TIER 2 MOLECULAR PATHOLOGY PROCEDURES

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Terms and Conditions

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POLICY SUMMARY

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Overview

According to The American Medical Association (AMA) Current Procedural Terminology (CPT®) manual, molecular pathology procedures are medical laboratory procedures involving the analyses of nucleic acid (i.e., DNA, RNA) to detect variants in genes that may be indicative of germline (e.g., constitutional disorders) or somatic (e.g., neoplasia) conditions, or to test for histocompatibility antigens (e.g., HLA). Code selection is typically based on the specific gene(s) that is being analyzed.

Codes that describe tests to assess for the presence of gene variants use common gene variant names. Typically, all of the listed variants would be tested. However, these lists are not exclusive. If other variants are also tested in the analysis, they would be included in the procedure and not reported separately. Full gene sequencing should not be reported using codes that assess for the presence of gene variants unless the CPT code specifically states full gene sequence in the code descriptor. In other words, you may only assign the CPT code that is described as "full gene sequence" if the test assay performed was a full gene sequence.

There are Tier 1 and Tier 2 molecular pathology procedure codes. Tier 1 codes generally describe testing for a specific gene or HLA locus. Tier 2 molecular pathology procedures represent procedures that are generally performed in lower volumes than Tier 1 molecular pathology procedures (e.g., the incidence of the disease being tested is rare). They are arranged by level of technical resources and interpretive work by the physician or other qualified healthcare professional.

Use the appropriate molecular pathology procedure level code that includes the specific analyte listed after the code descriptor. If the analyte/gene tested is not listed under one of the Tier 2 codes or is not represented by a Tier 1 code in CPT, use of the Not Otherwise Classified (NOC) CPT code is required.

Tier 1 and/or Tier 2 individual biomarker CPT codes should not be used for a single gene or any combination of genes when testing is performed as part of a Next-Generation Sequencing (NGS) or other multiplexing technology panel.

Molecular pathology procedures have broad clinical and research applications. The following examples of applications may not be relevant to a Medicare member or may not meet a Medicare benefit category and/or reasonable and necessary threshold for coverage. Such examples include Genetic Testing and Genetic Counseling (when applicable) for:

- Disease Risk
- Carrier Screening

- Hereditary Cancer Syndromes
- Gene Expression Profiling for certain cancers
- Prenatal Diagnostic testing
- Diagnosis and Monitoring Non-Cancer Indications, and
- Several Pharmacogenomic applications.

Guidelines

Tier 2 Molecular pathology procedures may be eligible for coverage when **all** of the following criteria are met:

- Alternative laboratory or clinical tests to definitively diagnose the disorder/identify the condition are unavailable or results are clearly equivocal; AND
- Availability of a clinically valid test, based on published peer reviewed medical literature; AND
- Testing assay(s) are Food and Drug Administration (FDA) approved/cleared or if LDT (lab developed test) or LDT protocol or FDA modified test(s) the laboratory documentation should support assay(s) analytical validity and clinical utility; AND
- Results of the testing must directly impact treatment or management of the member; AND
- For testing panels, including but not limited to, multiple genes or multiple conditions, and in cases where a tiered approach/method is clinically available, testing would be covered ONLY for the number of genes or test that are reasonable and necessary to establish a diagnosis; AND
- Individual has not previously received genetic testing for the disease/condition. (In general, diagnostic genetic testing for a disease should be performed once in a lifetime.)

Screening services such as pre-symptomatic genetic tests and services used to detect an undiagnosed disease or disease predisposition are not a Medicare benefit and are not covered. Similarly, Medicare may not reimburse the costs of tests/examinations that assess the risk of a condition unless the risk assessment clearly and directly effects the management of the patient.

A specific genetic test may only be performed once in a lifetime per member for inherited conditions; however, when medically reasonable and necessary, genetic testing may be done on acquired conditions such as malignancies (including separate malignancies developing at different times) as they are treated and are being followed, in order to assess response or other relevant clinical criteria. Likewise, there are situations where medical record and literature documentation are able to demonstrate that serial testing can be reasonably predicted to provide additional clinically useful information. When the record documents that this information, such as confirmed significant response to current therapy, is likely to assist in modifying treatment, serial testing can be considered reasonable and necessary and eligible for coverage.

Covered Indications

Specific diagnosis criteria for covered services can be found in the *Applicable Codes* section.

- **For CPT Code 81400**
  - ACE
  - F13B
  - F5
  - F7
  - FGB
- **For CPT Code 81401**
  - CBFB-MYH11
  - CCND1/IGH (BCL1/IgH, t) (e.g., mantle cell lymphoma) translocation analysis, major breakpoint, qualitative and quantitative, if performed is considered medical necessary for patients who have non- Hodgkin's lymphoma to guide therapeutic decision-making.
  - E2A/PBX1
  - EML4-ALK
  - ETV6-RUNX1
  - EWSR1/ERG
  - EWSR1/FLI1
  - EWSR1/WT1
  - F11 coagulation factor XI
  - FIP1L1-PDGFR
  - FOXO1/PAX3
  - FOXO1/PAX7
  - MUTYH (mutY homolog [E. coli])
  - NPM/ALK
  - PAX8/PPARG
  - RUNX1/RUNX1T1

