Stated as equivocal
	Borderline
3	Positive (Score 3+)
	Stated as positive
4	Stated as negative, but score not stated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record
	Cannot be determined (indeterminate)
	HER2 IHC Summary not assessed or unknown if assessed
<blank></blank>	N/A-Diagnosis year is after 2020

Return to Schema ID Table

## 3854: HER2 ISH Summary

Item Length: 1 NAACCR Item #: 3854 XML Parent-NAACCR ID: Tumor-her2IshSummary NAACCR Alternate Name: None Active years: 2018-2020 Schemas(s):

• 00480: Breast (2018+)

## **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 <u>3850-3855: HER2</u> for additional information.

### **Coding Instructions and Codes**

Note 1: This SSDI is n o longer required by any of the standard setters starting with 2021 diagnoses.

• For cases diagnosed 2021+, this SSDI may be left blank

**Note 2:** Physician statement of HER2 in situ hybridization (ISH) Summary can be used to code this data item when no other information is available.

Note 3: The HER2 ISH test performed on the primary breast tissue is to be recorded in this data item.

**Note 4:** Results from nodal or metastatic tissue may be used, ONLY when there is no evidence of primary tumor.

**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:** In cases where there are invasive and in situ components and HER2 ISH is done on both, ignore the in situ results.

- If HER2 ISH is positive on an in situ component and HER2 ISH is negative on all tested invasive components, code HER2 ISH as negative (code 0)
- If in situ and invasive components present and HER2 ISH only done on the in situ component, code unknown (code 9)

**Note 7:** In cases where there is a single tumor with multiple biopsies and/or surgical resection with different HER2 ISH results.

• Use the highest (positive versus negative)

**Note 8:** In cases where there are multiple tumors with different HER2 ISH results, code the results from the largest tumor size (determined either clinically or pathologically) when multiple tumors are present.

• Do not use specimen size to determine the largest tumor size

**Note 9:** 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 10:** 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.

**Note 11:** HER2 is not routinely done on pure in situ tumors (behavior /2); however, if you have an in situ tumor and there are HER2 results, go ahead and record it. Otherwise code 9.

Code	Description
0	Negative [not amplified]
2	Equivocal
3	Positive [amplified]
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 8 will result in an edit
	error.)
9	Not documented in medical record
	Results cannot be determined (indeterminate)
	Borderline
	HER2 ISH Summary not assessed or unknown if assessed
<blank></blank>	N/A-Diagnosis year is after 2020

Return to Schema ID Table

## 3855: HER2 Overall Summary

Item Length: 1 NAACCR Item #: 3855 XML Parent-NAACCR ID: Tumor-her2OverallSummary NAACCR Alternate Name: None Active years: 2018+Schemas(s):

• 00480: Breast (2018+)

### **Description**

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

### **Rationale**

This data item is required for prognostic stage grouping in AJCC 8<sup>th</sup> edition, Chapter 48 *Breast*. It was previously collected as Breast, CS SSF # 15. Experts recommend that every invasive breast cancer be tested for the presence of HER2 because anti-HER2 treatments are highly effective for these tumors.

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

### See <u>3850-3855: HER2</u> 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)

## **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 in situ or invasive carcinoma in the primary tumor.

**Note 4:** In cases where there are invasive and in situ components in the primary tumor and HER2 is done on both, ignore the in situ results.

- If HER2 is positive on an in situ component and HER2 is negative on all tested invasive components in the primary tumor, code HER2 as negative (code 0)
- If in situ and invasive components present and HER2 only done on the in situ component in the primary tumor, code unknown (code 9)

**Note 5:** In cases where there is a single tumor with multiple biopsies and/or surgical resection with different HER2 results.

• Use the highest (positive versus negative)

**Note 6:** In cases where there are multiple tumors with different HER2 results, code the results from the largest tumor size (determined either clinically or pathologically) when multiple tumors are present.

• Do not use specimen size to determine the largest tumor size

**Note 7:** 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 8:** 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

**Note 9:** HER2 is not routinely done on pure in situ tumors (behavior /2); however, if you have an in situ tumor and there are HER2 results, go ahead and record it. Otherwise code 9

Code	Description
0	HER2 negative; equivocal
1	HER2 positive
7	Test ordered, results not in chart
9	Not documented in medical record
	Cannot be determined (indeterminate)
	Borderline
	HER2 Overall Summary status not assessed or unknown if assessed

## 3853: HER2 ISH Single Probe Copy Number

Item Length: 4 NAACCR Item #: 3853 XML Parent-NAACCR ID: Tumor-her2IshSingleProbeCopyNumber NAACCR Alternate Name: None Active years: 2018-2020 Schemas(s):

• 00480: Breast (2018+)

### **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 <u>3850-3855: HER2</u> for additional information.

#### Coding Instructions and Codes

**Note 1:** This SSDI is no longer required by any of the standard setters starting with 2021 diagnoses.

• For cases diagnosed 2021+, this SSDI may be left blank

**Note 2:** Physician statement of HER2 in situ hybridization (ISH) Single Probe Copy Number can be used to code this data item.

**Note 3:** A single probe test will report average number or mean signals per cell for HER2. Record the HER2 average number or mean signals per cells in this data item. The average number or mean signals per cell is also called the copy number.

#### Example:

SISH RESULTS: FINAL HER 2 IN SITU HYBRIDIZATION INTERPRETATION: POSITIVE (>6 gene copies) HER-2/neu gene amplification.

HER-2/neu SILVER IN SITU HYBRIDIZATION (SISH)

HER-2neu gene (Inform HER2 DNA probe)

Number of tumor cell nuclei counted: 60

Number of Her-2/neu gene copies: 418

Mean HER-2/neu gene copy number: 6.9

Code Single Probe HER2 Copy Number: 6.9

[Note: This is calculated by dividing 418 by 60]

## Note 4: Registrars are not to calculate the copy number.

**Note 5:** Following ASCO-CAP guidelines, a 2+ (equivocal) finding by immunohistochemistry (IHC) should result in additional testing with ISH to determine gene copy number.

**Note 6:** Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. Code this data item using the same report used to record <u>3854: HER2 ISH Summary</u>.

**Note 7:** A HER2 ISH test may be called "*ERBB2*." *ERBB2* is the standard symbol for the gene 'erb-b2 receptor tyrosine kinase 2.' An IHC test identifies the protein expressed by the gene, and an ISH test identifies the gene itself.

**Note 8:** If a HER2 ISH single probe copy number test is done, and the results are between 4 and 6 (equivocal), dual probe tests are recommended.

**Note 9:** If the test results are presented to the hundredth decimal, ignore the hundredth decimal. Do NOT round.

## • Example:

Reported as 6.97, code 6.9

Code	Description
0.0-99.9	Reported HER2 copy number of 0.0-99.9
XX.1	Reported HER2 copy number of 100 or greater
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code XX.8 will result in an edit
	error.)
XX.9	Not documented in medical record
	Cannot be determined (indeterminate)
	Single probe test not done; only dual probe test performed
	HER2 ISH Single Probe Copy Number not assessed or unknown if assessed
<blank></blank>	N/A-Diagnosis year is after 2020

## Return to Schema ID Table

## 3851: HER2 ISH Dual Probe Copy Number

Item Length: 4 NAACCR Item #: 3851 XML Parent-NAACCR ID: Tumor-her2IshDualProbeCopyNumber NAACCR Alternate Name: None Active years: 2018-2020 Schemas(s):

• 00480: Breast (2018+)

### **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 <u>3850-3855: HER2</u> for additional information.

#### Coding Instructions and Codes

**Note 1:** This SSDI is no longer required by any of the standard setters starting with 2021 diagnoses.

• For cases diagnosed 2021+, this SSDI may be left blank

**Note 2:** Physician statement of HER2 in situ hybridization (ISH) Dual Probe Copy Number can be used to code this data item.

**Note 3:** A dual probe test will report average number or mean signals per cell for both HER2 and CEP17, the latter used as a control. Record the HER2 average number or mean signals per cells in this data item. The average number or mean signals per cells is also called the copy number.

#### Example:

SISH RESULTS: FINAL HER 2 IN SITU HYBRIDIZATION INTERPRETATION: EQUIVOCAL, INDETERMINATE. HER2 gene copy between 4 & 6 with HER2/CEP17 ratio <2.

HER2/CEP17 RATIO: 4.26 / 3.13 = 1.36

HER-2/neu SILVER IN SITU HYBRIDIZATION (SISH)

HER-2neu gene (Inform HER2 DNA probe)

Number of tumor cell nuclei counted: 120

Number of Her-2/neu gene copies: 511

Mean HER-2/neu gene copy number: 4.26

## CEP-17 SILVER IN SITU HYBRIDIZATION (SISH)

CEP-17 (Inform Chromosome 17 probe)

Number of cell nuclei counted: 60

Number of CEP-17 gene copies: 188

Mean CEP-17 gene copies/nucl: 3.13

Code Dual Probe HER2 Copy Number: 4.2

[Note: This is calculated by dividing 511 by 120]

## Note 4: Registrars are not to calculate the copy number.

**Note 5:** Following ASCO-CAP guidelines, a 2+ (equivocal) finding by immunohistochemistry (IHC) should result in additional testing with ISH to determine gene copy number.

**Note 6:** Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. Code this data item using the same report used to record <u>3854: HER2 ISH Summary</u>.

**Note 7:** A HER2 ISH test may be called "*ERBB2*." *ERBB2* is the standard symbol for the gene 'erb-b2 receptor tyrosine kinase 2.' An IHC test identifies the protein expressed by the gene, and an ISH test identifies the gene itself.

**Note 8:** If a HER2 ISH single probe copy number test is done, and the results are between 4 and 6 (equivocal), dual probe tests are recommended.

**Note 9:** If the test results are presented to the hundredth decimal, ignore the hundredth decimal. Do NOT round.

• Example:

Reported as 4.99, code as 4.9

Code	Description
0.0-99.9	Reported HER2 copy number of 0.0-99.9
XX.1	Reported HER2 copy number of 100 or greater
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code XX.8 will result in an edit error.)
XX.9	Not documented in medical record Cannot be determined (indeterminate) Dual probe test note done; only single probe test performed HER2 ISH Dual Probe Copy Number not assessed or unknown if assessed
<blank></blank>	N/A-Diagnosis year is after 2020

## Return to Schema ID Table

## **3852: HER2 ISH Dual Probe Ratio**

Item Length: 4 NAACCR Item #: 3852 XML Parent-NAACCR ID: Tumor-her2IshDualProbeRatio NAACCR Alternate Name: None Active years: 2018-2020 Schemas(s):

• 00480: Breast (2018+)

### **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 <u>3850-3855: HER2</u> for additional information.

#### Coding Instructions and Codes

**Note 1:** This SSDI is no longer required by any of the standard setters starting with 2021 diagnoses.

• For cases diagnosed 2021+, this SSDI may be left blank

**Note 2:** Physician statement of HER2 in situ hybridization (ISH) Dual Probe Ratio can be used to code this data item.

**Note 3:** A dual probe test will report results for both HER2 and CEP17, the latter used as a control. The HER2/CEP17 ratio will be reported. Record the ratio in this data item.

#### Example:

SISH RESULTS: FINAL HER 2 IN SITU HYBRIDIZATION INTERPRETATION: EQUIVOCAL, INDETERMINATE. HER2 gene copy between 4 & 6 with HER2/CEP17 ratio <2.

HER2/CEP17 RATIO: 4.26 / 3.13 = 1.36

HER-2/neu SILVER IN SITU HYBRIDIZATION (SISH)

HER-2neu gene (Inform HER2 DNA probe)

Number of tumor cell nuclei counted: 120

Number of Her-2/neu gene copies: 511

Mean HER-2/neu gene copy number: 4.26

## CEP-17 SILVER IN SITU HYBRIDIZATION (SISH)

CEP-17 (Inform Chromosome 17 probe)

Number of cell nuclei counted: 60

Number of CEP-17 gene copies: 188

Mean CEP-17 gene copies/nucl: 3.13

Code Dual Probe HER2 Copy Number: 4.2

Code Dual Probe Ratio: 1.3

## Note 4: Registrars are not to calculate the ratio.

**Note 5:** Following ASCO-CAP guidelines, a 2+ (equivocal) finding by immunohistochemistry (IHC) should result in additional testing with ISH to determine gene copy number.

**Note 6:** Any type of ISH test (e.g., FISH, CISH, SISH) can be used to code this data item. Code this data item using the same report used to record <u>3854: HER2 ISH Summary</u>.

**Note 7:** A HER2 ISH test may be called "*ERBB2*." *ERBB2* is the standard symbol for the gene 'erb-b2 receptor tyrosine kinase 2.' An IHC test identifies the protein expressed by the gene, and an ISH test identifies the gene itself.

**Note 8:** If the test results are presented to the hundredth decimal, ignore the hundredth decimal. Do NOT round.

## • Example:

Reported as 1.99, code as 1.9

Code	Description
0.0-99.9	Ratio of 0.0 to 99.9
XX.2	Less than 2.0
XX.3	Greater than or equal to 2.0
XX.7	Test ordered, results not in chart
XX.8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code XX.8 will result in an
	edit error.)
XX.9	Not documented in medical record
	Results cannot be determined (indeterminate)
	Dual probe test not done; only single probe test performed
	HER2 ISH Dual Probe Ratio not assessed or unknown if assessed
<blank></blank>	N/A-Diagnosis year is after 2020

### **Multigene Signature Method and Results**

#### **Definition**

Multigene testing is usually done for node-negative female breast cancer patients to predict risk of recurrence within a specified time period or to predict the likelihood that the patient will respond to specific types of chemotherapy. Multigene testing helps tailor treatment for the woman's specific cancer characteristics. Recent studies indicate that these tests may also be helpful in planning treatment and predicting recurrence in node positive women with small tumors. Some types of tests may be specific to ER positive or negative patients or women in a certain age range. Many different types of genetic testing are available, including IHC-, FISH-, RT-PCR-, and genomic microarray-based multigene predictors.

### For the Breast cases, there are 2 data items that record information on Multigene testing.

- 3894: Multigene Signature Method
- <u>3895: Multigene Signature Results</u>

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 nodenegative, 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-receptorpositive, 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

## 3894: Multigene Signature Method

Item Length: 1 NAACCR Item #: 3894 XML Parent-NAACCR ID: Tumor-multigeneSignatureMethod NAACCR Alternate Name: None Active years: 2018+ Schemas(s):

• 00480: Breast (2018+)

### **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 <u>3894, 3895: Multigene Signature Method and Results</u> 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.

- Only record tests done on tumor tissue that help determine if the cancer is likely to recur. Don't include other tests, such as those that evaluate hereditary mutations that influence a patient's risk of developing cancer (e.g. myRisk, BRCA)
- Only record tests that are based on gene assays. Don't include other tests which use a multivariate data model to eliminate the need for genetic assays

**Note 3:** Code the type of test performed. The same test should be used to record information in <u>3895</u>: <u>Multigene Signature Results</u>.

**Note 4:** Oncotype Dx tests are not recorded in this data item. See the following data items for Oncotype Dx.

- <u>3903: Oncotype Dx Recurrence Score-DCIS</u>
- <u>3904: Oncotype Dx Recurrence Score-Invasive</u>
- <u>3905: Oncotype Dx Risk Level-DCIS</u>
- <u>3906: Oncotype Dx Risk Level-Invasive</u>

Code	Description
1	Mammaprint
2	PAM50 (Prosigna)
3	Breast Cancer Index
4	EndoPredict
5	Test performed, type of test unknown
6	Multiple tests, any tests in codes 1-4
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record
	Multigene Signature Method not assessed or unknown if assessed

## **3895: Multigene Signature Results**

Item Length: 2 NAACCR Item #: 3895 XML Parent-NAACCR ID: Tumor-multigeneSignatureResults NAACCR Alternate Name: None Active years: 2018+ Schemas(s):

• 00480: Breast (2018+)

### **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 <u>3894, 3895: Multigene Signature Method and Results</u> 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.

- Only record tests done on tumor tissue that help determine if the cancer is likely to recur. Don't include other tests, such as those that evaluate hereditary mutations that influence a patient's risk of developing cancer (e.g. myRisk, BRCA)
- Only record tests that are based on gene assays. Don't include other tests which use a multivariate data model to eliminate the need for genetic assays

**Note 3:** Code the score or risk for the test performed. The same test should be used to record information in <u>3894: Multigene Signature Method</u>.

**Note 4:** Oncotype Dx tests are not recorded in this data item. See the following data items for Oncotype Dx.

- <u>3903: Oncotype Dx Recurrence Score-DCIS</u>
- <u>3904: Oncotype Dx Recurrence Score-Invasive</u>
- <u>3905: Oncotype Dx Risk Level-DCIS</u>
- <u>3906: Oncotype Dx Risk Level-Invasive</u>

**Note 5:** PAM50 (Prosigna) is a single numeric score of 0-100. If the score is available, record the score. If only the risk level is available, record that.

Code	Description
00-99	Enter actual recurrence score
	Note: Depending on the test, the range of values may be different
X1	Score 100
X2	Low risk
X3	Moderate [intermediate] risk
X4	High risk
X7	Test 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

**Note 6:** For Mammaprint, EndoPredict, and Breast Cancer Index, only record the risk level.

Return to Schema ID Table

## **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.

- <u>3903: Oncotype Dx Recurrence Score-DCIS</u>
- <u>3904: Oncotype Dx Recurrence Score-Invasive</u>
- <u>3905: Oncotype Dx Risk Level-DCIS</u>
- <u>3906: Oncotype Dx Risk Level-Invasive</u>

### 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 <a href="http://www.oncotypeiq.com/en-US/breast-cancer/patients-and-caregivers/stage-0-dcis/about-the-test">http://www.oncotypeiq.com/en-US/breast-cancer/patients-and-caregivers/stage-0-dcis/about-the-test</a>

## **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 AJCC 8<sup>th</sup> edition for patients with T1-2 N0, M0, ER-positive, HER2 negative breast cancers. Oncotype DX provides a quantitative score, based on a continuous scale from 0-100, with higher scores reflecting higher risk of distant recurrence and higher likelihood of chemotherapy benefit.

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 <a href="http://www.oncotypeiq.com/en-US/breast-cancer/healthcare-professionals/oncotype-dx-breast-recurrence-score/about-the-test">http://www.oncotypeiq.com/en-US/breast-cancer/healthcare-professionals/oncotype-dx-breast-recurrence-score/about-the-test</a>

### 3903: Oncotype Dx Recurrence Score-DCIS

Item Length: 3 NAACCR Item #: 3903 XML Parent-NAACCR ID: Tumor-oncotypeDxRecurrenceScoreDcis NAACCR Alternate Name: None Active years: 2018+ Schemas(s):

• 00480: Breast (2018+)

### **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 <u>3903-3906: Oncotype Dx Tests</u> 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:** In cases where Oncotype Dx-DCIS is reported on more than one in situ breast tumor specimen, record the highest value.

**Note 5:** Code XX9 for LCIS tumors.

**Note 6:** If the only information available is the Oncotype Dx-DCIS Risk Level, assign XX7.

Note 7: Code this data item using the same report used to record <u>3905: Oncotype Dx Risk Level-DCIS</u>.

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

### **3905: Oncotype Dx Risk Level-DCIS**

Item Length: 1 NAACCR Item #: 3905 XML Parent-NAACCR ID: Tumor-oncotypeDxRiskLevelDcis NAACCR Alternate Name: None Active years: 2018+ Schemas(s):

• 00480: Breast (2018+)

### **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 <u>3903-3906: Oncotype Dx Tests</u> 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: Code 9 for LCIS tumors.

**Note 4:** 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.

**Note 5:** Code this data item using the same report used to record <u>3903: Oncotype Dx Recurrence Score-</u> DCIS.

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

### 3904: Oncotype Dx Recurrence Score-Invasive

Item Length: 3 NAACCR Item #: 3904 XML Parent-NAACCR ID: Tumor-oncotypeDxRecurrenceScoreInvasiv NAACCR Alternate Name: None Active years: 2018+ Schemas(s):

• 00480: Breast (2018+)

### **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 <u>3903-3906: Oncotype Dx Tests</u> 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:** Predicted Oncotype Dx Recurrence Score based on linear regression models and Magee equations should not be reported in this field.

- If the only information you have on Oncotype Dx is based on a linear regression model and Magee score, code unknown
- Code the results of a Magee score in the Multigene Data Items: Multigene Signature Method [NAACCR Data Item #3894] and Multigene Signature Results [NAACCR Data Item #3895]

**Note 5:** In cases where Oncotype DX is reported on more than one breast tumor specimen, record the highest value.

**Note 6:** Results from nodal or metastatic tissue may be used ONLY when there is no evidence of primary tumor.

**Note 7:** 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 8:** If the only information available is the Oncotype Dx-Invasive Risk Level, assign XX7.

