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Article Title: Billing and Coding: Biomarkers for Oncology

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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 for 2013-2014

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 codes listed in ICD-10 code 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 codes listed in ICD-10 code group 23 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&ma 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 codes listed in ICD-10 code 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 codes listed in ICD-10 code 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.
 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 codes listed in ICD-10 code 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/HCPSC code must describe the service performed.
4. The medical record documentation must support the medical necessity of the services as stated in this article. 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

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 policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

999	Not Applicable
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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 policy 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 policy should be assumed to apply equally to all Revenue Codes.

99999	Not Applicable
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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 codes: 81292, 81293, 81294, 81321, 81322, 81323, 81437, 81438, 81479, 81520, 81525, 81540, and 81546.**

Providers should refer to the covered indications section of the LCD to determine if biomarkers included in the above codes are considered reasonable and necessary.

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

Medicare is establishing limited coverage for the following CPT/HCPCS codes, consistent with L35396-Biomarkers for Oncology.

Group 1 CPT Codes:

0018U

ONCOLOGY (THYROID), MICRORNA PROFILING BY RT-PCR OF 10 MICRORNA SEQUENCES, UTILIZING FINE NEEDLE ASPIRATE, ALGORITHM REPORTED AS A POSITIVE OR NEGATIVE RESULT FOR MODERATE TO HIGH RISK OF MALIGNANCY

0026U

ONCOLOGY (THYROID), DNA AND MRNA OF 112 GENES, NEXT-GENERATION SEQUENCING, FINE NEEDLE ASPIRATE OF THYROID NODULE, ALGORITHMIC ANALYSIS REPORTED AS A CATEGORICAL

	RESULT ("POSITIVE, HIGH PROBABILITY OF MALIGNANCY" OR "NEGATIVE, LOW PROBABILITY OF MALIGNANCY")
