

Article - Billing and Coding: Biomarkers for Oncology (A52986)

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Contractor Information

| CONTRACTOR NAME | CONTRACT TYPE | CONTRACT NUMBER | JURISDICTION | STATES |
|-------------------------|---------------|-----------------|--------------|---|
| Novitas Solutions, Inc. | A and B MAC | 04111 - MAC A | J - H | Colorado |
| Novitas Solutions, Inc. | A and B MAC | 04112 - MAC B | J - H | Colorado |
| Novitas Solutions, Inc. | A and B MAC | 04211 - MAC A | J - H | New Mexico |
| Novitas Solutions, Inc. | A and B MAC | 04212 - MAC B | J - H | New Mexico |
| Novitas Solutions, Inc. | A and B MAC | 04311 - MAC A | J - H | Oklahoma |
| Novitas Solutions, Inc. | A and B MAC | 04312 - MAC B | J - H | Oklahoma |
| Novitas Solutions, Inc. | A and B MAC | 04411 - MAC A | J - H | Texas |
| Novitas Solutions, Inc. | A and B MAC | 04412 - MAC B | J - H | Texas |
| Novitas Solutions, Inc. | A and B MAC | 04911 - MAC A | J - H | Colorado New Mexico Oklahoma Texas |
| Novitas Solutions, Inc. | A and B MAC | 07101 - MAC A | J - H | Arkansas |
| Novitas Solutions, Inc. | A and B MAC | 07102 - MAC B | J - H | Arkansas |
| Novitas Solutions, Inc. | A and B MAC | 07201 - MAC A | J - H | Louisiana |
| Novitas Solutions, Inc. | A and B MAC | 07202 - MAC B | J - H | Louisiana |
| Novitas Solutions, Inc. | A and B MAC | 07301 - MAC A | J - H | Mississippi |
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| Novitas Solutions, Inc. | A and B MAC | 12101 - MAC A | J - L | Delaware |
| Novitas Solutions, Inc. | A and B MAC | 12102 - MAC B | J - L | Delaware |
| Novitas Solutions, Inc. | A and B MAC | 12201 - MAC A | J - L | District of Columbia |
| Novitas Solutions, Inc. | A and B MAC | 12202 - MAC B | J - L | District of Columbia |
| Novitas Solutions, Inc. | A and B MAC | 12301 - MAC A | J - L | Maryland |
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| Novitas Solutions, Inc. | A and B MAC | 12401 - MAC A | J - L | New Jersey |
| Novitas Solutions, Inc. | A and B MAC | 12402 - MAC B | J - L | New Jersey |
| Novitas Solutions, Inc. | A and B MAC | 12501 - MAC A | J - L | Pennsylvania |
| Novitas Solutions, Inc. | A and B MAC | 12502 - MAC B | J - L | Pennsylvania |

| CONTRACTOR NAME | CONTRACT TYPE | CONTRACT NUMBER | JURISDICTION | STATES |
|-------------------------|---------------|-----------------|--------------|--|
| Novitas Solutions, Inc. | A and B MAC | 12901 - MAC A | J - L | Delaware District of Columbia Maryland New Jersey Pennsylvania |

Article Information

General Information

Article ID

A52986

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Article Title

Billing and Coding: Biomarkers for Oncology

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Article Type

Billing and Coding

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Retirement Date

N/A

CMS National Coverage Policy

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

Article Guidance

Article Text

This Billing and Coding Article provides billing and coding guidance for Local Coverage Determination (LCD) L35396, Biomarkers for Oncology. Please refer to the LCD for reasonable and necessary requirements.

Coding Guidance

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by the entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Test Panel Definition

A predetermined set of medical tests composed of individual laboratory tests related by medical condition, specimen type, frequency ordered, methodology or types of components to aid in the diagnosis/treatment of diseases. The performance of multiple molecular tests regardless of whether the requisition lists the tests as a panel or individually and completed on a single sample is considered to be a Panel of tests and should be billed under a single CPT code to prevent stacking of codes.

Consistent with the Limitations outlined in LCD, Biomarkers for Oncology, the following tests will all be covered once per lifetime per beneficiary:

- CPT code 81345 - Brain Molecular Biomarkers
- CPT code 81437 – Hereditary neuroendocrine tumor disorders
- CPT code 81438 – Hereditary neuroendocrine tumor disorders; duplication/deletion analysis
- ThyraMIR (CPT 0018U), Afirma (CPT 81546), ThyGeNEXT (CPT 0245U), RosettaGX Reveal (CPT 81479) and ThyroSeq tests (CPT 0026U) (CPT 0287U)
 - Should the unlikely situation of a second, unrelated thyroid nodule with indeterminate pathology occur, coverage may be considered upon appeal with supporting documentation
- CPT code 81540 TUO CTID (Cancer TYPE ID)

Review of General Molecular Pathology Coding Changes

In 2012, CPT created new Tier 1 (gene specific) and Tier 2 molecular pathology codes.

The Tier 1 molecular pathology codes are applicable to specific biomarkers. However, Tier 2 molecular pathology codes are used to identify groups of biomarkers that require the similar levels of technical and interpretive resources required to complete the testing. Tier 2 codes represent rare disease and molecular pathology procedures that are performed in lower volumes than Tier 1 procedures. These codes should rarely, if ever, be used unless instructed by other coding and billing articles.

Because there are multiple biomarkers represented by each of the Tier 2 codes, when billing for these codes, the specific biomarker must be reported in the claim narrative/remarks.

Reporting of the specific biomarker, WITHOUT providing the full descriptor will suffice. However, in some cases, such as the example provided below, it may be necessary to provide abbreviated information to identify the specific

service provided.

CPT code 81479 - Unlisted molecular pathology should be used to report a specific biomarker that is not represented by a Tier 1 code and is not accurately described by one of the Tier 2 codes.

- A description of the testing performed must be included in the narrative/remarks when using this code.

Billing Claims with Multiple Biomarkers

Please refer to the Local Coverage Article A58917, Billing and Coding: Molecular Pathology and Genetic Testing for information.

Selected Oncology Tests

1. UroVysion Bladder Kit services

The following information should be reported on the claim:

- CPT code 88120 or 88121 as appropriate.
- 'UroVysion' should be placed in the comment/narrative field for the following claim field/types:
 - Loop 2400, NTE02, or SV101-7 for the 5010A1 837P
- Submit 'UroVysion' on an attachment to the claim form when submitting a paper claim.

Laboratories reporting only the technical component for a UroVysion service should append the appropriate CPT code 88120 or 88121 with the TC HCPCS modifier.

Note: Physicians may not submit claims for a CPT code 88120 and 88121 professional component when the interpretive information is provided by a lab technician or scientist. Please refer to CMS IOM 100-04, Chapter 23, Section 20.9 for National Correct Coding Initiative (NCCI) information.

2. Rosetta Cancer Origin Test™ when a conventional surgical pathology/imaging work-up is unable to identify a primary neoplastic site.

The following information should be reported on the claim:

- CPT code 81479 Unlisted molecular pathology procedure
- Enter 'Initial Work-Up ...' in the comment/narrative field for the following claim field/types:
 - Loop 2400, NTE02, or SV101-7 for the 5010A1 837P
- Submit 'Initial Work-Up ...' on an attachment to the claim form when submitting a paper claim.

Note: The full, continued version of this Initial Work-Up comment DOES NOT have to be a standardized response, but simply a brief summary (totaling less than 80 characters) to ensure that a preliminary surgical pathology evaluation has been performed prior to the ordering of the biomarker. An example might read as follows: 'Initial Work-Up shows medium probability of breast CA via IHC'.

3. VeriStrat® assay (CPT code 81538)

- Enter 'Initial Work-Up ...' in the comment/narrative field for the following claim field/types:
 - Loop 2400, NTE02, or SV101-7 for the 5010A1 837P
- Submit 'Initial Work-Up ...' on an attachment to the claim form when submitting a paper claim.

Note: The full, continued version of this Initial Work-Up comment DOES NOT have to be a standardized response, but simply a brief summary (totaling less than 80 characters) to ensure that a preliminary predictive testing evaluation has been performed prior to the ordering of the VeriStrat® assay. Two examples might read as follows:

- 'Initial Work-Up shows EGFR wild-type'
- 'Initial Work-Up without ability to test EGFR'

4. OVA1™ and ROMA™ proteomic assays

OVA1 has been cleared by the FDA for women who meet all of the following criteria:

- Are over 18 years of age
- Have an ovarian mass
- Have surgery planned

Enter 'The patient meets all 3 FDA OVA1 criteria' in the comment/narrative field for the following claim field/types:

- Loop 2400, NTE02, or SV101-7 for the 5010A1 837P

Submit 'The patient meets all 3 FDA OVA1 criteria' on an attachment to the claim form when submitting a paper claim.

For OVA1™, use CPT code 81503.

5. PROGENSA PCA3 test (regarding prostate cancer):

- Should be billed with CPT code 81313
- Claim must include PCA3 and contain one of the corresponding ICD-10-CM codes listed in the ICD-10-CM Codes that Support Medical Necessity Group 9 below.

6. MyPRS Genetic Expression Profile Testing

- Should be billed with CPT code 81479
- 'MyPRS' should be entered in box 19, or electronic equivalent, on the claim
- Claim must include one of the corresponding ICD-10-CM codes listed in the ICD-10-CM Codes that Support Medical Necessity Group 24 below.

7. ThyraMIR, ThyGeNEXT, Afirma, RosettaGX Reveal or ThyroSeq Thyroid

Intended use of ThyraMIR

ThyraMIR may be used for cytologically indeterminate thyroid nodules categorized as either AUS/FLUS or FN/SFN within the Bethesda classification scheme for FNA cytology. It is performed following a negative ThyGeNEXT result for

all mutations or when mutations detected are not fully indicative of malignancy (i.e., ThyGeNEXT results which favor a benign nodule, but cancer could still be present). ThyGeNEXT, and ThyraMIR combination testing, along with other clinical information, may be used by physicians to help determine the need for surgery or clinical follow up when patients are diagnosed with indeterminate thyroid nodules.

The original FNA sample collected for molecular testing with ThyGeNEXT is also used to perform the ThyraMIR test; a separate sample is not required.