Note 9: Code this data item using the same report used to record <u>3906: Oncotype Dx Risk Level-Invasive</u>.

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 to Schema ID Table

### 3906: Oncotype Dx Risk Level-Invasive

Item Length: 1 NAACCR Item #: 3906 XML Parent-NAACCR ID: Tumor-oncotypeDxRiskLevelInvasive NAACCR Alternate Name: None Active years: 2018+ Schemas(s):

• 00480: Breast (2018+)

### **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 <u>3903-3906: Oncotype Dx Tests</u> 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.

**Note 4:** Code this data item using the same report used to record <u>3904: Oncotype Dx Recurrence Score-</u><u>Invasive</u>.

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 to Schema ID Table

## 3863: Ki-67

Item Length: 5 NAACCR Item #: 3863 XML Parent-NAACCR ID: Tumor-ki67 NAACCR Alternate Name: None Active years: 2018+ Schemas(s):

• 00480: Breast (2018+)

### **Description**

Ki-67 (MIB-1) (Proliferative Index) is a marker of cell proliferation. A high value indicates a tumor that is proliferating more rapidly. Codes and coding instructions for this data item are site-specific.

### Rationale

Ki-67 (MIB-1) (Proliferative Index) is a Registry Data Collection Variable in AJCC. It was a new data item for breast cases diagnosed 1/1/2018+. It will apply to neuroendocrine tumors (NET) of the gastrointestinal tract (AJCC Chapters 29 – 34) for cases diagnosed 1/1/2021+. High Ki-67 is an adverse prognostic factor and Ki-67 is a component of grade for these tumors. NCCN guidelines recommend that tumor differentiation, mitotic rate and Ki-67 should be recorded in the pathology report for these tumors.

### **Coding Instructions**

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

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

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

**Note 4:** Ki-67 results are reported as the percentage cell nuclei that stain positive. As of early 2017 there are no established standards for interpretation of results or for cutoffs for positive and negative.

• Examples: Ki-67 reported as 14%. Code 14.0 Ki-67 reported as 8.6%. Code 8.6

**Note 5**: In cases where there are invasive and in situ components in the primary tumor and Ki-67 is done on both, ignore the in situ results.

- If Ki-67 is done on both the in situ and invasive components in the primary tumor, code the Ki-67 value from the invasive component
- If in situ and invasive components present and Ki-67 only done on the in situ component in the primary tumor, code unknown

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						

## 3882: LN Positive Axillary Level I-II

Item Length: 2 NAACCR Item #: 3882 XML Parent-NAACCR ID: Tumor-InPositiveAxillaryLevel1To2 NAACCR Alternate Name: Lymph Nodes Positive Axillary Level I-II Active years: 2018+ Schemas(s):

• 00480: Breast (2018+)

### **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
  - o Axillary dissection was performed but no axillary lymph nodes were found

- o 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 that are positive during clinical workup
  - Positive nodes can be from an FNA, core biopsy or sentinel lymph node biopsy
    - Example: Patient with positive FNA of axillary lymph node, neoadjuvant therapy administered. Lymph node dissection revealed negative lymph nodes. Code X6 for the positive FNA.
- If the post-neoadjuvant nodal involvement is more extensive, include only those nodes positive during surgery
  - Positive nodes can be from an FNA, core biopsy, sentinel lymph node biopsy or lymph node dissection
    - Example: Patient with large breast mass, lymph node negative on clinical exam. Neoadjuvant therapy administered. Mastectomy and sentinel lymph node biopsy done, 1 of 2 SLN's positive. Code 01.

**Note 5**: Lymph nodes with only isolated tumor cells (ITCs) are not counted as positive lymph nodes. Only lymph nodes with metastases greater than 0.2 mm (micrometastases or larger) should be counted as positive. If the pathology report indicates that axillary nodes are positive, but size of the metastases is not stated, assume the metastases are greater than 0.2 mm and code the lymph nodes as positive in this field.

**Note 6**: When positive ipsilateral axillary lymph nodes are coded in this field, the number of positive ipsilateral axillary lymph nodes must be less than or equal to the number coded in Regional Nodes Positive (i.e., the number of positive ipsilateral axillary nodes will always be a subset of the number of positive regional nodes.)

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						

## 3922: Response to Neoadjuvant Therapy

Item Length: 1 NAACCR Item #: 3922 XML Parent-NAACCR ID: Tumor-responseToNeoadjuvantTherapy NAACCR Alternate Name: None Active years: 2018+ Schemas(s): • 00480: Breast (2018+)

Description

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

### **Rationale**

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

### **Definition**

Neoadjuvant therapy is defined as systemic or radiation treatment administered prior to surgery in an attempt to shrink the tumor or destroy regional metastases. This data item documents whether that neoadjuvant therapy was successful.

This data item is coded based on the clinician's statement regarding response to neoadjuvant therapy. Do not try to interpret or infer a response based on the medical record. As a guide for the clinician, the definitions below are from the AJCC Cancer Staging Manual, 8<sup>th</sup> edition.

#### The registrar should not use these definitions to code this field

- Complete Response (CR) absence of invasive carcinoma in breast and lymph nodes; must be determined by microscopic evaluation of tissues; residual in situ cancer at primary site
- Partial Response (PR) a decrease in T and/or N category compared to pretreatment value and no increase, using same method of evaluation as baseline value; residual tumor in lymph nodes of any size
- No Response (NR) no apparent change in the T or N category compared to pretreatment value, or an increase in T or N value at time of y pathological examination

## **Coding guidelines**

- Code 0 if there is no neoadjuvant therapy given
  - This includes in situ (behavior /2) cases
- Code 1 for a Residual Cancer Burden (RCB) result of '0' or an RCB Class of pCR (pathological complete response).
- Code 9 when
  - there is no statement of complete, partial or no response by the clinician or when the response is not documented in the medical record

## Additional Information

- For further information, refer to the **Breast** or **Breast Biomarker Reporting** cancer protocols published by the College of American Pathologists for the AJCC Staging System *Breast*
- **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:** The clinician's statement may be based on pathology reports, imaging, and other clinical findings.

Note 3: Code 1 is to be used only when the physician states the response is "total" or "complete."

Code	Description							
0	Neoadjuvant therapy not given							
	Non-invasive neoplasm (behavior /2)							
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							

## FEMALE REPRODUCTIVE ORGANS

## 3836: FIGO

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

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

## **Description**

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

## <u>Rationale</u>

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 system uses every possible FIGO code and the actual codes used are not the same for all systems.

## **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.

- 1 FIGO Stage I (all systems)
- 1B2 FIGO Stage IB2 (cervix only)
- 2 FIGO Stage II (all systems)
- 3A12 FIGO Stage IIIA1ii (ovary, fallopian tube, and primary peritoneal carcinoma only)
- 4 FIGO Stage IV (all systems)
- 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 Schemas

Code	Description	Vulva	Vagina	Cervix	Corpus Sarcoma	Corpus Adeno-	Corpus Carcinoma	Ovary, FT, PPC	Placenta
						Sarcoma			
1	FIGO Stage I	Х	Х	Х	Х	X	Х	Χ*	Х
1A	FIGO Stage IA	Х		Х	Х	X	Х	Χ*	
1A1	FIGO Stage IA1			Х					
1A2	FIGO Stage IA2			Х					
1B	FIGO Stage IB	Х		Х	Х	Х	Х	Χ*	
1B1	FIGO Stage IB1			Х					
1B2	FIGO Stage IB2			Х					
1B3	FIGO Stage IB3			X**					
1C	FIGO Stage IC					X		Χ*	
1C1	FIGO Stage IC1							Χ*	
1C2	FIGO Stage IC2							Χ*	
1C3	FIGO Stage IC3							Χ*	
2	FIGO Stage II	Х	Х	Х	Х	X	Х	Х	Х
2A	FIGO Stage IIA			Х	х	X		X	
2A1	FIGO Stage IIA1			Х					
2A2	FIGO Stage IIA2			Х					
2B	FIGO Stage IIB			Х	Х	Х			
3	FIGO Stage III	Х	Х	Х	Х	Х	Х	Х	Х
3A	FIGO Stage IIIA	Х		Х	Х	Х	Х	Х	
3A1	FIGO Stage IIIA1							Х	

Code	Description	Vulva	Vagina	Cervix	Corpus Sarcoma	Corpus Adeno-	Corpus Carcinoma	Ovary, FT, PPC	Placenta
						Sarcoma			
3A11	FIGO Stage IIIA1i							Х	
3A12	FIGO Stage IIIA1ii							Х	
3A2	FIGO Stage IIIA2							Х	
3B	FIGO Stage IIIB	X		Х	Х	X	Х	Х	
3C	FIGO Stage IIIC	X		Х	Х	X	Х	Х	
3C1	FIGO Stage IIIC1			X**			Х		
3C2	FIGO Stage IIIC2			X**			Х		
4	FIGO Stage IV	X	Х	Х	Х	Х	Х	Х	Х
4A	FIGO Stage IVA	Х	Х	Х	Х	X	Х	Х	
4B	FIGO Stage IVB	Х	Х	Х	Х	Х	Х	Х	

\*Not applicable for Primary Peritoneal Carcinoma

# \*\* Cervix Version 9 only (effective 1/1/2021 forward)

# In addition to the codes listed above, the following codes are also applicable

Code	Description					
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					

# \*Not applicable for the Cervix Sarcoma, Corpus Adenosarcoma, and Corpus Sarcoma

# 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 6 data items that collect information on regional lymph nodes. Three data items collect the individual 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.

- <u>3871: LN Assessment Method Femoral-Inguinal</u>
- <u>3872: LN Assessment Method Para-Aortic</u>
- <u>3873: LN Assessment Method Pelvic</u>
- <u>3957: LN Status: Pelvic</u>
- <u>3958: LN Status: Para-Aortic</u>
- <u>3959: LN Status: Femoral-Inguinal</u>

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.

- <u>3874: LN Distant Assessment Method</u>
- <u>3875: LN Distant: Mediastinal, Scalene</u>

For the 4 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)

# 3836: FIGO: Vulva

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

• 00500: Vulva (2018+)

**Note 1:** There must be a statement about FIGO stage from the managing physician in order to code this data item.

- Do **not** code FIGO stage based on the pathology report
- Do **not** code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do **not** assume it is a FIGO stage

**Note 2:** FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

• Code FIGO grade in the grade fields

**Note 3:** If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

Note 4: The FIGO stage definitions do not include Stage 0 (Tis).

• Code 97 for any non-invasive neoplasm (behavior /2)

Code	Description
1	FIGO Stage I
1A	FIGO Stage IA
1B	FIGO Stage IB
2	FIGO Stage II
3	FIGO Stage III
3A	FIGO Stage IIIA
3B	FIGO Stage IIIB
3C	FIGO Stage IIIC
4	FIGO Stage IV
4A	FIGO Stage IVA
4B	FIGO Stage IVB
97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
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

# 00500: Vulva (2018+)

# 3959: LN Status: Femoral-Inguinal

Item Length: 1 NAACCR Item #: 3959 XML Parent-NAACCR ID: Tumor-InStatusFemoralInguinal NAACCR Alternate Name: Lymph Nodes Status: Femoral-Inguinal Active years: 2018+ Schema(s):

- 00500: Vulva (2018+)
- 00510: Vagina (2018+)

#### **Description**

This data item describes the status of femoral-inguinal 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 Vulva, SSF #14

# 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 the femoral-inguinal status can be used to code this data item when no other information is available.

Note 2: The following are femoral-inguinal nodes

- Femoral
- Inguinal, NOS
  - Inguinofemoral (groin)
  - Node of Cloquet or Rosenmuller (highest deep inguinal)
  - Superficial inguinal

**Note 3:** If there is no mention of femoral-inguinal lymph node involvement in the area being imaged, biopsied, or in the surgical field and there is no mention of involvement, then assume that the femoral-inguinal lymph nodes are negative.

**Note 4:** For this data item, do not include isolated tumor cells (ITCs).

Note 5: Code 9 when there is no imaging, biopsy, surgical workup, or a physical exam only.

Note 6: The assessment method is recorded in <u>3871: LN Assessment Method Femoral-Inguinal</u>.

Code	Description
0	Negative femoral-inguinal lymph nodes
	Non-invasive neoplasm (behavior /2)
1	Positive femoral-inguinal lymph nodes
8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code 8 may result in an edit
	error.)
9	Not documented in medical record
	Femoral-Inguinal lymph node(s) not assessed or unknown if assessed

# 3871: LN Assessment Method Femoral-Inguinal

Item Length: 1 NAACCR Item #: 3871 XML Parent-NAACCR ID: Tumor-InAssessMethodFemoralInguinal NAACCR Alternate Name: Lymph Nodes Assessment Method Femoral-Inguinal Active years: 2018+ Schema(s):

- 00500: Vulva (2018+)
- 0510: Vagina (2018+)

#### **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: The following are femoral-inguinal nodes

- Femoral
- Inguinal, NOS
  - Inguinofemoral (groin)
  - Node of Cloquet or Rosenmuller (highest deep inguinal)
  - o Superficial inguinal

**Note 3:** Assign the highest applicable code (0-2) in the case of multiple assessments.

**Note 4**: For this data item, do not include isolated tumor cells (ITCs).

**Note 5:** Code 0 when there is only imaging or a physical exam.

Note 6: The status results are recorded in <u>3959: LN Status: Femoral-Inguinal</u>.

Code	Description
0	Radiography, imaging
	(Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI),
	positron emission tomography scan (PET))
	Physical exam only
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy
	Sentinel node biopsy
	Excisional biopsy or resection with microscopic confirmation
7	Femoral-inguinal lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record
	Femoral-inguinal lymph node(s) not assessed or unknown if assessed

# 00500: Vulva (2018+)

# **3957: LN Status: Pelvic**

Item Length: 1 NAACCR Item #: 3957 XML Parent-NAACCR ID: Tumor-InStatusPelvic NAACCR Alternate Name: Lymph Node Status: Pelvic Active years: 2018+ Schema(s):

- 00500: Vulva (2018+)
- 00510: Vagina (2018+)
- 00520: Cervix (2018-2020)
- 09520: Cervix (2021+)

#### **Description**

This data item describes the status of 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 Vulva, SSF #12

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

Note 2: For Vulva, pelvic lymph nodes are distant.

Note 3: The following are pelvic nodes

- Iliac, NOS
  - $\circ$  Common
  - External
  - Internal (hypogastric) (obturator)
- Paracervical
- Parametrial
- Pelvic, NOS
- Sacral, NOS
  - Lateral (laterosacral)
  - Middle (promontorial) (Gerota's node)
  - Uterosacral

**Note 4:** If there is no mention of pelvic lymph node involvement in the area being imaged, biopsied, or in the surgical field and there is no mention of involvement, then assume that the pelvic lymph nodes are negative.

**Note 5:** For this data item, do not include isolated tumor cells (ITCs).

**Note 6:** Code 9 when there is no imaging, biopsy, surgical workup, or a physical exam only.

Note 7: The assessment method is recorded in <u>3873: LN Assessment Method Pelvic.</u>

Code	Description
0	Negative pelvic lymph nodes Non-invasive neoplasm (behavior /2)
1	Positive pelvic lymph nodes
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Pelvic lymph node(s) not assessed or unknown if assessed

# 00500: Vulva (2018+)

# 3873: LN Assessment Method Pelvic

NAACCR Item #: 3873 XML Parent-NAACCR ID: Tumor-InAssessMethodPelvic NAACCR Alternate Name: Lymph Nodes Assessment Method Pelvic Active years: 2018+ Schemas(s):

- 00500: Vulva (2018+)
- 00510: Vagina (2018+)
- 00520: Cervix (2018-2020)
- 09520: Cervix (2021+)

#### **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 Vulva, SSF #13.

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: For Vulva, pelvic lymph nodes are distant.

**Note 3:** The following are pelvic nodes

- Iliac, NOS
  - $\circ$  Common
  - o External
  - Internal (hypogastric) (obturator)
- Paracervical
- Parametrial
- Pelvic, NOS
- Sacral, NOS
  - Lateral (laterosacral)
  - Middle (promontorial) (Gerota's node)
  - Uterosacral

Note 4: Assign the highest applicable code (0-2) in the case of multiple assessments.

**Note 5:** For this data item, do not include isolated tumor cells (ITCs).

**Note 6:** Code 0 when there is only imaging or a physical exam.

Code	Description
0	Radiography, imaging
	(Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI),
	positron emission tomography scan (PET))
	Physical exam only
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy
	Sentinel node biopsy
	Excisional biopsy or resection with microscopic confirmation
7	Pelvic lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record
	Pelvic lymph node(s) not assessed or unknown if assessed

# 00500: Vulva (2018+)

# 3881: LN Laterality

Item Length: 1 NAACCR Item #: 3881 XML Parent-NAACCR ID: Tumor-InLaterality NAACCR Alternate Name: Lymph Nodes Laterality Active years: 2018+ Schema(s):

• 00500: Vulva (2018+)

#### **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
  - o at least one regional lymph node is involved on each side of the pelvis
  - o 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
  - o 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
	Non-invasive neoplasm (behavior /2)
1	Unilateral - all positive regional nodes with same laterality
	OR only one regional node positive
2	Bilateral - positive bilateral regional lymph nodes
3	Laterality unknown - positive regional lymph nodes with unknown laterality
8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code 8 may result in an edit
	error.)
9	Not documented in medical record
	Lymph node laterality not assessed or unknown if assessed

# 3836: FIGO: Vagina

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

• 00510: Vagina (2018+)

**Note 1:** There must be a statement about FIGO stage from the managing physician in order to code this data item.

- Do **not** code FIGO stage based on the pathology report
- Do **not** code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do **not** assume it is a FIGO stage

**Note 2:** FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

• Code FIGO grade in the grade fields

**Note 3:** If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

Note 4: The FIGO stage definitions do not include Stage 0 (Tis).

• Code 97 for any non-invasive neoplasm (behavior /2)

Code	Description
1	FIGO Stage I
2	FIGO Stage II
3	FIGO Stage III
4	FIGO Stage IV
4A	FIGO Stage IVA
4B	FIGO Stage IVB
97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record
	FIGO stage unknown, not assessed or unknown if assessed

# 00510: Vagina (2018+)

# 3959: LN Status: Femoral-Inguinal

Item Length: 1 NAACCR Item #: 3959 XML Parent-NAACCR ID: Tumor-InStatusFemoralInguinal NAACCR Alternate Name: Lymph Nodes Status: Femoral-Inguinal Active years: 2018+ Schema(s):

- 00500: Vulva (2018+)
- 00510: Vagina (2018+)

#### **Description**

This data item describes the status of femoral-inguinal 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 Vulva, SSF #14

# 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 the femoral-inguinal status can be used to code this data item when no other information is available.

**Note 2:** Code this data item for the lower third of the vagina only.

• Code 9 for upper two thirds of the vagina, or unknown whether it's the lower third or upper two thirds

**Note 3:** The following are femoral-inguinal nodes

- Femoral
- Inguinal, NOS
  - Inguinofemoral (groin)
  - Node of Cloquet or Rosenmuller (highest deep inguinal)
  - Superficial inguinal

**Note 4:** If there is no mention of femoral-inguinal lymph node involvement in the area being imaged, biopsied, or in the surgical field and there is no mention of involvement, then assume that the femoral-inguinal lymph nodes are negative.

**Note 5:** For this data item, do not include isolated tumor cells (ITCs).

**Note 6:** Code 9 when there is no imaging, biopsy, surgical workup, or a physical exam only.

Note 7: The assessment method is recorded in <u>3871: LN Assessment Method Femoral-Inguinal</u>.

Code	Description
0	Negative femoral-inguinal lymph nodes
	Non-invasive neoplasm (behavior /2)
1	Positive femoral-inguinal lymph nodes
8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code 8 may result in an edit
	error.)
9	Not documented in medical record
	Femoral-Inguinal lymph node(s) not assessed or unknown if assessed

# 3871: LN Assessment Method Femoral-Inguinal

Item Length: 1 NAACCR Item #: 3871 XML Parent-NAACCR ID: Tumor-InAssessMethodFemoralInguinal NAACCR Alternate Name: Lymph Nodes Assessment Method Femoral-Inguinal Active years: 2018+ Schema(s):

- 00500: Vulva (2018+)
- 00510: Vagina (2018+)

#### **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: The following are femoral-inguinal nodes

- Femoral
- Inguinal, NOS
  - Inguinofemoral (groin)
  - Node of Cloquet or Rosenmuller (highest deep inguinal)
  - Superficial inguinal

**Note 3:** Code this data item for the lower third of the vagina only.

• Code 9 for upper two thirds of the vagina, or unknown whether it's the lower third or upper two thirds

Note 4: Assign the highest applicable code (0-2) in the case of multiple assessments.