0229U	BCAT1 (BRANCHED CHAIN AMINO ACID TRANSAMINASE 1) AND IKZF1 (IKAROS FAMILY ZINC FINGER 1) (EG, COLORECTAL CANCER) PROMOTER METHYLATION ANALYSIS
0245U	ONCOLOGY (THYROID), MUTATION ANALYSIS OF 10 GENES AND 37 RNA FUSIONS AND EXPRESSION OF 4 MRNA MARKERS USING NEXT-GENERATION SEQUENCING, FINE NEEDLE ASPIRATE, REPORT INCLUDES ASSOCIATED RISK OF MALIGNANCY EXPRESSED AS A PERCENTAGE
0287U	ONCOLOGY (THYROID), DNA AND MRNA, NEXT-GENERATION SEQUENCING ANALYSIS OF 112 GENES, FINE NEEDLE ASPIRATE OR FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) TISSUE, ALGORITHMIC PREDICTION OF CANCER RECURRENCE, REPORTED AS A CATEGORICAL RISK RESULT (LOW, INTERMEDIATE, HIGH)
81120	IDH1 (ISOCITRATE DEHYDROGENASE 1 [NADP+], SOLUBLE) (EG, GLIOMA), COMMON VARIANTS (EG, R132H, R132C)
81121	IDH2 (ISOCITRATE DEHYDROGENASE 2 [NADP+], MITOCHONDRIAL) (EG, GLIOMA), COMMON VARIANTS (EG, R140W, R172M)
81170	ABL1 (ABL PROTO-ONCOGENE 1, NON-RECEPTOR TYROSINE KINASE) (EG, ACQUIRED IMATINIB TYROSINE KINASE INHIBITOR RESISTANCE), GENE ANALYSIS, VARIANTS IN THE KINASE DOMAIN
81175	ASXL1 (ADDITIONAL SEX COMBS LIKE 1, TRANSCRIPTIONAL REGULATOR) (EG, MYELOYDYSPLASTIC SYNDROME, MYELOPROLIFERATIVE NEOPLASMS, CHRONIC MYELOMONOCYTIC LEUKEMIA), GENE ANALYSIS; FULL GENE SEQUENCE
81176	ASXL1 (ADDITIONAL SEX COMBS LIKE 1, TRANSCRIPTIONAL REGULATOR) (EG, MYELOYDYSPLASTIC SYNDROME, MYELOPROLIFERATIVE NEOPLASMS, CHRONIC MYELOMONOCYTIC LEUKEMIA), GENE ANALYSIS; TARGETED SEQUENCE ANALYSIS (EG, EXON 12)
81206	BCR/ABL1 (T(9;22)) (EG, CHRONIC MYELOGENOUS LEUKEMIA) TRANSLOCATION ANALYSIS; MAJOR BREAKPOINT, QUALITATIVE OR QUANTITATIVE
81207	BCR/ABL1 (T(9;22)) (EG, CHRONIC MYELOGENOUS LEUKEMIA) TRANSLOCATION ANALYSIS; MINOR BREAKPOINT, QUALITATIVE OR QUANTITATIVE
81208	BCR/ABL1 (T(9;22)) (EG, CHRONIC MYELOGENOUS LEUKEMIA) TRANSLOCATION ANALYSIS; OTHER BREAKPOINT, QUALITATIVE OR QUANTITATIVE
81210	BRAF (B-RAF PROTO-ONCOGENE, SERINE/THREONINE KINASE) (EG, COLON CANCER, MELANOMA), GENE ANALYSIS, V600 VARIANT(S)
81218	CEBPA (CCAAT/ENHANCER BINDING PROTEIN [C/EBP], ALPHA) (EG, ACUTE MYELOID LEUKEMIA), GENE ANALYSIS, FULL GENE SEQUENCE
81219	CALR (CALRETICULIN) (EG, MYELOPROLIFERATIVE DISORDERS), GENE ANALYSIS, COMMON VARIANTS IN EXON 9
81233	BTK (BRUTON'S TYROSINE KINASE) (EG, CHRONIC LYMPHOCYTIC LEUKEMIA) GENE ANALYSIS, COMMON VARIANTS (EG, C481S, C481R, C481F)
81235	EGFR (EPIDERMAL GROWTH FACTOR RECEPTOR) (EG, NON-SMALL CELL LUNG CANCER) GENE ANALYSIS, COMMON VARIANTS (EG, EXON 19 LREA DELETION, L858R, T790M, G719A, G719S, L861Q)