To report a ThyraMIR service, please submit the following claim information:

- CPT code 0018U
- Enter ThyraMIR in the comment/narrative field for the following claim field/types:
 - Part A claims:
 - Loop SV202-7 for 837I electronic claim
 - Block 80 for the UB04 claim form
 - Part B claims:
 - Loop 2400 or SV101-7 for the 5010A1 837P
 - Box 19 for the paper claim

To report ThyGeNEXT tests, please submit the following claim information:

- CPT code 0245U
- Enter ThyGeNEXT in the comment/narrative field
 - Part A claims:
 - Loop SV202-7 for 837I electronic claim
 - Block 80 for the UB04 claim form
 - Part B claims:
 - Loop 2400 or SV101-7 for the 5010A1 837P
 - Box 19 for the paper claim

To report Afirma tests, please submit the following claim information:

- CPT code 81546
- Enter Afirma in the comment/narrative field
 - Part A claims:
 - Loop SV202-7 for 837I electronic claim
 - Block 80 for the UB04 claim form
 - Part B claims:
 - Loop 2400 or SV101-7 for the 5010A1 837P
 - Box 19 for the paper claim

To report RosettaGX Reveal Thyroid tests, please submit the following claim information:

- CPT code 81479
- Enter Rosetta GX Reveal Thyroid in the comment/narrative field
 - Part A claims:
 - Loop SV202-7 for 837I electronic claim
 - Block 80 for the UB04 claim form

- Part B claims:
 - Loop 2400 or SV101-7 for the 5010A1 837P
 - Box 19 for the paper claim

To report ThyroSeq Thyroid tests, please submit the following claim information:

- CPT code 0026U or 0287U
- Enter ThyroSeq test in the comment/narrative field
 - Part A claims:
 - Loop SV202-7 for 837I electronic claim
 - Block 80 for the UB04 claim form
 - Part B claims:
 - Loop 2400 or SV101-7 for the 5010A1 837P
 - Box 19 for the paper claim

Please refer to LCD L35396-Biomarkers for Oncology for coverage details for ThyraMIR, Afirma, ThyGeNEXT, RosettaGX Reveal and ThyroSeq Thyroid tests.

8. Oncomine DX Test

To report Oncomine DX Test service, please submit the following claim information:

- CPT code 0022U - Tgt gen seq dna&rna 1-23 gene
- The identifier of 'Oncomine DX' must be in the comment/narrative field as follows:
 - Part A claims:
 - Loop SV202-7 for 837I electronic claim
 - Block 80 for the UB04 claim form
 - Part B claims:
 - Loop 2400 or SV101-7 for the 5010A1 837P
 - Box 19 for the paper claim

9. ColonSeq® test

- Should be billed with CPT code 81445
- Enter ColonSeq in the comment/narrative field for the following claim field/types.
 - Part A claims:
 - Loop SV202-7 for 837I electronic claim
 - Block 80 for the UB04 claim form
 - Part B claims:
 - Loop 2400 or SV101-7 for the 5010A1 837P
 - Box 19 for the paper claim
- The claim must contain one of the corresponding ICD-10-CM codes listed in the ICD-10-CM Codes that Support Medical Necessity Group 1 below.

10. LungSeq® test

- Should be billed with CPT code 81445
- Enter LungSeq in the comment/narrative field for the following claim field/types.

- Part A claims:
 - Loop SV202-7 for 837I electronic claim
 - Block 80 for the UB04 claim form
- Part B claims:
 - Loop 2400 or SV101-7 for the 5010A1 837P
 - Box 19 for the paper claim
- The claim must contain one of the corresponding ICD-10-CM codes listed in the ICD-10-CM Codes that Support Medical Necessity Group 2 below.

11. Colvera® test (BCAT1/IKZF1 promoter hypermethylation)

Intended use of Colvera

Colvera is a diagnostic laboratory test used to detect the presence of colorectal cancer circulating tumor DNA. Colvera is intended to be used to detect residual disease following surgery or treatment for primary or recurrent colorectal cancer, and to surveil for recurrence of a previously treated colorectal cancer. Testing is covered when all the following are met:

1. The patient has been previously diagnosed with an AJCC stage I, II, III or IV colorectal cancer, or a recurrence of colorectal cancer, within the previous five years.
2. The patient has no evidence of neoplastic disease at the time the test is ordered. (If the patient is known to be with cancer or presumed to have cancer, this testing is not indicated).
3. The patient is able to tolerate surgery or adjuvant chemotherapy for residual or recurrent colorectal cancer.
4. Testing may be ordered no more than four times per 12-month period.

To report a Colvera service, please submit the following claim information:

- CPT code 0229U
- Enter Colvera in the comment/narrative field for the following claim/field types:
 - Part A claims:
 - Loop SV202-7 for 837I electronic claim
 - Block 80 for the UB04 claim form
 - Part B claims:
 - Loop 2400 or SV101-7 for the 5010A1 837P
 - Box 19 for the paper claim
- The claim must contain one of the corresponding ICD-10-CM codes listed in the ICD-10-CM Codes that Support Medical Necessity Group 1 below.

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
4. The medical record documentation must support the medical necessity of the services as stated in the LCD.

Specifically, the medical record should reflect whether any biomarker ordered is diagnostic, prognostic or predictive, as well as be able to clearly correlate any test result with given interventions (**e.g., particular selection of chemotherapy**).

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

Note: Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book.

Note: Please see the indications and limitations section of the LCD for details regarding CPT/HCPCS codes: 81292, 81293, 81294, 81321, 81322, 81323, 81437, 81438, 81479, 81520, 81525, 81540, and 81546.

Please see NCD 90.2, Next Generation Sequencing (NGS) for Patients with Advanced Cancer.

Group 1 Codes: (71 Codes)

| CODE | DESCRIPTION |
|-------|------------------------------|
| 81120 | Idh1 common variants |
| 81121 | Idh2 common variants |
| 81170 | Abl1 gene |
| 81175 | Asxl1 full gene sequence |
| 81176 | Asxl1 gene target seq alys |
| 81206 | Bcr/abl1 gene major bp |
| 81207 | Bcr/abl1 gene minor bp |
| 81208 | Bcr/abl1 gene other bp |
| 81210 | Braf gene |
| 81218 | Cebpa gene full sequence |
| 81219 | Calr gene com variants |
| 81233 | Btk gene common variants |
| 81235 | Egfr gene com variants |
| 81236 | Ezh2 gene full gene sequence |
| 81237 | Ezh2 gene common variants |
| 81245 | Flt3 gene |
| 81246 | Flt3 gene analysis |
| 81261 | Igh gene rearrange amp meth |

| CODE | DESCRIPTION |
|-------|------------------------------|
| 81262 | Igh gene rearrang dir probe |
| 81263 | Igh vari regional mutation |
| 81270 | Jak2 gene |
| 81272 | Kit gene targeted seq analys |
| 81273 | Kit gene analys d816 variant |
| 81275 | Kras gene variants exon 2 |
| 81276 | Kras gene addl variants |
| 81287 | Mgmt gene prmtr mthyltn alys |
| 81292 | Mlh1 gene full seq |
| 81293 | Mlh1 gene known variants |
| 81294 | Mlh1 gene dup/delete variant |
| 81301 | Microsatellite instability |
| 81305 | Myd88 gene p.leu265pro vrnt |
| 81310 | Npm1 gene |
| 81311 | Nras gene variants exon 2&3 |
| 81313 | Pca3/klk3 antigen |
| 81314 | Pdgfra gene |
| 81315 | Pml/raralpha com breakpoints |
| 81316 | Pml/raralpha 1 breakpoint |
| 81320 | Plcg2 gene common variants |
| 81321 | Pten gene full sequence |
| 81322 | Pten gene known fam variant |
| 81323 | Pten gene dup/delet variant |
| 81327 | Sept9 gen prmtr mthyltn alys |
| 81334 | Runx1 gene targeted seq alys |
| 81340 | Trb@ gene rearrange amplify |
| 81342 | Trg gene rearrangement anal |
| 81345 | Tert gene targeted seq alys |
| 81347 | Sf3b1 gene common variants |
| 81348 | Srsf2 gene common variants |
| 81351 | Tp53 gene full gene sequence |
| 81352 | Tp53 gene trgt sequence alys |

| CODE | DESCRIPTION |
|-------|------------------------------|
| 81353 | Tp53 gene known famil vrnt |
| 81357 | U2af1 gene common variants |
| 81360 | Zrsr2 gene common variants |
| 81435 | Hereditary colon ca dsordrs |
| 81436 | Hereditary colon ca dsordrs |
| 81437 | Heredtry nurondcrn tum dsrdr |
| 81438 | Heredtry nurondcrn tum dsrdr |
| 81445 | So neo gsap 5-50dna/dna&rna |
| 81450 | HI neo gsap 5-50dna/dna&rna |
| 81479 | Unlisted molecular pathology |
| 81503 | Onco (ovar) five proteins |
| 81520 | Onc breast mrna 58 genes |
| 81525 | Oncology colon mrna |
| 81538 | Oncology lung |
| 81540 | Oncology tum unknown origin |
| 81546 | Onc thyr mrna 10,196 gen alg |
| 0018U | Onc thyr 10 microrna seq alg |
| 0026U | Onc thyr dna&mrna 112 genes |
| 0229U | Bcat1&ikzf1 prmtr mthyln aly |
| 0245U | Onc thyr mut alys 10 gen&37 |
| 0287U | Onc thyr dna&mrna 112 genes |

CPT/HCPCS Modifiers

N/A

ICD-10-CM Codes that Support Medical Necessity

Group 1 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claims(s) submitted.

Refer to NCD 90.2, Next Generation Sequencing (NGS) for Patients with Advanced Cancer for applicable ICD-10-CM codes for CPT code **0022U**.