- **For CPT Code 81402**
  - MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR) (e.g., myeloproliferative disorder), common variants (e.g., W515A, W515K, W515L, W515R) is considered medically necessary in the initial work-up of BCR-ABL negative, JAK2 negative, and CALR negative adults with clinical, laboratory, or pathological findings suggesting thrombocytosis, essential thrombocythemia (ET), or primary myelofibrosis (PMF).
- **For CPT Code 81403**
  - EpCAM
  - F8 (coagulation factor VIII)
  - MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR) (e.g., myeloproliferative disorder), exon 10 sequence is considered medically necessary in the initial work-up of BCR-ABL negative, JAK2 negative, and CALR negative adults with clinical, laboratory, or pathological findings suggesting thrombocytosis, essential thrombocythemia (ET), or primary myelofibrosis (PMF).
  - JAK2 (Janus kinase 2) (e.g., myeloproliferative disorder), exon 12 sequence and exon 13 sequence is considered medically necessary in the initial work-up of BCR-ABL and JAK2 (V617F variant) negative adults with clinical, laboratory, or pathological findings suggesting polycythemia vera.
  - VHL (von Hippel-Lindau tumor suppressor)
- **For CPT Code 81404**
  - CDKN2A (cyclin-dependent kinase inhibitor 2A)
  - MEN1 (multiple endocrine neoplasia 1) (e.g., multiple endocrine neoplasia type 1, Wermer syndrome), duplication/deletion
  - MEN2B
  - PRSS1 (protease, serine, 1 [trypsin 1])
  - RET (ret-proto-oncogene) is considered medically necessary in patients with medullary CA of thyroid, multiple endocrine neoplasia, pheochromocytoma, and parathyroid tumors) to guide therapeutic decision making.
  - TP53 (tumor protein 53) (e.g., tumor samples), targeted sequence analysis of 2-5 exons is considered medically necessary in individuals who have Acute Myelogenous Leukemia or Myeloplastic Disease to guide therapeutic decision-making.
  - VHL (von Hippel-Lindau tumor suppressor)
- **For CPT Code 81405**
  - MEN1 (multiple endocrine neoplasia 1) (e.g., multiple endocrine neoplasia type 1, Wermer syndrome), full gene sequence is considered medically necessary in patients with multiple endocrine neoplasia to guide therapeutic decision-making.
  - MEN2A
  - RET (ret-proto-oncogene) is considered medically necessary in patients with medullary CA of thyroid, multiple endocrine neoplasia, pheochromocytoma, and parathyroid tumors) to guide therapeutic decision making.
  - TP53 (tumor protein 53) (e.g., Li-Fraumeni syndrome, tumor samples), full gene sequence or targeted sequence analysis of >5 exons is considered medically necessary in individuals who have Acute Myelogenous Leukemia or Myeloplastic Disease to guide therapeutic decision-making.
- **For CPT Code 81406**
  - ATP7B (ATPase, Cu++ transporting, beta polypeptide) is considered medically necessary in patients with symptoms of Wilson's disease to guide therapeutic decision making.
  - MUTYH (mutY homolog [E. coli]

Noncovered Indications

The following individual Tier 2 genetic tests are unlikely to impact therapeutic decision-making, directly impact treatment, outcome and/or clinical management in the care of the member and will be denied as not medically necessary. (Please note that this list of non-covered genes is not exhaustive, and the fact that a specific gene is not mentioned does not mean it is covered. In addition, many genes have several names that are used. The most common names have been used in this policy.)

- **For CPT Code 81400**
  - ACADM
  - AGTR1
  - CCR5
  - CLRN1
  - DYT1 (TOR1A)
  - FGFR3
  - IL28B
  - IVD
  - TOR1A
- **For CPT Code 81401**
  - ADRB2
  - APOE

- CFH/ARMS2
- DEK/NUP214
- FGFR3
- GALT (galactose-1-phosphate uridylyltransferase)
- H19
- KCNQ10T1 (KCNQ1 overlapping transcript 1)
- MEG3/DLK1
- MLL/AFF
- MT-ATP6
- MT-ND4
- MT-ND6
- MT-ND5 mitochondrially encoded tRNA leucine 1 [UUA/G] mitochondrially encoded NADH dehydrogenase 5)
- MT-RNR1 (mitochondrially encoded 12S RNA)
- MT-TK (mitochondrially encoded tRNA lysine)
- MT-TL1
- MT-TS1
- PRSS1 (protease, serine, 1 [trypsin 1])