81236	EZH2 (ENHANCER OF ZESTE 2 POLYCOMB REPRESSIVE COMPLEX 2 SUBUNIT) (EG, MYELOYDYSPLASTIC SYNDROME, MYELOPROLIFERATIVE NEOPLASMS) GENE ANALYSIS, FULL GENE SEQUENCE
81237	EZH2 (ENHANCER OF ZESTE 2 POLYCOMB REPRESSIVE COMPLEX 2 SUBUNIT) (EG, DIFFUSE LARGE B-CELL LYMPHOMA) GENE ANALYSIS, COMMON VARIANT(S) (EG, CODON 646)
81245	FLT3 (FMS-RELATED TYROSINE KINASE 3) (EG, ACUTE MYELOID LEUKEMIA), GENE ANALYSIS; INTERNAL TANDEM DUPLICATION (ITD) VARIANTS (IE, EXONS 14, 15)
81246	FLT3 (FMS-RELATED TYROSINE KINASE 3) (EG, ACUTE MYELOID LEUKEMIA), GENE ANALYSIS; TYROSINE KINASE DOMAIN (TKD) VARIANTS (EG, D835, I836)
81261	IGH@ (IMMUNOGLOBULIN HEAVY CHAIN LOCUS) (EG, LEUKEMIAS AND LYMPHOMAS, B-CELL), GENE REARRANGEMENT ANALYSIS TO DETECT ABNORMAL CLONAL POPULATION(S); AMPLIFIED METHODOLOGY (EG, POLYMERASE CHAIN REACTION)
81262	IGH@ (IMMUNOGLOBULIN HEAVY CHAIN LOCUS) (EG, LEUKEMIAS AND LYMPHOMAS, B-CELL), GENE REARRANGEMENT ANALYSIS TO DETECT ABNORMAL CLONAL POPULATION(S); DIRECT PROBE METHODOLOGY (EG, SOUTHERN BLOT)
81263	IGH@ (IMMUNOGLOBULIN HEAVY CHAIN LOCUS) (EG, LEUKEMIA AND LYMPHOMA, B-CELL), VARIABLE REGION SOMATIC MUTATION ANALYSIS
81270	JAK2 (JANUS KINASE 2) (EG, MYELOPROLIFERATIVE DISORDER) GENE ANALYSIS, P.VAL617PHE (V617F) VARIANT
81272	KIT (V-KIT HARDY-ZUCKERMAN 4 FELINE SARCOMA VIRAL ONCOGENE HOMOLOG) (EG, GASTROINTESTINAL STROMAL TUMOR [GIST], ACUTE MYELOID LEUKEMIA, MELANOMA), GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (EG, EXONS 8, 11, 13, 17, 18)
81273	KIT (V-KIT HARDY-ZUCKERMAN 4 FELINE SARCOMA VIRAL ONCOGENE HOMOLOG) (EG, MASTOCYTOSIS), GENE ANALYSIS, D816 VARIANT(S)
81275	KRAS (KIRSTEN RAT SARCOMA VIRAL ONCOGENE HOMOLOG) (EG, CARCINOMA) GENE ANALYSIS; VARIANTS IN EXON 2 (EG, CODONS 12 AND 13)
81276	KRAS (KIRSTEN RAT SARCOMA VIRAL ONCOGENE HOMOLOG) (EG, CARCINOMA) GENE ANALYSIS; ADDITIONAL VARIANT(S) (EG, CODON 61, CODON 146)
81287	MGMT (O-6-METHYLGUANINE-DNA METHYLTRANSFERASE) (EG, GLIOBLASTOMA MULTIFORME) PROMOTER METHYLATION ANALYSIS
81292	MLH1 (MUTL HOMOLOG 1, COLON CANCER, NONPOLYPOSIS TYPE 2) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; FULL SEQUENCE ANALYSIS
81293	MLH1 (MUTL HOMOLOG 1, COLON CANCER, NONPOLYPOSIS TYPE 2) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; KNOWN FAMILIAL VARIANTS
81294	MLH1 (MUTL HOMOLOG 1, COLON CANCER, NONPOLYPOSIS TYPE 2) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; DUPLICATION/DELETION VARIANTS
81301	MICROSATELLITE INSTABILITY ANALYSIS (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) OF