The following ICD-10-CM codes support medical necessity and provide coverage for the **colorectal cancer** molecular biomarkers (also including the small intestine) listed below and for MAAA CPT code 81525, mRNA gene expression profiling by real time RT-PCR of 12 genes utilizing ffpe tissue, algorithm and report:

KRAS (12/13) **81275**
 KRAS codon 61 **81276**
 KRAS codon 146 **81276**
 NRAS **81311**
 BRAF **81210**
 MSI by PCR **81301**
 MLH1 promoter hypermethylation **81292, 81293, 81294**
 mRNA **81525**
 Sept9 **81327**
 BCAT1/IKZF1 promoter methylation **0229U**

Group 1 Codes: (26 Codes)

| CODE | DESCRIPTION |
|-------|--|
| C17.0 | Malignant neoplasm of duodenum |
| C17.1 | Malignant neoplasm of jejunum |
| C17.2 | Malignant neoplasm of ileum |
| C17.3 | Meckel's diverticulum, malignant |
| C17.8 | Malignant neoplasm of overlapping sites of small intestine |
| C17.9 | Malignant neoplasm of small intestine, unspecified |
| C18.0 | Malignant neoplasm of cecum |
| C18.1 | Malignant neoplasm of appendix |
| C18.2 | Malignant neoplasm of ascending colon |
| C18.3 | Malignant neoplasm of hepatic flexure |
| C18.4 | Malignant neoplasm of transverse colon |
| C18.5 | Malignant neoplasm of splenic flexure |
| C18.6 | Malignant neoplasm of descending colon |
| C18.7 | Malignant neoplasm of sigmoid colon |
| C18.8 | Malignant neoplasm of overlapping sites of colon |
| C18.9 | Malignant neoplasm of colon, unspecified |
| C19 | Malignant neoplasm of rectosigmoid junction |
| C20 | Malignant neoplasm of rectum |
| C21.0 | Malignant neoplasm of anus, unspecified |
| C21.1 | Malignant neoplasm of anal canal |
| C21.2 | Malignant neoplasm of cloacogenic zone |

| CODE | DESCRIPTION |
|---------|---|
| C21.8 | Malignant neoplasm of overlapping sites of rectum, anus and anal canal |
| Z85.030 | Personal history of malignant carcinoid tumor of large intestine |
| Z85.038 | Personal history of other malignant neoplasm of large intestine |
| Z85.040 | Personal history of malignant carcinoid tumor of rectum |
| Z85.048 | Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus |

Group 2 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **non-small cell lung carcinoma (NSCLC)** molecular biomarkers:

EGFR **81235**

KRAS (12/13) **81275**

KRAS codon 61 **81276**

KRAS codon 146 **81276**

BRAF **81210**

Oncology Lung (Veristrat) **81538**

Group 2 Codes: (19 Codes)

| CODE | DESCRIPTION |
|--------|--|
| C33 | Malignant neoplasm of trachea |
| C34.00 | Malignant neoplasm of unspecified main bronchus |
| C34.01 | Malignant neoplasm of right main bronchus |
| C34.02 | Malignant neoplasm of left main bronchus |
| C34.10 | Malignant neoplasm of upper lobe, unspecified bronchus or lung |
| C34.11 | Malignant neoplasm of upper lobe, right bronchus or lung |
| C34.12 | Malignant neoplasm of upper lobe, left bronchus or lung |
| C34.2 | Malignant neoplasm of middle lobe, bronchus or lung |
| C34.30 | Malignant neoplasm of lower lobe, unspecified bronchus or lung |
| C34.31 | Malignant neoplasm of lower lobe, right bronchus or lung |
| C34.32 | Malignant neoplasm of lower lobe, left bronchus or lung |
| C34.80 | Malignant neoplasm of overlapping sites of unspecified bronchus and lung |
| C34.81 | Malignant neoplasm of overlapping sites of right bronchus and lung |
| C34.82 | Malignant neoplasm of overlapping sites of left bronchus and lung |

| CODE | DESCRIPTION |
|--------|--|
| C34.90 | Malignant neoplasm of unspecified part of unspecified bronchus or lung |
| C34.91 | Malignant neoplasm of unspecified part of right bronchus or lung |
| C34.92 | Malignant neoplasm of unspecified part of left bronchus or lung |
| C38.4 | Malignant neoplasm of pleura |
| C45.0 | Mesothelioma of pleura |

Group 3 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **melanoma** molecular biomarkers:

BRAF 81210

KIT 81272

NRAS 81311

Group 3 Codes: (47 Codes)

| CODE | DESCRIPTION |
|---------|--|
| C43.0 | Malignant melanoma of lip |
| C43.10 | Malignant melanoma of unspecified eyelid, including canthus |
| C43.111 | Malignant melanoma of right upper eyelid, including canthus |
| C43.112 | Malignant melanoma of right lower eyelid, including canthus |
| C43.121 | Malignant melanoma of left upper eyelid, including canthus |
| C43.122 | Malignant melanoma of left lower eyelid, including canthus |
| C43.20 | Malignant melanoma of unspecified ear and external auricular canal |
| C43.21 | Malignant melanoma of right ear and external auricular canal |
| C43.22 | Malignant melanoma of left ear and external auricular canal |
| C43.30 | Malignant melanoma of unspecified part of face |
| C43.31 | Malignant melanoma of nose |
| C43.39 | Malignant melanoma of other parts of face |
| C43.4 | Malignant melanoma of scalp and neck |
| C43.51 | Malignant melanoma of anal skin |
| C43.52 | Malignant melanoma of skin of breast |
| C43.59 | Malignant melanoma of other part of trunk |
| C43.60 | Malignant melanoma of unspecified upper limb, including shoulder |

| CODE | DESCRIPTION |
|---------|--|
| C43.61 | Malignant melanoma of right upper limb, including shoulder |
| C43.62 | Malignant melanoma of left upper limb, including shoulder |
| C43.70 | Malignant melanoma of unspecified lower limb, including hip |
| C43.71 | Malignant melanoma of right lower limb, including hip |
| C43.72 | Malignant melanoma of left lower limb, including hip |
| C43.8 | Malignant melanoma of overlapping sites of skin |
| C43.9 | Malignant melanoma of skin, unspecified |
| D03.0 | Melanoma in situ of lip |
| D03.10 | Melanoma in situ of unspecified eyelid, including canthus |
| D03.111 | Melanoma in situ of right upper eyelid, including canthus |
| D03.112 | Melanoma in situ of right lower eyelid, including canthus |
| D03.121 | Melanoma in situ of left upper eyelid, including canthus |
| D03.122 | Melanoma in situ of left lower eyelid, including canthus |
| D03.20 | Melanoma in situ of unspecified ear and external auricular canal |
| D03.21 | Melanoma in situ of right ear and external auricular canal |
| D03.22 | Melanoma in situ of left ear and external auricular canal |
| D03.30 | Melanoma in situ of unspecified part of face |
| D03.39 | Melanoma in situ of other parts of face |
| D03.4 | Melanoma in situ of scalp and neck |
| D03.51 | Melanoma in situ of anal skin |
| D03.52 | Melanoma in situ of breast (skin) (soft tissue) |
| D03.59 | Melanoma in situ of other part of trunk |
| D03.60 | Melanoma in situ of unspecified upper limb, including shoulder |
| D03.61 | Melanoma in situ of right upper limb, including shoulder |
| D03.62 | Melanoma in situ of left upper limb, including shoulder |
| D03.70 | Melanoma in situ of unspecified lower limb, including hip |
| D03.71 | Melanoma in situ of right lower limb, including hip |
| D03.72 | Melanoma in situ of left lower limb, including hip |
| D03.8 | Melanoma in situ of other sites |
| D03.9 | Melanoma in situ, unspecified |

Group 4 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **Uveal Melanoma**:

GNA11 - **81479**

Group 4 Codes: (16 Codes)

| CODE | DESCRIPTION |
|--------|---|
| C69.01 | Malignant neoplasm of right conjunctiva |
| C69.02 | Malignant neoplasm of left conjunctiva |
| C69.11 | Malignant neoplasm of right cornea |
| C69.12 | Malignant neoplasm of left cornea |
| C69.21 | Malignant neoplasm of right retina |
| C69.22 | Malignant neoplasm of left retina |
| C69.31 | Malignant neoplasm of right choroid |
| C69.32 | Malignant neoplasm of left choroid |
| C69.41 | Malignant neoplasm of right ciliary body |
| C69.42 | Malignant neoplasm of left ciliary body |
| C69.51 | Malignant neoplasm of right lacrimal gland and duct |
| C69.52 | Malignant neoplasm of left lacrimal gland and duct |
| C69.61 | Malignant neoplasm of right orbit |
| C69.62 | Malignant neoplasm of left orbit |
| C69.81 | Malignant neoplasm of overlapping sites of right eye and adnexa |
| C69.82 | Malignant neoplasm of overlapping sites of left eye and adnexa |

Group 5 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **brain** molecular biomarkers:

BRAF **81210**

EGFR **81235**

MGMT **81287**

PTEN **81321, 81322, 81323, 81479**

CIMP **81479**

IDH1 **81120**

IDH2 **81121**
TERT **81345**

Group 5 Codes: (10 Codes)

| CODE | DESCRIPTION |
|-------|---|
| C71.0 | Malignant neoplasm of cerebrum, except lobes and ventricles |
| C71.1 | Malignant neoplasm of frontal lobe |
| C71.2 | Malignant neoplasm of temporal lobe |
| C71.3 | Malignant neoplasm of parietal lobe |
| C71.4 | Malignant neoplasm of occipital lobe |
| C71.5 | Malignant neoplasm of cerebral ventricle |
| C71.6 | Malignant neoplasm of cerebellum |
| C71.7 | Malignant neoplasm of brain stem |
| C71.8 | Malignant neoplasm of overlapping sites of brain |
| C71.9 | Malignant neoplasm of brain, unspecified |

Group 6 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **thyroid** molecular biomarkers:

BRAF - **81210**

KRAS - **81275, 81276**

NRAS - **81311**

ThyraMIR - **0018U**

Afirma - **81546**

RosettaGX Reveal Thyroid miRNA - **81479**

ThyGeNEXT - **0245U**

ThyroSeq - **0026U, 0287U**

Group 6 Codes: (13 Codes)

| CODE | DESCRIPTION |
|--------|---|
| C73* | Malignant neoplasm of thyroid gland |
| D34 | Benign neoplasm of thyroid gland |
| D44.0 | Neoplasm of uncertain behavior of thyroid gland |
| D44.2* | Neoplasm of uncertain behavior of parathyroid gland |
| D44.9 | Neoplasm of uncertain behavior of unspecified endocrine gland |

| CODE | DESCRIPTION |
|-------|---|
| E01.0 | Iodine-deficiency related diffuse (endemic) goiter |
| E01.1 | Iodine-deficiency related multinodular (endemic) goiter |
| E01.2 | Iodine-deficiency related (endemic) goiter, unspecified |
| E04.0 | Nontoxic diffuse goiter |
| E04.1 | Nontoxic single thyroid nodule |
| E04.2 | Nontoxic multinodular goiter |
| E04.8 | Other specified nontoxic goiter |
| E04.9 | Nontoxic goiter, unspecified |

Group 6 Medical Necessity ICD-10-CM Codes Asterisk Explanation:

* **Note:** C73 should not be reported for ThyraMIR, Afirma, Rosetta GX Reveal or ThyGeNEXT.

*D44.2 should not be reported for ThyraMIR, Afirma, Rosetta GX Reveal, ThyGeNEXT, or ThyroSeq.

