Molecular Pathology/Genetic Testing Reported with Unlisted Codes

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➲ Terms and Conditions

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Policy Summary

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Overview

When reporting the service performed, providers should select the specific code that accurately identifies the service performed. However, some services may not have a specific code; therefore, when reporting for these services, unlisted codes are designated. Unlisted codes provide the means of reporting and tracking services until a more specific code is established. If no such specific code exists, reporting the service using the appropriate unlisted service code would be appropriate. The service should be adequately documented in the medical record. Unlisted codes should be reported only if no other specific codes adequately describe the procedure or service.

When reporting a laboratory test(s) using an unlisted code, the specific name of the laboratory test(s) and/or a short descriptor of the test(s) must be included.

Guidelines

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; not experimental or investigational (exception: routine costs of qualifying clinical trial services which meet the requirements of the Clinical Trials NCD and are considered reasonable and necessary); 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 or treatment of the patient's condition or to improve the function of a malformed body member; 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.

Nationally Non-Covered Indications

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 used to detect an undiagnosed disease or disease predisposition are not a Medicare benefit and 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.

Documentation Requirements

Documentation must be adequate to verify that coverage guidelines 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 (ICD-10-CM code) that warrants the test(s).

Examples of documentation requirements of the ordering physician/nonphysician 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 LDT(s)/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 is used the documentation must clearly identify the unique molecular pathology 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 a billed code cannot be linked to the documentation, these services may be denied based on Title XVIII of the Social Security Act, §1833(e). For these tests, the ordering provider must provide to the laboratory copies of the signed informed consent documentation.

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 may be denied as not reasonable and necessary.

Gene Identification

Covered

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

For CPT Code 81479

Biomarkers for Oncology

- MyPRS Genetic Expression Profile Testing
  Myeloma Gene Expression Profile (MyPRS) (PROG) isolates plasma cells from myeloma patients, extracts DNA, which is then subjected to MicroArray testing and application of validated software programs to identifying patterns of genetic

abnormalities. Seventy highly predictive genes have been identified and correlated to myeloma early relapse. MyPRS gives a predictive risk signature as high-risk or low risk at this time. A high-risk score predicts a less than 20% three-year complete remission whereas a low risk predicts a five-year complete remission of greater than 60%. The predictive value for the stratification of therapeutic interventions allows these patients to be treated in a more personalized manner based on their own genetic profile. This test is considered reasonable and necessary only after the initial diagnosis of multiple myeloma has been made and will be available to be used in the stratification of therapeutic interventions. It would be inappropriate to use this test as a diagnostic tool or as a monitoring device of ongoing therapy. Other testing is available for this function

- Rosetta Cancer Origin Test™
  Molecular testing, using the Rosetta Cancer Origin Test™ (PROG), is considered reasonable and necessary in the pathologic diagnoses of CUP when a conventional surgical pathology/imaging work-up is unable to identify a primary neoplastic site. Other applications of this technology are considered not reasonable and necessary and are considered investigational in the use of diagnosis of specific tumor types such as NSCLC and renal cancers
- RosettaGX Reveal thyroid MicroRNA test, is an assay used for the classification of indeterminate thyroid nodules
- Uveal Melanoma GNA11
- CIMP
- PTEN
- AKT1
- RB1
- MLL/AF4
- DEK/CAN
- TET2
- CALR
- CSF3R
- TSC2
- FGFR1
- MTOR
- BIRC3
- FBXW7
- JAK1
- JAK3
- STAT5B

Pathfinder TG®

PathfinderTG® is considered medically reasonable and necessary when selectively used as an occasional second-line diagnostic supplement:

- Only where there remains clinical uncertainty as to either the current malignancy or the possible malignant potential of the pancreatic cyst based upon a comprehensive first-line evaluation; and
- A decision regarding treatment (e.g., surgery) has not already been made based on existing information.

BCR-ABL

- Breakpoint testing for BCR-ABL1 is commonly performed as a combination or panel of tests (major, minor, and other breakpoints). To report multiple tests assigned a single ID, submit CPT code 81479.
- 81479 should also be used to report BCR-ABL translocation analysis by Next Generation Sequencing (NGS).

ClonoSEQ® Assay

Indicated uses for ClonoSeq® include acute lymphoblastic leukemia (ALL), multiple myeloma (MM), chronic lymphocytic leukemia (CLL), and diffuse large B-cell lymphoma (DLBCL). For further guidance and coding/billing criteria, refer to the Minimal Residual Disease Testing for Cancer section and Minimal Residual Disease Testing for Hematologic Cancers sourcing below.

Cobas® EGFR Mutation Test

Cobas EGFR Mutation Test for the detection of epidermal growth factor receptor (EGFR) gene for non-small cell lung cancer (NSCLC) tumor tissue. The test is intended to be used to help select patients with NSCLC for whom Tarceva® (erlotinib), an EGFR tyrosine kinase inhibitor (TKI), is indicated.

Therascreen® EGFR RGQ PCR Kit

Therascreen EGFR RGQ PCR kit is covered for the detection of the epidermal growth factor receptor (EGFR) gene from non-small cell lung cancer (NSCLC) tumor tissue. The test is intended to be used to select patients with NSCLC for whom GILOTRIF™ (afatinib), an EGFR tyrosine kinase inhibitor (TKI), is indicated.

Germline Testing for Use of PARP Inhibitors

The United States (U.S.) Food and Drug Administration (FDA) has approved several poly ADP-ribose polymerase (PARP) inhibitor treatments indicated for patients with ovarian cancer, breast cancer, pancreatic cancer, and prostate cancer.

Results of tests that assess for deleterious variants in homologous recombination repair (HRR) genes such as BRCA1 and 2 can be used as an aid in patients who are being considered for treatment with PARP inhibitors in accordance with published guidelines and approved therapeutic product labeling. These genes are often tested as part of routine management of these cancer patients as part of services that interrogate a panel of genes. In rare circumstances, limited testing for only a select group of genes may be tested to ensure compliance with FDA indicated drug usage, wherein additional genes outlined in guidelines such as the NCCN are not necessary because the patient does not meet testing criteria for larger panels.