MARKERS FOR MISMATCH REPAIR DEFICIENCY (EG, BAT25, BAT26), INCLUDES COMPARISON OF NEOPLASTIC AND NORMAL TISSUE, IF PERFORMED

81305	MYD88 (MYELOID DIFFERENTIATION PRIMARY RESPONSE 88) (EG, WALDENSTROM'S MACROGLOBULINEMIA, LYMPHOPLASMACYTIC LEUKEMIA) GENE ANALYSIS, P.LEU265PRO (L265P) VARIANT
81310	NPM1 (NUCLEOPHOSMIN) (EG, ACUTE MYELOID LEUKEMIA) GENE ANALYSIS, EXON 12 VARIANTS
81311	NRAS (NEUROBLASTOMA RAS VIRAL [V-RAS] ONCOGENE HOMOLOG) (EG, COLORECTAL CARCINOMA), GENE ANALYSIS, VARIANTS IN EXON 2 (EG, CODONS 12 AND 13) AND EXON 3 (EG, CODON 61)
81313	PCA3/KLK3 (PROSTATE CANCER ANTIGEN 3 [NON-PROTEIN CODING]/KALLIKREIN-RELATED PEPTIDASE 3 [PROSTATE SPECIFIC ANTIGEN]) RATIO (EG, PROSTATE CANCER)
81314	PDGFRA (PLATELET-DERIVED GROWTH FACTOR RECEPTOR, ALPHA POLYPEPTIDE) (EG, GASTROINTESTINAL STROMAL TUMOR [GIST]), GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (EG, EXONS 12, 18)
81315	PML/RARALPHA, (T(15;17)), (PROMYELOCYTIC LEUKEMIA/RETINOIC ACID RECEPTOR ALPHA) (EG, PROMYELOCYTIC LEUKEMIA) TRANSLOCATION ANALYSIS; COMMON BREAKPOINTS (EG, INTRON 3 AND INTRON 6), QUALITATIVE OR QUANTITATIVE
81316	PML/RARALPHA, (T(15;17)), (PROMYELOCYTIC LEUKEMIA/RETINOIC ACID RECEPTOR ALPHA) (EG, PROMYELOCYTIC LEUKEMIA) TRANSLOCATION ANALYSIS; SINGLE BREAKPOINT (EG, INTRON 3, INTRON 6 OR EXON 6), QUALITATIVE OR QUANTITATIVE
81320	PLCG2 (PHOSPHOLIPASE C GAMMA 2) (EG, CHRONIC LYMPHOCYTIC LEUKEMIA) GENE ANALYSIS, COMMON VARIANTS (EG, R665W, S707F, L845F)
81321	PTEN (PHOSPHATASE AND TENSIN HOMOLOG) (EG, COWDEN SYNDROME, PTEN HAMARTOMA TUMOR SYNDROME) GENE ANALYSIS; FULL SEQUENCE ANALYSIS
81322	PTEN (PHOSPHATASE AND TENSIN HOMOLOG) (EG, COWDEN SYNDROME, PTEN HAMARTOMA TUMOR SYNDROME) GENE ANALYSIS; KNOWN FAMILIAL VARIANT
81323	PTEN (PHOSPHATASE AND TENSIN HOMOLOG) (EG, COWDEN SYNDROME, PTEN HAMARTOMA TUMOR SYNDROME) GENE ANALYSIS; DUPLICATION/DELETION VARIANT
81327	SEPT9 (SEPTIN9) (EG, COLORECTAL CANCER) PROMOTER METHYLATION ANALYSIS
81334	RUNX1 (RUNT RELATED TRANSCRIPTION FACTOR 1) (EG, ACUTE MYELOID LEUKEMIA, FAMILIAL PLATELET DISORDER WITH ASSOCIATED MYELOID MALIGNANCY) GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (EG, EXONS 3-8)
81340	TRB@ (T CELL ANTIGEN RECEPTOR, BETA) (EG, LEUKEMIA AND LYMPHOMA), GENE REARRANGEMENT ANALYSIS TO DETECT ABNORMAL CLONAL POPULATION(S); USING AMPLIFICATION METHODOLOGY (EG, POLYMERASE CHAIN REACTION)
81342	TRG@ (T CELL ANTIGEN RECEPTOR, GAMMA) (EG, LEUKEMIA AND LYMPHOMA), GENE REARRANGEMENT ANALYSIS, EVALUATION TO DETECT ABNORMAL CLONAL POPULATION(S)