Group 7 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **uterus/ovary/fallopian tube/peritoneum** molecular biomarkers:

AKT1 **81479**

BRAF **81210**

KRAS **81275, 81276**

MLH1 promoter hypermethylation **81292, 81293, 81294**

MSI by PCR **81301**

PTEN **81321, 81322, 81323, 81479**

Group 7 Codes: (26 Codes)

| CODE | DESCRIPTION |
|-------|---|
| C45.1 | Mesothelioma of peritoneum |
| C48.1 | Malignant neoplasm of specified parts of peritoneum |
| C48.2 | Malignant neoplasm of peritoneum, unspecified |
| C48.8 | Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum |
| C54.0 | Malignant neoplasm of isthmus uteri |
| C54.1 | Malignant neoplasm of endometrium |
| C54.2 | Malignant neoplasm of myometrium |
| C54.3 | Malignant neoplasm of fundus uteri |

| CODE | DESCRIPTION |
|--------|---|
| C54.8 | Malignant neoplasm of overlapping sites of corpus uteri |
| C54.9 | Malignant neoplasm of corpus uteri, unspecified |
| C55 | Malignant neoplasm of uterus, part unspecified |
| C56.1 | Malignant neoplasm of right ovary |
| C56.2 | Malignant neoplasm of left ovary |
| C56.3 | Malignant neoplasm of bilateral ovaries |
| C56.9 | Malignant neoplasm of unspecified ovary |
| C57.00 | Malignant neoplasm of unspecified fallopian tube |
| C57.01 | Malignant neoplasm of right fallopian tube |
| C57.02 | Malignant neoplasm of left fallopian tube |
| C57.10 | Malignant neoplasm of unspecified broad ligament |
| C57.11 | Malignant neoplasm of right broad ligament |
| C57.12 | Malignant neoplasm of left broad ligament |
| C57.20 | Malignant neoplasm of unspecified round ligament |
| C57.21 | Malignant neoplasm of right round ligament |
| C57.22 | Malignant neoplasm of left round ligament |
| C57.3 | Malignant neoplasm of parametrium |
| C57.4 | Malignant neoplasm of uterine adnexa, unspecified |

Group 8 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **urinary tract** molecular biomarkers:

MSI by PCR **81301**

MLH1 promoter hypermethylation **81292, 81293, 81294**

Group 8 Codes: (10 Codes)

| CODE | DESCRIPTION |
|-------|--|
| C65.1 | Malignant neoplasm of right renal pelvis |
| C65.2 | Malignant neoplasm of left renal pelvis |
| C65.9 | Malignant neoplasm of unspecified renal pelvis |
| C66.1 | Malignant neoplasm of right ureter |

| CODE | DESCRIPTION |
|-------|---|
| C66.2 | Malignant neoplasm of left ureter |
| C66.9 | Malignant neoplasm of unspecified ureter |
| C68.0 | Malignant neoplasm of urethra |
| C68.1 | Malignant neoplasm of paraurethral glands |
| C68.8 | Malignant neoplasm of overlapping sites of urinary organs |
| C68.9 | Malignant neoplasm of urinary organ, unspecified |

Group 9 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **prostate cancer** molecular biomarkers:

PROGENSA® PCA3 Assay - **81313**
PTEN – **81321, 81322, 81323**
RB1 - **81479**

Group 9 Codes: (13 Codes)

| CODE | DESCRIPTION |
|--------|---|
| C61 | Malignant neoplasm of prostate |
| D29.1 | Benign neoplasm of prostate |
| D40.0 | Neoplasm of uncertain behavior of prostate |
| N40.0 | Benign prostatic hyperplasia without lower urinary tract symptoms |
| N40.1 | Benign prostatic hyperplasia with lower urinary tract symptoms |
| N40.2 | Nodular prostate without lower urinary tract symptoms |
| N40.3 | Nodular prostate with lower urinary tract symptoms |
| N42.31 | Prostatic intraepithelial neoplasia |
| N42.32 | Atypical small acinar proliferation of prostate |
| N42.39 | Other dysplasia of prostate |
| N42.83 | Cyst of prostate |
| R31.1 | Benign essential microscopic hematuria |
| R31.29 | Other microscopic hematuria |

Group 10 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the

ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **gastrointestinal stromal tumor** molecular biomarkers:

KIT **81272**

PDGFRA **81314**

Group 10 Codes: (9 Codes)

| CODE | DESCRIPTION |
|--------|--|
| C49.A0 | Gastrointestinal stromal tumor, unspecified site |
| C49.A1 | Gastrointestinal stromal tumor of esophagus |
| C49.A2 | Gastrointestinal stromal tumor of stomach |
| C49.A3 | Gastrointestinal stromal tumor of small intestine |
| C49.A4 | Gastrointestinal stromal tumor of large intestine |
| C49.A5 | Gastrointestinal stromal tumor of rectum |
| C49.A9 | Gastrointestinal stromal tumor of other sites |
| D48.19 | Other specified neoplasm of uncertain behavior of connective and other soft tissue |
| D48.2 | Neoplasm of uncertain behavior of peripheral nerves and autonomic nervous system |

Group 11 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **acute lymphoid leukemia (ALL)** molecular biomarkers:

BCR/ABL1 **81206, 81207, 81208**

ABL1 (kinase domain) **81170**

IGH **81261**

JAK1 **81479**

JAK2 **81270**

NRAS **81311**

FBXW7 **81479**

TCRB **81340**

TCRG **81342**

MLL/AF4 **81479**

RUNX1 **81334**

Group 11 Codes: (3 Codes)

| CODE | DESCRIPTION |
|--------|--|
| C91.00 | Acute lymphoblastic leukemia not having achieved remission |

| CODE | DESCRIPTION |
|--------|--|
| C91.01 | Acute lymphoblastic leukemia, in remission |
| C91.02 | Acute lymphoblastic leukemia, in relapse |

Group 12 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **acute myeloid leukemia (AML, and including acute promyelocytic leukemia)** molecular biomarkers:

PML/RARA **81315**
PML/RARalpha **81316**
FLT3D835 **81245**
FLT3 ITD **81245**
NPM1 **81310**
KRAS **81275, 81276**
NRAS **81311**
KIT **81273**
CEBPA **81218**
JAK2 (p.V617F) **81270**
DEK/CAN **81479**
ASXL1 **81175, 81176**
EZH2 **81236, 81237**
TET2 **81479**
IDH1 **81120**
IDH2 **81121**
RUNX1 **81334**
U2AF1 **81357**
SRSF2 **81348**
TP53 **81351, 81352, 81353**
ZRSR2 **81360**

Group 12 Codes: (15 Codes)

| CODE | DESCRIPTION |
|--------|--|
| C92.00 | Acute myeloblastic leukemia, not having achieved remission |
| C92.01 | Acute myeloblastic leukemia, in remission |
| C92.02 | Acute myeloblastic leukemia, in relapse |
| C92.40 | Acute promyelocytic leukemia, not having achieved remission |
| C92.41 | Acute promyelocytic leukemia, in remission |
| C92.42 | Acute promyelocytic leukemia, in relapse |
| C92.50 | Acute myelomonocytic leukemia, not having achieved remission |
| C92.51 | Acute myelomonocytic leukemia, in remission |

| CODE | DESCRIPTION |
|--------|---|
| C92.52 | Acute myelomonocytic leukemia, in relapse |
| C92.60 | Acute myeloid leukemia with 11q23-abnormality not having achieved remission |
| C92.61 | Acute myeloid leukemia with 11q23-abnormality in remission |
| C92.62 | Acute myeloid leukemia with 11q23-abnormality in relapse |
| C92.A0 | Acute myeloid leukemia with multilineage dysplasia, not having achieved remission |
| C92.A1 | Acute myeloid leukemia with multilineage dysplasia, in remission |
| C92.A2 | Acute myeloid leukemia with multilineage dysplasia, in relapse |

Group 13 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **hairy cell leukemia** molecular biomarkers:

IGH somatic hypermutation **81263**

IGH **81261**

Group 13 Codes: (3 Codes)

| CODE | DESCRIPTION |
|--------|---|
| C91.40 | Hairy cell leukemia not having achieved remission |
| C91.41 | Hairy cell leukemia, in remission |
| C91.42 | Hairy cell leukemia, in relapse |

Group 14 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **aplastic anemia** molecular biomarkers:

TCRB **81340**

TCRG **81342**

Group 14 Codes: (12 Codes)

| CODE | DESCRIPTION |
|-------|--|
| D60.0 | Chronic acquired pure red cell aplasia |
| D60.1 | Transient acquired pure red cell aplasia |
| D60.8 | Other acquired pure red cell aplasias |

| CODE | DESCRIPTION |
|--------|--|
| D60.9 | Acquired pure red cell aplasia, unspecified |
| D61.01 | Constitutional (pure) red blood cell aplasia |
| D61.03 | Fanconi anemia |
| D61.09 | Other constitutional aplastic anemia |
| D61.1 | Drug-induced aplastic anemia |
| D61.2 | Aplastic anemia due to other external agents |
| D61.3 | Idiopathic aplastic anemia |
| D61.89 | Other specified aplastic anemias and other bone marrow failure syndromes |
| D61.9 | Aplastic anemia, unspecified |

Group 15 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **Burkitt's lymphoma** molecular biomarkers:

IGH **81261**

Group 15 Codes: (11 Codes)

| CODE | DESCRIPTION |
|--------|---|
| C83.70 | Burkitt lymphoma, unspecified site |
| C83.71 | Burkitt lymphoma, lymph nodes of head, face, and neck |
| C83.72 | Burkitt lymphoma, intrathoracic lymph nodes |
| C83.73 | Burkitt lymphoma, intra-abdominal lymph nodes |
| C83.74 | Burkitt lymphoma, lymph nodes of axilla and upper limb |
| C83.75 | Burkitt lymphoma, lymph nodes of inguinal region and lower limb |
| C83.76 | Burkitt lymphoma, intrapelvic lymph nodes |
| C83.77 | Burkitt lymphoma, spleen |
| C83.78 | Burkitt lymphoma, lymph nodes of multiple sites |
| C83.79 | Burkitt lymphoma, extranodal and solid organ sites |
| C83.7A | Burkitt lymphoma, in remission |

Group 16 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **myeloproliferative diseases (MPD - essential thrombocytosis [ET], myelofibrosis & polycythemia vera [PV])** molecular biomarkers:

