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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 Guidelines

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 to be a Panel of tests and bill under a single CPT code to prevent stacking of codes.

When multiple biomarkers are performed on one specimen and ordered in the context of a set panel of tests then this scenario should be billed as the specific panel if it has its own CPT code or as 81479 if it does not have a specific CPT code. Billing each code separately is incorrect billing and may result in the denial of the claim.

Consistent with the Utilization Guidelines outlined in LCD L35396, 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 81545), ThyGenX (CPT 81445), RosettaGX Reveal (CPT 81479) and ThyroSeq tests (CPT 0026U)
 - 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.

Because there are multiple biomarkers represented by each of the Tier 2 codes, when billing for these codes, it will be necessary to report the specific biomarker in the claim narrative/remarks. Please report information in the narrative/remarks that provides ample information to uniquely identify the specific biomarker.

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.

Examples:

- CPT code 81404 represents “level 5” biomarker tests.
- CPT identifies an extensive list of biomarkers that should be reported using CPT code 81404.
- When billing for “ret proto-oncogene” testing, report RET in the narrative/remarks of the claim.
- If reporting a biomarker such as facioscapulohumeral muscular dystrophy A1, where there is greater non-uniqueness among two similar biomarkers, then in addition to reporting “FSHMD1A”, include a brief additional note in the narrative/remarks section of the claim to report that the testing was for detection of abnormal alleles or haplotype characterization.
- 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 listed under one of the Tier 2 codes.
 - A description of the testing performed is required in the narrative/remarks when using this code.

Providing the descriptive information for the Tier 2 and the unlisted molecular pathology code will assist in timely processing of your claims.

Failure to provide the information may result in delayed processing or claim denials.

Billing Claims With Multiple Biomarkers

1. There are typically submissions of claims where multiple biomarkers on the same date of service (DOS) can better support the further diagnosis, prognosis or chemotherapy prediction of a neoplastic disease.
2. Such claims may involve different coverable combinations of Tier 1, Tier 2 and NOC (i.e., CPT code 81479) codes.
3. Each code will be adjudicated individually, whether manually or electronically, such that these coverable combinations follow the LCD.
4. It would not typically be expected for providers to order multiple biomarkers on different DOS's, since the molecular evaluation of a particular neoplasm is typically comprehensive in nature (per the intent of #1 above). However, staged, algorithmic or incremental molecular testing may be necessary based upon the particular neoplasm encountered.
5. Targeted genomic sequence analysis panel, hematolymphoid Neoplasm or disorder, DNA analysis, and RNA analysis when performed, 5-50 genes, should be billed with CPT code 81450. The Panel name and a minimum of five (5) genes with Class-2A rating by NCCN from the Panel must be listed in the Remarks area of the claim for Part A and the Narrative area of the claim for Part B.

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, ThyGenX, 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 ThyGenX result for all mutations or when mutations detected are not fully indicative of malignancy (i.e., ThyGenX results which favor a benign nodule but cancer could still be present). ThyGenX, 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 ThyGenX 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 ThyGenX tests, please submit the following claim information:

- CPT code 81445
- Enter ThyGenX 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 81545
- 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
- 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, ThyGenX, 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

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.

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.

12	Hospital Inpatient (Medicare Part B only)
13	Hospital Outpatient
14	Hospital - Laboratory Services Provided to Non-patients
22	Skilled Nursing - Inpatient (Medicare Part B only)
23	Skilled Nursing - Outpatient
71	Clinic - Rural Health
72	Clinic - Hospital Based or Independent Renal Dialysis Center
73	Clinic - Freestanding
75	Clinic - Comprehensive Outpatient Rehabilitation Facility (CORF)
77	Clinic - Federally Qualified Health Center (FQHC)
83	Ambulatory Surgery Center
85	Critical Access Hospital

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.

0300	Laboratory - General Classification
0301	Laboratory - Chemistry
0302	Laboratory - Immunology
0303	Laboratory - Renal Patient (Home)
0304	Laboratory - Non-Routine Dialysis
0305	Laboratory - Hematology
0306	Laboratory - Bacteriology & Microbiology
0307	Laboratory - Urology
0309	Laboratory - Other Laboratory
0310	Laboratory Pathology - General Classification
0311	Laboratory Pathology - Cytology
0312	Laboratory Pathology - Histology
0314	Laboratory Pathology - Biopsy
0319	Laboratory Pathology - Other Laboratory Pathology

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 81545. Providers should refer to the covered indications section of the LCD to determine if biomarkers included in these codes are considered reasonable and necessary.

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.

Note: A minimum of five (5) genes with Class-2A NCCN rating must be contained in the Panel for CPT code 81450.