81345	TERT (TELOMERASE REVERSE TRANSCRIPTASE) (EG, THYROID CARCINOMA, GLIOBLASTOMA MULTIFORME) GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (EG, PROMOTER REGION)
81347	SF3B1 (SPLICING FACTOR [3B] SUBUNIT B1) (EG, MYELODYSPLASTIC SYNDROME/ACUTE MYELOID LEUKEMIA) GENE ANALYSIS, COMMON VARIANTS (EG, A672T, E622D, L833F, R625C, R625L)
81348	SRSF2 (SERINE AND ARGININE-RICH SPLICING FACTOR 2) (EG, MYELODYSPLASTIC SYNDROME, ACUTE MYELOID LEUKEMIA) GENE ANALYSIS, COMMON VARIANTS (EG, P95H, P95L)
81351	TP53 (TUMOR PROTEIN 53) (EG, LI-FRAUMENI SYNDROME) GENE ANALYSIS; FULL GENE SEQUENCE
81352	TP53 (TUMOR PROTEIN 53) (EG, LI-FRAUMENI SYNDROME) GENE ANALYSIS; TARGETED SEQUENCE ANALYSIS (EG, 4 ONCOLOGY)
81353	TP53 (TUMOR PROTEIN 53) (EG, LI-FRAUMENI SYNDROME) GENE ANALYSIS; KNOWN FAMILIAL VARIANT
81357	U2AF1 (U2 SMALL NUCLEAR RNA AUXILIARY FACTOR 1) (EG, MYELODYSPLASTIC SYNDROME, ACUTE MYELOID LEUKEMIA) GENE ANALYSIS, COMMON VARIANTS (EG, S34F, S34Y, Q157R, Q157P)
81360	ZRSR2 (ZINC FINGER CCCH-TYPE, RNA BINDING MOTIF AND SERINE/ARGININE-RICH 2) (EG, MYELODYSPLASTIC SYNDROME, ACUTE MYELOID LEUKEMIA) GENE ANALYSIS, COMMON VARIANT(S) (EG, E65FS, E122FS, R448FS)
81435	HEREDITARY COLON CANCER DISORDERS (EG, LYNCH SYNDROME, PTEN HAMARTOMA SYNDROME, COWDEN SYNDROME, FAMILIAL ADENOMATOSIS POLYPOSIS); GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 10 GENES, INCLUDING APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, AND STK11
81436	HEREDITARY COLON CANCER DISORDERS (EG, LYNCH SYNDROME, PTEN HAMARTOMA SYNDROME, COWDEN SYNDROME, FAMILIAL ADENOMATOSIS POLYPOSIS); DUPLICATION/DELETION ANALYSIS PANEL, MUST INCLUDE ANALYSIS OF AT LEAST 5 GENES, INCLUDING MLH1, MSH2, EPCAM, SMAD4, AND STK11
81437	HEREDITARY NEUROENDOCRINE TUMOR DISORDERS (EG, MEDULLARY THYROID CARCINOMA, PARATHYROID CARCINOMA, MALIGNANT PHEOCHROMOCYTOMA OR PARAGANGLIOMA); GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 6 GENES, INCLUDING MAX, SDHB, SDHC, SDHD, TMEM127, AND VHL
81438	HEREDITARY NEUROENDOCRINE TUMOR DISORDERS (EG, MEDULLARY THYROID CARCINOMA, PARATHYROID CARCINOMA, MALIGNANT PHEOCHROMOCYTOMA OR PARAGANGLIOMA); DUPLICATION/DELETION ANALYSIS PANEL, MUST INCLUDE ANALYSES FOR SDHB, SDHC, SDHD, AND VHL
81445	TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, SOLID ORGAN NEOPLASM, DNA ANALYSIS, AND RNA ANALYSIS WHEN PERFORMED, 5-50 GENES (EG, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), INTERROGATION FOR SEQUENCE VARIANTS AND COPY NUMBER VARIANTS OR REARRANGEMENTS, IF PERFORMED
81450	TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, HEMATOLYMPHOID NEOPLASM OR DISORDER, DNA ANALYSIS, AND RNA ANALYSIS WHEN PERFORMED, 5-50 GENES (EG, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1,