BCR/ABL1 **81206, 81207, 81208**

JAK2 (p.V617F) **81270**

CALR **81479**

CALR (exon 9) **81219**

CSF3R **81479**

ASXL1 **81175, 81176**

TET2 **81479**

EZH2 **81236, 81237**

KIT **81272, 81273**

TP53 **81351, 81352, 81353**

Group 16 Codes: (4 Codes)

| CODE | DESCRIPTION |
|--------|--|
| D45 | Polycythemia vera |
| D47.1 | Chronic myeloproliferative disease |
| D47.3 | Essential (hemorrhagic) thrombocytopenia |
| D75.81 | Myelofibrosis |

Group 17 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **chronic myeloid leukemia (CML) and chronic myelomonocytic leukemia (CMML)** molecular biomarkers:

KRAS **81275, 81276**

NRAS **81311**

BCR/ABL1 **81206, 81207, 81208**

ABL1 (kinase domain) **81170**

FLT3 ITD **81245**

KIT **81273**

JAK2 (p.V617F) **81270**

Group 17 Codes: (6 Codes)

| CODE | DESCRIPTION |
|--------|---|
| C92.10 | Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission |
| C92.11 | Chronic myeloid leukemia, BCR/ABL-positive, in remission |
| C92.12 | Chronic myeloid leukemia, BCR/ABL-positive, in relapse |
| C93.10 | Chronic myelomonocytic leukemia not having achieved remission |

| CODE | DESCRIPTION |
|--------|---|
| C93.11 | Chronic myelomonocytic leukemia, in remission |
| C93.12 | Chronic myelomonocytic leukemia, in relapse |

Group 18 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **chronic lymphoid leukemia (CLL)** molecular biomarkers:

IGH **81261**

IGH direct probe method **81262**

IGH somatic hypermutation **81263**

BTK **81233**

PLCG2 **81320**

BIRC3 **81479**

SF3B1 **81347**

Group 18 Codes: (3 Codes)

| CODE | DESCRIPTION |
|--------|---|
| C91.10 | Chronic lymphocytic leukemia of B-cell type not having achieved remission |
| C91.11 | Chronic lymphocytic leukemia of B-cell type in remission |
| C91.12 | Chronic lymphocytic leukemia of B-cell type in relapse |

Group 19 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM code supports medical necessity and provides coverage for **T-cell Large Granular Lymphocytic Leukemia** molecular biomarkers:

STAT5B **81479**

Group 19 Codes: (3 Codes)

| CODE | DESCRIPTION |
|--------|---|
| C91.Z0 | Other lymphoid leukemia not having achieved remission |
| C91.Z1 | Other lymphoid leukemia, in remission |
| C91.Z2 | Other lymphoid leukemia, in relapse |

Group 20 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the

ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **Hypereosinophilia Syndrome (HES)** molecular biomarkers:

KIT (including p.D816V) **81273**

Group 20 Codes: (4 Codes)

| CODE | DESCRIPTION |
|---------|---|
| D72.110 | Idiopathic hypereosinophilic syndrome [IHES] |
| D72.111 | Lymphocytic Variant Hypereosinophilic Syndrome [LHES] |
| D72.118 | Other hypereosinophilic syndrome |
| D72.119 | Hypereosinophilic syndrome [HES], unspecified |

Group 21 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **mastocytosis** molecular biomarkers:

KIT (including p.D816V) **81273**

TCRG **81342**

Group 21 Codes: (3 Codes)

| CODE | DESCRIPTION |
|--------|---|
| C96.20 | Malignant mast cell neoplasm, unspecified |
| C96.22 | Mast cell sarcoma |
| C96.29 | Other malignant mast cell neoplasm |

Group 22 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **T-cell prolymphocytic leukemia** molecular biomarkers:

JAK1 **81479**

JAK3 **81479**

TCRB **81340**

TCRG **81342**

Group 22 Codes: (6 Codes)

| CODE | DESCRIPTION |
|--------|--|
| C91.60 | Prolymphocytic leukemia of T-cell type not having achieved remission |
| C91.61 | Prolymphocytic leukemia of T-cell type, in remission |
| C91.62 | Prolymphocytic leukemia of T-cell type, in relapse |
| C95.90 | Leukemia, unspecified not having achieved remission |
| C95.91 | Leukemia, unspecified, in remission |
| C95.92 | Leukemia, unspecified, in relapse |

Group 23 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **myelodysplastic syndrome (MDS)** molecular biomarkers:

FLT3 ITD **81245**

NPM1 **81310**

KRAS **81275, 81276**

NRAS **81311**

KIT **81273**

CEBPA **81218**

JAK2 (p.V617F) **81270**

ASXL1 **81175, 81176**

EZH2 **81236, 81237**

TET2 **81479**

IDH1 **81120**

IDH2 **81121**

Group 23 Codes: (11 Codes)

| CODE | DESCRIPTION |
|--------|--|
| D46.0 | Refractory anemia without ring sideroblasts, so stated |
| D46.1 | Refractory anemia with ring sideroblasts |
| D46.20 | Refractory anemia with excess of blasts, unspecified |
| D46.21 | Refractory anemia with excess of blasts 1 |
| D46.22 | Refractory anemia with excess of blasts 2 |
| D46.A | Refractory cytopenia with multilineage dysplasia |
| D46.B | Refractory cytopenia with multilineage dysplasia and ring sideroblasts |
| D46.C | Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality |
| D46.4 | Refractory anemia, unspecified |

| CODE | DESCRIPTION |
|-------|---------------------------------------|
| D46.Z | Other myelodysplastic syndromes |
| D46.9 | Myelodysplastic syndrome, unspecified |

Group 24 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **Myeloma gene expression profile (MyPRS) (CPT code 81479)**:

Group 24 Codes: (2 Codes)

| CODE | DESCRIPTION |
|---------|--|
| C90.00* | Multiple myeloma not having achieved remission |
| C90.02* | Multiple myeloma in relapse |

Group 24 Medical Necessity ICD-10-CM Codes Asterisk Explanation:

***Note: C90.00** should be reported after initial diagnosis has been made and **C90.02** should be reported if there has been a relapse with a change in treatment planned.

Group 25 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **CPT code 81520**:

Group 25 Codes: (18 Codes)

| CODE | DESCRIPTION |
|---------|---|
| C50.011 | Malignant neoplasm of nipple and areola, right female breast |
| C50.012 | Malignant neoplasm of nipple and areola, left female breast |
| C50.111 | Malignant neoplasm of central portion of right female breast |
| C50.112 | Malignant neoplasm of central portion of left female breast |
| C50.211 | Malignant neoplasm of upper-inner quadrant of right female breast |
| C50.212 | Malignant neoplasm of upper-inner quadrant of left female breast |
| C50.311 | Malignant neoplasm of lower-inner quadrant of right female breast |
| C50.312 | Malignant neoplasm of lower-inner quadrant of left female breast |
| C50.411 | Malignant neoplasm of upper-outer quadrant of right female breast |
| C50.412 | Malignant neoplasm of upper-outer quadrant of left female breast |

| CODE | DESCRIPTION |
|---------|---|
| C50.511 | Malignant neoplasm of lower-outer quadrant of right female breast |
| C50.512 | Malignant neoplasm of lower-outer quadrant of left female breast |
| C50.611 | Malignant neoplasm of axillary tail of right female breast |
| C50.612 | Malignant neoplasm of axillary tail of left female breast |
| C50.811 | Malignant neoplasm of overlapping sites of right female breast |
| C50.812 | Malignant neoplasm of overlapping sites of left female breast |
| C50.911 | Malignant neoplasm of unspecified site of right female breast |
| C50.912 | Malignant neoplasm of unspecified site of left female breast |

Group 26 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **Neuroendocrine Tumors:**

MAX – **81437**

MGMT – **81287**

PTEN – **81321, 81322, 81323**

RB1 - **81479**

SDHB – **81437, 81438**

SDHC – **81437, 81438**

SDHD – **81437, 81438**

TMEM127 – **81437**

TSC2 - **81479**

VHL – **81437, 81438**

Group 26 Codes: (50 Codes)

| CODE | DESCRIPTION |
|---------|---|
| C7A.010 | Malignant carcinoid tumor of the duodenum |
| C7A.011 | Malignant carcinoid tumor of the jejunum |
| C7A.012 | Malignant carcinoid tumor of the ileum |
| C7A.019 | Malignant carcinoid tumor of the small intestine, unspecified portion |
| C7A.020 | Malignant carcinoid tumor of the appendix |
| C7A.021 | Malignant carcinoid tumor of the cecum |
| C7A.022 | Malignant carcinoid tumor of the ascending colon |
| C7A.023 | Malignant carcinoid tumor of the transverse colon |
| C7A.024 | Malignant carcinoid tumor of the descending colon |
| C7A.025 | Malignant carcinoid tumor of the sigmoid colon |

| CODE | DESCRIPTION |
|-------------|---|
| C7A.026 | Malignant carcinoid tumor of the rectum |
| C7A.029 | Malignant carcinoid tumor of the large intestine, unspecified portion |
| C7A.090 | Malignant carcinoid tumor of the bronchus and lung |
| C7A.091 | Malignant carcinoid tumor of the thymus |
| C7A.092 | Malignant carcinoid tumor of the stomach |
| C7A.093 | Malignant carcinoid tumor of the kidney |
| C7A.094 | Malignant carcinoid tumor of the foregut, unspecified |
| C7A.095 | Malignant carcinoid tumor of the midgut, unspecified |
| C7A.096 | Malignant carcinoid tumor of the hindgut, unspecified |
| C7A.098 | Malignant carcinoid tumors of other sites |
| C7A.1 | Malignant poorly differentiated neuroendocrine tumors |
| C7A.8 | Other malignant neuroendocrine tumors |
| C7B.01 | Secondary carcinoid tumors of distant lymph nodes |
| C7B.02 | Secondary carcinoid tumors of liver |
| C7B.03 | Secondary carcinoid tumors of bone |
| C7B.04 | Secondary carcinoid tumors of peritoneum |
| C7B.09 | Secondary carcinoid tumors of other sites |
| C7B.1 | Secondary Merkel cell carcinoma |
| C7B.8 | Other secondary neuroendocrine tumors |
| D3A.010 | Benign carcinoid tumor of the duodenum |
| D3A.011 | Benign carcinoid tumor of the jejunum |
| D3A.012 | Benign carcinoid tumor of the ileum |
| D3A.019 | Benign carcinoid tumor of the small intestine, unspecified portion |
| D3A.020 | Benign carcinoid tumor of the appendix |
| D3A.021 | Benign carcinoid tumor of the cecum |
| D3A.022 | Benign carcinoid tumor of the ascending colon |
| D3A.023 | Benign carcinoid tumor of the transverse colon |
| D3A.024 | Benign carcinoid tumor of the descending colon |
| D3A.025 | Benign carcinoid tumor of the sigmoid colon |
| D3A.026 | Benign carcinoid tumor of the rectum |
| D3A.029 | Benign carcinoid tumor of the large intestine, unspecified portion |
| D3A.090 | Benign carcinoid tumor of the bronchus and lung |

| CODE | DESCRIPTION |
|---------|--|
| D3A.091 | Benign carcinoid tumor of the thymus |
| D3A.092 | Benign carcinoid tumor of the stomach |
| D3A.093 | Benign carcinoid tumor of the kidney |
| D3A.094 | Benign carcinoid tumor of the foregut, unspecified |
| D3A.095 | Benign carcinoid tumor of the midgut, unspecified |
| D3A.096 | Benign carcinoid tumor of the hindgut, unspecified |
| D3A.098 | Benign carcinoid tumors of other sites |
| D3A.8 | Other benign neuroendocrine tumors |