Billing for these services can occur in the following situation:

- The patient meets clinical indication for immediate use of a PARP inhibitor for an FDA-approved use; **and**
- The patient has had no previous germline testing for hereditary cancer or somatic testing of the same cancer that included the genes necessary for testing; **and**
- The patient does not meet germline testing requirements per existing guidelines or standards of care requiring more comprehensive testing. (For further guidance and clinical criteria, refer to the sourcing below for Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer.)

Guardant360®

Guardant360® is covered only when all of the following conditions are met:

- Patient has been diagnosed with a recurrent, relapsed, refractory, metastatic, or advanced solid tumor that did not originate from the central nervous system. Patients who would meet all of the indications on the FDA label for larotrectinib if they are found to have an NTRK mutation may be considered to have advanced cancer; and
- Patient has not previously been tested with the Guardant360® test for the same genetic content. For a patient who has been tested previously using Guardant360® for cancer, that patient may not be tested again unless there is clinical evidence that the cancer has evolved wherein testing would be performed for different genetic content. Specifically, in patients with previously tested cancer, who have evidence of new malignant growth despite response to a prior targeted therapy, that growth may be considered to be sufficiently genetically different to require additional genetic testing; and
- Patient is untreated for the cancer being tested, or the patient is not responding to treatment (e.g., progression or new lesions on treatment); and
- The patient has decided to seek further cancer treatment with the following conditions:
    - The patient is a candidate for further treatment with a drug that is either FDA-approved for that patient's cancer, or has an NCCN 1 or NCCN 2A recommendation for that patient's cancer; and
    - The FDA-approved indication or NCCN recommendation is based upon information about the presence or absence of a genetic biomarker tested for in the Guardant360® assay; and
- Tissue-based, CGP is infeasible (e.g., quantity not sufficient for tissue-based CGP or invasive biopsy is medically contraindicated) or specifically in NSLC Tissue-based CGP has shown no actionable mutations.

InVisionFirst, Liquid Biopsy

Limited coverage is allowed for InVisionFirst™ Lung (Inivata, Research Triangle Park, NC) (hereafter InVision) a plasma-based, somatic comprehensive genomic profiling test (CGP) for patients with advanced (Stage IIIB/IV) non-small cell lung cancer (NSCLC):

- At diagnosis:
  - When results for EGFR single nucleotide variants (SNVs) and insertions and deletions (indels); rearrangements in ALK and ROS1; and SNVs for BRAF are not available; and
  - When tissue-based CGP is infeasible [i.e., quantity not sufficient (QNS) for tissue-based CGP or invasive biopsy is medically contraindicated];

  or
- At progression:
  - For patients progressing on or after chemotherapy or immunotherapy who have not been tested for EGFR SNVs and indels; rearrangements in ALK and ROS1; and SNVs for BRAF, and for whom tissue based CGP is infeasible;
    or
  - For patients progressing on EGFR tyrosine kinase inhibitors (TKIs).

If no genetic alteration is detected by InVision® or if circulating tumor DNA (ctDNA) is insufficient/not detected, tissue-based genotyping should be considered.

KRAS

Two tests have met the Food and Drug Administration (FDA) criteria for KRAS genetic testing:

- Therascreen® KRAS to detect 7 somatic mutations in the human KRAS oncogene was developed to aid in the identification of colorectal cancer (CRC) patients for treatment with Erbitux® (cetuximab).
- Cobas® KRAS to detect mutations in codons 12 and 13 of the KRAS gene was developed to aid in identification of CRC patients for treatment with Erbitux® (cetuximab) or Vectibix® (panitumumab).

MammaPrint®

MammaPrint® is a diagnostic test that analyzes the gene expression profile of FFPE breast cancer tissue samples to assess a patients' risk for distant metastasis.

The test can be performed using either an FDA-cleared in vitro microarray assay or a next generation sequencing (NGS)-based assay.

MammaPrint® was prospectively validated as a microarray assay in the 6,693 patient MINDACT trial in early stage breast cancer, < 5cm up to 3 positive lymph nodes and independent of receptor status. The Mammaprint® NGS test has demonstrated technically equivalent performance to the predicate microarray test.

Only one test - NGS or microarray may be performed on a given date of service for a given patient.

Melanoma Risk Stratification Molecular Testing

Molecular diagnostic tests used to assist in risk stratification of melanoma patients are covered when all of the following are true:

- The patient has a personal history of melanoma and:
  - Either:
    - Has Stage T1b and above; or
    - Has T1a with documented concern about adequacy of microstaging
  - Is undergoing workup or being evaluated for treatment; and
  - Does not have metastatic disease; and
  - Presumed risk for a positive Sentinel Lymph Node Biopsy (SLNB) based on clinical, histological, or other information is > 5%; and
  - Has a disease stage, grade, and Breslow thickness (or other qualifying conditions) within the intended use of the test
- The test has demonstrated, as part of a Technical Assessment:

- Clinical validity of analytes tested in predicting metastatic disease (or the absence of metastatic disease) in peer-reviewed scientific literature
- Utility beyond clinical, histological, and radiographical factors in the ability to accurately stratify patients into risk groups to manage patient care, such by precluding unnecessary sentinel lymph node biopsies
- Appropriate analytical validity
- Performance characteristics equivalent or superior to other covered, similar tests

Note: These tests may also be reported with CPT code 81599.

Molecular Assays for the Diagnosis of Cutaneous Melanoma

The purpose of this test is to assist dermatopathologists to arrive at the correct diagnosis of melanoma versus non-melanoma when examining skin biopsies.

There is limited coverage for molecular Deoxyribonucleic acid (DNA)/Ribonucleic acid (RNA) assays that aid in the diagnosis or exclusion of melanoma from a biopsy when **all** of the following clinical conditions are met:

- The test is ordered by a board-certified or board-eligible dermatopathologist
- The specimen is a primary (non-metastatic, non-re-excision specimen) cutaneous melanocytic neoplasm for which the diagnosis is equivocal/uncertain (i.e., clear distinction between benign or malignant cannot be achieved using clinical and/or histopathological features alone) despite the performance of standard-of-care test procedures and relevant ancillary tests (i.e., immunohistochemical stains)
- The specimen includes an area representative of the lesion or portion of the lesion that is suspicious for malignancy
- The patient may be subjected to additional intervention, such as re-excision and/or sentinel lymph node biopsy, as a result of the diagnostic uncertainty
- The patient has not been tested with the same or similar assay for the same clinical lesion
- The test is validated for use in the intended-use population and is performed according to its stated intended-use
- The test demonstrates Analytical and Clinical Validity (AV and CV) and Clinical Utility (CU) and undergoes a technical assessment (TA) to demonstrate compliance of the service with this policy

Tests that demonstrate similar indicated uses and equivalent or superior performance to covered tests may similarly be covered.

Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR)

The use of Keytruda for treatment of patients with unresectable or metastatic solid tumors having either microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers. Keytruda, a human PD-1 blocking antibody, is indicated for the treatment of metastatic melanoma, non-small cell lung cancer, recurrent or metastatic head and neck squamous cancer, advanced/metastatic urothelial cancer and classical Hodgkin's lymphoma.

One of the following is allowed:

- dMMR by immunohistochemistry (IHC); or
- MSI by PCR; or
- Multi-gene NGS panel inclusive of MSI microsatellite loci, and MLH1, MSH2, MSH6 and PMS2 genes

Testing by one of the above methodologies is reasonable and necessary if testing for dMMR or MSI has not previously been performed on the patient's tumor sample. A multi-gene NGS panel inclusive of MSI microsatellite loci and MLH1, MSH2, MSH6 and PMS2 gene is reasonable and necessary. A multi-gene NGS panel and separate MSI by PCR will be denied as not reasonable and necessary. If testing is performed by NGS, the test must be a properly designed and appropriately validated assay demonstrating 95% concordance to the reference method (MSI by PCR)

- To report a dMMR or MSI service, reference specific CPT codes
- To report by NGS, use CPT code 81479

Minimal Residual Disease Testing for Cancer

Limited coverage is allowed for minimally invasive molecular deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) tests that detect minimal residual disease (MRD) in patients with a personal history of cancer.

Limited coverage is provided for MRD testing in cancer when **all** of the following are true:

- If Next-Generation Sequencing (NGS) methodology is used in testing, the conditions set by NCD 90.2 are fulfilled (summarized: the patient has advanced cancer; plans on being treated for said cancer, and has not been previously tested with the same test for the same genetic content) or are not applicable (the patient does not have cancer as defined below).
- The patient has a personal history of cancer, the type and staging of which is within the intended use of the MRD test.
- The identification of recurrence or progression of disease within the intended use population of the test is identified in the National Comprehensive Cancer Network (NCCN) or other established guidelines as a condition that requires a definitive change in patient management.
- The test is demonstrated to identify molecular recurrence or progression before there is clinical, biological or radiographical evidence of recurrence or progression and demonstrates sensitivity and specificity of subsequent recurrence or progression comparable with or superior to radiographical or other evidence (as per the standard-of-care for monitoring a given cancer type) of recurrence or progression.
- To be reasonable and necessary, it must also be medically acceptable that the test being utilized precludes other surveillance or monitoring tests intended to provide the same or similar information, unless they either (a) are required to follow-up or confirm the findings of this test or (b) are medically required for further assessment and management of the patient.
- If the test is to be used for monitoring a specific therapeutic response, it must demonstrate the clinical validity of its results in published literature for the explicit management or therapy indication (allowing for the use of different drugs within the same therapeutic class, so long as they are considered 'equivalent and interchangeable' for the purpose of MRD testing, as determined by national or society guidelines).
- Clinical validity (CV) of any analytes (or expression profiles) measured must be established through a study published in the peer-reviewed literature for the intended use of the test in the intended population.
- The test is being used (a) in a patient who is part of the population in which the test was analytically validated and (b) according to the intended use of the test.
- The MRD test [unless it is a Food and Drug Administration (FDA) approved and established standard-of-care single-gene polymerase chain reaction (PCR)] satisfactorily completes a technical assessment (TA) that will evaluate and confirm that the analytical validity, clinical validity, and clinical utility criteria set in this policy are met to establish the test as Reasonable and Necessary.
- Tests utilizing a similar methodology or evaluating a similar molecular analyte to a test for which there is a generally accepted testing standard or for which existing coverage exists must demonstrate equivalent or superior test performance (i.e., sensitivity and/or specificity) when used for the same indication in the same intended-use population.

MRD testing often requires two types of assays to be performed as part of the service. First, a sample is taken from tumor diagnostic material to establish a baseline tumor signature as defined by the test methodology. This is followed by a series assays run on blood to detect the presence or recurrence of tumor based on the measured biomarkers, expression, or other analytes over various timepoints. This series of assays comprises a single test when the patient is known to have cancer. When the patient is NOT known to have cancer (specifically when there is no clinical, radiographical, or other biological evidence that tumor cells remain post treatment and subsequently the patient is no longer being subjected to therapeutic interventions for cancer), a second kind of test may exist wherein a single additional timepoint may constitute a single test.

Next-Generation Sequencing for Solid Tumors and for Myeloid Malignancies and Suspected Myeloid Malignancies

Next-Generation Sequencing (NGS) is not a specific test, but a sequencing methodology utilized to capture genomic information. Unlike Sanger sequencing (the prior standard technology) that typically provides sequence information for a single deoxyribonucleic acid (DNA) strand/molecule, NGS allows for massively parallel sequencing of millions of DNA molecules concurrently. This allows for capturing many relevant genomic targets simultaneously, usually by utilizing capture technologies such as by polymerase chain reaction (PCR) amplification or hybrid capture. As such, NGS tests for use in cancer are often comprised of gene panels whose content is either relevant to a specific tumor type or condition, or a larger panel of genes that can be used for multiple tumor types.

For Next-Generation Sequencing for Solid Tumors, all the following must be present for coverage eligibility:

- As per NCD 90.2, this test is reasonable and necessary when the patient has either:
  - Recurrent cancer, relapsed cancer, refractory cancer, metastatic cancer, advanced cancer (stages III or IV); **and**
  - Has not been previously tested by the same test for the same genetic content; **and**

- Is seeking further treatment.
- The test has satisfactorily completed a Technical Assessment (TA) for the stated indications of the test.
- The assay performed includes at least the minimum genes and genomic positions required for the identification of clinically relevant FDA-approved therapies with a companion diagnostic biomarker as well as other biomarkers known to be necessary for clinical decision making for its intended use that can be reasonably detected by the test. These genes and variants will change as the literature and drug indications evolve.