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

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")
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, MYELODYSPLASTIC SYNDROME, MYELOPROLIFERATIVE NEOPLASMS, CHRONIC MYELOMONOCYTIC LEUKEMIA), GENE ANALYSIS; FULL GENE SEQUENCE
81176	ASXL1 (ADDITIONAL SEX COMBS LIKE 1, TRANSCRIPTIONAL REGULATOR) (EG, MYELODYSPLASTIC 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, MYELODYSPLASTIC 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)
81350	UGT1A1 (UDP GLUCURONOSYLTRANSFERASE 1 FAMILY, POLYPEPTIDE A1) (EG, DRUG METABOLISM, HEREDITARY UNCONJUGATED HYPERBILIRUBINEMIA [GILBERT SYNDROME]) GENE ANALYSIS, COMMON VARIANTS (EG, *28, *36, *37)
81400	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 1 (EG, IDENTIFICATION OF SINGLE GERMLINE VARIANT [EG, SNP] BY TECHNIQUES SUCH AS RESTRICTION ENZYME DIGESTION OR MELT CURVE ANALYSIS)
81401	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 2 (EG, 2-10 SNPS, 1 METHYLATED VARIANT, OR 1 SOMATIC VARIANT [TYPICALLY USING NONSEQUENCING TARGET VARIANT ANALYSIS], OR DETECTION OF A DYNAMIC MUTATION DISORDER/TRIPLET REPEAT)
81402	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 3 (EG, >10 SNPS, 2-10 METHYLATED VARIANTS, OR 2-10 SOMATIC VARIANTS [TYPICALLY USING NON-SEQUENCING TARGET VARIANT ANALYSIS], IMMUNOGLOBULIN AND T-CELL RECEPTOR GENE REARRANGEMENTS, DUPLICATION/DELETION VARIANTS OF 1 EXON, LOSS OF HETEROZYGOSITY [LOH], UNIPARENTAL DISOMY [UPD])
81403	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 4 (EG, ANALYSIS OF SINGLE EXON BY DNA SEQUENCE ANALYSIS, ANALYSIS OF >10 AMPLICONS USING

	MULTIPLEX PCR IN 2 OR MORE INDEPENDENT REACTIONS, MUTATION SCANNING OR DUPLICATION/DELETION VARIANTS OF 2-5 EXONS)
81404	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 5 (EG, ANALYSIS OF 2-5 EXONS BY DNA SEQUENCE ANALYSIS, MUTATION SCANNING OR DUPLICATION/DELETION VARIANTS OF 6-10 EXONS, OR CHARACTERIZATION OF A DYNAMIC MUTATION DISORDER/TRIPLET REPEAT BY SOUTHERN BLOT ANALYSIS) UGT1A1 (UDP GLUCURONOSYLTRANSFERASE 1 FAMILY, POLYPEPTIDE A1) (EG, HEREDITARY UNCONJUGATED HYPERBILIRUBINEMIA [CRIGLER-NAJJAR SYNDROME]) FULL GENE SEQUENCE
81405	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 6 (EG, ANALYSIS OF 6-10 EXONS BY DNA SEQUENCE ANALYSIS, MUTATION SCANNING OR DUPLICATION/DELETION VARIANTS OF 11-25 EXONS, REGIONALLY TARGETED CYTOGENOMIC ARRAY ANALYSIS)
81406	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 7 (EG, ANALYSIS OF 11-25 EXONS BY DNA SEQUENCE ANALYSIS, MUTATION SCANNING OR DUPLICATION/DELETION VARIANTS OF 26-50 EXONS, CYTOGENOMIC ARRAY ANALYSIS FOR NEOPLASIA)
81407	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 8 (EG, ANALYSIS OF 26-50 EXONS BY DNA SEQUENCE ANALYSIS, MUTATION SCANNING OR DUPLICATION/DELETION VARIANTS OF >50 EXONS, SEQUENCE ANALYSIS OF MULTIPLE GENES ON ONE PLATFORM) APOB (APOLIPOPROTEIN B) (EG, FAMILIAL HYPERCHOLESTEROLEMIA TYPE B) FULL GENE SEQUENCE
81408	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 9 (EG, ANALYSIS OF >50 EXONS IN A SINGLE GENE BY DNA SEQUENCE ANALYSIS)
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, BMP1A, 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
81545	ONCOLOGY (THYROID), GENE EXPRESSION ANALYSIS OF 142 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=AAAAQAAAAAAAA>

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**
 ColonSeq® **81445**

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

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**
 LungSeq® **81445**

C33	Malignant neoplasm of trachea
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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

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

BRAF 81210
KIT 81272
NRAS 81311

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
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

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

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

Medicare is establishing the following limited coverage for thyroid molecular biomarkers:

BRAF - 81210
KRAS - 81275, 81276
NRAS - 81311
ThyraMIR - 0018U
Afirma - 81545
ThyGenX - 81445
RosettaGX Reveal Thyroid miRNA - 81479
ThyroSeq – 0026U

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

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

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
C56.9	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

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

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

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

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
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

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
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

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

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

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

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

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

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

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

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

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

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

KIT (including p.D816V) 81273

D72.1	Eosinophilia
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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

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

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

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

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

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.

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

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

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

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
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
C79.89	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

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

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

MYD88 81305

C88.0	Waldenstrom macroglobulinemia
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