Group 27 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **CPT code 81540 – TUO CTID (Cancer Type ID):**

Group 27 Codes: (106 Codes)

| CODE | DESCRIPTION |
|--------|--|
| C18.1 | Malignant neoplasm of appendix |
| C18.9 | Malignant neoplasm of colon, unspecified |
| C22.0 | Liver cell carcinoma |
| C22.2 | Hepatoblastoma |
| C22.3 | Angiosarcoma of liver |
| C22.4 | Other sarcomas of liver |
| C22.7 | Other specified carcinomas of liver |
| C22.8 | Malignant neoplasm of liver, primary, unspecified as to type |
| C22.9 | Malignant neoplasm of liver, not specified as primary or secondary |
| C25.2 | Malignant neoplasm of tail of pancreas |
| C25.7 | Malignant neoplasm of other parts of pancreas |
| C25.8 | Malignant neoplasm of overlapping sites of pancreas |
| C25.9 | Malignant neoplasm of pancreas, unspecified |
| C33 | Malignant neoplasm of trachea |
| C34.01 | Malignant neoplasm of right main bronchus |
| C34.02 | Malignant neoplasm of left main bronchus |

| CODE | DESCRIPTION |
|---------|---|
| C34.11 | Malignant neoplasm of upper lobe, right bronchus or lung |
| C34.12 | Malignant neoplasm of upper lobe, left bronchus or lung |
| C34.2 | Malignant neoplasm of middle lobe, bronchus or lung |
| C34.32 | Malignant neoplasm of lower lobe, left bronchus or lung |
| C34.81 | Malignant neoplasm of overlapping sites of right bronchus and lung |
| C34.82 | Malignant neoplasm of overlapping sites of left bronchus and lung |
| C34.91 | Malignant neoplasm of unspecified part of right bronchus or lung |
| C34.92 | Malignant neoplasm of unspecified part of left bronchus or lung |
| C43.51 | Malignant melanoma of anal skin |
| C43.52 | Malignant melanoma of skin of breast |
| C43.59 | Malignant melanoma of other part of trunk |
| C45.9 | Mesothelioma, unspecified |
| C47.0 | Malignant neoplasm of peripheral nerves of head, face and neck |
| C47.9 | Malignant neoplasm of peripheral nerves and autonomic nervous system, unspecified |
| C48.0 | Malignant neoplasm of retroperitoneum |
| C49.0 | Malignant neoplasm of connective and soft tissue of head, face and neck |
| C49.9 | Malignant neoplasm of connective and soft tissue, unspecified |
| C50.411 | Malignant neoplasm of upper-outer quadrant of right female breast |
| C50.412 | Malignant neoplasm of upper-outer quadrant of left female breast |
| C50.511 | Malignant neoplasm of lower-outer quadrant of right female breast |
| C50.512 | Malignant neoplasm of lower-outer quadrant of left female breast |
| C50.811 | Malignant neoplasm of overlapping sites of right female breast |
| C50.812 | Malignant neoplasm of overlapping sites of left female breast |
| C50.911 | Malignant neoplasm of unspecified site of right female breast |
| C50.912 | Malignant neoplasm of unspecified site of left female breast |
| C56.1 | Malignant neoplasm of right ovary |
| C56.2 | Malignant neoplasm of left ovary |
| C56.3 | Malignant neoplasm of bilateral ovaries |
| C61 | Malignant neoplasm of prostate |
| C64.1 | Malignant neoplasm of right kidney, except renal pelvis |
| C64.2 | Malignant neoplasm of left kidney, except renal pelvis |

| CODE | DESCRIPTION |
|-------------|---|
| C67.5 | Malignant neoplasm of bladder neck |
| C67.9 | Malignant neoplasm of bladder, unspecified |
| C76.0 | Malignant neoplasm of head, face and neck |
| C77.0 | Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck |
| C77.1 | Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes |
| C77.2 | Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes |
| C77.3 | Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes |
| C77.4 | Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes |
| C77.5 | Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes |
| C77.8 | Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions |
| C77.9 | Secondary and unspecified malignant neoplasm of lymph node, unspecified |
| C78.01 | Secondary malignant neoplasm of right lung |
| C78.02 | Secondary malignant neoplasm of left lung |
| C78.5 | Secondary malignant neoplasm of large intestine and rectum |
| C78.6 | Secondary malignant neoplasm of retroperitoneum and peritoneum |
| C78.7 | Secondary malignant neoplasm of liver and intrahepatic bile duct |
| C79.01 | Secondary malignant neoplasm of right kidney and renal pelvis |
| C79.02 | Secondary malignant neoplasm of left kidney and renal pelvis |
| C79.2 | Secondary malignant neoplasm of skin |
| C79.31 | Secondary malignant neoplasm of brain |
| C79.49 | Secondary malignant neoplasm of other parts of nervous system |
| C79.51 | Secondary malignant neoplasm of bone |
| C79.52 | Secondary malignant neoplasm of bone marrow |
| C79.61 | Secondary malignant neoplasm of right ovary |
| C79.62 | Secondary malignant neoplasm of left ovary |
| C79.63 | Secondary malignant neoplasm of bilateral ovaries |
| C79.89 | Secondary malignant neoplasm of other specified sites |
| C80.0 | Disseminated malignant neoplasm, unspecified |
| C80.1 | Malignant (primary) neoplasm, unspecified |
| C82.57 | Diffuse follicle center lymphoma, spleen |

| CODE | DESCRIPTION |
|---------|--|
| C84.A7 | Cutaneous T-cell lymphoma, unspecified, spleen |
| C84.Z7 | Other mature T/NK-cell lymphomas, spleen |
| C84.97 | Mature T/NK-cell lymphomas, unspecified, spleen |
| C85.17 | Unspecified B-cell lymphoma, spleen |
| C85.27 | Mediastinal (thymic) large B-cell lymphoma, spleen |
| C85.87 | Other specified types of non-Hodgkin lymphoma, spleen |
| C85.97 | Non-Hodgkin lymphoma, unspecified, spleen |
| C86.10 | Hepatosplenic T-cell lymphoma not having achieved remission |
| D01.5 | Carcinoma in situ of liver, gallbladder and bile ducts |
| D01.7 | Carcinoma in situ of other specified digestive organs |
| D01.9 | Carcinoma in situ of digestive organ, unspecified |
| D02.21 | Carcinoma in situ of right bronchus and lung |
| D02.22 | Carcinoma in situ of left bronchus and lung |
| D03.51 | Melanoma in situ of anal skin |
| D03.52 | Melanoma in situ of breast (skin) (soft tissue) |
| D03.59 | Melanoma in situ of other part of trunk |
| D49.0 | Neoplasm of unspecified behavior of digestive system |
| D49.1 | Neoplasm of unspecified behavior of respiratory system |
| D49.2 | Neoplasm of unspecified behavior of bone, soft tissue, and skin |
| D49.3 | Neoplasm of unspecified behavior of breast |
| D49.4 | Neoplasm of unspecified behavior of bladder |
| D49.511 | Neoplasm of unspecified behavior of right kidney |
| D49.512 | Neoplasm of unspecified behavior of left kidney |
| D49.59 | Neoplasm of unspecified behavior of other genitourinary organ |
| CODE | DESCRIPTION |
| D49.6 | Neoplasm of unspecified behavior of brain |
| D49.7 | Neoplasm of unspecified behavior of endocrine glands and other parts of nervous system |
| D49.89 | Neoplasm of unspecified behavior of other specified sites |
| D49.9 | Neoplasm of unspecified behavior of unspecified site |
| J91.0 | Malignant pleural effusion |

Group 28 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for **Bladder:**

FGFR1 – **81479**
 MTOR – **81479**
 PTEN – **81321, 81322, 81323**
 RB1 – **81479**

Group 28 Codes: (10 Codes)

| CODE | DESCRIPTION |
|-------|--|
| C67.0 | Malignant neoplasm of trigone of bladder |
| C67.1 | Malignant neoplasm of dome of bladder |
| C67.2 | Malignant neoplasm of lateral wall of bladder |
| C67.3 | Malignant neoplasm of anterior wall of bladder |
| C67.4 | Malignant neoplasm of posterior wall of bladder |
| C67.5 | Malignant neoplasm of bladder neck |
| C67.6 | Malignant neoplasm of ureteric orifice |
| C67.7 | Malignant neoplasm of urachus |
| C67.8 | Malignant neoplasm of overlapping sites of bladder |
| C67.9 | Malignant neoplasm of bladder, unspecified |

Group 29 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM code supports medical necessity and provides coverage for **Waldenstrom's/Lymphoplasmacytic Lymphoma** molecular biomarkers:

MYD88 **81305**

Group 29 Codes: (1 Code)

| CODE | DESCRIPTION |
|--------|---|
| C88.00 | Waldenstrom macroglobulinemia not having achieved remission |

ICD-10-CM Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

All those not listed under the "ICD-10-CM Codes that Support Medical Necessity" section of this article.