**Note 5**: For this data item, do not include isolated tumor cells (ITCs).

**Note 6:** Code 0 when there is only imaging or a physical exam.

**Note 7:** The status results are recorded in <u>3959: LN Status: Femoral-Inguinal</u>.

Code	Description
0	Radiography, imaging
	(Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI),
	positron emission tomography scan (PET))
	Physical exam only
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy
	Sentinel node biopsy
	Excisional biopsy or resection with microscopic confirmation
7	Femoral-inguinal lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record
	Femoral-inguinal lymph node(s) not assessed or unknown if assessed

# 3958: LN Status: Para-Aortic

Item Length: 1 NAACCR Item #: 3958 XML Parent-NAACCR ID: Tumor-InStatusParaAortic NAACCR Alternate Name: Lymph Node Status: Para-aortic Active years: 2018+ Schema(s):

- 00510: Vagina (2018+)
- 00520: Cervix (2018-2020)
- 09520: Cervix (2021+)

# **Description**

This data item describes the status of para-aortic 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 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 para-aortic status can be used to code this data item when no other information is available.

Note 2: The following are para-aortic nodes

- Aortic
- Lateral aortic/lumbar aortic
- Para-aortic, NOS
- Periaortic

**Note 3:** If there is no mention of para-aortic lymph node involvement in the area being imaged, biopsied, or in the surgical field and there is no mention of involvement, then assume that the para-aortic lymph nodes are negative.

Note 4: For this data item, do not include isolated tumor cells (ITCs).

**Note 5:** Code 9 when there is no imaging, biopsy, surgical workup, or a physical exam only.

Note 6: The assessment method is recorded in <u>3872: LN Assessment Method Para-Aortic</u>.

Code	Description
0	Negative para-aortic lymph nodes
	Non-invasive neoplasm (behavior /2)
1	Positive para-aortic lymph nodes
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Para-aortic lymph node(s) not assessed or unknown if assessed

# 3872: LN Assessment Method Para-Aortic

Item Length: 1 NAACCR Item #: 3872 XML Parent-NAACCR ID: Tumor-InAssessMethodParaaortic NAACCR Alternate Name: Lymph Nodes Assessment Method Para-aortic Active years: 2018+ Schema(s):

- 00510: Vagina (2018+)
- 00520: Cervix (2018-2020)
- 09520: Cervix (2021+)

#### **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: The following are para-aortic nodes

- Aortic
- Lateral aortic/lumbar aortic
- Para-aortic, NOS
- Periaortic

Note 3: Assign the highest applicable code (0-2) in the case of multiple assessments.

Note 4: For this data item, do not include isolated tumor cells (ITCs).

**Note 5:** Code 0 when there is only imaging or a physical exam.

Note 6: The assessment results are recorded in <u>3958: LN Status: Para-Aortic</u>.

Code	Description
0	Radiography, imaging (Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI), positron emission tomography scan (PET))
	Physical exam only

Code	Description
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy
	Sentinel node biopsy
	Excisional biopsy or resection with microscopic confirmation
7	Para-aortic lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record
	Para-aortic lymph node(s) not assessed or unknown if assessed

# 00510: Vagina

# **3957: LN Status: Pelvic**

Item Length: 1 NAACCR Item #: 3957 XML Parent-NAACCR ID: Tumor-InStatusPelvic NAACCR Alternate Name: Lymph Node Status: Pelvic Active years: 2018+ Schema(s):

- 00500: Vulva (2018+)
- 00510: Vagina (2018+)
- 00520: Cervix (2018-2020)
- 09520: Cervix (2021+)

# **Description**

This data item describes the status of 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 Vulva, SSF #12

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

Note 2: The following are pelvic nodes

- Iliac, NOS
  - o Common
  - o External
  - Internal (hypogastric) (obturator)
- Paracervical
- Parametrial
- Pelvic, NOS
- Sacral, NOS
  - Lateral (laterosacral)
  - Middle (promontorial) (Gerota's node)
  - o Uterosacral

**Note 3:** If there is no mention of pelvic lymph node involvement in the area being imaged, biopsied, or in the surgical field and there is no mention of involvement, then assume that the pelvic lymph nodes are negative.

Note 4: For this data item, do not include isolated tumor cells (ITCs).

**Note 5:** Code 9 when there is no imaging, biopsy, surgical workup, or a physical exam only.

Code	Description
0	Negative pelvic lymph nodes Non-invasive neoplasm (behavior /2)
1	Positive pelvic lymph nodes
8	Not applicable: Information not collected for this case (If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record Pelvic lymph node(s) not assessed or unknown if assessed

# 00510: Vagina (2018+)

# 3873: LN Assessment Method Pelvic

NAACCR Item #: 3873 XML Parent-NAACCR ID: Tumor-InAssessMethodPelvic NAACCR Alternate Name: Lymph Nodes Assessment Method Pelvic Active years: 2018+ Schemas(s):

- 00500: Vulva (2018+)
- 00510: Vagina (2018+)
- 00520: Cervix (2018-2020)
- 09520: Cervix (2021+)

#### 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 Vulva, SSF #13.

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: The following are pelvic nodes

- Iliac, NOS
  - o Common
  - External
  - Internal (hypogastric) (obturator)
- Paracervical
- Parametrial
- Pelvic, NOS
- Sacral, NOS
  - Lateral (laterosacral)
  - Middle (promontorial) (Gerota's node)
  - o Uterosacral

Note 3: Assign the highest applicable code (0-2) in the case of multiple assessments.

**Note 4:** For this data item, do not include isolated tumor cells (ITCs).

Note 5: Code 0 when there is only imaging or a physical exam.

Note 6: The assessment results are recorded in <u>3957: LN Status: Pelvic.</u>

Code	Description
0	Radiography, imaging
	(Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI),
	positron emission tomography scan (PET))
	Physical exam only
1	Incisional biopsy; fine needle aspiration (FNA)
2	Lymphadenectomy
	Sentinel node biopsy
	Excisional biopsy or resection with microscopic confirmation
7	Pelvic lymph node(s) assessed, unknown assessment method
8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record
	Pelvic lymph node(s) not assessed or unknown if assessed

# 3875: LN Distant: Mediastinal, Scalene

Item Length: 1 NAACCR Item #: 3875 XML Parent-NAACCR ID: Tumor-InDistantMediastinalScalene NAACCR Alternate Name: Lymph Nodes Distant: Mediastinal, Scalene Active years: 2018+ Schema(s):

- 00510: Vagina
- 00520: Cervix (2018-2020)
- 09520: Cervix (2021+)

# **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 when there is no imaging, biopsy, surgical workup, or a physical exam only.

Note 5: The assessment method is recorded in <u>3874: LN Distant Assessment Method</u>.

Code	Description
0	Negative mediastinal and scalene lymph nodes
	Non-invasive neoplasm (behavior /2)
1	Positive mediastinal lymph nodes
2	Positive scalene lymph nodes
3	Positive mediastinal and scalene lymph nodes
8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record
	Mediastinal and scalene lymph nodes not assessed or unknown if assessed

# 00510: Vagina

# 3874: LN Distant Assessment Method

Item Length: 1 NAACCR Item #: 3874 XML Parent-NAACCR ID: Tumor-InDistantAssessMethod NAACCR Alternate Name: Lymph Nodes Distant Assessment Method Active years: 2018+ Schema(s):

- 00510: Vagina
- 00520: Cervix (2018-2020)
- 09520: Cervix (2021+)

# **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:** Code 0 when there is only imaging or a physical exam.

Note 4: The assessment results are recorded in <u>3875: LN Distant: Mediastinal, Scalene</u>.

Code	Description	
0	Radiography, imaging	
	(Ultrasound (US), computed tomography scan (CT), magnetic resonance imaging (MRI),	
	positron emission tomography scan (PET))	
	Physical exam only	
1	Incisional biopsy; fine needle aspiration (FNA)	
2	Lymphadenectomy	
	Excisional biopsy or resection with microscopic confirmation	
7	Distant lymph node(s) assessed, unknown assessment method	
8	Not applicable: Information not collected for this case	
	(If this item is required by your standard setter, use of code 8 will result in an edit error.)	
9	Not documented in medical record	
	Distant lymph node(s) not assessed or unknown if assessed	
Doturn	Poturn to Schoma ID Table	

# 00520: Cervix (2018-2020)

See 00510: Vagina (2018+)

- <u>3958: LN Status: Para-Aortic</u>
- <u>3872: LN Assessment Method Para-Aortic</u>
- <u>3957: LN Status: Pelvic</u>
- <u>3873: LN Assessment Method Pelvic</u>
- <u>3874: LN Distant Assessment Method</u>
- <u>3875: LN Distant: Mediastinal, Scalene</u>

# 00520: Cervix (2018-2020)

#### 3836: FIGO: Cervix

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

- 00520: Cervix (2018-2020)
- 009520: Cervix (2021+)

**Note 1:** There must be a statement about FIGO stage from the managing physician in order to code this data item.

- Do **not** code FIGO stage based on the pathology report
- Do **not** code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do **not** assume it is a FIGO stage

**Note 2:** FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

• Code FIGO grade in the grade fields

**Note 3:** If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

Note 4: The FIGO stage definitions do not include Stage 0 (Tis).

• Code 97 for any non-invasive neoplasm (behavior /2)

Code	Description
1	FIGO Stage I
1A	FIGO Stage IA
1A1	FIGO Stage IA1
1A2	FIGO Stage IA2
1B	FIGO Stage IB
1B1	FIGO Stage IB1
1B2	FIGO Stage IB2
1B3	FIGO Stage IB3
2	FIGO Stage II
2A	FIGO Stage IIA
2A1	FIGO Stage IIA1
2A2	FIGO Stage IIA2
2B	FIGO Stage IIB
3	FIGO Stage III
3A	FIGO Stage IIIA
3B	FIGO Stage IIIB
3C	FIGO Stage IIIC
3C1	FIGO Stage IIIC1
3C2	FIGO Stage IIIC2
4	FIGO Stage IV

Code	Description
4A	FIGO Stage IVA
4B	FIGO Stage IVB
97	Not applicable: Carcinoma in situ (intraepithelial, noninvasive, preinvasive)
98	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record
	FIGO stage unknown, not assessed or unknown if assessed

# 09520: Cervix (2021+)

See 00510: Vagina (2018+)

- <u>3958: LN Status: Para-Aortic</u>
- <u>3872: LN Assessment Method Para-Aortic</u>
- <u>3957: LN Status: Pelvic</u>
- <u>3873: LN Assessment Method Pelvic</u>
- <u>3874: LN Distant Assessment Method</u>
- <u>3875: LN Distant: Mediastinal, Scalene</u>

See 00520: Cervix (2018-2020)

• <u>3836: FIGO: Cervix</u>

# 09520: Cervix (2021+)

# 3956: p16

Item Length: 1 NAACCR Item #: 3956 XML Parent-NAACCR ID: Tumor-p16 NAACCR Alternate Name: None Active years: 2021+ Schema(s):

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

#### **Description**

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

#### **Rationale**

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

#### **Definition**

p16 is a tumor suppressor protein also known as cyclin-dependent kinase inhibitor 2A. The p16 biomarker is overexpressed (produced) in response to HPV. It is therefore a surrogate marker for HPV disease.

#### **Coding Instructions and Codes**

Note 1: This SSDI is effective for diagnosis years 2021+.

• For cases diagnosed 2018-2020, leave this SSDI blank

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

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

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

Code	Description
0	p16 Negative; Nonreactive
1	p16 Positive; Diffuse, Strong reactivity
8	Not applicable: Information not collected for this case
	(If this time is required by your standard setter, use of code 8 will result in an edit
	error)
9	Not tested for p16; Unknown
<blank></blank>	N/A-Diagnosis year prior to 2021

# 00528: Cervix Sarcoma

See 00541: Corpus Sarcoma (2018+)

• <u>3836: FIGO Stage (Sarcoma)</u>

See 00530: Corpus Carcinoma and Carcinosarcoma (2018+)

- <u>3901: Number of Positive Para-Aortic Nodes</u>
- <u>3899: Number of Examined Para-Aortic Nodes</u>
- <u>3902: Number of Positive Pelvic Nodes</u>
- <u>3900: Number of Examined Pelvic Nodes</u>
- <u>3911: Peritoneal Cytology</u>

# 00530: Corpus Carcinoma and Carcinosarcoma (2018+)

# 3836: FIGO: Corpus Carcinoma and Carcinosarcoma

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

• 00530: Corpus Carcinoma and Carcinosarcoma (2018+)

**Note 1:** There must be a statement about FIGO stage from the managing physician in order to code this data item.

- Do **not** code FIGO stage based on the pathology report
- Do **not** code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do not assume it is a FIGO stage

**Note 2:** FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

• Code FIGO grade in the grade fields

**Note 3:** If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

**Note 4:** For Endometrial intraepithelial carcinoma (EIC) (8380/2) and Serous endometrial intraepithelial carcinoma (SEIC) (8441/2), assign the FIGO staged based on the managing physician's documentation of FIGO. (See Note 1).

- If FIGO stage for EIC or SEIC is not documented by the managing physician, code unknown (code 99)
- Do not code 97 (in situ) for EIC or SEIC since FIGO does not have a Stage 0
- If diagnosis is Endometrial intraepithelial neoplasia (EIN) (8380/2), code 97.

**Note 5:** Code 97 for any remaining in situ histologies (/2) since the FIGO stage definitions do not include Stage 0.

Code	Description
1	FIGO Stage I
1A	FIGO Stage IA
1B	FIGO Stage IB
2	FIGO Stage II
3	FIGO Stage III
3A	FIGO Stage IIIA
3B	FIGO Stage IIIB
3C	FIGO Stage IIIC
3C1	FIGO Stage IIIC1
3C2	FIGO Stage IIIC2
4	FIGO Stage IV
4A	FIGO Stage IVA
4B	FIGO Stage IVB

Code	Description
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

# 00530: Corpus Carcinoma and Carcinosarcoma (2018+)

# 3899-3902: 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.

Para-aortic nodes

- Aortic
- Lateral aortic/lumbar aortic
- Para-aortic, NOS
- Periaortic

Pelvic nodes

- Iliac, NOS
  - o Common
  - o External
  - Internal (hypogastric) (obturator)
- Paracervical
- Parametrial
- Pelvis, NOS
- Sacral
  - o Lateral (laterosacral)
  - Middle (promontorial) (Gerota's node)
  - Presacral
  - Uterosacral

For the Cervix sarcoma 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

- <u>3899: Number of Examined Para-Aortic Nodes</u>
- <u>3900: Number of Examined Pelvic Nodes</u>
- <u>3901: Number of Positive Para-Aortic Nodes</u>
- <u>3902: Number of Positive Pelvic Nodes</u>

Number of nodes positive must ALWAYS be less than or equal to number of nodes examined.

# Additional Information

Source documents: pathology report

## **3901: Number of Positive Para-Aortic Nodes**

Item Length: 2 NAACCR Item #: 3901 XML Parent-NAACCR ID: Tumor-numberOfPositiveParaAorticNodes NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00528: Cervical Sarcoma (2021+)
- 00530: Corpus Carcinoma and Carcinosarcoma
- 00541: Corpus Sarcoma
- 00542: Corpus Adenosarcoma

#### **Description**

Number of Positive Para-Aortic Nodes is the number of positive nodes based on para-aortic nodal dissection.

#### **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)
  - No lymph node dissection performed
  - o Unknown if Para-Aortic lymph nodes evaluated (assessed)

## See <u>3899-3902: Number of Positive and Examined Para-Aortic and Pelvic Nodes</u> 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: The following are para-aortic nodes

- Aortic
- Lateral aortic/lateral lumbar
- Para-aortic, NOS

• Periaortic

**Note 3**: Record the number of positive para-aortic lymph nodes documented in the medical record.

Note 4: For this data item, do not include isolated tumor cells (ITCs).

**Note 5:** Micrometastasis and macrometastasis may be listed separately on the pathology report. Add these two together to get the total number of positive nodes.

**Note 6**: Code X9 if no lymph node dissection is performed.

- If only a FNA or core biopsy is done and it is **positive**, then code X6
- If only a FNA or core biopsy is done and it is negative, then code X9
- Code X9 when no lymph nodes are removed

**Note 7:** The number of examined para-aortic nodes is recorded in <u>3899: Number of Examined Para-Aortic Nodes</u>.

Code	Description
00	All para-aortic lymph nodes examined negative
01-	1-99 para-aortic lymph nodes positive
99	(Exact number of nodes positive)
X1	100 or more para-aortic nodes positive
X2	Positive para-aortic nodes identified, number unknown
X6	Positive aspiration or core biopsy of para-aortic lymph node(s)
X8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record
	Cannot be determined, indeterminate if positive para-aortic nodes present
	No lymph node dissection performed
	Para-aortic lymph nodes not assessed or unknown if assessed

Return to <u>Schema ID Table</u>

## 3899: Number of Examined Para-Aortic Nodes

Item Length: 2 NAACCR Item #: 3899 XML Parent-NAACCR ID: Tumor-numberOfExaminedParaAorticNodes NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00528: Cervical Sarcoma (2021+)
- 00530: Corpus Carcinoma and Carcinosarcoma (2018+)
- 00541: Corpus Sarcoma (2018+)
- 00542: Corpus Adenosarcoma (2018+)

#### **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)
  - No lymph node dissection performed
  - Unknown if Para-Aortic lymph nodes not evaluated (assessed)

## See <u>3899-3902: Number of Positive and Examined Para-Aortic and Pelvic Nodes</u> 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: The following are para-aortic nodes

- Aortic
- Lateral aortic/lateral lumbar
- Para-aortic, NOS

• Periaortic

**Note 3**: Record the number of examined para-aortic lymph nodes documented in the medical record.

Note 4: For the following

- Code 00 when no lymph nodes are examined by FNA, core biopsy or removal of lymph node(s) (e.g., sentinel lymph node biopsy or lymph node dissection)
  - If a lymph node dissection is done and only pelvic lymph nodes are assessed, or only "nodes" are documented without specifying pelvic or para-aortic, code to 00
- Code X6 If only a FNA or core biopsy is done
- Code X9 if it's unknown if lymph nodes were removed

**Note 5 :** The number of positive para-aortic nodes is recorded in <u>3901: Number of Positive Para-Aortic</u> <u>Nodes</u>.

Code	Description
00	No para-aortic nodes examined
01-99	1 - 99 para-aortic nodes examined
	(Exact number of para-aortic lymph nodes examined)
X1	100 or more para-aortic nodes examined
X2	Para-aortic nodes examined, number unknown
X6	No para-aortic lymph nodes removed, but aspiration or core biopsy of para-aortic node(s)
	only
X8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record
	Cannot be determined, indeterminate if examined para-aortic nodes present
	No lymph node dissection performed
	Para-aortic lymph nodes not assessed or unknown if assessed

## 00530: Corpus Carcinoma and Carcinosarcoma

#### **3902: Number of Positive Pelvic Nodes**

Item Length: 2 NAACCR Item #: 3902 XML Parent-NAACCR ID: Tumor-numberOfPositivePelvicNodes NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00528: Cervical Sarcoma (2021+)
- 00530: Corpus Carcinoma and Carcinosarcoma
- 00541: Corpus Sarcoma
- 00542: Corpus Adenosarcoma

#### **Description**

Number of Positive Pelvic Nodes is the number of positive nodes based on pelvic nodal dissection.

#### **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 <u>3899-3902: Number of Positive and Examined Para-Aortic and Pelvic Nodes</u> 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)
  - No lymph node dissection performed
  - 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: The following are pelvic nodes

- Iliac, NOS
  - o **Common**
  - o External
  - Internal (hypogastric) (obturator)
- Paracervical
- Parametrial
- Pelvis, NOS
- Sacral
  - o Lateral (laterosacral)
  - Middle (promontorial) (Gerota's node)
  - o Presacral
  - Uterosacral

**Note 3**: Record the number of positive pelvic lymph nodes documented in the medical record.

Note 4: For this data item, do not include isolated tumor cells (ITCs).

**Note 5:** Micrometastasis and macrometastasis may be listed separately on the pathology report. Add these two together to get the total number of positive nodes.