- **For CPT Code 81402**
  - CYP21A2
  - Chromosome 18q-
  - MEFV (Mediterranean fever) (e.g., familial Mediterranean fever)
  - TRD 81402 Uniparental disomy (UPD)
- **For CPT Code 81403**
  - ANG (angiogenin, ribonuclease, RNase A family, 5)
  - FGFR3 (fibroblast growth factor receptor 3) one exon
  - GJB1 (gap junction protein, beta 1) (e.g., Charcot-Marie-Tooth X-linked), full gene sequence
  - HRAS (v-Ha-ras Harvey rat sarcoma viral oncogene homolog Costello syndrome)
  - MT-RNR1 (mitochondrially encoded 12S RNA)
  - MT-TS1 (mitochondrially encoded tRNA serine 1)
- **For CPT Code 81404**
  - ACADS (acyl-CoA dehydrogenase)
  - AQP2 (aquaporin 2 [collecting duct])
  - ARX (aristaless related homeobox)
  - BTD (biotinidase)
  - CAV3 (caveolin 3) (e.g., CAV3-related distal myopathy, limb-girdle muscular dystrophy type 1C), full gene sequence
  - CLRN1 (clarin 1)
  - CYP1B1 (cytochrome P450, family 1, subfamily B, polypeptide 1)
  - EGR2 (early growth response 2) (e.g., Charcot-Marie-Tooth)
  - FGFR2 (fibroblast growth factor receptor 2) (2 EXONS)
  - FGFR3 (fibroblast growth factor receptor 3) (4 EXONS)
  - FKRP (Fukutin related protein)
  - FOXG1 (forkhead box G1)
  - FSHMD1A (facioscapulohumeral muscular dystrophy 1A)
  - FSHMD1A (facioscapulohumeral muscular dystrophy 1A)
  - HNF1B (HNF1 homeobox B)
  - HRAS (v-Ha-ras Harvey rat sarcoma viral oncogene homolog)
  - KCNJ10 (potassium inwardly-rectifying channel, subfamily J, member 10)
  - MMACHC (Methylmalonic aciduria (cobalamin deficiency) cblC type, with homocystinuria) is associated with the most common error of vitamin B12 metabolism. Although considered a disease of infancy or childhood, some individuals develop symptoms in adulthood. However, to date, the exact function of the protein encoded by this gene is not known. Therefore, MMACHC testing does not meet the clinical utility requirements for a Medicare Benefit and is considered a statutorily excluded service.
  - SLC25A4 (solute carrier family 25 [mitochondrial carrier; adenine nucleotide translocation])
  - VWF (von Willebrand factor)
- **For CPT Code 81405**
  - ACADS (acyl-CoA dehydrogenase)
  - CASR (CAR, EIG8, extracellular calcium-sensing receptor, FHH, FIH, GPRC2A, HHC, HHC1, NSHPT, PCAR1)
  - CDKL5 (cyclin-dependent kinase-like 5)
  - CYP21A2 (cytochrome P450, family 21, subfamily A, polypeptide2)
  - ENG
  - HNF1B (HNF1 homeobox B)
  - MPZ (myelin protein zero)

- NF2 (neurofibromin 2 [merlin])
- NSD1
- RPS19
- STAT3
- TSC1 (tuberous sclerosis 1

- **For CPT Code 81406**
  - ACADVL (acyl-CoA dehydrogenase, very long chain)
  - AIRE
  - BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide)
  - CBS (cystathionine-beta-synthase)
  - CDH1, full gene sequence
  - CDKL5 (cyclin-dependent kinase-like 5)
  - DLAT (dihydrolipoamide S-acetyltransferase)
  - DLD (dihydrolipoamide dehydrogenase)
  - ENG
  - F8 (coagulation factor VIII)
  - GALT (galactose-1-phosphate uridylyltransferase)
  - HADHA (hydroxyacyl-CoA dehydrogenase/3-ketoacyl-CoA thiolase/enoyl-CoA hydratase [trifunctional protein] alpha subunit)
  - HEXA (hexosaminidase A, alpha polypeptide)
  - IVD
  - LMNA (lamin A/C)
  - NF2 (neurofibromin 2 [merlin])
  - NSD1 (nuclear receptor binding SET domain protein 1)
  - PAH (phenylalanine hydroxylase)
  - PAX2 (paired box 2)
  - PDHA1 (pyruvate dehydrogenase [lipoamide] alpha1)
  - POLG (polymerase [DNA directed], gamma)
  - PRKAG2 (protein kinase, AMP-activated gamma 2 non-catalytic subunit)
  - PTPN11 (protein tyrosine phosphatase, non-receptor type 11)
  - RET (ret-proto-oncogene) (e.g., Hirschsprung disease), full gene sequence
  - SLC9A6 (solute carrier family 9 [sodium/hydrogen exchanger] member 6)
  - SOS1 (son of sevenless homolog 1)
  - TAZ (tafazzin)
  - TSC1 (tuberous sclerosis 1)
  - TSC2 (tuberous sclerosis 2)
  - UBE3A (ubiquitin protein ligase)
- **For CPT Code 81407, level 8 Molecular Pathology Procedures are noncovered.**
- **For CPT Code 81408, level 9 Molecular Pathology Procedures are noncovered.**

Based on the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (100 - 08), this policy addresses the circumstances under which the item or service is reasonable and necessary under the Social Security Act, §1862(a)(1)(A). For laboratory services, a service can be reasonable and necessary if the service is safe and effective; and appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is furnished in accordance with accepted standards of medical practice for the diagnosis of the patient's condition; furnished in a setting appropriate to the patient's medical needs and condition; ordered and furnished by qualified personnel; one that meets, but does not exceed, the patient's medical need; and is at least as beneficial as an existing and available medically appropriate alternative.

Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review. Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states " ...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." Furthermore, it has been longstanding CMS policy that ***"tests that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered unless explicitly authorized by statute". Screening services, such as pre - symptomatic genetic tests and services, are those used to detect an undiagnosed disease or disease predisposition, and as such are not a Medicare benefit and not covered by Medicare.*** Similarly, Medicare may not reimburse the costs of tests/examinations that assess the risk for and/or of a condition unless the risk assessment clearly and directly effects the management of the patient. However, Medicare does cover a broad range of legislatively mandated preventive services to prevent disease, detect disease early when it is most treatable and curable, and manage disease so that complications can be avoided. These services can be found on the CMS website at http://www.cms.gov/PrevntionGenInfo/.

Many applications of the molecular pathology procedures are not covered services by Medicare given lack of benefit category (preventive service) and/or failure to reach the reasonable and necessary threshold for coverage (based on quality of clinical evidence and strength of recommendation). Furthermore, payment of claims in the past (based on stacking codes) or in the future (based on the new code series) is not a statement of coverage since the service was not audited for compliance with program requirements and documentation supporting the reasonable and necessary testing for the member. Certain tests and procedures may be subject to prepayment medical review (records requested) and paid claims must be supportable, if selected, for post payment audit. Tests for diseases or conditions that manifest severe signs or symptoms in newborns and in early childhood or that result in early death (e.g., Canavan disease) could be subject to automatic denials since these tests are not usually relevant to a Medicare member.

Documentation Guidelines

Documentation must be adequate to verify that coverage guidelines listed above have been met. Thus, the medical record must contain documentation that the testing is expected to influence treatment of the condition toward which the testing is directed. The laboratory or billing provider must have on file the physician requisition which sets forth the diagnosis or condition that warrants the test(s).

Examples of documentation requirements of the ordering physician/non - physician practitioner (NPP) include, but are not limited to, history and physical or exam findings that support the decision making, problems/diagnoses, relevant data (e.g., lab testing, imaging results).

Documentation requirements of the performing laboratory (when requested) include, but are not limited to, lab accreditation, test requisition, test record/procedures, reports (preliminary and final), and quality control record.

Documentation requirements for lab developed tests/protocols (when requested) include diagnostic test/assay, lab/manufacturer, names of comparable assays/services (if relevant), description of assay, analytical validity evidence, clinical validity evidence, and clinical utility.

Providers are required to code to specificity; however, if an unlisted CPT code is used, the documentation must clearly identify the unique procedure performed. When multiple procedure codes are submitted on a claim (unique and/or unlisted) the documentation supporting each code should be easily identifiable. If on review UnitedHealthcare cannot link a billed code to the documentation, these services will be denied.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act.

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. Report information in the narrative/remarks that provides ample information to uniquely identify the specific biomarker.

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

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

Billing Claims with Multiple Biomarkers

- 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.
- Such claims may involve different coverable combinations of Tier 1, Tier 2 and unlisted molecular pathology codes.
- Each code will be adjudicated individually, whether manually or electronically, such that these coverable combinations follow the policy guidelines.

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non - covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
81400	Molecular pathology procedure, Level 1 (short description)
81401	Molecular pathology procedure, Level 2 (short description)

CPT Code	Description
81402	Molecular pathology procedure, Level 3 (short description)
81403	Molecular pathology procedure, Level 4 (short description)
81404	Molecular pathology procedure, Level 5 (short description)
81405	Molecular pathology procedure, Level 6 (short description)
81406	Molecular pathology procedure, Level 7 (short description)
81407	Molecular pathology procedure, Level 8 (short description)
81408	Molecular pathology procedure, Level 9 (short description)

ICD-10 Diagnosis Code	Description
CPT Codes 81406 for MUTYH	
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
D12.0	Benign neoplasm of cecum
D12.1	Benign neoplasm of appendix
D12.2	Benign neoplasm of ascending colon
D12.3	Benign neoplasm of transverse colon
D12.4	Benign neoplasm of descending colon
D12.5	Benign neoplasm of sigmoid colon
D12.6	Benign neoplasm of colon, unspecified
D12.7	Benign neoplasm of rectosigmoid junction
D12.8	Benign neoplasm of rectum
Z85.038	Personal history of other malignant neoplasm of large intestine
Z86.010	Personal history of colonic polyps
CPT Code 81404, 81405 for RET – MEN Type 2	
C73	Malignant neoplasm of thyroid gland
C74.10	Malignant neoplasm of medulla of unspecified adrenal gland
C74.11	Malignant neoplasm of medulla of right adrenal gland
C74.12	Malignant neoplasm of medulla of left adrenal gland
C75.0	Malignant neoplasm of parathyroid gland
D35.1	Benign neoplasm of parathyroid gland
CPT Codes 81404, 81405 for TP53	
C88.8	Other malignant immunoproliferative diseases
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse
C92.30	Myeloid sarcoma, not having achieved remission