	NOTCH1), INTERROGATION FOR SEQUENCE VARIANTS, AND COPY NUMBER VARIANTS OR REARRANGEMENTS, OR ISOFORM EXPRESSION OR MRNA EXPRESSION LEVELS, IF PERFORMED
81479	UNLISTED MOLECULAR PATHOLOGY PROCEDURE
81503	ONCOLOGY (OVARIAN), BIOCHEMICAL ASSAYS OF FIVE PROTEINS (CA-125, APOLIPOPROTEIN A1, BETA-2 MICROGLOBULIN, TRANSFERRIN, AND PRE-ALBUMIN), UTILIZING SERUM, ALGORITHM REPORTED AS A RISK SCORE
81520	ONCOLOGY (BREAST), MRNA GENE EXPRESSION PROFILING BY HYBRID CAPTURE OF 58 GENES (50 CONTENT AND 8 HOUSEKEEPING), UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS A RECURRENCE RISK SCORE
81525	ONCOLOGY (COLON), MRNA, GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR OF 12 GENES (7 CONTENT AND 5 HOUSEKEEPING), UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS A RECURRENCE SCORE
81538	ONCOLOGY (LUNG), MASS SPECTROMETRIC 8-PROTEIN SIGNATURE, INCLUDING AMYLOID A, UTILIZING SERUM, PROGNOSTIC AND PREDICTIVE ALGORITHM REPORTED AS GOOD VERSUS POOR OVERALL SURVIVAL
81540	ONCOLOGY (TUMOR OF UNKNOWN ORIGIN), MRNA, GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR OF 92 GENES (87 CONTENT AND 5 HOUSEKEEPING) TO CLASSIFY TUMOR INTO MAIN CANCER TYPE AND SUBTYPE, UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS A PROBABILITY OF A PREDICTED MAIN CANCER TYPE AND SUBTYPE
81546	ONCOLOGY (THYROID), MRNA, GENE EXPRESSION ANALYSIS OF 10,196 GENES, UTILIZING FINE NEEDLE ASPIRATE, ALGORITHM REPORTED AS A CATEGORICAL RESULT (EG, BENIGN OR SUSPICIOUS)

ICD-10 Codes That Are Covered

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.

Please use the following link to NCD 90.2, Next Generation Sequencing (NGS) for Patients with Advanced Cancer, for a list of ICD-10-CM diagnosis codes for NGS allowable for CPT code 0022U: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=372&ncdver=1&bc=AAAAQAAAAAA>

Medicare is establishing the following limited 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

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
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

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.

Medicare is establishing the following limited 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**

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
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

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.

Medicare is establishing the following limited coverage for **melanoma** molecular biomarkers:

BRAF **81210**
 KIT **81272**
 NRAS **81311**

C43.0	Malignant melanoma of lip
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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
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

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.

Medicare is establishing the following limited coverage for **Uveal Melanoma**

GNA11 - 81479

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

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.

Medicare is establishing the following limited coverage for **brain** molecular biomarkers:

BRAF 81210
EGFR 81235
MGMT 81287
PTEN 81321, 81322, 81323, 81479
CIMP 81479
IDH1 81120
IDH2 81121
TERT 81345

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

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.

Medicare is establishing the following limited 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

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
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

*

*** Note: C73 and D44.2 should not be reported for ThyraMIR, Afirma, Rosetta GX Reveal, ThyGeNEXT or ThyroSeq.**

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.

Medicare is establishing the following limited 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**

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
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

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.

Medicare is establishing the following limited coverage for **urinary tract** molecular biomarkers:

MSI by PCR **81301**

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

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
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

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.

Medicare is establishing the following limited coverage for **prostate cancer** molecular biomarkers:

PROGENSA® PCA3 Assay - **81313**

PTEN – **81321, 81322, 81323**

RB1 - **81479**

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

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.

Medicare is establishing the following limited coverage for **gastrointestinal stromal tumor** molecular biomarkers:

KIT **81272**

PDGFRA **81314**

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
D48.1	Neoplasm of uncertain behavior of connective and other soft tissue
D48.2	Neoplasm of uncertain behavior of peripheral nerves and autonomic nervous system

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.

Medicare is establishing the following limited 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**

C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse

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.

Medicare is establishing the following limited 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**

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
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

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.

Medicare is establishing the following limited coverage for **hairy cell leukemia** molecular biomarkers:

IGH somatic hypermutation **81263**
 IGH **81261**

C91.40	Hairy cell leukemia not having achieved remission
C91.41	Hairy cell leukemia, in remission
C91.42	Hairy cell leukemia, in relapse

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.

Medicare is establishing the following limited coverage for **aplastic anemia** molecular biomarkers:

TCRB 81340
TCRG 81342

D60.0	Chronic acquired pure red cell aplasia
D60.1	Transient acquired pure red cell aplasia
D60.8	Other acquired pure red cell aplasias
D60.9	Acquired pure red cell aplasia, unspecified
D61.01	Constitutional (pure) red blood cell aplasia
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

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.