Situations in which Test should not be used or coverage is denied:
The test in question will be non-covered if:
- It does not fulfill all the criteria set forth in the NCD 90.2 as stated above.
- Another CGP test was performed on the same tumor specimen (specimen obtained on the same date of service).
- A TA is not completed satisfactorily for new tests.

For Next-Generation Sequencing for Myeloid Malignancies and Suspected Myeloid Malignancies, the following must be present for coverage eligibility:
- For tests that are specifically indicated in patients whom are known to have a myeloid malignancy at the time of testing, NCD 90.2 applies.
- The patient has a diagnosis of AML, MDS, or MPN. AML, MDS, and MPN are herein classified as refractory and/or metastatic cancers and fulfil the NCD 90.2 criteria.
- The test has satisfactorily completed a TA for the stated indications of the test.
- The assay performed includes at least the minimum genes and positions indicated for its intended use.
- For patients that do not have a diagnosis of a myeloid malignancy, where one is suspected, the patient must have an undefined cytopenia for greater than 4 months, other possible causes have been reasonably excluded.
- Testing is performed on bone marrow biopsies, bone marrow aspirates, bone marrow clots, peripheral blood samples, or extramedullary sites suspected of harboring a myeloid malignancy.

Situations in which Test should not be used or coverage is denied:
The test in question will be non-covered if:
- A TA has not been satisfactorily completed.
- Another NGS test was performed on the same surgical specimen/ blood draw (specimen obtained on the same date of service).
- Testing falls within scope of NCD 90.2 and has been tested with the same test for the same genetic content.

Percepta© Bronchial Genomic Classifier

Limited coverage is allowed for the Percepta Bronchial Genomic Classifier (Veracyte, Inc., South San Francisco, CA) to identify patients with clinical low- or intermediate-risk of malignancy, after a non-diagnostic bronchoscopy, who may be followed with CT surveillance in lieu of further invasive biopsies or surgery.

Pharmacogenomics Testing (PGx)

PGx tests are indicated when medications are being considered for use (or already being administered) that are medically necessary, appropriate, and approved for use in the patient's condition and are known to have a gene(s)-drug interaction that has been demonstrated to be clinically actionable as defined by the FDA (PGx information required for safe drug administration) or Clinical Pharmacogenetic Implementation Consortium (CPIC) guidelines (category A and B).

The selection of the medications in question must be derived from clinical factors/necessity rather than from a PGx test. Once the putative therapeutic agents are selected, and those agents are known to have gene-drug interactions as identified above, then a PGx test may be considered reasonable and necessary when the result of that test is necessary for the physician's decision-making process regarding safely administering or dosing the drug.

PGx testing is not considered reasonable and necessary merely on the basis of a patient having a particular diagnosis. Unless the record reflects that the treating clinician has already considered non-genetic factors to make a preliminary drug selection, PGx testing is not considered reasonable and necessary.

PGx testing is not covered when a treating clinician is not considering treatment with a medication that has an actionable drug-gene interaction, or when the use of a medication with a drug-gene interaction is not reasonable and necessary.

The clinical record must clearly show the use of or intent to prescribe a drug that has known drug-gene interactions that require a PGx test to be ordered to define the safe use of that drug in that patient.

If a treating clinician orders a single gene test or a test for a particular allele(s), but as a matter of operational practicality, the laboratory tests that single gene or allele on a platform that looks for variants in other genes / alleles as well, that particular test done in that particular instance is considered a single gene / allele test for coverage purposes. In this scenario the provider may bill for the component of the test that was reasonable and necessary (in this example, the single gene test).

A multi-gene panel is considered reasonable and necessary if more than one single gene on that panel would be considered reasonable and necessary for safe use of the medication in question or if multiple drugs are being considered (each fulfilling the criteria of actionable gene-drug interactions) that have different relevant genes. Additionally, a gene panel must contain at a minimum all the necessary relevant gene/allele content required for their indicated use to meet clinical utility requirements. Such minimum criteria are determined by experts including relevant associations such as the Association for Molecular Pathology and are considered during the technical assessment. A multi-gene panel is not considered reasonable and necessary if only a single gene on the panel is considered reasonable and necessary.

The patient has a diagnosis for which pharmacologic therapy is reasonable and necessary, and the drug or drugs that the clinician is considering using must be reasonable and necessary for the treatment of the patient's diagnosis.

The clinician has made an initial personalized decision for the patient based on the patient's diagnosis, the patient's other medical conditions, other medications the patient is taking, professional judgement, clinical science and basic science pertinent to the drug (e.g., mechanism of action, side effects), the patient's past medical history and when pertinent family history and the patient's preferences and values.

The provider performing the service must have a record of what drug(s) is/are being considered and for what indication(s) to ensure the test performed is reasonable and necessary.

Genes not identified as having actionable use are not considered reasonable and necessary. The algorithms employed in combinatorial testing are also not currently considered reasonable and necessary components of multi-gene testing.

If no CPT code is available for the gene being tested, the code 81479 may be used.
The following do not have a specific CPT code available:

- BCHE
- CACNA1S
- CYP2B6
- CYP4F2
- IFNL4
- NAT
- NAT2
- Genesight
- NeuroIDgenetix
- Genomind Professional PGx Express™
- Neuropharmagen
- Psychotropic Pharmacogenomics Gene Panel

For further guidance and clinical criteria, please refer to the Pharmacogenomics Testing sourcing below.

Phenotypic Biomarker Detection from Circulating Tumor Cells

Limited coverage is allowed for assays that detect biomarkers from circulating tumor cells (CTCs).