Group 1 Codes: (1 Code)

| CODE | DESCRIPTION |
|-------|----------------|
| XX000 | Not Applicable |

ICD-10-PCS Codes

N/A

Additional ICD-10 Information

N/A

Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

| CODE | DESCRIPTION |
|------|----------------|
| 999x | Not Applicable |

Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

| CODE | DESCRIPTION |
|-------|----------------|
| 99999 | Not Applicable |

Other Coding Information

N/A

Revision History Information

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION |
|-----------------------|-------------------------|--|
| 10/01/2024 | R45 | Article revised and published on 10/24/2024 effective for dates of service on and after 10/01/2024 to reflect the Annual ICD-10-CM Code Updates. The following code has been deleted and therefore removed from Group 27 Codes: C86.1. The following code has been deleted and therefore removed from Group 29 Codes: C88.0. The following codes have been added: D61.03 to Group 14 Codes, C83.7A to Group 15 Codes, C86.10 to Group 27 Codes, and C88.00 to Group 29 Codes. |
| 02/29/2024 | R44 | Article revised and published on 02/29/2024 to correct the Note in the CPT/HCPCS Codes Group 1 Paragraph. This paragraph was inadvertently changed with the 10/26/2023 revision. The diagnosis limitations outlined in the various ICD-10-CM Codes that Support Medical Necessity groups continue to apply. |
| 01/01/2024 | R43 | Article revised and published on 01/25/2024 effective for dates of service on and after 01/01/2024 to reflect the Annual HCPCS/CPT Code Updates. For the following CPT codes either the short description and/or the long description was changed. Depending on which description is used in this article, there may not be any change in how the code displays: 81445 and 81450 in Group 1 CPT/HCPCS Codes. |
| 10/01/2023 | R42 | Article revised and published on 10/26/2023 effective for dates of service on and after 10/01/2023 to reflect the Annual ICD-10-CM Code Updates. The following ICD-10-CM code has been deleted and therefore has been removed from the article: D48.1 in Group 10 Codes. The following ICD-10-CM code has been added to the article: D48.19 in Group 10 Codes. Minor formatting changes have been made throughout the article. |
| 08/07/2023 | R41 | Article revised and published on 09/07/2023 effective for dates of service on and after 08/07/2023 to remove the link and to revise the verbiage referring to NCD 90.2 located in the ICD-10-CM Codes that Support Medical Necessity Group 1 Paragraph. The link for NCD 90.2 has been added to the Associated Documents section at the bottom of this article under Related National Coverage Documents. |
| 08/07/2023 | R40 | Article revised and published on 08/31/2023 effective for dates of service on and after 08/07/2023 with the updated link to NCD 90.2 Transmittal TN 12017 in response to CMS Change Request (CR) 13166. This updated link is located in the ICD-10-CM Codes that Support Medical Necessity Group 1 Paragraph. |
| 01/01/2023 | R39 | Article revised and published on 01/26/2023 effective for dates of service on and after 01/01/2023 to reflect the Annual HCPCS/CPT Code Updates. For the following CPT codes either the short description and/or the long description was changed. Depending on which description is used in this article, there may not be any change in how the code displays: 81445 and 81450. In response to an inquiry the Group 6 Medical Necessity ICD-10-CM Codes Asterisk Explanation note has been revised effective for dates of service on or after 05/15/2018 to reflect that C73 should not be reported for ThyraMIR, Afirma, Rosetta GX |

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION |
|-----------------------|-------------------------|---|
| | | Reveal, or ThyGeNEXT and that D44.2 should not be reported for ThyraMIR, Afirma, Rosetta GX Reveal, ThyGeNEXT or ThyroSeq. |
| 10/01/2022 | R38 | Article revised and published on 10/06/2022 effective for dates of service on and after 10/01/2022 to reflect the Quarter 4 Quarterly CPT/HCPCS Code Updates. CPT code 0229U underwent either a short description and/or long description change. Depending on which description was changed there may not be any change in how the code displays. |
| 07/01/2022 | R37 | Article revised and published on 08/04/2022 effective for dates of service on and after 07/01/2022 to reflect the July Quarterly CPT/HCPCS Code Update. For the following CPT code either the short description and/or the long description was changed. Depending on which description is used in this article, there may not be any change in how the code displays: 0229U in the 'CPT/HCPCS Codes' section for 'Group 1 Codes'. |
| 01/30/2022 | R36 | Article revised and published on 01/27/2022 effective for dates of service on and after 01/30/2022. Tier 2 codes 81400 thru 81405 have been removed from the CPT code 'Group1'. Additionally, billing & coding instructions specific for the Tier 2 codes have been removed from the article along with formatting changes throughout the article. |
| 01/01/2022 | R35 | Article revised and published on 01/20/2022 effective for dates of service on and after 01/01/2022 to reflect the Annual HCPCS/CPT Code Updates. CPT code 0287U has been added to the following sections: Under 'Coding Guidance' in the 'Test Panel Definition' section for ThyroSeq Tests; In the 'Selected Oncology Tests' section under Bullet #7 in the directions 'To report ThyroSeq Thyroid tests'; In the 'CPT/HCPCS Codes' section for 'Group 1 Codes' and; In the 'ICD-10-CM Codes that Support Medical Necessity' section for 'Group 6 Paragraph' for ThyroSeq. For the following CPT code either the short description and/or the long description was changed. Depending on which description is used in this article, there may not be any change in how the code displays: 81405. |
| 12/12/2021 | R34 | Article revised and published on 12/9/2021 effective for dates of service on and after 12/12/2021 to remove the following Group 1 CPT codes: 81350, 81406, 81407 and 81408. These codes have been removed due to the new Pharmacogenomics article becoming effective. |
| 10/01/2021 | R33 | <p>Article revised and published on 10/14/2021 effective for dates of service on and after 10/01/2021 to reflect the Annual ICD-10-CM Code updates.</p> <p>The following ICD-10-CM code has been added to the Group 7 ICD-10-CM codes that support medical necessity: C56.3.</p> <p>The following ICD-10-CM codes have been added to the Group 27 ICD-10-CM codes that support medical necessity: C56.3 and C79.63.</p> |

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION |
|-----------------------|-------------------------|--|
| 09/30/2021 | R32 | <p>Article revised and published on 09/30/2021 effective for dates of service on and after 1/1/2021 in response to an inquiry. The 'Selected Oncology Tests' section has been revised to add bullet #15 for the Colvera® test (BCAT1/IKZF1 promoter hypermethylation), the 'CPT/HCPCS Codes' section has been revised for the 'Group 1 Codes' to add CPT code 0229U, the 'ICD-10-CM Codes that Support Medical Necessity' section has been revised for the 'Group 1 Paragraph' to add BCAT1/IKZF1 promoter methylation 0229U, and the following ICD-10-CM codes have been added to the Group 1 Codes: Z85.030, Z85.038, Z85.040 and Z85.048.</p> |
| 04/01/2021 | R31 | <p>Article revised and published on 04/22/2021 effective for dates of service on and after 04/01/2021 in response to the April 1, 2021 CPT code updates. The following CPT code has been added to the Article: 0245U under group 1 and ICD10 group 6.</p> <p>The following CPT code has been deleted and therefore has been removed from the text of the article, from CPT/HCPCS Code Group 1 and from ICD-10 Code Group 6 Paragraph: 81455.</p> |
| 01/01/2021 | R30 | <p>Article revised and published on 02/11/2021 effective for dates of service on 01/01/2021 to add codes 81347, 81348, 81351, 81352, 81353, 81357, 81360 and 81546 to the list of group 1 CPT/HCPCS codes. 81347 has been added to group 18 paragraph to report SF3B1, 81348 has been added to group 12 paragraph to report SRSF2, 81351, 81352 and 81353 have been added to group paragraphs 12 & 16 to report TP53, 81357 has been added to group 12 paragraph to report U2AF1, 81360 has been added to group 12 paragraph to report ZRSR2, 81546 has been added to group 6 paragraph to report oncology thyroid mRNA and replaces the deleted code 81545. CPT code 81545 has been deleted and replaced with code 81546 in the group 1 codes, group 6 paragraph, Test Panel Definition and Selected Oncology Tests sections. The following codes have descriptor revisions: 81206, 81207, 81436.</p> |
| 12/13/2020 | R29 | <p>Article revised and published on 11/05/2020 effective for dates of service on and after 12/13/2020 to add Tgt gen seq dna&ma 23 gene to the Article Text under Oncomine DX Test and to add FLT3D835 81245 to Group 12 Paragraph.</p> |
| 12/13/2020 | R28 | <p>Article revised in response to DL35396 and published on 10/29/2020 effective for dates of service on and after 12/13/2020 to add the following leukemia biomarkers and corresponding Current Procedural Terminology (CPT) codes: Group 11 – JAK1, NOTCH1, FBXW7 (81479), NRAS (81311); Group 12 – U2AF1, SRSF2, ZRSR2 (81479); Group 16 – KIT (81272, 81273); Group 18 – BIRC3, SF3B1 (81479), BTK (81233), PLCG2 (81320); Group 19 – STAT5B (81479); Group 22 – JAK1, JAK3 (81479). Added a group paragraph and group ICD-10 codes for T-cell Large Granular Lymphocytic Leukemia biomarkers STAT5B (81479), renumbered the group paragraphs and group codes. Procedure codes 81445, 81450 and 81455 have been removed from all group paragraphs as they will not have procedure to diagnosis editing. The following note has been removed from the Group 1 Paragraph as these codes do not have procedure to diagnosis editing: "Please</p> |