**Note 6:** Code X9 if no lymph node dissection is performed.

- If only a FNA or core biopsy is done and it is **positive**, then code X6
- If only a FNA or core biopsy is done and it is negative, then code X9
- Code X9 when no lymph nodes are removed

Note 7: The number of examined pelvic nodes is recorded in <u>3900: Number of Examined Pelvic Nodes</u>.

Code	Description
00	All pelvic nodes examined negative
01-99	1 - 99 pelvic nodes positive
	(Exact number of nodes positive)
X1	100 or more pelvic nodes positive
X2	Positive pelvic nodes identified, number unknown
X6	Positive aspiration or core biopsy of pelvic lymph node(s)
X8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record
	Cannot be determined, indeterminate if positive pelvic nodes present
	No lymph node dissection performed
	Pelvic lymph nodes not assessed or unknown if assessed

## **3900: Number of Examined Pelvic Nodes**

Item Length: 2 NAACCR Item #: 3900 XML Parent-NAACCR ID: Tumor-numberOfExaminedPelvicNodes NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00528: Cervical Sarcoma (2021+)
- 00530: Corpus Carcinoma and Carcinosarcoma (2018+)
- 00541: Corpus Sarcoma (2018+)
- 00542: Corpus Adenosarcoma (2018+)

#### **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)
  - No lymph node dissection performed
  - Unknown if Pelvic lymph nodes not evaluated (assessed)

## See <u>3899-3902: Number of Positive and Examined Para-Aortic and Pelvic Nodes</u> 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:** The following are pelvic nodes

- Iliac, NOS
  - o Common
  - o External
  - Internal (hypogastric) (obturator)

- Paracervical
- Parametrial
- Pelvis, NOS
- Sacral
  - Lateral (laterosacral)
  - Middle (promontorial) (Gerota's node)
  - o Presacral
  - Uterosacral

**Note 3**: Record the number of examined pelvic lymph nodes documented in the medical record.

Note 4: For the following

- Code 00 when no lymph nodes are examined by FNA, core biopsy or removal of lymph node(s) (e.g., sentinel lymph node biopsy or lymph node dissection)
  - If a lymph node dissection is done and only "nodes" are documented without specifying pelvic or para-aortic, assume they are pelvic
- Code X6 If only a FNA or core biopsy is done
- Code X9 if it's unknown if lymph nodes were removed

Note 5: The number of positive pelvic nodes is recorded in <u>3902: Number of Positive Pelvic Nodes</u>.

Code	Description
00	No pelvic lymph nodes examined
01-	1 - 99 pelvic lymph nodes examined
99	(Exact number of pelvic lymph nodes examined)
X1	100 or more pelvic nodes examined
X2	Pelvic nodes examined, number unknown
X6	No pelvic lymph nodes removed, but aspiration or core biopsy of pelvic node(s) only
X8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record
	Cannot be determined, indeterminate if examined pelvic nodes present
	No lymph node dissection performed
	Pelvic lymph nodes not assessed or unknown if assessed

## 00530: Corpus Carcinoma and Carcinosarcoma (2018+)

## **3911: Peritoneal Cytology**

Item Length: 1 NAACCR Item #: 3911 XML Parent-NAACCR ID: Tumor-peritonealCytology NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00528: Cervical Sarcoma (2021+)
- 00530: Corpus Carcinoma and Carcinosarcoma (2018+)
- 00541: Corpus Sarcoma (2018+)
- 00542: Corpus Adenosarcoma (2018+)

#### **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)

## **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

## 00541: Corpus Sarcoma (2018+)

See 00541: Corpus Sarcoma (2018+)

• <u>3836: FIGO Stage (Sarcoma)</u>

See 00530: Corpus Carcinoma and Carcinosarcoma (2018+)

- <u>3901: Number of Positive Para-Aortic Nodes</u>
- <u>3899: Number of Examined Para-Aortic Nodes</u>
- <u>3902: Number of Positive Pelvic Nodes</u>
- <u>3900: Number of Examined Pelvic Nodes</u>
- <u>3911: Peritoneal Cytology</u>

## 3836: FIGO Stage (Sarcoma)

Item Length: 5 NAACCR Item #: 3836 XML Parent-NAACCR ID: Tumor-figoStage NAACCR Alternate Name: FIGO Stage Active years: 2021+ Schema(s):

- 00528: Cervical Sarcoma (2021+)
- 00541: Corpus Sarcoma (2018+)

**Note 1:** There must be a statement about FIGO stage from the managing physician in order to code this data item.

- Do **not** code FIGO stage based on the pathology report
- Do **not** code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do **not** assume it is a FIGO stage

**Note 2:** FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

• Code FIGO grade in the grade fields

**Note 3:** If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage

Code	Description
1	FIGO Stage I
1A	FIGO Stage IA
1B	FIGO Stage IB
2	FIGO Stage II
2A	FIGO Stage IIA
2B	FIGO Stage IIB
3	FIGO Stage III
3A	FIGO Stage IIIA
3B	FIGO Stage IIIB
3C	FIGO Stage IIIC
4	FIGO Stage IV
4A	FIGO Stage IVA
4B	FIGO Stage IVB
98	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record
	FIGO stage not assessed or unknown if assessed

## 00542: Corpus Adenosarcoma (2018+)

See 00541: Corpus Sarcoma (2018+)

• <u>3836: FIGO Stage (Sarcoma)</u>

See 00530: Corpus Carcinoma and Carcinosarcoma (2018+)

- <u>3901: Number of Positive Para-Aortic Nodes</u>
- <u>3899: Number of Examined Para-Aortic Nodes</u>
- <u>3902: Number of Positive Pelvic Nodes</u>
- <u>3900: Number of Examined Pelvic Nodes</u>
- <u>3911: Peritoneal Cytology</u>

## 00542: Corpus Adenosarcoma (2018+)

## 3836: FIGO Stage (Adenosarcoma)

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

• 00542: Corpus Adenosarcoma (2018+)

**Note 1:** There must be a statement about FIGO stage from the managing physician in order to code this data item.

- Do **not** code FIGO stage based on the pathology report
- Do not code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do **not** assume it is a FIGO stage

**Note 2:** FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

• Code FIGO grade in the grade fields

**Note 3:** If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

Code	Description
1	FIGO Stage I
1A	FIGO Stage IA
1B	FIGO Stage IB
1C	FIGO Stage IC
2	FIGO Stage II
2A	FIGO Stage IIA
2B	FIGO Stage IIB
3	FIGO Stage III
3A	FIGO Stage IIIA
3B	FIGO Stage IIIB
3C	FIGO Stage IIIC
4	FIGO Stage IV
4A	FIGO Stage IVA
4B	FIGO Stage IVB
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

## 3836: FIGO: Ovary, Fallopian Tube, and Peritoneal Carcinoma

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

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

**Note 1:** There must be a statement about FIGO stage from the managing physician in order to code this data item.

- Do **not** code FIGO stage based on the pathology report
- Do **not** code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do **not** assume it is a FIGO stage

**Note 2:** FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

• Code FIGO grade in the grade fields

**Note 3:** If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

**Note 4:** For High-grade (HGSC) serous tubal intraepithelial carcinoma (STIC) (8441/2), assign the FIGO stage based on the managing physician's documentation of FIGO. (See Note 1).

- If FIGO stage for HGSC or STIC is not documented by the managing physician, code unknown (code 99)
- Do not code 97 (in situ) for HGSC or STIC since FIGO does not have a Stage 0
- If diagnosis is low grade serous intraepithelial carcinoma (LGSC) (8441/2) or serous intraepithelial carcinoma (no grade stated) (8441/2), code 97

**Note 5:** Code 97 for any remaining in situ histologies (/2) since the FIGO stage definitions do not include Stage 0.

Code	Description
1	FIGO Stage I
1A	FIGO Stage IA
1B	FIGO Stage IB
1C	FIGO Stage IC
1C1	FIGO Stage IC1
1C2	FIGO Stage IC2
1C3	FIGO Stage IC3
2	FIGO Stage II
2A	FIGO Stage IIA
2B	FIGO Stage IIB
3	FIGO Stage III

Code	Description
3A	FIGO Stage IIIA
3A1	FIGO Stage IIIA1
3A11	FIGO Stage IIIA1i
3A12	FIGO Stage IIIA1ii
3A2	FIGO Stage IIIA2
3B	FIGO Stage IIIB
3C	FIGO Stage IIIC
4	FIGO Stage IV
4A	FIGO Stage IVA
4B	FIGO Stage IVB
97	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 to <u>Schema ID Table</u>

## 3818: CA-125 Pretreatment Interpretation

Item Length: 1 NAACCR Item #: 3818 XML Parent-NAACCR ID: Tumor-ca125PretreatmentInterpretation NAACCR Alternate Name: CA-125 (Carbohydrate Antigen 125) Pretreatment Interpretation Active years: 2018+ Schema(s):

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

## **Description**

Carbohydrate Antigen 125 (CA-125)/CA-125 II is a tumor marker that is useful for following the response to therapy in patients with ovarian cancer, who may have elevated levels of this marker.

#### **Rationale**

Preoperative CA-125/CA-125 II is a Registry Data Collection Variable listed in AJCC. It was previously collected as Ovary, CS SSF #1.

#### **Definition**

CA-125/CA-125 II is a tumor marker that is not specific to ovarian or primary peritoneal cancer but is useful to monitor for success of treatment and recurrence. Because it can be elevated in many diseases affecting the peritoneal lining of the abdominal and pelvic cavity, it is not a screening test for women who have no history of cancer. Any value over 35 is highly correlated with cancer and about 80% of ovarian cancers show an elevated CA-125/CA-125 II. However, a result in the normal range does not rule out cancer. Values up to 65 U/ml may be considered borderline, and values over 200 are unlikely to be due to a benign condition. CA-125/CA-125 II monitors for success of treatment and recurrence. After obtaining a baseline value prior to treatment, a lower result on a subsequent test indicates a response to treatment, and an increasing value indicates possible recurrence.

#### 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/CA-125 II is reported as negative or normal.
- Code 1 when the CA-125/CA-125 II is reported as positive or elevated.
- Code 2 when the CA-125/CA-125 II is reported as borderline; undetermined whether positive or negative.
- Code 7 when the CA-125/CA-125 II test was ordered but the results are not in the medical record.
- Code 9 when
  - No information in the medical record
  - CA-125/CA-125 II test not done (not assessed)

o Unknown if CA-125/CA-125 II 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, CA 125 II
- Normal reference range
  - < 35 units per milliliter (U/ml); SI: < 35 kiloUnits/Liter (KU/L).
  - $\circ$  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/CA-125 II pretreatment interpretation can be used to code this data item when no other information is available.

**Note 2**: Carbohydrate Antigen 125 (CA-125/CA-125 II), 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/CA-125 II interpretation for this data item. Do not record CA-125 test results based on fluid from the chest or abdominal cavity.

**Note 4**: Record the CA-125/CA-125 II 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/CA-125 II is positive/elevated, negative/normal, and the lab value with its normal range (from which you can determine interpretation) is not documented.

Code	Description
0	Negative/normal; within normal limits
1	Positive/elevated
2	Stated as borderline; undetermined whether positive or negative
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 8 will result in an edit error)
9	Not documented in medical record
	CA-125 not assessed or unknown if assessed

Return to <u>Schema ID Table</u>

## **3921: Residual Tumor Volume Post Cytoreduction**

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

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

## **Description**

Gross residual tumor after primary cytoreductive surgery is a prognostic factor for ovarian cancer and residual tumor volume after cytoreductive surgery is a prognostic factor for late stage ovarian cancers.

#### **Rationale**

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

#### **Definition**

The amount of ovarian tumor and the location of tumor remaining in the patient after initial ovarian or peritoneal cancer surgery are the most important prognostic factors for advanced disease. The intent of cytoreductive or debulking surgery—particularly for Stage III cancer—is to remove as much of the cancer in the pelvis and abdomen as possible so that chemotherapy will be more effective. The less tumor left behind, the more likely the patient will respond well to adjuvant hemotherapy. Information about residual tumor volume will be in the operative report.

#### Additional Information

- **Source documents:** operative report, discharge summary, chemotherapy records (inpatient and outpatient)
- For further information, refer to the **Ovary, Fallopian Tube, or Peritoneum** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Ovary, Fallopian Tube, and Primary Peritoneal Carcinoma*
- Other names: debulking, cytoreduction, residual tumor volume
- **Change for SSDI (effective v2.0):** Further review of this SSDI indicated that the distinction of whether patient had neoadjuvant therapy or not was not needed. The purpose of this data item is to determine the residual tumor left behind. The codes have been redone so that they only collect that information.

## **Coding Instructions and Codes**

**Note 1:** Physician statement of residual tumor status after primary cytoreduction surgery can be used to code this data item when no other information is available.

**Note 2:** Information for this SSDI is found in the operative report, procedure report, or managing physician notes.

**Note 3**: The surgery to remove as much cancer in the pelvis and/or abdomen as possible, reducing the "bulk" of the cancer, is called "debulking" or "cytoreductive" surgery. It is performed when there is widespread evidence of advanced stage of ovarian cancer with obvious spread to other organs outside the ovary, typically in the upper abdomen, intestines, the omentum (the fat pad suspended from the transverse colon like an apron), the diaphragm, or liver.

**Note 4**: Optimal debulking is described as removal of all tumor except for residual nodules that measure no more than 1 centimeter (cm) in maximum diameter.

**Note 5**: Gross residual tumor after primary cytoreductive surgery is a prognostic factor that has been demonstrated in large studies. The best prognostic category after surgery includes those who are left with no gross residual tumor.

• Physicians should record the presence or absence of residual disease, if residual disease is observed, the size of the largest visible lesion should be documented

Code	Description
00	No gross residual tumor nodules
50	Residual tumor nodule(s) 1 centimeter (cm) or less
60	Residual tumor nodule(s) greater than 1 cm
70	Macroscopic residual tumor, size not stated
80	Procedure described as optimal debulking and size of residual tumor nodule(s) not given
97	No cytoreductive surgery performed
	Non-invasive neoplasm (behavior /2)
98	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 98 will result in an edit error.)
99	Not documented in medical record
	Residual tumor status after cytoreductive surgery not assessed or unknown if assessed

## 00552: Primary Peritoneal Carcinoma (2018+)

See 00551: Ovary

- <u>3836: FIGO: Ovary, Fallopian Tube, and Peritoneal Carcinoma</u>
- <u>3818: CA-125 Pretreatment Interpretation</u>
- <u>3921: Residual Tumor Volume Post Cytoreduction</u>

See 00551: Ovary

- <u>3836: FIGO: Ovary, Fallopian Tube, and Peritoneal Carcinoma</u>
- <u>3818: CA-125 Pretreatment Interpretation</u>
- <u>3921: Residual Tumor Volume Post Cytoreduction</u>

## 3836: FIGO: Gestational Trophoblastic Tumors (Placenta)

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

• 00560: Placenta (2018+)

**Note 1:** There must be a statement about FIGO stage from the managing physician in order to code this data item.

- Do **not** code FIGO stage based on the pathology report
- Do **not** code FIGO stage based only on T, N, M
- If "FIGO" is not included with a stated stage, then do **not** assume it is a FIGO stage

**Note 2:** FIGO stage is not the same thing as FIGO grade. Only code FIGO stage in this field, do not code FIGO grade.

• Code FIGO grade in the grade fields

**Note 3:** If there is more than one FIGO stage provided from the clinical and pathological work up, code the most extensive FIGO stage.

Note 4: The FIGO stage definitions do not include Stage 0 (Tis).

• Code 97 for any non-invasive neoplasm (behavior /2)

Code	Description
1	FIGO Stage I
2	FIGO Stage II
3	FIGO Stage III
4	FIGO Stage IV
97	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 to <u>Schema ID Table</u>

## 00560: Placenta (2018+)

## 3837: Gestational Trophoblastic Prognostic Scoring Index

Item Length: 2 NAACCR Item #: 3837 XML Parent-NAACCR ID: Tumor-gestationalTrophoblasticPxIndex NAACCR Alternate Name: None Active years: 2018+ Schema(s): • 00560: Placenta (2018+)

#### **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 8<sup>th</sup> 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) (mIU/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	
X9	Not documented in medical record	
	Prognostic scoring index not assessed, or unknown if assessed	

Return to <u>Schema ID Table</u>

## MALE GENITAL ORGANS

See 00460: Merkel Cell Carcinoma (2018+)

- <u>3830: Extranodal Extension Clin (non-Head and Neck)</u>
- <u>3833: Extranodal Extension Path (non-Head and Neck)</u>

## 3920: PSA (Prostatic Specific Antigen) Lab Value

Item Length: 5 NAACCR Item #: 3920 XML Parent-NAACCR ID: Tumor-psaLabValue NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00580: Prostate (2018+)

#### **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.

#### <u>Rationale</u>

This data item is required for prognostic stage grouping in AJCC 8<sup>th</sup> 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	5.2	PSA lab value closest and prior to the
1/29/2018: PSA 5.2		diagnostic biopsy
2/22/2018: Biopsy positive for adenocarcinoma		
12/19/2017: PSA 44.3	42.8	PSA lab value closest to the initiation of
3/11/2018: PSA 42.8		treatment
5/1/2018: DRE positive for bilateral palpable		
nodularity		
5/5/2018: Casodex initiated without needle core		
biopsy		
2/16/2018: PSA 18.6, adjusted PSA value due to	18.6	Record the adjusted PSA value ONLY if
patient taking Medication for benign prostatic		documented by the clinician in the
hypertrophy		record.
		Registrar does not adjust the PSA value
		due to BPH medication use
1,100 ng/ml	XXX.1	XXX.1 is defined for values of 1,000 or
		greater
No PSA done or unknown if done	XXX.9	Definition of unknown

## **Coding Instructions and Codes**

**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.
- Examples:
  - PSA of 7.2. Code 7.2
  - $\circ$   $\,$  PSA of 10. Code 10.0  $\,$
  - o PSA of 8.56. Code 8.6
  - PSA of 110.35. Code 110.4

**Note 4:** A known lab value takes priority over codes XXX.2 and XXX.3

- The lab value takes priority even if the physician documents the interpretation
- *Example*: Patient noted to have a PSA of 7.6. Physician notes that the value is elevated
  - Code 7.6 instead of XXX.3 (elevated)

**Note 5:** 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.2	Lab value not available, physician states PSA is negative/normal
XXX.3	Lab value not available, physician states PSA is
	positive/elevated/high
XXX.7	Test ordered, results not in chart
XXX.9	Not documented in medical record
	PSA lab value not assessed or unknown if assessed

Return to <u>Schema ID Table</u>

## **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.

- <u>3838: Gleason Patterns Clinical</u>
- <u>3839: Gleason Patterns Pathological</u>
- <u>3840: Gleason Score Clinical</u>
- <u>3841: Gleason Score Pathological</u>
- <u>3842: Gleason Tertiary Pattern</u>

## **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	49	X9
pattern and code unknown (9) in the second digit)		
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	Х9

## **Additional Information**

- **Clinical**: pathology reports from needle biopsies or transurethral resection of prostate/bladder that contains prostate tissue
  - **Pathological**: pathology report from prostatectomy or autopsy report
- For further information, refer to the **Prostate** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Prostate*

Return to <u>Schema ID Table</u>

## 00580: Prostate (2018+)

## **3838: Gleason Patterns Clinical**

Item Length: 2 NAACCR Item #: 3838 XML Parent-NAACCR ID: Tumor-gleasonPatternsClinical NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00580: Prostate (2018+)

## **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 <u>Gleason Patterns and Scores</u> 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 a needle core biopsy, trans rectal ultrasound (TRUS) guided biopsy, or transurethral resection of prostate (TURP) and/or simple prostatectomy in this field.

• Gleason primary and secondary patterns provided for any prostate tissue identified from a transurethral resection of a bladder tumor (TURBT) specimen can also be used in this field.

Note 3: 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 the only information available is the Gleason Score, code the patterns X6 (primary pattern unknown, secondary pattern unknown).

**Note 6:** 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 7:** If multiple procedures are performed (e.g., needle core biopsy, trans rectal ultrasound (TRUS) guided biopsy, transurethral resection of prostate (TURP), and/or simple prostatectomy), code the pattern that reflects the highest score.

Note 8: Do not infer Gleason Primary and Secondary Pattern from Grade Group (Code X9).