Cancers with established biomarker testing, as recommended by society or national guidelines:

Assays that detect biomarkers from CTCs are covered when **all** of the following are met:

- The patient has been diagnosed with cancer.
- The specific cancer type has an associated biomarker.
- The associated biomarker has already established clinical utility (CU) in the peer-reviewed published literature for the intended cancer type and for the specific indication in the intended patient population.
  - The biomarker's CU may include any of the following: it can be used to diagnose, risk-stratify, predict, or monitor response to therapy, as recommended by national or society guidelines [i.e., American Society of Clinical Oncology (ASCO), National Comprehensive Cancer Network (NCCN)].
- At least 1 of the following criteria are met AND there is clear documentation of at least 1 of these in the medical record:
  - The patient's cancer has not previously been tested for the specific biomarker; **or**
  - The patient has newly metastatic cancer, and a metastatic lesion has not been tested for the specific biomarker; **or**
  - The patient demonstrates signs of clinical, radiological or pathologic disease progression; **or**
  - There is concern for resistance to treatment based on specific and well-established clinical indications.
- Testing for the biomarker can be performed using CTCs.
- The CTC-based biomarker test successfully completes a comprehensive Technical Assessment (TA) that will ensure that Analytical Validity (AV) (including an analytical and clinical validation), Clinical Validity (CV), and CU criteria are met to establish the test as Reasonable and Necessary.
  - The clinical validation has demonstrated performance that is equivalent or superior to tissue-based testing or another already-accepted test for the same biomarker for the same intended use.
  - CV (for new analytes) must be established through studies published in the peer-reviewed literature for the intended use of the test in the intended population.
- Tissue-based testing for the specific biomarker is infeasible (e.g., quantity not sufficient or invasive biopsy is medically contraindicated) or will not provide sufficient information for subsequent medical management (e.g., in cases where human epidermal growth factor receptor 2 (HER2) overexpression is negative in a tissue biopsy but may be positive in the CTCs, due to tumor heterogeneity). There is clear documentation of at least 1 of these reasons for testing in the medical record.
- For a given patient encounter, only 1 test for assessing the biomarker may be performed UNLESS a second test, meeting all the criteria established herein, is reasonable and necessary as an adjunct to the first test.
- Duplicate testing of the same biomarker (from the same sample type and for the same clinical indication) using different methodologies is not covered. For example, testing for androgen receptor splice variant 7 (AR-V7) from CTCs by messenger RNA (mRNA) as well as immunohistochemistry (IHC)-based methodologies, for the same clinical indication, will not be covered.

The following tests are reasonable and necessary:

- Biocept Target Selector HER2 Assay
- Androgen Receptor Variant (AR-V7) Protein Test

Predictive Classifiers for Early-Stage Non-Small Cell Lung Cancer (NSCLC) (Razor 14-Gene Lung Cancer Assay)

The use of molecular diagnostic laboratory tests as a predictive classifier for NSCLC are considered reasonable and necessary when all of the following criteria is met:

- The patient has a non-squamous NSCLC with a tumor size < 5cm, and there are no positive lymph nodes (i.e., American Joint Committee on Cancer Eighth Edition Stages I and IIa).
- The patient is sufficiently healthy to tolerate chemotherapy.
- Adjuvant platinum-containing chemotherapy is being considered for the patient.
- The test is ordered by a physician who is treating the patient for NSCLC (generally a medical oncologist, surgeon, or radiation oncologist) to help in the decision of whether or not to recommend adjuvant chemotherapy.

ProMark Risk Score

Limited coverage is allowed for the ProMark (Metamark Genetics) to help determine which patients with early stage, needle biopsy proven prostate cancer can be conservatively managed rather than treated with definitive surgery or radiation therapy.

Prognostic and Predictive Molecular Classifiers for Bladder Cancer

Molecular diagnostic tests for use in a member with bladder cancer are covered when all of the following conditions are met:

- The member is being actively managed for bladder cancer.
- The member is within the population and has the indication for which the test was developed and is covered. The laboratory will make available the appropriate indications of the test to the treating/ordering physician.
- At least 1 of the 2 criteria are met:
  - The patient is a candidate for multiple potential treatments, which could be considered to have varied or increasing levels of intensity based on a consensus guideline, and the physician and patient must decide among these treatments; **or**
  - The patient is a candidate for multiple therapies, and the test has shown that it predicts response to a specific therapy among accepted therapy options based on nationally recognized consensus guidelines [i.e., National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO), Society of Urologic Oncology (SUO), or American Urological Association (AUA)].
- If Next-Generation Sequencing (NGS) methodology is used in testing, the conditions set by NCD 90.2 are fulfilled (summarized: the patient has advanced cancer; plans on being treated for said cancer and has not been previously tested with the same test for the same genetic content).
- The test demonstrates analytical validity including both analytical and clinical validations. If the test relies on an algorithm (which may range in complexity from a threshold determination of a single numeric value to a complex mathematical or computational function), the algorithm must be validated in a cohort that is not a development cohort for the algorithm.
- The test has demonstrated clinical validity and utility, establishing a clear and significant biological/molecular basis for stratifying patients and subsequently selecting (either positively or negatively) a clinical management decision (in the bullet above) in a clearly defined population.
- The test successfully completes a technical assessment that ensures the test is reasonable and necessary as described above.
- Only 1 test may be performed prior to the initiation of therapy **unless** a second test that interrogates different genomic content **and** meets all the criteria established herein, is reasonable and necessary.
  - The genomic content interrogated by the test must be relevant to the therapy under consideration.

Solid Organ Allograft Rejection

Limited coverage is allowed for molecular diagnostic tests used in the evaluation and management of patients who have undergone solid organ transplantation. These tests can inform decision making along with standard clinical assessments in their evaluation of organ injury for active rejection (AR).

These tests may be ordered by qualified physicians considering the diagnosis of AR affiliated with a transplant center, helping to rule in or out this condition when assessing the need for or results of a diagnostic biopsy. They should be considered along with other clinical evaluations and results and may be particularly useful in patients with significant contraindications to invasive procedures.