ICD-10 Diagnosis Code	Description
CPT Codes 81404, 81405 for TP53	
C92.32	Myeloid sarcoma, in relapse
C92.40	Acute promyelocytic leukemia, not having achieved remission
C92.42	Acute promyelocytic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.62	Acute myeloid leukemia with 11q23-abnormality in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C92.Z0	Other myeloid leukemia not having achieved remission
C92.Z2	Other myeloid leukemia, in relapse
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.92	Myeloid leukemia, unspecified in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C93.10	Chronic myelomonocytic leukemia not having achieved remission
C93.12	Chronic myelomonocytic leukemia, in relapse
C93.Z0	Other monocytic leukemia, not having achieved remission
C93.Z2	Other monocytic leukemia, in relapse
C93.90	Monocytic leukemia, unspecified, not having achieved remission
C93.92	Monocytic leukemia, unspecified in relapse
C94.00	Acute erythroid leukemia, not having achieved remission
C94.02	Acute erythroid leukemia, in relapse
C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
C94.41	Acute panmyelosis with myelofibrosis, in remission
C94.42	Acute panmyelosis with myelofibrosis, in relapse
C94.6	Myelodysplastic disease, not classified
C94.80	Other specified leukemias not having achieved remission
C94.82	Other specified leukemias, in relapse
C95.00	Acute leukemia of unspecified cell type not having achieved remission
C95.02	Acute leukemia of unspecified cell type, in relapse
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C95.90	Leukemia, unspecified not having achieved remission
C95.92	Leukemia, unspecified, in relapse
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
D45	Polycythemia vera
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.22	Refractory anemia with excess of blasts 2
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality

ICD-10 Diagnosis Code	Description
CPT Codes 81404, 81405 for TP53	
D46.4	Refractory anemia, unspecified
D46.Z	Other myelodysplastic syndromes
D46.9	Myelodysplastic syndrome, unspecified
D47.1	Chronic myeloproliferative disease
D47.3	Essential (hemorrhagic) thrombocythemia
D47.4	Osteomyelofibrosis
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
D47.9	Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified
D61.818	Other pancytopenia
D69.49	Other primary thrombocytopenia
D69.6	Thrombocytopenia, unspecified
D69.8	Other specified hemorrhagic conditions
D69.9	Hemorrhagic condition, unspecified
D70.8	Other neutropenia
D70.9	Neutropenia, unspecified
D72.810	Lymphocytopenia
D72.818	Other decreased white blood cell count
D72.819	Decreased white blood cell count, unspecified
D72.821	Monocytosis (symptomatic)
D72.828	Other elevated white blood cell count
D72.829	Elevated white blood cell count, unspecified
D72.89	Other specified disorders of white blood cells
D72.9	Disorder of white blood cells, unspecified
D75.81	Myelofibrosis
D75.89	Other specified diseases of blood and blood-forming organs
D75.9	Disease of blood and blood-forming organs, unspecified
D77	Other disorders of blood and blood-forming organs in diseases classified elsewhere
R16.1	Splenomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified
CPT Code 81406 for ATP7B	
E83.01	Wilson's disease

Non-Covered ICD-10 Diagnosis Codes

Non-Covered ICD-10 Diagnosis Codes List

This list contains ICD-10 diagnosis codes that are **never covered when given as the primary reason for the test.** If a code from this section is given as the reason for the test and you know or have reason to believe the service may not be covered, call UnitedHealthcare to issue an Integrated Denial Notice (IDN) to the member and you. The IDN informs the member of their liability for the non-covered service or item and appeal rights. You must make sure the member has received the IDN prior to rendering or referring for non-covered services or items in order to collect payment.

PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

REFERENCES

CMS National Coverage Determinations (NCDs)
Related NCDs:
NCD 90.2 Next Generation Sequencing (NGS)
NCD 190.3 Cytogenetic Studies
NCD 190.7 Human Tumor Stem Cell Drug Sensitivity Assays

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
APC and MUTYH Gene Testing				
L36910 (MolDX: APC and MUTYH Gene Testing)	A56828 (Billing and Coding: MolDX: APC and MUTYH Gene)	CGS	KY, OH	KY, OH
L36882 (MolDX: APC and MUTYH Gene Testing)	A57352 (Billing and Coding: MolDX: APC and MUTYH Gene Testing)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36884 (MolDX: APC and MUTYH Gene Testing)	A57353 (Billing and Coding: MolDX: APC and MUTYH Gene Testing)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L36827 (MolDX: APC and MUTYH Gene Testing)	A56824 (Billing and Coding: MolDX: APC and MUTYH Gene Testing)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L37224 (MolDX: APC and MUTYH Gene Testing)	A56901 (Billing and Coding: MolDX: APC and MUTYH Gene Testing)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
ApoE Genotype				
L36021 (MolDX: Molecular Diagnostic Tests (MDT))	A54244 (Billing and Coding: MolDX: ApoE Genotype)	CGS	KY, OH	KY, OH
L36358 (MolDX: Biomarkers in Cardiovascular Risk Assessment)	A55094 (Billing and Coding: MolDX: ApoE Genotype)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36362 (MolDX: Biomarkers in Cardiovascular Risk Assessment)	A55095 (Billing and Coding: MolDX: ApoE Genotype)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A53652 (Billing and Coding: MolDX: ApoE Genotype)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 (MolDX: Molecular Diagnostic Tests (MDT))	A55141 (Billing and Coding: MolDX: ApoE Genotype)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC,	IA, IN, KS, MI, MO, NE