Code	Description
11	Primary pattern 1, secondary pattern 1
12	Primary pattern 1, secondary pattern 2
13	Primary pattern 1, secondary pattern 3
14	Primary pattern 1, secondary pattern 4
15	Primary pattern 1, secondary pattern 5
19	Primary pattern 1, secondary pattern unknown
21	Primary pattern 2, secondary pattern 1
22	Primary pattern 2, secondary pattern 2
23	Primary pattern 2, secondary pattern 3
24	Primary pattern 2, secondary pattern 4
25	Primary pattern 2, secondary pattern 5
29	Primary pattern 2, secondary pattern unknown
31	Primary pattern 3, secondary pattern 1
32	Primary pattern 3, secondary pattern 2
33	Primary pattern 3, secondary pattern 3
34	Primary pattern 3, secondary pattern 4
35	Primary pattern 3, secondary pattern 5
39	Primary pattern 3, secondary pattern unknown
41	Primary pattern 4, secondary pattern 1
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

Note 9: The clinical score is recorded in <u>3840: Gleason Score Clinical</u>.

Code	Description
52	Primary pattern 5, secondary pattern 2
53	Primary pattern 5, secondary pattern 3
54	Primary pattern 5, secondary pattern 4
55	Primary pattern 5, secondary pattern 5
59	Primary pattern 5, secondary pattern unknown
X6	TURP and/or Biopsy done, primary pattern unknown, secondary pattern unknown
X7	No needle core biopsy/TURP performed
X8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code X8 may result in an edit
	error.)
X9	Not documented in medical record
	Gleason Patterns Clinical not assessed or unknown if assessed
	Unknown whether TURP and/or Biopsy done

## **3840: Gleason Score Clinical**

Item Length: 2 NAACCR Item #: 3840 XML Parent-NAACCR ID: Tumor-gleasonScoreClinical NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00580: Prostate (2018+)

## **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 <u>Gleason Patterns and Scores</u> 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 a needle core biopsy, trans rectal ultrasound (TRUS) guided biopsy, transurethral resection of prostate (TURP), and/or simple prostatectomy in this field.

• Gleason primary and secondary patterns provided for any prostate tissue identified from a transurethral resection of a bladder tumor (TURBT) specimen can also be used in this field.

**Note 3:** 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 multiple procedures are performed (e.g., needle core biopsy, trans rectal ultrasound (TRUS) guided biopsy, transurethral resection of prostate (TURP), and/or simple prostatectomy), code the 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 <u>3838: Gleason Patterns Clinical</u>.

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

## 3839: Gleason Patterns Pathological

Item Length: 2 NAACCR Item #: 3839 XML Parent-NAACCR ID: Tumor-gleasonPatternsPathological NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00580: Prostate (2018+)

## **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 <u>Gleason Patterns and Scores</u> 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 a radical prostatectomy or autopsy only in this field. Unlike Grade Group Pathological, do not include patterns from tissues taken prior to a radical prostatectomy.

• Code results from a transurethral resection of prostate (TURP) or simple prostatectomy in Gleason Patterns Clinical

**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 the only information available is the Gleason Score, code the patterns X6 (primary pattern unknown, secondary pattern unknown).

**Note 5:** If different patterns are documented on multiple specimens, code the pattern that reflects the highest or most aggressive score regardless if the pathologist provides and overall pattern in a final summary. If different patterns equal the same high score, give priority to the highest primary pattern and then the highest secondary pattern.

**Note 6:** If neoadjuvant therapy was given, code Gleason pathological patterns as X9.

Note 7: Do not infer Gleason Primary and Secondary Pattern from Grade Group (Code X9).

**Note 8:** If a tertiary pattern is documented on prostatectomy or autopsy, code in <u>3842: Gleason Tertiary</u> <u>Pattern</u>.

**Note 9:** The pathological score is recorded in <u>3841: Gleason Score Pathological</u>.

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

Code	Description
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	Prostatectomy done, primary pattern unknown, secondary pattern unknown
X7	No radical prostatectomy/autopsy performed
X8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code X8 may result in an edit
	error.)
X9	Not documented in medical record
	Gleason Patterns Pathological not assessed or unknown if assessed
	Unknown if radical prostatectomy done

## 3841: Gleason Score Pathological

Item Length: 2 NAACCR Item #: 3841 XML Parent-NAACCR ID: Tumor-gleasonScorePathological NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00580: Prostate (2018+)

## **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 <u>Gleason Patterns and Scores</u> 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 a radical prostatectomy or autopsy only in this field. Unlike Grade Group Pathological, do not include patterns from tissues taken prior to a radical prostatectomy.

• Code results from a transurethral resection of prostate (TURP) or simple prostatectomy in Gleason Score Clinical

**Note 3:** 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).

**Note 6**: Record the Gleason score based on the addition of the primary and secondary patterns coded in <u>3839</u>: <u>Gleason Patterns Pathological</u>.

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 radical prostatectomy done/autopsy performed
X8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code X8 may result in an edit
	error.)
X9	Not documented in medical record
	Gleason Score Pathological not assessed or unknown if assessed
	Unknown if radical prostatectomy done

## 3842: Gleason Tertiary Pattern

Item Length: 2 NAACCR Item #: 3842 XML Parent-NAACCR ID: Tumor-gleasonTertiaryPattern NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00580: Prostate (2018+)

## **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 <u>Gleason Patterns and Scores</u> 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 radical prostatectomy or autopsy only. Record the tertiary pattern prior to neoadjuvant treatment.

- If a tertiary pattern is documented on needle core biopsy or transurethral resection of prostate (TURP), it should be disregarded
- Do not code the tertiary pattern on radical prostatectomy or autopsy in Gleason Patterns Pathological

**Note 4:** The CAP Prostate protocol does not include Patterns 1 and 2 for Tertiary Pattern.

Code	Description
10	Tertiary pattern 1
20	Tertiary pattern 2
30	Tertiary pattern 3
40	Tertiary pattern 4
50	Tertiary pattern 5
X7	No radical prostatectomy/autopsy performed
X8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code X8 may result in an edit error.)
X9	Not documented in medical record
	Gleason Tertiary Pattern not assessed or unknown if assessed

## **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.

- <u>3897: Number of Cores Examined</u>
- <u>3898: Number of Cores Positive</u>

*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

- **Clinical**: pathology reports from needle biopsies or transurethral resection of prostate/bladder that contains prostate tissue
- For further information, refer to the **Prostate** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Prostate*
- **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.

## **3898: Number of Cores Positive**

Item Length: 2 NAACCR Item #: 3898 XML Parent-NAACCR ID: Tumor-numberOfCoresPositive NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00580: Prostate (2018+)

## **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 <u>Number of Cores Positive and Examined</u> 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.

• Information from the first core biopsy is preferred since the physician is usually examining the entire prostate. If a second core biopsy is done, this is usually done on a specified area, so more cores will be found to be positive

**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.

- Do not include cores of other area like seminal vesicles
- Information from the gross description of the core biopsy pathology report can be used to code this data item when the gross findings provide the actual number of cores and not pieces, chips, fragments, etc.

**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).

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

Note 5: The number of cores examined is recorded in <u>3897: Number of Cores Examined</u>.

## 3897: Number of Cores Examined

Item Length: 2 NAACCR Item #: 3897 XML Parent-NAACCR ID: Tumor-numberOfCoresExamined NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00580: Prostate (2018+)

## **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 <u>Number of Cores Positive and Examined</u> 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.

• Information from the first core biopsy is preferred since the physician is usually examining the entire prostate. If a second core biopsy is done, this is usually done on a specified area, so more cores will be found to be positive

**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.

• Do not include cores of other area like seminal vesicles

• Information from the gross description of the core biopsy pathology report can be used to code this data item when the gross findings provide the actual number of cores and not pieces, chips, fragments, etc.

**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).

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

Note 5: The number of cores positive is recorded in <u>3898: Number of Cores Positive</u>.

## **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

- <u>3807: AFP Pre-Orchiectomy Lab Value</u>
- <u>3808: AFP Pre-Orchiectomy Range</u>
- <u>3848: hCG Pre-Orchiectomy Lab Value</u>
- <u>3849: hCG Pre-Orchiectomy Range</u>
- <u>3868: LDH Pre-Orchiectomy Range</u>
- <u>3923: S Category Clinical</u>

## For pathological staging

- <u>3805: AFP Post-Orchiectomy Lab Value</u>
- <u>3806: AFP Post-Orchiectomy Range</u>
- <u>3846: hCG Post-Orchiectomy Lab Value</u>
- <u>3847: hCG Post-Orchiectomy Range</u>
- <u>3867: LDH Post-Orchiectomy Range</u>
- <u>3924: S Category Pathological</u>

In **Collaborative Stage v2 (CSv2**), the "ranges" were used to derive the S category. New data items for AJCC 8<sup>th</sup> edition is for the assignment of the S category in addition to collecting the individual data items.

## 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.

- <u>3805: AFP Post-Orchiectomy Lab Value</u>
- <u>3806: AFP Post-Orchiectomy Range</u>
- <u>3807: AFP Pre-Orchiectomy Lab Value</u>
- <u>3808: AFP Pre-Orchiectomy Range</u>

#### **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
270 ug/l	270.0	1
	(ng/ml = ug/L)	
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	XXXXX.9	4
documented		
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
- For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*
- ο **Other names:**  $\alpha$ FP, aFP, Alpha Fetoprotein, Alpha-fetoprotein,  $\alpha$ -fetoprotein; fetal alpha globulin
- Normal Reference Range: Adult men 0-15 ng/ml (SI: 0-15  $\mu$ g/L)
- **Measurements:** micrograms/liter ( $\mu$ g/L or ug/L) is equivalent to nanograms per milliliter (ng/ml)
  - If measurements are given in IU/ml, use the following conversion:
    - 1 ng/mL = 0.83 IU/mL
      - To calculate ng from IU/mL, divide the value for IU by 0.83.
      - Example: 10 IU/mL: 10/0.83 = 12.04 ng/mL; 5 IU/mL: 5/0.83= 6.02 ng/mL

#### 3807: AFP Pre-Orchiectomy Lab Value

Item Length: 7 NAACCR Item #: 3807 XML Parent-NAACCR ID: Tumor-afpPreOrchiectomyLabValue NAACCR Alternate Name: AFP (Alpha Fetoprotein) Pre-Orchiectomy Lab Value Active years: 2018+ Schema(s):

• 00590: Testis (2018+)

#### **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: If the lab value is expressed in IU/ml, use the following conversion: 1 ng/mL = 0.83 IU/mL.

- To calculate ng from IU/mL, divide the value for IU by 0.83.
- *Example*: 10 IU/mL: 10/0.83 = 12.04 ng/mL; 5 IU/mL: 5/0.83 = 6.02 ng/mL

**Note 5:** The same laboratory test should be used to record information in <u>3808: AFP Pre-Orchiectomy</u> <u>Range</u>.

Code	Description
0.0	0.0 nanograms/milliliter (ng/mL)
0.1-	0.1 – 99,999.9 ng/mL
99999.9	
XXXXX.1	100,000 ng/mL or greater
XXXXX.7	Test ordered, results not in chart

Code	Description
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

## 3808: AFP Pre-Orchiectomy Range

Item Length: 1 NAACCR Item #: 3808 XML Parent-NAACCR ID: Tumor-afpPreOrchiectomyRange NAACCR Alternate Name: AFP (Alpha Fetoprotein) Pre-Orchiectomy Range Active years: 2018+ Schema(s):

• 00590: Testis (2018+)

## **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 <u>Alpha-fetoprotein (AFP) (Testis)</u> 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: If the lab value is expressed in IU/ml, use the following conversion: 1 ng/mL = 0.83 IU/mL.

- To calculate ng from IU/mL, divide the value for IU by 0.83.
- *Example*: 10 IU/mL: 10/0.83 = 12.04 ng/mL; 5 IU/mL: 5/0.83= 6.02 ng/mL

**Note 5:** The same laboratory test should be used to record information in <u>3807: AFP Pre-Orchiectomy</u> <u>Lab Value</u>.

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

Code	Description
4	Pre-Orchiectomy alpha fetoprotein (AFP) stated to be elevated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record
	AFP (Alpha Fetoprotein) Pre-Orchiectomy Range not assessed or unknown if assessed

#### 3805: AFP Post-Orchiectomy Lab Value

Item Length: 7 NAACCR Item #: 3805 XML Parent-NAACCR ID: Tumor-afpPostOrchiectomyLabValue NAACCR Alternate Name: AFP (Alpha Fetoprotein) Post-Orchiectomy Lab Value Active years: 2018+ Schema(s):

• 00590: Testis (2018+)

#### **Description**

AFP (Alpha Fetoprotein) Post-Orchiectomy Lab Value refers to the lowest AFP value measured postorchiectomy. 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 lab value is expressed in IU/ml, use the following conversion: 1 ng/mL = 0.83 IU/mL.

- To calculate ng from IU/mL, divide the value for IU by 0.83.
- *Example*: 10 IU/mL: 10/0.83 = 12.04 ng/mL; 5 IU/mL: 5/0.83= 6.02 ng/mL

**Note 6:** 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 7: If the only information available is a statement of elevated or normal, code XXXXX.9.

**Note 8:** The same laboratory test should be used to record information in <u>3806: AFP Post-Orchiectomy</u> <u>Range</u>.

Code	Description
0.0	0.0 nanograms/milliliter (ng/mL)
0.1-	0.1 – 99,999.9 ng/mL
99999.9	
XXXXX.1	100,000 ng/mL or greater
XXXXX.7	Test ordered, results not in chart
XXXXX.8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code XXXXX.8 may result
	in an edit error.)
XXXXX.9	Not documented in medical record
	No orchiectomy performed
	AFP (Alpha Fetoprotein) Post-Orchiectomy Lab Value not assessed or unknown if
	assessed

#### 3806: AFP Post-Orchiectomy Range

Item Length: 1 NAACCR Item #: 3806 XML Parent-NAACCR ID: Tumor-afpPostOrchiectomyRange NAACCR Alternate Name: AFP (Alpha Fetoprotein) Post-Orchiectomy Range Active years: 2018+ Schema(s):

• 00590: Testis (2018+)

#### **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 <u>Alpha-fetoprotein (AFP) (Testis)</u> 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 lab value is expressed in IU/ml, use the following conversion: 1 ng/mL = 0.83 IU/mL.

- To calculate ng from IU/mL, divide the value for IU by 0.83.
- *Example*: 10 IU/mL: 10/0.83 = 12.04 ng/mL; 5 IU/mL: 5/0.83= 6.02 ng/mL

**Note 6:** If the pre-orchiectomy AFP was normal, a post-orchiectomy AFP may not be performed. In this case, code 5 should be recorded.

**Note 7:** The same laboratory test should be used to record information in <u>3805: AFP Post-Orchiectomy</u> <u>Lab Value</u>.

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	Post-Orchiectomy alpha fetoprotein (AFP) stated to be elevated
5	Post-Orchiectomy alpha fetoprotein (AFP) unknown or not done but pre-orchiectomy AFP was
	normal
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code 8 may result in an edit
	error.)
9	Not documented in medical record
	No orchiectomy performed
	AFP (Alpha Fetoprotein) Post-Orchiectomy Range not assessed or unknown if assessed

## 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.

- <u>3846: hCG Post-Orchiectomy Lab Value</u>
- <u>3847: hCG Post-Orchiectomy Range</u>
- <u>3848: hCG Pre-Orchiectomy Lab Value</u>
- <u>3849: hCG Pre-Orchiectomy Range</u>

## **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
- For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*
- **Other names:** Human chorionic gonadotropin, b-hCG, beta subunit HCG, beta hCG,  $\beta$ -hCG
- Normal Reference Range
  - $\circ$  < 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/mI)

## 3848: hCG Pre-Orchiectomy Lab Value

Item Length: 7 **NAACCR Item #: 3848** XML Parent-NAACCR ID: Tumor-hcgPreOrchiectomyLabValue NAACCR Alternate Name: hCG (Human Chorionic Gonadotropin) Pre-Orchiectomy Lab Value Active years: 2018+ Schema(s):

00590: Testis (2018+)

## 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 <u>3849: hCG Pre-Orchiectomy</u> Range.

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

## 3849: hCG Pre-Orchiectomy Range

Item Length: 1 NAACCR Item #: 3849 XML Parent-NAACCR ID: Tumor-hcgPreOrchiectomyRange NAACCR Alternate Name: hCG Schema(s):

• 00590: Testis (2018+)

#### **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 <u>Human Chorionic Gonadotropin (hCG) (Testis)</u> 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 <u>3848: hCG Pre-Orchiectomy</u> <u>Lab Value</u>.

Code	Description
0	Within normal limits
1	Above normal and less than 5,000 milli-International Units/milliliter (mIU/mL)
2	5,000 - 50,000 mIU/mL
3	Greater than 50,000 mIU/mL
4	Pre-orchiectomy human chorionic gonadotropin (hCG) stated to be elevated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code 8 may result in an edit error.)
9	Not documented in medical record
	hCG pre-orchiectomy range not assessed or unknown if assessed

#### 3846: hCG Post-Orchiectomy Lab Value

Item Length: 7 NAACCR Item #: 3846 XML Parent-NAACCR ID: Tumor-hcgPostOrchiectomyLabValue NAACCR Alternate Name: hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Lab Value Active years: 2018+ Schema(s):

00590: Testis (2018+)

#### 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 <u>Human Chorionic Gonadotropin (hCG) (Testis)</u> 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 <u>3847: hCG Post-Orchiectomy</u> Range.

Code	Description
0.0	0.0 milli-International Units/milliliter (mIU/mL)
0.1-	0.1 – 99,999.9 mIU/mL
99999.9	
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

## 3847: hCG Post-Orchiectomy Range

Item Length: 1 NAACCR Item #: 3847 XML Parent-NAACCR ID: Tumor-hcgPostOrchiectomyRange NAACCR Alternate Name: hCG (Human Chorionic Gonadotropin) Post-Orchiectomy Range Active years: 2018+ Schema(s):

• 00590: Testis (2018+)

## **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 <u>Human Chorionic Gonadotropin (hCG) (Testis)</u> 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 5 should be recorded.

**Note 6:** The same laboratory test should be used to record information in <u>3846: hCG Post-Orchiectomy</u> <u>Lab Value</u>.

Code	Description
0	Within normal limits
1	Above normal and less than 5,000 milli-International Units/milliliter (mIU/mL)
2	5,000 - 50,000 mIU/mL
3	Greater than 50,000 mIU/mL
4	Post-orchiectomy human chorionic gonadotropin (hCG) stated to be elevated
5	Post-Orchiectomy human chorionic gonadotropin (hCG) unknown or not done but pre-
	orchiectomy hCG was normal
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

## 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.

- <u>3867: LDH Post-Orchiectomy Range</u>
- <u>3868: LDH Pre-Orchiectomy Range</u>

#### **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 lowest LDH **after orchiectomy** but prior to adjuvant treatment. If the first postorchiectomy 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).

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)

Categories used for Pre- and Post-Orchiectomy LDH Range are:

Code	Description
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	0
(within normal range 100-225)	
282	1
(elevated but less than 337.5)	
1081	2
(elevated and between 337.5 and 2250)	
2795	3
(elevated and greater than 2250)	
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

## 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
- For further information, refer to the **Testis** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Testis*
- Other names: LD, Lactate dehydrogenase, lactase dehydrogenase, lactic acid dehydrogenase
- Normal reference range: varies widely by laboratory, patient age, and the units of measurement.

## 3868: LDH Pre-Orchiectomy Range

Item Length: 1 NAACCR Item #: 3868 XML Parent-NAACCR ID: Tumor-IdhPreOrchiectomyRange NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Pre-Orchiectomy Range Active years: 2018+ Schema(s):

• 00590: Testis (2018+)

## **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
	LDH (Lactate Dehydrogenase) Pre-Orchiectomy Range not assessed or unknown if assessed

## 3867: LDH Post-Orchiectomy Range

Item Length: 1 NAACCR Item #: 3867 XML Parent-NAACCR ID: Tumor-IdhPostOrchiectomyRange NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Post-Orchiectomy Range Active years: 2018+ Schema(s):

00590: Testis (2018+)

## **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 5 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)

Code	Description	
3	Greater than 10 x N	
	(Greater than 10 times the upper limit of normal for LDH)	
4	Post-Orchiectomy lactate dehydrogenase (LDH) range stated to be elevated	
5	Post-Orchiectomy lactage dehydrogenase (LDH) unknown or not done but pre-orchiectomy	
	LDH was normal	
7	Test ordered, results not in chart	
8	Not applicable: Information not collected for this case	
	(If this information is required by your standard setter, use of code 8 may result in an edit	
	error.)	
9	Not documented in medical record	
	No orchiectomy performed	
	LDH (Lactate Dehydrogenase) Post-Orchiectomy Range not assessed or unknown if assessed	

Return to <u>Schema ID Table</u>

## 00590: Testis (2018+)

## **3923: S Category Clinical**

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

• 00590: Testis (2018+)

### **Description**

S Category Clinical combines the results of pre-orchiectomy Alpha Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG) and Lactate Dehydrogenase (LDH) into a summary S value.