Molecular diagnostic tests that assess a transplanted allograft for rejection status are covered when All of the following criteria are met:

- The test must provide information about at least one of the two following clinical status determinations:
  - AR status
  - Cellular or Antibody-mediated rejection (ACR or AMR) status
- The intended use of the test must be:
  - To assist in the evaluation of adequacy of immunosuppression, wherein a non-invasive or minimally invasive test can be used in lieu of a tissue biopsy in a patient for whom information from a tissue biopsy would be used to make a management decision regarding immunosuppression; or
  - As a rule-out test for AR in validated populations of patients with clinical suspicion of rejection with a non-invasive or minimally invasive test to make a clinical decision regarding obtaining a biopsy; or
  - For further evaluation of allograft status for the probability of allograft rejection after a physician-assessed pretest; or
  - To assess rejection status in patients that have received a biopsy, but the biopsy results are inconclusive or limited by insufficient material
- The test demonstrates analytical validity (AV), including an analytical and clinical validation for any given measured analytes, and has demonstrated equivalence or superiority for sensitivity or specificity (depending on intended use) of detecting allograft rejection to other already-accepted tests for the same intended use measuring the same or directly comparable analytes.

- Clinical validity (CV) of any analytes (or expression profiles) measured must be established through a study published in the peer-reviewed literature for the intended use of the test in the intended population. The degree of validity must be similar or superior to established and covered tests (refer to associated coverage articles). If conducted with concordance to tissue histologic evaluation the Banff Classification for renal allografts or other accepted criteria (if existing) for other organs must be used.
- The test is being used in a patient who is part of the population in which the test was analytically validated and has demonstrated CV.
- For a given patient encounter, only one molecular test for assessing allograft status may be performed unless a second test, meeting all the criteria established herein, is reasonable and necessary as an adjunct to the first test.
- For minimally or non-invasive tests, the benefit to risk profile of the molecular test is considered by the ordering clinician to be more favorable than the benefit to risk profile of a tissue biopsy, or a tissue biopsy cannot be obtained. For example, this may be the case if a biopsy is considered medically contraindicated in a patient.
- The test successfully completes a Technical Assessment that will ensure that AV, CV, and clinical utility criteria set in this policy are met to establish the test as Reasonable and Necessary.

Covered tests with analytical validity (AV) that is significantly below similar services may have coverage rescinded.

Targeted and Comprehensive Genomic Profile Next Generation Sequencing (NGS) Testing

Targeted Next-Generation Sequencing (NGS) panels are defined as tests that identify somatic alterations known to occur in certain regions (i.e., 'hotspots') within specific genes of interest for cancer management (i.e., diagnosis, selection of molecularly targeted therapies, prognosis in a context where prognostic classification is essential for treatment selection). Generally, these NGS panels can detect single nucleotide variants (SNVs) and small insertions or deletions (INDELs) within these regions. These alterations typically represent response or lack of response to corresponding targeted cancer therapies. The hotspot test should include relevant regions in the genes required for companion diagnostic testing and/or known to be necessary for proper patient management.

Comprehensive Genomic Profile (CGP) refers to NGS-based molecular assays that provide additional insight beyond individual gene hotspots; these assays seek to describe the genomic makeup of a tumor and can help identify underlying mechanisms of disease to guide clinical decision making. These tests include not only mutations in individual relevant genes, but also patterns of mutations across related genes in established cancer pathways and often include an assessment of overall mutational burden. These tests typically involve sequencing of entire exonic regions of genes of interest (within a comprehensive gene panel or whole exome sequencing) and may also include selected intronic regions. CGP can detect multiple types of molecular alterations (i.e., SNVs, small and large INDELs, copy number alterations (CNAs), structural variants (SVs), and splice-site variants) in a single assay. Patterns of mutations seen across multiple genes may be used to infer clinically relevant etiologies, such as DNA mismatch repair deficiency and microsatellite instability, and total mutational load/burden (TMB) may be determined. CGP testing may also include RNA sequencing to detect structural variations, such as translocations or large deletions, and to detect functional splicing mutations. CGP is not defined as a targeted panel.

Laboratories with 2 to 4 gene(s) on their targeted NGS panel should use CPT 81479. For other targeted NGS gene panel services for somatic variant detection, more specific CPT codes exist.

CGP testing is not defined as a targeted panel, and it is a test not currently described by any existing CPT code. Therefore, to report a CGP service, use CPT code 81479. Coverage of CGP is limited to one test per surgical specimen and precludes the use of any other molecular testing on that specimen.

For NGS-based tests that do not fit under the above definitions of “targeted” or “Comprehensive” panels, reporting CPT code 81479 is appropriate.

For CPT Code 81599

Solid Organ Allograft Rejection

Refer to criteria above under CPT code 81479.

Melanoma Risk Stratification Molecular Testing

Refer to criteria above under CPT code 81479.

Non-Covered

The test descriptions under the following unlisted codes are appropriate to be reported with the unlisted code; however, there is no coverage for these services.

For CPT Code 81479

- 4q25-AF risk genotype test
- 9p21 genotype test
- Asparoacyclase 2 Deficiency (ASPA) test
- ATP7B Gene test
- BluePrint® test
- CardiaRisk
- CHD7 gene analysis
- ENG and/or ACVRL1 genetic testing and panels of tests that include ENG/ACVRL1
- HAX1 gene sequencing and panels of tests that include the HAX1 gene
- Serotonin Transporter genotyping (HTTLPR)/ HTTLPR Gene Testing
- KIF6 genotype test
- LPA-Aspirin genotype test
- LPA-Intron 25 genotype test
- MECP2 genetic testing and panels of tests that include a MECP2 gene test
- Mitochondrial nuclear gene test
- NSD1 gene testing and tests that include one or more of NSD1 analysis
- PAX6 gene sequencing
- Prometheus IBD sgi Diagnostic test
- PTCH1 gene test
- RPS19 gene tests
- SULT4A1 genetic testing and panels of tests that include the SULT4A1 gene
- TERC gene test
- VEGFR2 testing and panels of tests that include the VEGFR2 receptor

For CPT Code 84999

- know error® DNA Specimen Provenance Assay
- myPAP™ DNA test

Applicable Codes

The following list(s) of procedure and/or diagnosis 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
81479	Unlisted molecular pathology procedure
81599	Unlisted multianalyte assay with algorithmic analysis
84999	Unlisted chemistry procedure

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Diagnosis Code
Molecular Pathology/Genetic Testing Reported with Unlisted Codes: Diagnosis Codes

Non-Covered Diagnosis Code
Non-Covered Diagnosis Codes List This list contains 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.