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION |
|-----------------------|-------------------------|--|
| | | <p>note that because the following CPT codes represent multiple biomarkers these codes will not have procedure to diagnosis code limitations at this time: 81246, 81350, 81400, 81401, 81402, 81403, 81404, 81405, 81406, 81407, 81408, 81435, 81436, 81450. and 81503." Also effective 10/01/2020, for dates of service on and after 10/01/2020, to reflect the annual ICD-10-CM Code Updates, the following ICD-10-CM code has been deleted and therefore removed from the Article Code Group 20: D72.1. The following ICD-10-CM code(s) have been added to the Article Code Group 20: D72.110, D72.111, D72.118, and D72.119. Minor formatting revisions made throughout the article.</p> |
| 10/01/2020 | R27 | <p>Article revised and published on 10/01/2020 effective for dates of service on and after 10/01/2020 to reflect the Annual ICD-10-CM Code Updates. The following ICD-10-CM code(s) have been added to the Article Code Group 19: D72.110, D72.111, D72.118, and D72.119. The following ICD-10-CM code has been deleted and therefore has been removed from the Article Code Group 19: D72.1. The notes in ICD-10 Code Groups 6 and 23 were moved to the bottom of the table in the asterisk explanation paragraph and asterisks were added to the ICD-10 codes in the groups as applicable.</p> |
| 07/01/2020 | R26 | <p>Article revised and published on 06/25/2020 effective for dates of service on and after 07/01/2020, as a non-discretionary update to remove the Group 2 paragraph and CPT codes. Minor formatting changes were made.</p> |
| 01/01/2020 | R25 | <p>Article revised and published on 01/16/2020 effective for dates of service on and after 01/01/2020 to reflect the annual CPT/HCPCS code updates. The following CPT code(s) either have a short description or long description change. Depending on which description is used in this article, there may not be any change in how the code displays in the document: 81350, 81404, 81406 and 81407. Minor formatting changes and spelling errors have been corrected throughout the article.</p> |
| 07/10/2019 | R24 | <p>Article revised and published on 09/12/2019 effective for dates of service on and after 07/10/2019. The CPT code for ThyraMIR has been changed from 81479 to 0018U in the Test Panel Definitions, Intended use of ThyraMIR sections, added to the Group 1 codes, and the Group 6 paragraph. Due to system changes in response to CMS Change Request 10901, this article has undergone some reorganization in the coding section and the following new fields have been added: CPT/HCPCS Modifier, Additional ICD-10 Information, and Other Coding Information. There has been no change to the LCD coverage as a result of this revision.</p> |
| 06/13/2019 | R23 | <p>Article revised and published on 09/12/2019 effective for dates of service on and after 07/10/2019. The CPT code for ThyraMIR has been changed from 81479 to 0018U in the Test Panel Definitions, Intended use of ThyraMIR sections, added to the Group 1 codes, and the Group 6 paragraph. There has been no change to the LCD coverage as a result of this revision.</p> |

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION |
|-----------------------|-------------------------|---|
| 06/13/2019 | R22 | Article revised and published on 06/13/2019 effective for dates of service on and after 03/27/2019 the following CPT code has been removed from the CPT/HCPCS Code Group 2 and added to CPT/HCPCS Code Group 1 in response to an inquiry; it will have no diagnosis to procedure code restrictions at this time: 81450. This change is a clarification to ensure proper billing. The CPT and ICD-10 codes from related LCD, L35396-Biomarkers for Oncology, have been added in response to CMS Change Request 10901. The coding guidance section has been updated accordingly. There has been no change to the LCD coverage indications as a result of this revision. |
| 04/04/2019 | R21 | Article revised and published on 04/04/2019 effective for dates of service on and after 03/16/2018 to remove CPT code 0022U from CPT/HCPCS Code Group 1 due to implementation of NCD 90.2. Statement and link added to ICD-10 Group 1 Paragraph stating ICD-10-CM diagnosis codes for CPT code 0022U may be found in NCD 90.2, Next Generation Sequencing (NGS) for Patients with Advanced Cancer. NCD 90.2 listed as a Related National Coverage Document. |
| 01/01/2019 | R20 | Article revised and published on 02/14/2019 effective for dates of service on and after 01/01/2019 to reflect the annual CPT/HCPCS code updates. The following CPT/HCPCS code(s) have been added to Group 1 Codes: 81233, 81236, 81237, 81305, 81320, and 81345. For the following CPT/HCPCS codes either the short description and/or the long description was changed. Depending on which description is used in this article, there may not be any change in how the code displays in the document: 81287, 81327, 81400, 81401, 81403, 81404, 81405, and 81407. |
| 10/25/2018 | R19 | Article revised and published on 10/25/2018 effective for dates of service on and after 05/18/2018 to add billing and coding guidance for ColonSeq® and LungSeq®. |
| 10/04/2018 | R18 | Article revised and published on 10/04/2018 effective for dates of service on and after 05/15/2018 to add CPT code 0026U to CPT Group 1 Codes and billing and coding guidance for ThyroSeq thyroid test. Effective for dates of service on and after 05/18/2018, CPT code 0022U has been added to CPT Group 1 Codes and billing and coding guidance for Oncomine DX has been updated to change the CPT code from 81445 to 0022U. |
| 07/26/2018 | R17 | Article revised and published on 07/26/2018 effective for dates of service on and after 04/09/2018 to add billing and coding guidance for ThyGenX and RosettaGX Reveal Thyroid tests. Clarification added to coding guidance for Afirma and ThyraMIR. Updated the example for billing certain tests and corrected a typographical error in the CPT code for Oncomine Dx. |
| 03/08/2018 | R16 | Article revised and published on 03/08/2018 effective for dates of service on and after 12/22/2017 to add billing and coding guidance for Oncomine DX target test and to add |

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| | | CPT code 81445 to list of CPT/HCPCS Group 1 Codes. Link to L36715-BRCA1 and BRCA2 Genetic Testing and L35062-Biomarkers Overview added to the Related Local Coverage Documents section. For provider education/guidance per Annual Review, removed Bill Types 18x and 21x as those Bill Types are not for inpatient services claims. |
| 01/01/2018 | R15 | Article revised and published on 01/25/2018 effective for dates of service on and after 01/01/2018 to reflect the annual CPT/HCPCS code updates. For the following CPT/HCPCS codes either the short description and/or the long description was changed: 81400, 81401, 81403, 81404, 81405, 81406. Depending on which description is used in this article there may not be any change in how the code displays in the document. The following CPT/HCPCS codes have been added to CPT/HCPCS Code Group 1: 81120, 81121, 81175, 81176, 81334, 81520. The following CPT/HCPCS code has been deleted from CPT/HCPCS Code Group 1: 0008M. |
| 11/09/2017 | R14 | Article revised and published on 11/09/2017 effective for dates of service on and after 08/01/2017 to add the following new CPT/HCPCS codes for Proprietary Laboratory Analyses (PLA) to Group 2 CPT/HCPCS Codes as non-covered: 0009U, 0013U, 0014U, 0016U, and 0017U. Article revised with effective dates of service on and after 10/02/2017 to reflect the 4Q17 CPT/HCPCS code updates. For the following CPT/HCPCS code(s) either the short description and/or the long description was changed: 81405 and 0002U. Depending on which description is used in this article, there may not be any change in how the code displays in the document. |
| 08/10/2017 | R13 | Article revised and published on 08/10/2017 effective for dates of service on and after 05/01/2017 to add the following CPT code as non-covered to Group 2 Codes: 0005U. |
| 06/08/2017 | R12 | Article revised and published on 06/08/2017 to add coding guidance for billing multiple biomarkers performed on one specimen. |
| 02/01/2017 | R11 | Article revised and published on 05/11/2017 effective for dates of service on and after 02/01/2017 to add the following CPT codes as non-covered to Group 2 Codes: 0002U and 0003U. |
| 01/01/2017 | R10 | Article revised and published on 01/12/2017 effective for dates of service on and after 01/01/2017 to reflect the annual CPT/HCPCS code updates. The following CPT/HCPCS code 81327 has been added to group 1 CPT code group of the Article. |
| 12/01/2016 | R9 | Article revised and published on 12/01/2016 effective for dates of service on and after 12/01/2016 to add the following CPT/HCPCS codes to Group 1: 0008M, 81219, 81262, 81316, 81437, 81438, 81525, 81540, and 81545; and to remove the following CPT codes from Group 2: 81445, 81455, and 81595. Article revised and published on 12/01/2016 effective for dates of service on and after 01/01/2017 to reflect the annual CPT/HCPCS code updates. For the following CPT/HCPCS code(s) either the short description and/or the long description was changed. Depending on which description is used in this article, |

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION |
|-----------------------|-------------------------|--|
| | | there may not be any change in how the code displays in the document: 81402 and 81407. |
| 09/26/2016 | R8 | Article revised and published on 10/13/2016 effective for dates of service on and after 09/26/2016 to remove the following three requirements from OVA1 testing: have not yet been referred to a gynecologic oncologist; have not had cancer in the past five years; and have a rheumatoid factor concentration <250 IU/mL. |
| 03/09/2016 | R7 | Article revised and published on 06/09/2016 effective for dates of service on or after 03/09/2016 to add guidance for OVA1 testing. |
| 01/01/2016 | R6 | Article revised and published on 02/11/2016 to add coding guidance for ThyraMIR effective for dates of service 12/14/2015 or after. |
| 01/01/2016 | R5 | Article revised and published on 01/28/2016 to reflect the annual CPT/HCPCS code updates effective for dates of service on and after 01/01/2016. For the following CPT/HCPCS codes, either the short description and/or the long description was changed. Depending on which description is used in this article, there may not be any change in how the code displays in the document: 81210, 81275, 81402, 81435, 81436, 81445, 81450, 81455. The following codes have been added to CPT Group 1: 81272, 81273, 81276, 81311, 81314, 81538. The following code has been added to CPT group 2 as NON-COVERED; 81595 please refer to LCD L35396. CPT code 81538 has been added to #3 in the Article Text section to replace 84999 for reporting VeriStrat ® Assay. |
| 10/01/2015 | R4 | Article revised and published on 10/08/2015 to reflect that OVA1 should be reported with CPT 81503 rather than 84999 effective for dates of service on and after 10/01/2015. |
| 10/01/2015 | R3 | Article revised and published on 01/23/2015 to reflect the annual CPT/HCPCS code updates For the following CPT/HCPCS code(s) either the short description and/or the long description was changed. Depending on which description is used in this article, there may not be any change in how the code displays in the document: 81245; 81402; 81403; 81404; 81405. The following codes have been added to CPT group 2 as NON-COVERED; 81445, 81450 and 81455. The following codes have been added to the article but will not have any diagnosis to procedure code editing at this time; 81246; 81435; and 81436. CPT code 81313 has been added to #5 in the Article Text section to replace 81479 for reporting PROGENSA® PCA3 Assay. |
| 10/01/2015 | R2 | Article revised and published on 10/09/2014, effective for dates of service 10/01/2015 to add billing and coding information for MyPRS Genetic Expression Profile Testing. |
| 10/01/2015 | R1 | Article revised and published on 7/24/2014 to provide billing and coding guidance regarding various Tier 1 and Tier 2 molecular pathology procedures. |

Associated Documents

Related Local Coverage Documents

Articles

[A58917 - Billing and Coding: Molecular Pathology and Genetic Testing](#)

[A58801 - Billing and Coding: Pharmacogenomics Testing](#)

[A58529 - Response to Comments: Biomarkers for Oncology \(MCD Archive Site\)](#)

LCDs

[L35396 - Biomarkers for Oncology](#)

Related National Coverage Documents

NCDs

[90.2 - Next Generation Sequencing \(NGS\)](#)

Statutory Requirements URLs

N/A

Rules and Regulations URLs

N/A

CMS Manual Explanations URLs

N/A

Other URLs

N/A

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