### **Rationale**

S Category Clinical is required for prognostic stage grouping in Chapter 59 *Testis*. It is a new data item for cases diagnosed 1/1/2018+.

### **Additional Information**

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

#### **Coding Instructions and Codes**

**Note 1:** Code the S category as described by the physician. If the S category determined by available lab values or calculated by vendor software differs from the physician statement of the S category, the physician's statement takes precedence.

**Note 2:** Code the pre-orchiectomy S category according to the table below. This table is also available in AJCC 8<sup>th</sup> edition, Chapter 59, *Testis*.

• For AFP, a lab value expressed in micrograms per liter (ug/L) is equivalent to the same value expressed in nanograms per milliliter (ng/ml).

**Note 3:** Clinical stage values are those based on physician statement or lab values at diagnosis, prior to orchiectomy, and prior to any systemic treatment.

**Note 4:** All three lab values are needed for S0-S1. Only one elevated test is needed to assign S2-3. If any individual test is not available and none of the available tests results meets the S2-3 criterion for that test, assign code 9 (SX).

Code	Description
0	S0: Marker study levels within normal levels
1	S1: At least one of these values is elevated AND
	LDH less than 1.5 x N* AND
	hCG (mIU/L) less than 5,000 AND
	AFP (ng/mL) less than 1,000
2	S2:
	LDH 1.5 x N* to 10 x N* OR
	hCG (mIU/L) 5,000 to 50,000 OR
	AFP (ng/mL) 1,000 to 10,000
3	S3: Only one elevated test is needed
	LDH greater than 10 x N* OR
	hCG (mIU/mL) greater than 50,000 OR
	AFP (ng/mL) greater than 10,000
9	SX: Not documented in medical record
	S Category Clinical not assessed or unknown if assessed

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

Return to <u>Schema ID Table</u>

## 00590: Testis (2018+)

## **3924: S Category Pathological**

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

• 00590: Testis (2018+)

### **Description**

S Category Pathological combines the results of post-orchiectomy Alpha Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG) and Lactate Dehydrogenase (LDH) into a summary S value.

### Rationale

S Category Pathological is required for prognostic stage grouping in AJCC 8<sup>th</sup> edition, Chapter 59 *Testis*. It is a new data item for cases diagnosed 1/1/2018+.

### **Additional Information**

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

#### **Coding Instructions and Codes**

**Note 1:** Code the S category as described by the physician. If the S category determined by available lab values or calculated by vendor software differs from the physician statement of the S category, the physician's statement takes precedence.

**Note 2:** Code the post-orchiectomy S category according to the table below. This table is also available in AJCC 8<sup>th</sup> edition, Chapter 59, *Testis*.

• For AFP, a lab value expressed in micrograms per liter (ug/L) is equivalent to the same value expressed in nanograms per milliliter (ng/ml).

**Note 3:** Pathological stage values are those based on physician statement or lab values after orchiectomy and prior to adjuvant therapy.

**Note 4:** If the initial post-orchiectomy lab values remain elevated, review the subsequent tests and use the lowest lab values (normalization or plateau) prior to adjuvant therapy or before the value rises again.

**Note 5:** All three lab values are needed for S0-S1. Only one elevated test is needed to assign S2-3. If any individual test is not available and none of the available tests results meets the S2-3 criterion for that test, assign code 9 (SX).

**Note 6:** When all the serum tumor markers are normal pre-orchiectomy and they are not repeated postorchiectomy, code 5.

Code	Description
0	S0: Marker study levels within normal levels
1	S1: At least one of these values is elevated AND
	LDH less than 1.5 x N* AND
	hCG (mIU/L) less than 5,000 AND
	AFP (ng/mL) less than 1,000
2	S2
	LDH 1.5 x N* to 10 x N* OR
	hCG (mIU/L) 5,000 to 50,000 OR
	AFP (ng/mL) 1,000 to 10,000
3	S3: Only one elevated test is needed
	LDH greater than 10 x N* OR
	hcG (mIU/mL) greater than 50,000 OR
	AFP (ng/mL) greater than 10,000
5	Post-orchiectomy serum tumor markers unknown or not done but pre-orchiectomy
	serum tumor markers were normal
9	SX: Not documented in medical record
	S Category Pathological not assessed or unknown if assessed

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

**URINARY TRACT** 

## 3864: Invasion Beyond Capsule

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

• 00600: Kidney (2018+)

### **Description**

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

### **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
  - If surgical resection is done and tumor is "confined to kidney" and staging is based on size, then there has been no invasion through the capsule (no invasion into perinephric fat)
- 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
  - Synonyms include: renal hilum, renal sinus fat, medial invasion
- 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
  - $\circ$   $\;$  Evaluation of capsule invasion not done or unknown if done

## Additional Information

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

• If surgical resection is done and tumor is "confined to kidney" and staging is based on size, then there has been no invasion through the capsule (no invasion into perinephric fat)

**Note 3:** Perinephric/sinus fat invasion should be confirmed microscopically and is invasion into fat by tumor cells, with or without desmoplastic reaction, and vascular invasion into perinephric/sinus soft tissue.

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

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

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

**Note 6:** Code 9 if surgical resection of the primary site is performed and there is no mention of invasion beyond capsule.

Code	Description
0	Invasion beyond capsule not identified
1	Perinephric (beyond renal capsule) fat or tissue
2	Renal sinus
3	Gerota's fascia
4	Any combination of codes 1-3
5	Invasion beyond capsule, NOS
8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code 8 may result in an edit
	error.)
9	Not documented in medical record
	Invasion beyond capsule not assessed or unknown if assessed
	No surgical resection of primary site is performed

## Return to <u>Schema ID Table</u>

## 00600: Kidney Parenchyma (2018+)

### 3886: Major Vein Involvement

Item Length: 1 NAACCR Item #: 3886 XML Parent-NAACCR ID: Tumor-majorVeinInvolvement NAACCR Alternate Name: None Active years: 2018+ Schema(s): • 00600: Kidney

#### Description

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

#### **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
  - If surgical resection is done and tumor is "confined to kidney" and staging is based on size, then there is no involvement of major veins
- 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
  - o There is no documentation in the medical record
  - Clinical diagnosis only
  - Evaluation of major vein involvement not done or unknown if done

## Additional Information

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

• If surgical resection is done and tumor is "confined to kidney" and staging is based on size, then there is no involvement of major veins

**Note 3:** Record the involvement of specific named veins as documented in the pathology report. Do not code invasion of small unnamed vein(s) of the type collected as lymph-vascular invasion. Lymph-vascular invasion is usually only seen microscopically.

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

**Note 5:** Code 9 if surgical resection of the primary site is performed and there is no mention of major vein involvement.

Code	Description
0	Major vein involvement not present/not identified
1	Renal vein or its segmental branches
2	Inferior vena cava (IVC)
3	Major vein invasion, NOS
4	Any combination of codes 1-3
8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code 8 may result in an edit
	error.)
9	Not documented in medical record
	Vein involvement not assessed or unknown if assessed
	No surgical resection of primary site is performed

## 3861: Ipsilateral Adrenal Gland Involvement

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

• 00600: Kidney (2018+)

### **Description**

Ipsilateral adrenal gland involvement pertains to direct extension of the tumor into the ipsilateral adrenal gland (continuous) or ipsilateral adrenal gland involvement by a separate nodule (discontiguous).

### **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
  - If surgical resection is done and tumor is "confined to kidney" and staging is based on size, then there is no involvement of the adrenal gland
- 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
- For further information, refer to the **Kidney** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Kidney*
- **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.

• If surgical resection is done and tumor is "confined to kidney" and staging is based on size, then there is no involvement of the adrenal gland

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

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

**Note 5:** Code 9 if surgical resection of the primary site is performed and there is no mention of ipsilateral adrenal gland involvement.

Code	Description
0	Ipsilateral adrenal gland involvement not present/not identified
1	Adrenal gland involvement by direct involvement (contiguous involvement)
2	Adrenal gland involvement by separate nodule (discontiguous involvement)
3	Combination of code 1-2
4	Ipsilateral adrenal gland involvement, unknown if direct involvement or separate nodule
8	Not applicable: Information not collected for this case
	(If this information is required by your standard setter, use of code 8 may result in an edit
	error.)
9	Not documented in medical record
	Ipsilateral adrenal gland not resected
	Ipsilateral adrenal gland involvement not assessed or unknown if assessed
	No surgical resection of primary site is performed

## Return to <u>Schema ID Table</u>

## 00600: Kidney Parenchyma (2018+)

### **3925: Sarcomatoid Features**

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

• 00600: Kidney (2018+)

#### **Description**

Sarcomatoid features: present or absent and percentage refers to the observation of sheets and fascicles of malignant spindle cells in a kidney tumor which can occur across all histologic subtypes. The percentage of sarcomatoid component has been shown to correlate with cancer-specific mortality.

#### **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 Sarcomatoid features 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 XX5 when the only information available about Sarcomatoid features is from a metastatic site
- 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

- For further information, refer to the **Kidney** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Kidney*
- **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:** Sarcomatoid features is mostly seen with renal cell carcinoma (all variants); however, if it's seen with other histologies, it can be coded.

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

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

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

**Note 7:** Code XX9 if surgical resection of the primary site is performed and there is no mention of sarcomatoid features.

Code	Description	
000	Sarcomatoid features not present/not identified	
001-100	Sarcomatoid features 1-100%	
R01	Sarcomatoid features stated as less than 10%	
R02	Sarcomatoid features stated as range 10%-30% present	
R03	Sarcomatoid features stated as a range 31% to 50% present	
R04	Sarcomatoid features stated as a range 51% to 80% present	
R05	Sarcomatoid features stated as greater than 80%	
XX5	Sarcomatoid features present from metastatic site only AND	
	Sarcomatoid features not present, or unknown if present, in primary site	
XX6	Sarcomatoid features present, percentage unknown	
XX7	Not applicable: Not a renal cell carcinoma morphology	
XX8	Not applicable: Information not collected for this case	
	(If this information is required by your standard setter, use of code XX8 may result in an	
edit error.)		
XX9	Not documented in medical record	
	Sarcomatoid features not assessed or unknown if assessed	
	No surgical resection of primary site is performed	

## 3926: Schema Discriminator 1: Urethra/Prostatic Urethra

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

- 00631: Urethra (2018+)
- 00633: Urethra-Prostatic (2018+)

### **Definition**

Urethra (male and female) and prostatic urethra have the same ICD-O topography code (C680). However, for purposes of stage grouping AJCC 8<sup>th</sup> 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.

- 00631: Urethra (see code 1)
  - Subsites include: Urethra, NOS; Urethral gland, Cowper gland
- 00633: Urethra-Prostatic Urethra (see code 2)
  - Subsites include: Prostatic urethra, Prostatic utricle

Code	Description	Schema ID#/Description
1	Male penile urethra	00631: Urethra
	Female urethra	
	Urethral gland	
	Cowper gland	
	Urethra, NOS	
2	Males only	00633: Urethra-Prostatic
	Prostatic urethra	
	Prostatic utricle	

## 00633: Urethra-Prostatic (2018+)

See 00631: Urethra (2018+)

• <u>3926: Schema Discriminator 1: Urethra/Prostatic Urethra</u>

## **OPHTHALMIC SITES**

## 00640: Skin Eyelid (2018+)

## **3909: Perineural Invasion**

Item Length: 1 NAACCR Item #: 3909 XML Parent-NAACCR ID: Tumor-perineuralInvasion NAACCR Alternate Name: None Active years: 2018+ AJCC 8th Edition Chapter(s):

- Chapter 15: Cutaneous Carcinoma of the Head and Neck (2018+)
- Chapter 20: Colon and Rectum (2018+)
- Chapter 64: Eyelid Carcinoma (2018+)
- Chapter 69: Lacrimal Gland (2018+)

### **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
- 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 <u>statement</u> 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.

**Note 3:** Information on **presence** of perineural invasion can be taken from either a biopsy or resection. Absence of perineural invasion can only be taken from a surgical resection pathology report.

**Note 4:** Code 9 if surgical resection of the primary site is performed and there is no mention of perineural invasion.

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

00660: Melanoma Conjunctiva (2018+)

See 00671: Melanoma Iris (2018+)

• <u>3888: Measured Thickness</u>

## 3926: Schema Discriminator 1: Melanoma Ciliary Body/Melanoma Iris

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

- 00671: Melanoma Iris (2018+)
- 00672: Melanoma Choroid and Ciliary Body (2018+)

### Definition

Iris and ciliary body have the same ICD-O topography code (C694). However, for purposes of stage grouping AJCC 8<sup>th</sup> 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.

- 00672: Melanoma Choroid and Ciliary Body (see code 1)
  - Subsites include: Ciliary body, crystalline lens, sclera, uveal tract, intraocular, eyeball
- 00671: Melanoma Iris (see code 2)
  - Subsite includes: Iris

Code	Description	Schema ID#/Description
1	Ciliary Body	00672: Melanoma Choroid and Ciliary Body
	Crystalline lens	
	Sclera	
	Uveal tract	
	Intraocular	
	Eyeball	
2	Iris	00671: Iris

### Return to <u>Schema ID Table</u>

## 00671: Melanoma Iris (2018+)

### 3821: Chromosome 3 Status

Item Length: 1 NAACCR Item #: 3821 XML Parent-NAACCR ID: Tumor-chromosome3Status NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00671: Melanoma Iris (2018+)
- 00672: Melanoma Choroid and Ciliary Body (2018+)

#### **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, specialty/reference lab report, gene expression profile report, other statement in medical record
- For further information, refer to the **Uveal Melanoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Uveal Melanoma*
- **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 <u>3822: Chromosome 8g Status</u>.

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 to <u>Schema ID Table</u>

## 00671: Melanoma Iris (2018+)

### 3822: Chromosome 8q Status

Item Length: 1 NAACCR Item #: 3822 XML Parent-NAACCR ID: Tumor-chromosome8qStatus NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00671: Melanoma Iris (2018+)
- 00672: Melanoma Choroid and Ciliary Body (2018+)

#### **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, specialty/reference lab report, gene expression profile report, other statement in medical record

- For further information, refer to the **Uveal Melanoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Uveal Melanoma*
- 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 <u>3821: Chromosome 3 Status</u>.

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

### 00671: Melanoma Iris (2018+)

### 3834: Extravascular Matrix Patterns

Item Length: 1 NAACCR Item #: 3834 XML Parent-NAACCR ID: Tumor-extravascularMatrixPatterns NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00671: Melanoma Iris (2018+)
- 00672: Melanoma Choroid and Ciliary Body (2018+)

#### **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, confocal indocyanine green angiography report, clinician comment
- For further information, refer to the **Uveal Melanoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Uveal Melanoma*

### **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

## 00671: Melanoma Iris (2018+)

### 3887: Measured Basal Diameter

Item Length: 4 NAACCR Item #: 3887 XML Parent-NAACCR ID: Tumor-measuredBasalDiameter NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00671: Melanoma Iris (2018+)
- 00672: Melanoma Choroid and Ciliary Body (2018+)

#### **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 a uveal tumor becomes larger, the risk of hematogenous metastases and death increases. In addition, knowing the size of the melanoma is important for treatment planning.

Per the CAP guidelines for Uveal Melanoma, "in clinical practice, the largest tumor basal diameter may be estimated in optic disc diameters (dd, average: 1 dd = 1.5 mm). Techniques such as ultrasonography and fundus photography are used to provide more accurate measurement. When histopathological measurements are recorded after fixation, tumor diameter and thickness may be underestimated because of tissue shrinkage."

#### Additional Information

- **Source documents**: high-frequency ultrasonography (ultrasound biomicroscopy) report, pathology report, wide-angle fundus camera measurement, clinician report or other documentation in medical record
- For further information, refer to the **Uveal Melanoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Uveal Melanoma*
- **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

## 00671: Melanoma Iris (2018+)

### **3888: Measured Thickness**

Item Length: 4 NAACCR Item #: 3888 XML Parent-NAACCR ID: Tumor-measuredThickness NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00671: Melanoma Iris (2018+)
- 00672: Melanoma Choroid and Ciliary Body (2018+)

### **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

- **Source documents:** high-frequency ultrasonography (ultrasound biomicroscopy) report, pathology report, wide-angle fundus camera measurement, clinician report or other documentation in medical record
- For further information, refer to the **Uveal Melanoma** cancer protocol published by the College of American Pathologists for the AJCC Staging System *Uveal Melanoma*
- 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

## 00671: Melanoma Iris (2018+)

### **3891: Microvascular Density**

Item Length: 2 NAACCR Item #: 3891 XML Parent-NAACCR ID: Tumor-microvascularDensity NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00671: Melanoma Iris (2018+)
- 00672: Melanoma Choroid and Ciliary Body (2018+)

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

#### **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

## 3892: Mitotic Count Uveal Melanoma

Item Length: 4 NAACCR Item #: 3892 XML Parent-NAACCR ID: Tumor-mitoticCountUvealMelanoma NAACCR Alternate Name: Mitotic None Active years: 2018+ Schema(s):

- 00671: Melanoma Iris (2018+)
- 00672: Melanoma Choroid and Ciliary Body (2018+)

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

#### **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
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 to <u>Schema ID Table</u>

## 00672: Melanoma Choiroid and Ciliary Body (2018+)

See 00671: Melanoma Iris

- <u>3926: Schema Discriminator 1: Melanoma Ciliary Body/Melanoma Iris</u>
- <u>3821: Chromosome 3 Status</u>
- <u>3822: Chromosome 8q Status</u>
- <u>3834: Extravascular Matrix Patterns</u>
- <u>3887: Measured Basal Diameter</u>
- <u>3888: Measured Thickness</u>
- <u>3891: Microvascular Density</u>
- <u>3892: Mitotic Count Uveal Melanoma</u>

### 00680: Retinoblastoma (2018+)

### 3856: Heritable Trait

Item Length: 1 NAACCR Item #: 3856 XML Parent-NAACCR ID: Tumor-heritableTrait NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00680: Retinoblastoma (2018+)

### **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 8<sup>th</sup> 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 the AJCC Staging System *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

00690: Lacrimal Gland (2018+)

See 00640: Skin Eyelid (2018+)

• <u>3909: Perineural Invasion</u>

### 3926: Schema Discriminator 1: Lacrimal Gland/Sac

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

- 00690: Lacrimal Gland (2018+)
- 00698: Lacrimal Duct (2018+)

### **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 AJCC 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 the AJCC Staging System stage grouping, lacrimal gland is AJCC staged while lacrimal sac is not (Summary Stage only). A schema discriminator is necessary to distinguish between these primary sites so that the appropriate system/schema is used.

### **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.

- 00690: Lacrimal Gland (see code 1)
  - Subsites include: lacrimal gland
- 00698: Lacrimal Sac (see code 2)
  - Subsites include: lacrimal sac, lacrimal duct (NOS), nasal lacrimal duct

Code	Description	Schema ID#/Description
1	Lacrimal gland	00690: Lacrimal Gland
2	Lacrimal sac	00698: Lacrimal Sac
	Lacrimal duct, NOS	
	Nasal lacrimal duct/sac	
	Nasolacrimal duct	
9	Lacrimal, NOS	00698: Lacrimal Sac

### 00690: Lacrimal Gland (2018+)

### 3803: Adenoid Cystic Basaloid Pattern

Item Length: 5 NAACCR Item #: 3803 XML Parent-NAACCR ID: Tumor-adenoidCysticBasaloidPattern NAACCR Alternate Name: None Active years: 2018+ Schema(s): • 00690: Lacrimal Gland (2018+)

#### 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	

# 00698: Lacrimal Sac (2018+)

See 00690: Lacrimal Gland

• <u>3926: Schema Discriminator 1: Lacrimal Gland/Sac</u>

### **CENTRAL NERVOUS SYSTEM**

### **3816: Brain Molecular Markers**

Item Length: 2 NAACCR Item #: 3816 XML Parent-NAACCR ID: Tumor-brainMolecularMarkers NAACCR Alternate Name: None Active years: 2018+ Schema(s):

- 00721: Brain (2018-2022)
- 09721: Brain (2023+)
- 00722: CNS Other (2018-2022)
- 09722: CNS Other (2023+)

### **Description**

Multiple brain molecular markers have become standard pathology components necessary for diagnosis. This data item captures clinically important brain cancer subtypes identified by molecular markers that are not distinguishable by ICD-O-3 codes.

### **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 microscopically confirmed histology is not included in this list, assign, code 85.