LCD	Article	Contractor	Medicare Part A	Medicare Part B
			ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	
ATP7B Gene Tests				
L36021 (MolDX: Molecular Diagnostic Tests (MDT))	A54254 (Billing and Coding: MolDX: ATP7B Gene Tests)	CGS	KY, OH	KY, OH
N/A	A55097 (Billing and Coding: MolDX: ATP7B Gene Tests)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A55098 (Billing and Coding: MolDX: ATP7B Gene Tests)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A53550 (Billing and Coding: MolDX: ATP7B Gene Tests)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 (MolDX: Molecular Diagnostic Tests (MDT))	A55143 (Billing and Coding: MolDX: ATP7B Gene Tests)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
BCKDHB Gene Test				
L36021 (MolDX: Molecular Diagnostic Tests (MDT))	A54255 (Billing and Coding: MolDX: BCKDHB Gene Test)	CGS	KY, OH	KY, OH
N/A	A55099 (Billing and Coding: MolDX: BCKDHB Gene Test)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A55100 (Billing and Coding: MolDX: BCKDHB Gene Test)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A53600 (Billing and Coding: MolDX: BCKDHB Gene Test)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 (MolDX: Molecular Diagnostic Tests (MDT))	A55145 (Billing and Coding: MolDX: BCKDHB Gene Test)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
CDH1 Genetic Testing				
N/A	A54878 (Billing and Coding: MolDX: CDH1 Genetic Testing)	CGS	KY, OH	KY, OH
N/A	A55970 (Billing and Coding: MolDX: CDH1 Genetic Testing)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
CDH1 Genetic Testing				
N/A	A55971 (Billing and Coding: MolDX: CDH1 Genetic Testing)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A54835 (Billing and Coding: MolDX: CDH1 Genetic Testing)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 (MolDX: Molecular Diagnostic Tests (MDT))	A55622 (Billing and Coding: MolDX: CDH1 Genetic Testing)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
CHD7 Gene Analysis				
L36021 (MolDX: Molecular Diagnostic Tests (MDT))	A54243 (Billing and Coding: MolDX: *CHD7* Gene Analysis Guidelines)	CGS	KY, OH	KY, OH
N/A	A55085 (Billing and Coding: MolDX: CHD7 Gene Analysis)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A55086 (MolDX: *CHD7* Gene Analysis Coding and Billing Guidelines)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A53565 (Billing and Coding: MolDX: *CHD7* Gene Analysis)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 (MolDX: Molecular Diagnostic Tests (MDT))	A55157 (Billing and Coding: MolDX: CHD7 Gene Analysis)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
ENG and ACVRL1 Gene Tests				
L36021 (MolDX: Molecular Diagnostic Tests (MDT))	A54262 (Billing and Coding: MolDX: ENG and ACVRL1 Gene Tests)	CGS	KY, OH	KY, OH
N/A	A55181 (Billing and Coding: MolDX: ENG and ACVRL1 Gene Tests)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A55182 (Billing and Coding: MolDX: ENG and ACVRL1 Gene Tests)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A53536 (Billing and Coding: MolDX: ENG and ACVRL1 Gene Tests)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
ENG and ACVRL1 Gene Tests				
L36807 (MolDX: Molecular Diagnostic Tests (MDT))	A55159 (Billing and Coding: MolDX: ENG and ACVRL1 Gene Tests)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
Genetic Testing for BCR - ABL Negative Myeloproliferative Disease				
L36117 (MolDX: Genetic Testing for BCR - ABL Negative Myeloproliferative Disease)	A56999 (Billing and Coding: MolDX: Genetic Testing for BCR - ABL Negative Myeloproliferative Disease)	CGS	KY, OH	KY, OH
L36180 (MolDX: Genetic Testing for BCR - ABL Negative Myeloproliferative Disease)	A57421 (Billing and Coding: MolDX: Genetic Testing for BCR - ABL Negative Myeloproliferative Disease)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36186 (MolDX: Genetic Testing for BCR - ABL Negative Myeloproliferative Disease)	A57422 (Billing and Coding: MolDX: Genetic Testing for BCR - ABL Negative Myeloproliferative Disease)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L36044 (MolDX: Genetic Testing for BCR - ABL Negative Myeloproliferative Disease)	A56959 (Billing and Coding: MolDX: Genetic Testing for BCR - ABL Negative Myeloproliferative Disease)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36815 (MolDX: Genetic Testing for BCR - ABL Negative Myeloproliferative Disease)	A57570 (Billing and Coding: MolDX: Genetic Testing for BCR - ABL Negative Myeloproliferative Disease)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
Genetic Testing for Lynch Syndrome				
L34912 (Genetic Testing for Lynch Syndrome)	A57450 (Billing and Coding: Genetic Testing for Lynch Syndrome)	First Coast	FL, PR, VI	FL, PR, VI
L35349 (MolDX: Genetic Testing for Lynch Syndrome)	A56882 (Billing and Coding: MolDX: Genetic Testing for Lynch Syndrome)	CGS	KY, OH	KY, OH
L35024 (MolDX: Genetic Testing for Lynch Syndrome)	A54987 (Billing and Coding: MolDX: Genetic Testing for Lynch Syndrome)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36370 (MolDX: Genetic Testing for Lynch Syndrome)	A54995 (Billing and Coding: MolDX: Genetic Testing for Lynch Syndrome)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
Genetic Testing for Lynch Syndrome				
L36374 (MolDX: Genetic Testing for Lynch Syndrome)	A54996 (Billing and Coding: MolDX: Genetic Testing for Lynch Syndrome)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L36793 (MolDX: Genetic Testing for Lynch Syndrome)	A55135 (Billing and Coding: MolDX: Genetic Testing for Lynch Syndrome)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
HEXA Gene Analysis				
L36021 (MolDX: Molecular Diagnostic Tests (MDT))	A54268 (Billing and Coding: MolDX: HEXA Gene Analysis)	CGS	KY, OH	KY, OH
N/A	A55255 (Billing and Coding: MolDX: HEXA Gene Analysis)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A55256 (Billing and Coding: MolDX: HEXA Gene Analysis)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A53598 (Billing and Coding: MolDX: HEXA Gene Analysis)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 (MolDX: Molecular Diagnostic Tests (MDT))	A55168 (Billing and Coding: MolDX: HEXA Gene Analysis)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
L1CAM Gene Sequencing				
L36021 (MolDX: Molecular Diagnostic Tests (MDT))	A54274 (Billing and Coding: MolDX: L1CAM Gene Sequencing Guidelines)	CGS	KY, OH	KY, OH
N/A	A55277 (Billing and Coding: MolDX: L1CAM Gene Sequencing)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A55278 (Billing and Coding: MolDX: L1CAM Gene Sequencing)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A53659 (Billing and Coding: MolDX: L1CAM Gene Sequencing)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L1CAM Gene Sequencing				
L36807 (MolDX: Molecular Diagnostic Tests (MDT))	A55192 (Billing and Coding: MolDX: L1CAM Gene Sequencing)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
MMACHC Test				
L36021 (MolDX: Molecular Diagnostic Tests (MDT))	A54209 (Billing and Coding: MolDX: MMACHC Test)	CGS	KY, OH	KY, OH
N/A	A55288 (Billing and Coding: MolDX: MMACHC Test)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A55289 (Billing and Coding: MolDX: MMACHC Test)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A54035 (Billing and Coding: MolDX: MMACHC Test)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 (MolDX: Molecular Diagnostic Tests (MDT))	A55191 (Billing and Coding: MolDX: MMACHC Test)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
NSD1 Gene Tests				
L36021 (MolDX: Molecular Diagnostic Tests (MDT))	A54291 (Billing and Coding: MolDX: NSD1 Gene Tests)	CGS	KY, OH	KY, OH
N/A	A55609 (Billing and Coding: MolDX: NSD1 Gene Tests)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A55615 (Billing and Coding: MolDX: NSD1 Gene Tests)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A53585 (Billing and Coding: MolDX: NSD1 Gene Tests)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 (MolDX: Molecular Diagnostic Tests (MDT))	A55198 (Billing and Coding: MolDX: NSD1 Gene Tests)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE

LCD	Article	Contractor	Medicare Part A	Medicare Part B
RPS19 Gene Tests				
L36021 (MolDX: Molecular Diagnostic Tests (MDT))	A54299 (Billing and Coding: MolDX: RPS19 Gene Tests)	CGS	KY, OH	KY, OH
N/A	A55610 (Billing and Coding: MolDX: RPS19 Gene Tests)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A55614 (Billing and Coding: MolDX: RPS19 Gene Tests)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A53587 (Billing and Coding: MolDX: RPS19 Gene Tests)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 (MolDX: Molecular Diagnostic Tests (MDT))	A55205 (Billing and Coding: MolDX: RPS19 Gene Tests)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
STAT3 Gene Testing				
L36021 (MolDX: Molecular Diagnostic Tests (MDT))	A54284 (Billing and Coding: MolDX: STAT3 Gene Testing)	CGS	KY, OH	KY, OH
N/A	A55480 (Billing and Coding: MolDX: STAT3 Gene Testing)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A55481 (Billing and Coding: MolDX: STAT3 Gene Testing)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A53562 (Billing and Coding: MolDX: STAT3 Gene Testing)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 (MolDX: Molecular Diagnostic Tests (MDT))	A55209 (Billing and Coding: MolDX: STAT3 Gene Testing)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
TP53 Gene Test				
L36021 (MolDX: Molecular Diagnostic Tests (MDT))	A54281 (Billing and Coding: MolDX: TP53 Gene Test)	CGS	KY, OH	KY, OH
N/A	A53591 (Billing and Coding: MolDX: TP53 Gene Test)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
TP53 Gene Test				
L36807 (MolDX: Molecular Diagnostic Tests (MDT))	A55221 (Billing and Coding: MolDX: TP53 Gene Test)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
N/A	A55484 (Billing and Coding: MolDX: TP53 Gene Tests)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A55487 (Billing and Coding: MolDX: TP53 Gene Tests)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
General Molecular Diagnostic Tests				
L34519 (Molecular Pathology Procedures)	A57451 (Billing and Coding: Molecular Pathology Procedures)	First Coast	FL, PR, VI	FL, PR, VI
L35396 (Biomarkers for Oncology)	A52986 (Billing and Coding: Biomarkers for Oncology)	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L35000 (Molecular Pathology Procedures)	A56199 (Billing and Coding: Molecular Pathology Procedures)	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
L36021 (MolDX: Molecular Diagnostic Tests (MDT))	A56973 (Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT))	CGS	KY, OH	KY, OH
L35025 (MolDX: Molecular Diagnostic Tests (MDT))	A56853 (Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT))	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L35160 (MolDX: Molecular Diagnostic Tests (MDT))	A57526 (Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT))	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 (MolDX: Molecular Diagnostic Tests (MDT))	A57527 (Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT))	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L36807 (MolDX: Molecular Diagnostic Tests (MDT)	A57772 (Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT))	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE

LCD	Article	Contractor	Medicare Part A	Medicare Part B
Testing of Multiple Genes				
N/A	A57910 (Billing and Coding: MolDX: Testing of Multiple Genes	CGS	KY, OH	KY, OH
N/A	A57503 (Billing and Coding: MolDX: Testing of Multiple Genes)	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
N/A	A57880 (Billing and Coding: MolDX: Testing of Multiple Genes)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE

CMS Benefit Policy Manual
Chapter 15; § 80.1 - 80.1.3 Clinical Laboratory Services

CMS Claims Processing Manual
Chapter 12; § 60 Payment for Pathology Services
Chapter 16, § 10.2 General Explanation of Payment; § 20 Calculation of Payment Rates - Clinical Laboratory Test Fee Schedules; § 40 Billing for Clinical Laboratory Tests

Others
CMS Clinical Laboratory Fee Schedule, CMS Website
Palmetto GBA MolDx Website

GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Action/Description
05/13/2020	**Policy Summary** ***Overview*** • Removed reference to unlisted CPT code 81479 ***Covered Indications*** (new to policy) • Added list of covered tier 2 molecular pathology tests ***Non-Covered Indications*** (new to policy) • Added list of non-covered tier 2 molecular pathology tests • Removed language pertaining to: ○ *42 Code of Federal Regulations (CFR)* section: ▪ *§410.32(a)* ▪ *§410.32(a)(3)* ▪ *§42 411.15(k)(1)* ○ *Clinical Laboratory Improvement Amendments of 1988 (CLIA)* (*§42 CFR Part 493*) ***Documentation Guidelines*** • Added language to indicate: ○ When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act ○ 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

Date	Action/Description
	▪ Report information in the narrative/remarks that provides ample information to uniquely identify the specific biomarker. ○ Providing the descriptive information for the Tier 2 molecular pathology code will assist in timely processing of claims ○ Failure to provide the information may result in delayed processing or claim denials ***Billing Claims with Multiple Biomarkers*** (new to policy) • Added language to indicate: ○ 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 ○ Such claims may involve different coverable combinations of Tier 1, Tier 2 and unlisted molecular pathology codes ○ Each code will be adjudicated individually, whether manually or electronically, such that these coverable combinations follow the policy guidelines **Applicable Codes** ***ICD-10 Diagnosis Codes*** • Updated and reformatted list of *Non-Covered ICD-10 Diagnosis Codes*; removed ICD-10 codes Z04.8, Z13.3, and Z13.4 *For CPT Code 81406 (for MUTYH)* • Added ICD codes C18.0, C18.1, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9, C19, C20, D12.0, D12.1, D12.2, D12.3, D12.4, D12.5, D12.6, D12.7, D12.8, Z85.038, and Z86.010 *For CPT Code 81404 and 81405 (for RET- MEN Type 2)* • Added ICD-10 codes C73, C74.10, C74.11, C74.12, C75.0, and D35.1 *For CPT Code 81404 and 81405 (for TP53)* • Added ICD-10 codes C88.8, C92.00, C92.02, C92.20, C92.22, C92.30, C92.32, C92.40, C92.42, C92.50, C92.52, C92.60, C92.62, C92.A0, C92.A2, C92.Z0, C92.Z2, C92.90, C92.92, C93.00, C93.02, C93.10, C93.12, C93.Z0, C93.Z2, C93.90, C93.92, C94.00, C94.02, C94.40, C94.41, C94.42, C94.6, C94.80, C94.82, C95.00, C95.02, C95.10, C95.12, C95.90, C95.92, C96.Z, C96.9, D45, D46.0, D46.1, D46.20, D46.21, D46.22, D46.A, D46.B, D46.C, D46.4, D46.Z, D46.9, D47.1, D47.3, D47.4, D47.Z9, D47.9, D61.818, D69.49, D69.6, D69.8, D69.9, D70.8, D70.9, D72.810, D72.818, D72.819, D72.821, D72.828, D72.829, D72.89, D72.9, D75.81, D75.89, D75.9, D77, R16.1, and R16.2 *For CPT Code 81406 (for ATP7B)* • Added ICD-10 code E83.01 **Supporting Information** • Updated *References* section to reflect the most current information • Archived previous policy version MPG381.01

TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.