Questions and Answers

1	Q:	When should an unlisted code be used to report a service?
	A:	Unlisted codes should be reported only if no other specific codes adequately describe the procedure or service.
2	Q:	When reporting molecular pathology or genetic testing services with an unlisted code how is the specific test performed identified?
	A:	When reporting a laboratory test using an unlisted code, the specific name of the laboratory test(s) and/or a short descriptor of the test(s) must be included in the appropriate field of the claim form.

References

CMS National Coverage Determinations (NCDs)

Refer to NCD 90.2 Next Generation Sequencing (NGS) for additional information using CPT code 81479 on: xT CDx.

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L39040 MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer	A58756 Billing and Coding: MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
	A59116 Response to Comments: MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer (DL39040)			
L38966 MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer	A58652 Billing and Coding: MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
	A59058 Response to Comments: MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer			

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L39017 MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer	A58734 Billing and Coding: MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer	CGS	KY, OH	KY, OH
	A59063 Response to Comments: MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer			
L38972 MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer	A58679 Billing and Coding: MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
	A59130 Response to Comments: MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer			
L38974 MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer	A58681 Billing and Coding: MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
	A59131 Response to Comments: MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer			
L36139 MolDX: Biomarkers in Cardiovascular Risk Assessment	A57386 Billing and Coding: MolDX: Biomarkers in Cardiovascular Risk Assessment	CGS	KY, OH	KY, OH
L36358 MolDX: Biomarkers in Cardiovascular Risk Assessment	A57037 Billing and Coding: MolDX: Biomarkers in Cardiovascular Risk Assessment	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36362 MolDX: Biomarkers in Cardiovascular Risk Assessment	A57055 Billing and Coding: MolDX: Biomarkers in Cardiovascular Risk Assessment	Noridian	AK, AZ, ID, WA, MT, ND, OR, SD, UT, WY	AK, AZ, ID, WA, MT, ND, OR, SD, UT, WY
L36129 MolDX: Biomarkers in Cardiovascular Risk Assessment	A56943 Billing and Coding: MolDX: Biomarkers in Cardiovascular Risk Assessment	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L36523 MolDX: Biomarkers in Cardiovascular Risk Assessment	A57559 Billing and Coding: MolDX: Biomarkers in Cardiovascular Risk Assessment	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35396 Biomarkers for Oncology	A52986 Billing and Coding: Biomarkers for Oncology	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L34864 Loss-of-Heterozygosity Based Topographic Genotyping with Pathfinder TG®	A56897 Billing and Coding: Loss-of-Heterozygosity Based Topographic Genotyping with Pathfinder TG®	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L39042 MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer	A58759 Billing and Coding: MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L38985 MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer	A58700 Billing and Coding: MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L38997 MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer	A58713 Billing and Coding: MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer	CGS	KY, OH	KY, OH
L39005 MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer	A58718 Billing and Coding: MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L39007 MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer	A58724 Billing and Coding: MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L38582 MolDX: Molecular Testing for Solid Organ Allograft Rejection	A58061 Billing and Coding: MolDX: Molecular Testing for Solid Organ Allograft Rejection	CGS	KY, OH	KY, OH
L38680 MolDX: Molecular Testing for Solid Organ Allograft Rejection	A58207 Billing and Coding: MolDX: Molecular Testing for Solid Organ Allograft Rejection	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L38629 MolDX: Molecular Testing for Solid Organ Allograft Rejection	A58168 Billing and Coding: MolDX: Molecular Testing for Solid Organ Allograft Rejection	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L38671 MolDX: Molecular Testing for Solid Organ Allograft Rejection	A58170 Billing and Coding: MolDX: Molecular Testing for Solid Organ Allograft Rejection	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L38568 MolDX: Molecular Testing for Solid Organ Allograft Rejection	A58019 Billing and Coding: MolDX: Molecular Testing for Solid Organ Allograft Rejection	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L38380 MolDX: AlloSure® or Equivalent Cell-Free DNA Testing for Kidney and Heart Allografts **Retired 06/09/2023**	A57233 Billing and Coding: MolDX: AlloSure® or Equivalent Cell-Free DNA Testing for Kidney and Heart Allografts **Retired 06/09/2023**	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L38355 MolDX: AlloSure® or Equivalent Cell-Free DNA Testing for Kidney and Heart Allografts **Retired 06/09/2023**	A57380 Billing and Coding: MolDX: AlloSure® or Equivalent Cell-Free DNA Testing for Kidney and Heart Allografts **Retired 06/09/2023**	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36044 MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease	A53531 Billing and Coding: MolDX: BCR-ABL A56959 Billing and Coding: MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36815 MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease	A55233 Billing and Coding: MolDx: BCR-ABL A57570 Billing and Coding: MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L36180 MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease	A55595 Billing and Coding: MolDX: BCR-ABL 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	A55600 Billing and Coding: MolDX: BCR-ABL 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
L36117 MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease	A54686 Billing and Coding: MolDX: BCR-ABL A56999 Billing and Coding: MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease	CGS	KY, OH	KY, OH

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L38822 MolDX: Minimal Residual Disease Testing for Cancer	A58434 Billing and Coding: MolDX: Minimal Residual Disease Testing for Solid Tumor Cancers	CGS	KY, OH	KY, OH
	A58998 Billing and Coding: MolDX: Minimal Residual Disease Testing for Hematologic Cancers			
L38835 MolDX: Minimal Residual Disease Testing for Cancer	A58468 Billing and Coding: MolDX: Minimal Residual Disease Testing for Solid Tumor Cancers	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
	A59004 Billing and Coding: MolDX: Minimal Residual Disease Testing for Hematologic Cancers			
L38779 MolDX: Minimal Residual Disease Testing for Cancer	A58376 Billing and Coding: MolDX: Minimal Residual Disease Testing for Solid Tumor Cancers	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
	A58988 Billing and Coding: MolDX: Minimal Residual Disease Testing for Hematologic Cancers			
L38814 MolDX: Minimal Residual Disease Testing for Cancer **Effective 01/02/2022**	A58454 Billing and Coding: MolDX: Minimal Residual Disease Testing for Solid Tumor Cancers **Effective 01/02/2022**	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
	A58996 Billing and Coding: MolDX: Minimal Residual Disease Testing for Hematologic Cancers	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L38816 MolDX: Minimal Residual Disease Testing for Cancer **Effective 01/02/2022**	A58456 Billing and Coding: MolDX: Minimal Residual Disease Testing for Solid Tumor Cancers **Effective 01/02/2022**	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
	A58997 Billing and Coding: MolDX: Minimal Residual Disease Testing for Hematologic Cancers	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54189 Billing and Coding: MolDX: cobas® EGFR Mutation Test Guidelines	CGS	KY, OH	KY, OH
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54199 Billing and Coding: MolDX: Therascreen® EGFR RGQ PCR Kit Guidelines	CGS	KY, OH	KY, OH