• If your case is not microscopically confirmed, code 99

**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:

- 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 medical record	
	No microscopic confirmation	
	Brain molecular markers not assessed or unknown if assessed	

### 00721: Brain (2018-2022)

### 3801, 3802: 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

# 3801: Chromosome 1p: Loss of Heterozygosity (LOH)

Item Length: 1 NAACCR Item #: 3801 XML Parent-NAACCR ID: Tumor-chromosome1pLossHeterozygosity NAACCR Alternate Name: None Active years: 2018+ Schema(s): • 00721: Brain (2018-2022)

- 09721: Brain (2018 202
  09721: Brain (2023+)
- 09721. Brain (2023+)
- 00722: CNS Other (2018-2022)
- 09722: CNS Other (2023+)

### **Description**

Chromosome 1p: Loss of Heterozygosity (LOH) refers to the loss of genetic material normally found on the short arm of one of the patient's two copies of chromosome 1. Codeletion of Chromosome 1p and 19q is a diagnostic, prognostic and predictive marker for gliomas and is strongly associated with the oligodendroglioma phenotype.

### **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 <u>3801, 3802: Loss of Heterozygosity: Chromosome 1p and Chromosome 19q (CNS)</u> 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 <u>3802</u>: <u>Chromosome 19q</u>: <u>Loss of Heterozygosity (LOH)</u>.

Code	Description
0	Chromosome 1p deletion/LOH not identified/not present
1	Chromosome 1p deletion/LOH identified/present
6	Benign or borderline tumor
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case (If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record
	Cannot be determined by the pathologist
	Chromosome 1p deletion/LOH not assessed or unknown if assessed

# 3802: Chromosome 19q: Loss of Heterozygosity (LOH)

Item Length: 1 NAACCR Item #: 3802 XML Parent-NAACCR ID: Tumor-chromosome19qLossHeterozygosity NAACCR Alternate Name: None Active years: 2018+ Schema(s): • 00721: Brain

• 00722: CNS Other

### **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 <u>3801, 3802: Loss of Heterozygosity: Chromosome 1p and Chromosome 19q (CNS)</u> 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 <u>3801</u>: <u>Chromosome 1p</u>: <u>Loss of Heterozygosity (LOH)</u>.

Code	Description
0	Chromosome 19q deletion/LOH not identified/not present
1	Chromosome 19q deletion/LOH present
6	Benign or borderline tumor
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record
	Cannot be determined by the pathologist
	Chromosome 19q: LOH not assessed or unknown if assessed

# 3889: Methylation of O6-Methylguanine-Methyltransferase

Item Length: 1 NAACCR Item #: 3889 XML Parent-NAACCR ID: Tumor-methylationOfO6MGMT NAACCR Alternate Name: Methylation of O6-Methylguanine-Methyltransferase (MGMT) Active years: 2018+ Schema(s):

- 00721: Brain (2018)
- 09721: Brain (2023+)
- 00722: CNS Other

### **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)
  - o 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 medical record
	Cannot be determined by the pathologist
	MGMT not assessed or unknown if assessed

# 09721: Brain (2023+)

### See 00721: Brain (2018-2022)

- <u>3816: Brain Molecular Markers</u>
- <u>3801: Chromosome 1p: Loss of Heterozygosity (LOH)</u>
- <u>3802: Chromosome 19q: Loss of Heterozygosity (LOH)</u>
- <u>3889: Methylation of O6-Methylguanine-Methyltransferase</u>

# 00722: CNS Other (2018-2022)

See 00721: Brain (2018-2022)

- <u>3816: Brain Molecular Markers</u>
- <u>3801: Chromosome 1p: Loss of Heterozygosity (LOH)</u>
- <u>3802: Chromosome 19q: Loss of Heterozygosity (LOH)</u>
- <u>3889: Methylation of O6-Methylguanine-Methyltransferase</u>

# 09722: CNS Other (2023+)

### See 00721: Brain (2018-2022)

- <u>3816: Brain Molecular Markers</u>
- <u>3801: Chromosome 1p: Loss of Heterozygosity (LOH)</u>
- <u>3802: Chromosome 19q: Loss of Heterozygosity (LOH)</u>
- <u>3889: Methylation of O6-Methylguanine-Methyltransferase</u>

# 09724: Medulloblastoma (2023+)

See <u>00721, 00722, 09721, 09722: Brain and CNS Other</u>

• <u>3816: Brain Molecular Markers</u> (applicable for 2023+ only)

### **ENDOCRINE SYSTEM**

### 00730: Thyroid (2018+)

### 3926: Schema Discriminator 1: Thyroid Gland/Thyroglossal Duct

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

- 00730: Thyroid (2018+)
- 00740: Thyroid Medullary (2018+)

### **Definition**

Thyroid, NOS and thyroglossal duct have the same ICD-O topography code (C739). However, for purposes of the AJCC Staging Systems *Thyroid* and *Thyroid Medullary* stage groupings, Thyroid, NOS is applicable for AJCC staging while thyroglossal duct is not (Summary Stage only). A schema discriminator is necessary to distinguish between these primary sites so that the appropriate system/schema is used.

### **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
1	Thyroid gland
	Thyroid, NOS
2	Thyroglossal duct cyst

# 00740: Thyroid Medullary (2018+)

See 00730: Thyroid (2018+)

• <u>3926: Schema Discriminator 1: Thyroid Gland/Thyroglossal Duct</u>

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

# 3926: Schema Discriminator 1: Histology Discriminator for 9591/3

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

- 00790: Lymphoma (2018+)
- 00830: HemeRetic (2018+)

### **Coding Notes and Instructions**

**Note:** A schema discriminator is used to discriminate for histology 9591/3: Non-Hodgkin lymphoma to determine which AJCC 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	Schema ID#/Description
1	Splenic B-cell lymphoma/leukemia, unclassifiable	00830: HemeRetic
2	Hairy cell leukemia variant	00830: HemeRetic
	Prolymphocytic variant of hairy cell leukemia	
3	Splenic diffuse red pulp small B-cell lymphoma	00790: Lymphoma
	Splenic marginal zone lymphoma, diffuse variant	(excluding CLL/SLL)
	Splenic red pulp lymphoma with numerous basophilic	
	villous lymphocytes	
	Splenic lymphoma with villous lymphocytes	
9	Non-Hodgkin lymphoma, NOS	00790: Lymphoma
		(excluding CLL/SLL)
	Any other terminology describing NHL	
<blank></blank>	Histology is NOT 9591, Discriminator is not necessary	

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

### 3812: B Symptoms

Item Length: 1 NAACCR Item #: 3812 XML Parent-NAACCR ID: Tumor-bSymptoms NAACCR Alternate Name: None Active years: 2018+ Schema(s):

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

### **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.
  - Per AJCC 8<sup>th</sup> edition: "The designation A or B is not included in the revised staging of NHL, although clinicians are encouraged to record the presence of these symptoms in the medical record."
  - If your physicians no longer record the B symptoms because of this change, code 9
- 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

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

### 3859: HIV Status

Item Length: 1 NAACCR Item #: 3859 XML Parent-NAACCR ID: Tumor-hivStatus NAACCR Alternate Name: None Active years: 2018+ Schema(s):

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

### **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
  - $\circ$   $\;$  the patient has been tested and is negative for HIV or AIDS  $\;$
  - $\circ$   $\;$  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)
  - o 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
  - o 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

- $\circ$   $\;$  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.

Note 5: If patient has a histor	v of HIV, assign code 1 even	if HIV is not currently detectable.
note 5. Il patient nas a mistor	y or my, assign couc <u>r</u> cvcn	in the is not callently acceedable.

Code	Description
0	Not associated with Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency
	Syndrome (AIDS)
	HIV negative
1	Associated with HIV/AIDS
	HIV positive
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record
	HIV status not assessed or unknown if assessed

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

### 3896: NCCN International Prognostic Index (IPI)

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

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

### **Description**

The NCCN International Prognostic Index (IPI) (previously only "IPI") is used to define risk groups for specific lymphomas using a 0-8 score range, based on age, stage, number of extranodal sites of involvement, patient's performance status and LDH level.

### **Rationale**

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

### **Definition**

The NCCN International Prognostic Index (IPI) has been developed for lymphomas and predicts outcome based on the following adverse factors:

- Age greater than or equal to 60 years
- Serum LDH greater than normal
- Performance status 2-4
- Stage III or IV
- Extranodal involvement greater than 1 site

### Additional Information

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

#### **Coding Instructions and Codes**

**Note 1:** Physician statement of NCCN IPI must be used to code this data item. Do not calculate points or assign risk. Only record points or risk if a physician has documented them. Use points over risk if both are available.

**Note 2:** NCCN is applicable for non-Hodgkin lymphomas only.

• If you have a score for Hodgkin lymphomas (IPS), do not record that information here. Code X9.

Note 3: A low, intermediate or high risk associated with Rai Stage is not recorded in this data item.

Code	Description
00-08	0-8 points
X1	Stated as low risk (0-1 point)
X2	Stated as low intermediate risk (2-3 points)
X3	Stated as intermediate risk (4-5 points)
X4	Stated as high risk (6-8 points)
X8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code X8 will result in an edit error.)
X9	Not documented in medical record
	NCCN International Prognostic Index (IPI) status not assessed or unknown if assessed

# 00795: Lymphoma-CLL/SLL (2018+)

See 00790: Lymphoma (excluding CLL/SLL)

- <u>3812: B Symptoms</u>
- <u>3859: HIV Status</u>
- <u>3896: NCCN International Prognostic Index (IPI)</u>

# 00795: Lymphoma-CLL/SLL (2018+)

# **Rai Classification**

### **Definition**

The Rai classification system is now used to stage chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) (9823/3) when bone marrow and/or peripheral blood are involved using several different criteria. The stages are based on the absence or presence of the following criteria

- <u>3885: Lymphocytosis</u>
- <u>3804: Adenopathy</u>
- <u>3907: Organomegaly</u>
- <u>3811: Anemia</u>
- <u>3933: Thrombocytopenia</u>

Note: All of these data items are required for Staging for the AJCC Staging System Hodgkin and Non-Hodgkin Lymphomas (9823/3 only) and EOD.

Rai stages

- Stage 0 CLL is characterized by absolute lymphocytosis (>15,000/mm3) without adenopathy, hepatosplenomegaly, anemia, or thrombocytopenia
- Stage I CLL is characterized by absolute lymphocytosis with lymphadenopathy without hepatosplenomegaly, anemia, or thrombocytopenia
- Stage II CLL is characterized by absolute lymphocytosis with either hepatomegaly or splenomegaly with or without lymphadenopathy
- Stage III CLL is characterized by absolute lymphocytosis and anemia (hemoglobin <11 g/dL) with or without lymphadenopathy, hepatomegaly, or splenomegaly
- Stage IV CLL is characterized by absolute lymphocytosis and thrombocytopenia (<100,000/mm3) with or without lymphadenopathy, hepatomegaly, splenomegaly, or anemia

Per confirmation from medical oncologists, Rai stage is only recorded for patients who have bone marrow and/or peripheral blood involvement. Per the Hematopoietic Rules, primary site would be C421 (See <u>Hematopoietic Manual</u>, Module 3: Rules PH 5, 6). A new code has been added to the 5 SSDIs (code 5) to use when primary site is not C421.

A Derived Rai stage will be implemented in the 2022 updates. This new data item will take the information from the 5 SSDIs (Lymphocytosis, Adenopathy, Organomegaly, Anemia, Thrombocytopenia), where primary site is C421 and automatically derive the Rai stage

This table below can be used when the **ONLY** information available is the documented Rai stage from the managing physician. (Note: The Rai stage cannot be found on a pathology report).

Rai Stage	Definition	Lymphocytosis	Adenopathy	Organomegaly	Anemia	Thrombocytopenia
0	Lymphocytosis only Absolute Lymphocyte count > 5,000 cell/uL)	6	0	0	0	0
I	Lymphocytosis AND Adenopathy	6	1	0	0	0

Rai Stage	Definition	Lymphocytosis	Adenopathy	Organomegaly	Anemia	Thrombocytopenia
11	Lymphocytosis AND Enlarged spleen and/or liver (Organomegaly)	6	9	1	0	0
	Lymphocytosis AND Hemoglobin (Hgb) less than 11 g/dL (Anemia)	6	9	9	6	0
IV	Lymphocytosis AND Platelet count < 100,000 /uL (Thrombocytopenia)	6	9	9	9	6

For cases with diagnosis date of 2018+ and already abstracted with a primary site **not equal to C421** (bone marrow), the SSDIs will be updated with a new code of 5, which is "Not applicable: Primary site is not C421." A Rai Stage of 88 will then be derived.

For CLL/SLL cases abstracted after the updates and primary site not equal to C421 (bone marrow), code the SSDIs to 5.

# 00795: Lymphoma-CLL/SLL (2018+)

### 3885: Lymphocytosis

Item Length: 1 NAACCR Item #: 3885 XML Parent-NAACCR ID: Tumor-lymphocytosis NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00795: Lymphoma-CLL/SLL (2018+)

### **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 8<sup>th</sup> edition, Chapter 79 *Hodgkin and Non-Hodgkin Lymphomas*. It is a new data item for cases diagnosed 1/1/2018+.

See <u>Rai Classification</u> 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 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:** Rai stage is only applicable for CLL, in which the bone marrow and/or peripheral blood are involved (primary site C421 for bone marrow, see Hematopoietic Manual, Module 3: PH 5, 6).

• If primary site is not C421, code 5

**Note 3:** Lymphocytosis (lymphocyte number) is defined by an absolute lymphocyte count (ALC) > 5,000 cells/ $\mu$ L 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 4:** 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 5:** If there is no mention of lymphocytosis, or relevant lab results, code 9.

Note 6: The physician's stated Rai stage always takes priority when there is conflicting information.

Code	Description	
0	Lymphocytosis not present	
	Absolute lymphocyte count <= 5,000 cells/µL	
1	Lymphocytosis present	
	Absolute lymphocyte count > 5,000 cells/µL	
5	Not applicable: Primary site is not C421	
6	Lab value unknown, physician states lymphocytosis is present	
	Physician states Rai stage 0-IV	
7	Test ordered, results not in chart	
9	Not documented in medical record	
	Lymphocytosis not assessed or unknown if assessed	
	No Rai stage is documented in the record and there is no documentation of	
	lymphocytosis	

# 3804: Adenopathy

Item Length: 1 NAACCR Item #: 3804 XML Parent-NAACCR ID: Tumor-adenopathy NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00795: Lymphoma-CLL/SLL (2018+)

### **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 8<sup>th</sup> edition, Chapter 79 *Hodgkin and Non-Hodgkin Lymphomas*. It is a new data item for cases diagnosed 1/1/2018+.

### See <u>Rai Classification</u> 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 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:** Rai stage is only applicable for CLL, in which the bone marrow and/or peripheral blood are involved (primary site C421 for bone marrow, see Hematopoietic Manual, Module 3: PH 5, 6).

• If primary site is not C421, code 5

**Note 3:** Physician statement of presence or absence of adenopathy should be used to code this data item.

- Physician's statement regarding the presence of adenopathy (present or absent) takes priority. If a physician's statement and imaging are both available and in disagreement, go with the physician's statement
- If a physician's statement is not available, use the definition of adenopathy in Note 3 to determine if adenopathy is present or not

**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:** This data item is determined from physical exam alone. If a physical exam cannot be used to detect adenopathy due to issues related to the patient's obesity, a physician statement of peripheral adenopathy based on a CT scan can be used.

• A finding of retroperitoneal or mesenteric adenopathy on CT is not used in determining adenopathy and does not affect the assigned stage

**Note 6:** If there is no mention of adenopathy (present or absent), code 9.

**Note 7**: The physician's stated Rai stage always takes priority when there is conflicting information.

Code	Description	
0	Adenopathy not identified/not present	
	No lymph nodes > 1.5 cm	
	Physician states Rai Stage 0	
1	Adenopathy present	
	Presence of lymph nodes > 1.5 cm	
	Physician stated Rai Stage I	
5	Not applicable: Primary site is not C421	
9	Not documented in medical record	
	Adenopathy not assessed or unknown if assessed	
	No Rai stage is documented in the record and there is no documentation	
	of adenopathy	
	Physician states Rai stage II-IV and there is no documentation of	
	adenopathy	

### **3907: Organomegaly**

Item Length: 1 NAACCR Item #: 3907 XML Parent-NAACCR ID: Tumor-organomegaly NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00795: Lymphoma-CLL/SLL (2018+)

### **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 8<sup>th</sup> edition, Chapter 79 *Hodgkin and Non-Hodgkin Lymphomas*. It is a new data item for cases diagnosed 1/1/2018+.

#### See <u>Rai Classification</u> 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 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:** Rai stage is only applicable for CLL, in which the bone marrow and/or peripheral blood are involved (primary site C421 for bone marrow, see Hematopoietic Manual, Module 3: PH 5, 6).

• If primary site is not C421, code 5

**Note 3:** Physician statement of presence or absence of organomegaly should be used to code this data item.

**Note 4:** Organomegaly is defined as presence of enlarged liver and/or spleen on physical examination and is part of the staging criteria.

**Note 5:** This data item is determined from physical exam alone. If a physical exam cannot be used to detect organomegaly due to issues related to the patient's obesity, a physician statement of organomegaly based on a CT scan can be used.

**Note 6:** I If there is no mention of the presence or absence of organomegaly (hepatomegaly and splenomegaly), code 9.

• Both the liver and spleen mut be evaluated and determined to be normal to code 0. If only one is evaluated and determined to be normal, code 9.

**Note 7**: The physician's stated Rai stage always takes priority when there is conflicting information.

Code	Description	
0 Neither hepatomegaly (liver) nor splenomegaly (spleen) preser		
	Physician states Rai Stage 0-I	
1	Hepatomegaly (liver) and/or splenomegaly (spleen) present	
	Physician states Rai Stage II	
5	Not applicable: Primary site is not C421	
9	Not documented in medical record	
	Organomegaly (hepatomegaly and/or splenomegaly) not assessed or	
	unknown if assessed	
	No Rai stage is documented in the record and there is no documentation	
	of organomegaly	
	Physician states Rai stage III-IV and there is no documentation of	
	organomegaly	

### **3811: Anemia**

Item Length: 1 NAACCR Item #: 3811 XML Parent-NAACCR ID: Tumor-anemia NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00795: Lymphoma-CLL/SLL (2018+)

### **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 8<sup>th</sup> edition, Chapter 79 *Hodgkin and Non-Hodgkin Lymphomas*. It is a new data item for cases diagnosed 1/1/2018+.

### See <u>Rai Classification</u> 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 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:** Rai stage is only applicable for CLL, in which the bone marrow and/or peripheral blood are involved (primary site C421 for bone marrow, see Hematopoietic Manual, Module 3: PH 5, 6).

• If primary site is not C421, code 5

**Note 3:** 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/L is equivalent to 110 g/L

**Note 4:** Record this data item based on a blood test (CBC, hemoglobin & hematocrit, H&H) performed at diagnosis (pre-treatment). In the absence of the lab test, a physician's statement can be used.

Note 5: If there is no mention of anemia, or relevant lab results, code 9.

**Note 6:** The physician's stated Rai Stage always takes priority when there is conflicting information.

Code	Description	
0	Anemia not present	
	Hgb >=11.0 g/dL	
	Physician states Rai Stage 0-II	
1	Anemia present	
	Hgb <11.0 g/dL	
5	Not applicable: Primary site is not C421	
6	Lab value unknown, physician states patient is anemic	
	Physician states Rai Stage III	
7	Test ordered, results not in chart	
9	Not documented in medical record	
	Anemia not assessed or unknown if assessed	
	No Rai stage is documented in the record and there is no	
	documentation of anemia	
	Physician states Rai stage IV and there is no documentation of anemia	

# 3933: Thrombocytopenia

Item Length: 1 NAACCR Item #: 3933 XML Parent-NAACCR ID: Tumor-thrombocytopenia NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00795: Lymphoma-CLL/SLL (2018+)

### **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 8<sup>th</sup> edition, Chapter 79 *Hodgkin and Non-Hodgkin Lymphomas*. It is a new data item for cases diagnosed 1/1/2018+.

See <u>Rai Classification</u> 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 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:** Rai stage is only applicable for CLL, in which the bone marrow and/or peripheral blood are involved (primary site C421 for bone marrow, see Hematopoietic Manual, Module 3: PH 5, 6).

• If primary site is not C421, code 5

**Note 3:** Thrombocytopenia is defined as platelets (Plt) <100,000/ $\mu$ L. 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), (100 cells x 10^9/L, or (100 cells x 10E9/L)

**Note 4:** 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 5:** If there is no mention of thrombocytopenia, or the relevant lab tests, code 9.