Medicare is establishing the following limited coverage for **Burkitt's lymphoma** molecular biomarkers:

IGH 81261

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

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.

Medicare is establishing the following limited 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**

D45	Polycythemia vera
D47.1	Chronic myeloproliferative disease
D47.3	Essential (hemorrhagic) thrombocythemia
D75.81	Myelofibrosis

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.

Medicare is establishing the following limited 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**

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
C93.11	Chronic myelomonocytic leukemia, in remission
C93.12	Chronic myelomonocytic leukemia, in relapse

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.

Medicare is establishing the following limited 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**

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

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.

Medicare is establishing the following limited coverage for **T-cell Large Granular Lymphocytic Leukemia** molecular biomarkers:

STAT5B **81479**

C91.Z0	Other lymphoid leukemia not having achieved remission
C91.Z1	Other lymphoid leukemia, in remission
C91.Z2	Other lymphoid leukemia, in relapse

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.

Medicare is establishing the following limited coverage for **Hypereosinophilia Syndrome (HES)** molecular biomarkers:

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

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

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.

Medicare is establishing the following limited coverage for **mastocytosis** molecular biomarkers:

KIT (including p.D816V) **81273**
TCRG **81342**

C96.20	Malignant mast cell neoplasm, unspecified
C96.22	Mast cell sarcoma
C96.29	Other malignant mast cell neoplasm

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.

Medicare is establishing the following limited coverage for **T-cell prolymphocytic leukemia** molecular biomarkers:

JAK1 **81479**
JAK3 **81479**
TCRB **81340**
TCRG **81342**

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

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.

Medicare is establishing the following limited 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

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
D46.4	Refractory anemia, unspecified
D46.9	Myelodysplastic syndrome, unspecified
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.Z	Other myelodysplastic syndromes

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.

Medicare is establishing the following limited coverage for **Myeloma gene expression profile (MyPRS) (CPT code 81479)**:

C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

*

***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.**

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.

Medicare is establishing the following limited coverage for **CPT code 81520**:

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
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

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.

Medicare is establishing the following limited 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

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
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
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

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.

Medicare is establishing the following limited coverage for **CPT code 81540 – TUO CTID (Cancer Type ID)**:

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
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
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
C84.97	Mature T/NK-cell lymphomas, unspecified, spleen
C84.A7	Cutaneous T-cell lymphoma, unspecified, spleen
C84.Z7	Other mature T/NK-cell lymphomas, 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
C86.1	Hepatosplenic T-cell lymphoma
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
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

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.

Medicare is establishing the following limited coverage for **Bladder:**

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

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

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.

Medicare is establishing the following limited coverage for **Waldenstrom's/Lymphoplasmacytic Lymphoma** molecular biomarkers:

MYD88 **81305**

C88.0	Waldenstrom macroglobulinemia
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ICD-10 Codes That Are Not Covered

XX000

Revision History Information		
Revision History Date	Revision History Number	Revision History Explanation
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.

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.

- 10/01/2021 R33 The following ICD-10-CM code has been added to the Group 7 ICD-10-CM codes that support medical necessity: C56.3.
- 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.
- 09/30/2021 R32 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.
- 04/01/2021 R31 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.
- 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**.
- 01/01/2021 R30 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.
- 12/13/2020 R29 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.
- 12/13/2020 R28 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 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.

10/01/2020	R27	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.
07/01/2020	R26	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.
01/01/2020	R25	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.
07/10/2019	R24	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.
06/13/2019	R23	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.
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	<p>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.</p>
01/01/2019	R20	<p>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.</p>
10/25/2018	R19	<p>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®.</p>
10/04/2018	R18	<p>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.</p>
07/26/2018	R17	<p>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.</p>
03/08/2018	R16	<p>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 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.</p>
01/01/2018	R15	<p>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.</p>
11/09/2017	R14	<p>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</p>

		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, 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.