**Note 6:** The physician's stated Rai Stage always takes priority when there is conflicting information.

Code	Description	
0	Thrombocytopenia not present	
	Platelets (Plt) >=100,000/μL	
	Physician states Rai Stage 0-III	
1	Thrombocytopenia present	
	Platelets (Plt) < 100,000/μL	
5	Not applicable: Primary site is not C421	
6	Lab value unknown, physician states thrombocytopenia is present	
	Physician states Rai Stage IV	
7	Test ordered, results not in chart	
9	Not documented in medical record	
	Thrombocytopenia not assessed or unknown if assessed	
	No Rai stage is documented in the record and there is no documentation	
	of thrombocytopenia	

# **3955: Derived Rai stage**

Item Length: 1 NAACCR Item #: 3955 XML Parent-NAACCR ID: Tumor-derivedRaiStage NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00795: Lymphoma-CLL/SLL (2018+)

# Description

This data item stores the Derived Rai stage value derived from the values coded in the following SSDIs for the Lymphoma-CLL/SLL schema (9823/3).

- <u>3885: Lymphocytosis</u>
- <u>3804: Adenopathy</u>
- <u>3907: Organomegaly</u>
- <u>3811: Anemia</u>
- <u>3933: Thrombocytopenia</u>

The Rai stage is only applicable for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) (9823/3) cases where the primary site is bone marrow (C421). For cases with a primary site other than bone marrow (C421), the derived Rai stage will be 8 and all the SSDIs will be coded to 5.

Derivation will be run on all cases diagnosed 1/1/2018 and forward.

#### Rationale

The Derived Rai stage can be used to evaluate disease spread at diagnosis, treatment patterns and outcomes over time.

Rai Stage	Rai Code	Description	
0	0	Lymphocytosis	
1	I	Lymphocytosis and Adenopathy	
2	II	Lymphocytosis and Organomegaly (Adenopathy is any value other than 5)	
3		Lymphocytosis and Anemia (Adenopathy and Organomegaly are any value other than 5)	
4	IV	Lymphocytosis and Thrombocytopenia (Adenopathy, Organomegaly and Anemia are any value other than 5)	
8	N/A	Does not apply, primary site not bone marrow (C421) (All 5 SSDIs should be set to 5)	
9	9	Unknown(All 5 SSDIs are 9 or blank) At least one is set to 9 OR Lymphocytosis is 0,7,9 OR Lymphocytosis is blank and one of the other SSDIs is a value other than 5 or 9)	

This field should be left blank for all cases diagnosed prior to 2018, for schemas other than 00795, and when not required by standard setter.

## 00811: Mycosis Fungoides (2018+)

## **3910: Peripheral Blood Involvement**

Item Length: 1 NAACCR Item #: 3910 XML Parent-NAACCR ID: Tumor-peripheralBloodInvolvement NAACCR Alternate Name: None Active years: 2018+ Schema(s): • 00811: Mycosis Fungoides (2018+)

### **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 8<sup>th</sup> 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	В Мар
0	Absence of significant blood involvement	BO
	5% or less of peripheral blood lymphocytes are atypical (Sezary) cells	
	Clone unknown	
	Stated as BO	
1	Absence of significant blood involvement	BOa
	5% or less of peripheral blood lymphocytes are atypical (Sezary) cells	
	Clone negative	
	Stated as BOa	
2	Absence of significant blood involvement:	BOb
	5% or less of peripheral blood lymphocytes are atypical (Sezary) cells	
	Clone positive	
	Stated as B0b	
3	Low blood tumor burden	B1
	More than 5% of peripheral blood lymphocytes are atypical (Sezary) cells	
	but does not meet the criteria of B2	
	Clone unknown	
	Stated as B1	
4	Low blood tumor burden	B1a
	More than 5% of peripheral blood lymphocytes are atypical (Sezary) cells	
	but does not meet the criteria of B2	
	Clone negative	
	Stated as B1a	
5	Low blood tumor burden	B1b
	More than 5% of peripheral blood lymphocytes are atypical (Sezary) cells	
	but does not meet the criteria of B2	
	Clone positive	
	Stated as B1b	

Code	Description	В Мар
6	High blood tumor burden	
	Greater than or equal to 1000 Sezary cells per microliter (uL)	
	Clone positive	
	Stated as B2	
7	Test ordered, results not in chart	BX
9	Not documented in medical record	BX
	Peripheral Blood Involvement not assessed or unknown if assessed	

# **RISS Stage (Plasma Cell Myeloma)**

### **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

- <u>3931: Serum Beta-2 Microglobulin Pretreatment Level</u>
- <u>3930: Serum Albumin Pretreatment Level</u>
- <u>3857: High Risk Cytogenetics</u>
- <u>3869: LDH Level</u>

**Required for Staging:** The AJCC Staging System *Plasma Cell Myeloma and Plasma Cell Disorders* (9732/3 only) and EOD.

 Note: RISS stage is not applicable for the descriptions of plasma multiple myeloma that are listed in the codes 1 and 9 in the SSDI Schema Discriminator 1: Plasma Cell Myeloma Terminology. If you have coded 1 or 9 for this Schema Discriminator, the four data items listed above are BLANK.

### The RISS stages are

- Stage I: Serum Beta-2-microglobulin <3.5 mg/L and serum albumin 
   <u>></u> 3.5 g/dL and no high-risk cytogenetics and Normal LDH
- Stage II: Not R-ISS I or III
- Stage III: Serum Beta-2-microglobulin > 5.5 mg/L and high-risk cytogenetics and/or high LDH

### Additional Information

• Other names: R-ISS

## 3926: Schema Discriminator 1: Plasma Cell Myeloma Terminology

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

• 00821: Plasma Cell Myeloma (2018+)

### **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 8<sup>th</sup> 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 8<sup>th</sup> 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)	RISS Stage
	Multiple myeloma	
	Myeloma, NOS	
	Non-secretory myeloma	
	Ultra-High-Risk Smoldering MM (SMM)	
1	Smoldering plasma cell myeloma (SPCM)	No RISS Stage
	Asymptomatic plasma cell myeloma	
	Early myeloma	
	Evolving myeloma	
9	Other terminology describing myeloma	No RISS Stage
	Unknown terminology used	

### 3931: Serum Beta-2 Microglobulin Pretreatment Level

Item Length: 1 NAACCR Item #: 3931 XML Parent-NAACCR ID: Tumor-serumBeta2MicroglobulinPretxLvl NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00821: Plasma Cell Myeloma (2018+)

### **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  $\beta$ 2 (beta-2) Microglobulin level to increase. Elevated Serum  $\beta$ 2 (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 8<sup>th</sup> 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 <u>RISS Stage (Plasma Cell Myeloma)</u> 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.

Note 4: If Schema Discriminator 1: Plasma Cell Myeloma Terminology is coded to 1 or 9, code 5.

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	
5	Schema Discriminator 1: Plasma Cell Myeloma Terminology coded to 1 or 9	
7	Test ordered, results not in chart	
9	Not documented in medical record	
	Serum Beta-2 Microglobulin Pretreatment Level not assessed or unknown	
	if assessed	

### **3930: Serum Albumin Pretreatment Level**

Item Length: 1 NAACCR Item #: 3930 XML Parent-NAACCR ID: Tumor-serumAlbuminPretreatmentLevel NAACCR Alternate Name: None Active years: 2018+ Schema(s):

• 00821: Plasma Cell Myeloma (2018+)

### **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 8<sup>th</sup> 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 <u>RISS Stage (Plasma Cell Myeloma)</u> for additional information.

#### **Coding Instructions and Codes**

**Note 1:** Elevated serum albumin is defined by  $\geq$ 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.

Note 4: If Schema Discriminator 1: Plasma Cell Myeloma Terminology is coded to 1 or 9, code 5.

Code	Description	
0	Serum albumin <3.5 g/dL	
1	Serum albumin ≥3.5 g/dL	
5	Schema Discriminator 1: Plasma Cell Myeloma Terminology coded to 1 or 9	
7	Test ordered, results not in chart	
9	Not documented in medical record	
	Serum Albumin Pretreatment Level not assessed or unknown if assessed	

### **3857: High Risk Cytogenetics**

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

• 00821: Plasma Cell Myeloma (2018+)

### **Description**

High Risk Cytogenetics is defined as one or more of t(4;14), t(14;16), or del 17p identified from FISH test results and is part of the staging criteria for plasma cell myeloma.

### **Rationale**

High Risk Cytogenetics is a prognostic factor required in **AJCC 8<sup>th</sup> 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 <u>RISS Stage (Plasma Cell Myeloma)</u> for additional information.

### **Coding Instructions and Codes**

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

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

**Note 3:** If the presence/absence of high-risk cytogenetics determined by available test results differs from the physician statement of presence/absence, the physician's statement takes precedence.

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

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

Code	Description
0	High-risk cytogenetics not identified/not present
1	High-risk cytogenetics present
5	Schema Discriminator 1: Plasma Cell Myeloma Terminology coded to 1 or 9
7	Test ordered, results not in chart
9	Not documented in medical record
	High Risk Cytogenetics not assessed or unknown if assessed

### 3869: LDH Level

Item Length: 1 NAACCR Item #: 3869 XML Parent-NAACCR ID: Tumor-IdhPretreatmentLevel NAACCR Alternate Name: LDH (Lactate Dehydrogenase) Pretreatment Level Active years: 2018+ Schema(s):

• 00821: Plasma Cell Myeloma (2018+)

### **Description**

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

#### <u>Rationale</u>

LDH (Lactate Dehydrogenase) Level is a prognostic factor required in AJCC 8<sup>th</sup> edition for Chapter 82 Plasma Cell Myeloma and Plasma Cell Disorders and Chapter 47 Melanoma Skin. For Plasma Cell Myeloma, LDH is part of the RISS Stage and is new for cases diagnosed 1/1/2018+. For Melanoma Skin, LDH is used to define the M subcategories and was previously collected as Melanoma Skin, SSF #4.

#### See <u>RISS Stage (Plasma Cell Myeloma)</u> 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.

**Note 4:** If Schema Discriminator 1: Plasma Cell Myeloma Terminology is coded to 1 or 9, code 5.

Code	Description
0	Normal LDH level
	Low, below normal
1	Above normal LDH level; High
5	Schema Discriminator 1: Plasma Cell Myeloma Terminology coded to 1 or 9
7	Test ordered, results not in chart
9	Not documented in medical record
	LDH (Lactate Dehydrogenase) Level not assessed or unknown if assessed

# 00830: HemeRetic (2018+)

See 00790: Lymphoma

• <u>3926: Schema Discriminator 1: Histology Discriminator for 9591/3</u>

# 3862: JAK 2

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

• 00830: HemeRetic (2018+)

### **Description**

Janus Kinase 2 (JAK2, JAK 2) is a gene mutation that increases susceptibility to several myeloproliferative neoplasms (MPNs). Testing for the JAK2 mutation is done on whole blood. Nearly all people with polycythemia vera, and about half of those with primary myelofibrosis and essential thrombocythemia, have the mutation. JAK2 analysis continues to increase in use for hematopoietic neoplasms.

### **Rationale**

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

### **Definition**

JAK2, a gene found in all humans, is involved in the development of blood cells. If JAK2 has mutated, the person is more susceptible to develop a myeloproliferative disorder (MPD). The JAK2 mutation, which is acquired rather than inherited, is found in as many as 90% of patients with polycythemia vera (PV), about half of patients with essential thrombocythemia (ET), and slightly fewer patients with primary myelofibrosis (also known as agnogenic myeloid metaplasia and other terms). JAK2 is used by clinicians to help classify MPDs. The most common histologies for which JAK-2 is tested are those listed above. Registrars can use JAK2 information to help determine whether the MPD is reportable. JAK2 positivity indicates a malignant (clonal, irreversible) reportable disease, but is not diagnostic of a specific MPD. Additional tests, such as a bone marrow biopsy, are necessary to determine the specific MPD histology. As the use of JAK2 increases and is investigated for other hematopoietic histologies, it also has future potential for development of targeted therapeutics for the MPDs.

The principal JAK2 test looks for a change (mutation) in an amino acid at a specific place on the JAK2 gene called V617F. If the V617F test is negative, other JAK2 mutation tests, such as those in exon 12 or 13 may be ordered to investigate a possible diagnosis of polycythemia vera. (An exon is a segment of a gene that contains instructions for making a protein.)

### **Coding guidelines**

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

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

### Additional Information

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

### Coding Instructions and Codes

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

**Note 2:** Janus Kinase 2 (JAK2, JAK 2) is a gene mutation that increases susceptibility to several myeloproliferative neoplasms (MPNs). Testing for the JAK2 mutation is done on whole blood. Nearly all people with polycythemia vera, and about half of those with primary myelofibrosis and essential thrombocythemia, have the mutation.

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

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

Code	Description
0	JAK2 result stated as negative
1	JAK2 positive for mutation V617F WITH or WITHOUT other mutations
2	JAK2 positive for exon 12 mutation
3	JAK2 positive for other specified mutation
4	JAK2 positive for more than one mutation other than V617F
5	JAK2 positive NOS
	Specific mutation(s) not stated
7	Test ordered, results not in chart
8	Not applicable: Information not collected for this case
	(If this item is required by your standard setter, use of code 8 will result in an edit error.)
9	Not documented in medical record
	JAK2 not assessed or unknown if assessed

# 99999: Ill-Defined Other (2018+)

See 00060: Cervical Lymph Nodes and Unknown Primary Tumors of the Head and Neck

- <u>3926: Schema Discriminator 1: Occult Head and Neck Lymph Nodes</u>
  - Primary Site C760 only

### **ALPHABETICAL INDEX**

Adenoid Cystic Basaloid Pattern, 394 Adenopathy (Rai Classification: CLL/SLL), 427 AFP Post-Orchiectomy Lab Value, 338 AFP Post-Orchiectomy Range, 340 AFP Pre-Orchiectomy Lab Value, 334 AFP Pre-Orchiectomy Range, 336 AFP Pretreatment Interpretation, 120 AFP Pretreatment Lab Value, 119 Anemia (Rai Classification: CLL/SLL), 431 B Symptoms, 416 Bilirubin Pretreatment Total Lab Value, 124 Bilirubin Pretreatment Unit of Measure, 126 Bone Invasion, 164 Brain Molecular Markers, 398 Breslow Tumor Thickness, 185 CA-125 Pretreatment Interpretation, 298 **CEA Pretreatment Interpretation**, 96 CEA Pretreatment Lab Value, 94 Chromosome 19q: Loss of Heterozygosity (LOH), 403 Chromosome 1p: Loss of Heterozygosity (LOH), 401 Chromosome 3 Status, 375 Chromosome 8g Status, 377 Circumferential Resection Margin (CRM), 98 Creatinine Pretreatment Lab Value. 127 Creatinine Pretreatment Unit of Measure, 129 Esophagus and EGJ Tumor Epicenter, 86 Estrogen Receptor Percent Positive or Range, 204 Estrogen Receptor Summary, 202 Estrogen Receptor Total Allred Score, 206 Extranodal Extension Clin (non-Head and Neck), 177 Extranodal Extension Head and Neck Clinical, 56 Extranodal Extension Path (non-Head and Neck), 179 Extravascular Matrix Patterns, 379 Fibrosis Score, 131 FIGO Stage (Adenosarcoma), 295 FIGO: Cervix, 274 FIGO: Corpus Carcinoma and Carcinosarcoma, 279 FIGO: Gestational Trophoblastic Tumors (Placenta), 304 FIGO: Ovary, Fallopian Tube, and Peritoneal Carcinoma, 296 FIGO: Vagina, 266 FIGO: Vulva, 254

Gestational Trophoblastic Prognostic Scoring Index, 305 Gleason Patterns Clinical, 315 Gleason Patterns Pathological, 320 Gleason Score Clinical, 318 Gleason Score Pathological, 323 Gleason Tertiary Pattern, 325 hCG Post-Orchiectomy Lab Value, 346 hCG Post-Orchiectomy Range, 348 hCG Pre-Orchiectomy Lab Value, 344 hCG Pre-Orchiectomy Range, 345 HER2 IHC Summary, 217 HER2 ISH Dual Probe Copy Number, 225 HER2 ISH Dual Probe Ratio, 227 HER2 ISH Single Probe Copy Number, 223 HER2 ISH Summary, 219 HER2 Overall Summary, 221 Heritable Trait, 390 High Risk Cytogenetics, 443 High Risk Histologic Features, 79 HIV Status, 418 International Normalized Ratio, 130 Invasion Beyond Capsule, 360 Ipsilateral Adrenal Gland Involvement, 364 JAK 2, 446 Ki-67, 242 KIT Gene Immunohistochemistry, 173 KRAS, 101 LDH Post-Orchiectomy Range, 353 LDH Pre-Orchiectomy Range, 352 LDH Pretreatment Lab Value, 192 LDH Pretreatment Level, 194 LDH Upper Limits of Normal, 195 LN Assessment Method Femoral-Inguinal, 257 LN Assessment Method Para-Aortic, 267, 269 LN Assessment Method Pelvic, 261 LN Distant Assessment Method, 272 LN Distant: Mediastinal, Scalene, 271 LN Head and Neck Levels I-III, 61 LN Head and Neck Levels IV-V, 63 LN Head and Neck Levels VI-VII, 65 LN Head and Neck Other, 67 LN Isolated Tumor Cells (ITC), 181 LN Laterality, 263 LN Positive Axillary Level I-II, 244 LN Status Femoral-Inguinal, Para-Aortic, Pelvic, 255.259 Lymphocytosis (Rai Classification: CLL/SLL), 425 Major Vein Involvement, 362

Measured Basal Diameter, 381 Measured Thickness, 383 Methylation of O6-Methylguanine-Methyltransferase, 405 Microsatellite Instability (MSI), 104 Microvascular Density, 385 Mitotic Count Uveal Melanoma, 387 Mitotic Rate Melanoma, 190 Multigene Signature Method, 231 Multigene Signature Results, 233 NCCN International Prognostic Index (IPI), 420 Number of Cores Examined, 329 Number of Cores Positive, 327 Number of Examined Para-Aortic Nodes, 284 Number of Examined Pelvic Nodes, 288 Number of Positive Para-Aortic Nodes, 282 Number of Positive Pelvic Nodes, 286 Oncotype Dx Recurrence Score-DCIS, 237 Oncotype Dx Recurrence Score-Invasive, 239 Oncotype Dx Risk Level-DCIS, 238 Oncotype Dx Risk Level-Invasive, 241 Organomegaly (Rai Classification: CLL/SLL), 429 Percent Necrosis Post Neoadjuvant, 160 Perineural Invasion, 107 Peripheral Blood Involvement, 436 Peritoneal Cytology, 290 Pleural Effusion, 157 Primary Sclerosing Cholangitis, 134 Profound Immune Suppression, 183 **Progesterone Receptor Percent Positive or** Range, 210 Progesterone Receptor Summary, 208 Progesterone Receptor Total Allred Score, 212 PSA (Prostatic Specific Antigen) Lab Value, 309 **Residual Tumor Volume Post Cytoreduction**, 300

Response to Neoadjuvant Therapy, 247

S Category Clinical, 355 S Category Pathological, 357 Sarcomatoid Features, 366 Schema Discriminator 1 (Histology Discriminator for 9591/3), 415 Schema Discriminator 1: BileDuctsDistal/BileDuctsPerihilar/CysticDuct, 138 Schema Discriminator 1: Lacrimal Gland/Sac, 393 Schema Discriminator 1: Melanoma Ciliary Body/Melanoma Iris, 374 Schema Discriminator 1: Nasopharynx/Pharyngeal Tonsil, 73 Schema Discriminator 1: Occult Head and Neck Lymph Nodes, 49 Schema Discriminator 1: Plasma Cell Myeloma Terminology, 440 Schema Discriminator 1: Primary Peritoneum Tumor, 172 Schema Discriminator 1: Thyroid Gland/Thyroglossal Duct, 412 Schema Discriminator 1: Urethra/Prostatic Urethra, 368 Schema Discriminator 2: Histology Discriminator for 8020/3, 85 Schema Discriminator 2: Oropharyngeal p16, 75 Separate Tumor Nodules, 147 Serum Albumin Pretreatment Level, 442 Serum Beta-2 Microglobulin Pretreatment Level, 441 Thrombocytopenia (Rai Classification: CLL/SLL), 433, 435 Tumor Deposits, 109 Tumor Growth Pattern, 136 Ulceration, 188 Visceral and Parietal Pleural Invasion, 150, 153