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54689 Billing and Coding: Germline testing for use of PARP inhibitors	CGS	KY, OH	KY, OH
L35025 MolDX: Molecular Diagnostic Tests (MDT)	A54338 Billing and Coding: MolDX: Germline testing for use of PARP inhibitors	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55294 Billing and Coding: MolDX: Germline testing for use of PARP inhibitors	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55295 Billing and Coding: MolDX: Germline testing for use of PARP inhibitors	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L39040 MolDx: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer	A55224 Billing and Coding: MolDX: Germline testing for use of PARP inhibitors	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
N/A	A58192 Billing and Coding: Guardant360®	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A58214 Billing and Coding: Guardant360®	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L35025 MolDX: Molecular Diagnostic Tests (MDT)	A53104 Billing and Coding: MolDX: MammaPrint	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54194 Billing and Coding: MolDX: MammaPrint	CGS	KY, OH	KY, OH
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A54445 Billing and Coding: MolDX: MammaPrint	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A54447 Billing and Coding: MolDX: MammaPrint	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)	A55175 Billing and Coding: MolDX: MammaPrint®	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L38043 MolDX: Plasma-Based Genomic Profiling in Solid Tumors	A57867 Billing and Coding: MolDX: Plasma-Based Genomic Profiling in Solid Tumors	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L38168 MolDX: Plasma-Based Genomic Profiling in Solid Tumors	A57936 Billing and Coding: MolDX: Plasma-Based Genomic Profiling in Solid Tumors	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L38065 MolDX: Plasma-Based Genomic Profiling in Solid Tumors	A57917 Billing and Coding: MolDX: Plasma-Based Genomic Profiling in Solid Tumors	CGS	KY, OH	KY, OH
L39230 MolDX: Plasma-Based Genomic Profiling in Solid Tumors	A58973 Billing and Coding: MolDX: Plasma-Based Genomic Profiling in Solid Tumors	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L39232 MolDX: Plasma-Based Genomic Profiling in Solid Tumors	A58975 Billing and Coding: MolDX: Plasma-Based Genomic Profiling in Solid Tumors	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L38238 MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer	A58031 Billing and Coding: MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L38284 MolDX: Predictive Classifiers for Early Stage Non-small Cell Lung Cancer	A58038 Billing and Coding: MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer	CGS	KY, OH	KY, OH
L38443 MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer	A57112 Billing and Coding: MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L38327 MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer	A57329 Billing and Coding: MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L38329 MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer	A57330 Billing and Coding: MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L38684 MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer	A58211 Billing and Coding: MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L38576 MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer	A58028 Billing and Coding: MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L38586 MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer	A58065 Billing and Coding: MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer	CGS	KY, OH	KY, OH
L38647 MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer	A58181 Billing and Coding: MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L38649 MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer	A58187 Billing and Coding: MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L38678 MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells	A58205 Billing and Coding: MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L38566 MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells	A58021 Billing and Coding: MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L38584 MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells	A58063 Billing and Coding: MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells	CGS	KY, OH	KY, OH
L38643 MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells	A58183 Billing and Coding: MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L38645 MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells	A58185 Billing and Coding: MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
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
L35062 Biomarkers Overview	A58917 Billing and Coding: Molecular Pathology and Genetic Testing	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L34519 Molecular Pathology Procedures	A58918 Billing and Coding: Molecular Pathology and Genetic Testing	First Coast	FL, PR, VI	FL, PR, VI
	A57451 Billing and Coding: Molecular Pathology Procedures			
L35025 MolDX: Molecular Diagnostic Tests (MDT)	A54472 Billing and Coding: MolDX: FDA-Approved KRAS Tests	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54688 Billing and Coding: MolDX: FDA-Approved KRAS Tests	CGS	KY, OH	KY, OH
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55162 Billing and Coding: MolDX: FDA-Approved KRAS Tests	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A54498 Billing and Coding: MolDX: FDA-Approved KRAS Tests	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A54500 Billing and Coding: MolDX: FDA-Approved KRAS Tests	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L37921 MolDX: Inivata™, InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer	A56333 Billing and Coding: MolDX: Inivata™, InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L37870 MolDX: Inivata™, InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer	A56924 Billing and Coding: MolDX: Inivata™, InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L37903 MolDX: Inivata, InVisionFirst, Liquid Biopsy for Patients with Lung Cancer	A56982 Billing and Coding: MolDX: Inivata™, InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer	CGS	KY, OH	KY, OH
L37897 MolDX: Inivata™, InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer	A57664 Billing and Coding: MolDX: Inivata™, InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L37899 MolDX: Inivata™, InvisionFirst®, Liquid Biopsy for Patients with Lung Cancer	A57665 Billing and Coding: MolDX: Inivata™, InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A56103 Billing and Coding: MolDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker for Patients with Unresectable or Metastatic Solid Tumors	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A56104 Billing and Coding: MolDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker Billing and Coding Guidelines for Patients with Unresectable or Metastatic Solid Tumors	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L35025 MolDX: Molecular Diagnostic Tests (MDT)	A56072 Billing and Coding: MolDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker for Patients with Unresectable or Metastatic Solid Tumors	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A56106 Billing and Coding: MolDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker for Patients with Unresectable or Metastatic Solid Tumors	CGS	KY, OH	KY, OH

LCD	Article	Contractor	Medicare Part A	Medicare Part B
N/A	A56501 Billing and Coding: MolDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker for Patients with Unresectable or Metastatic Solid Tumors **Retired 01/26/2023**	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L36886 MolDX: Percepta© Bronchial Genomic Classifier	A57502 Billing and Coding: MolDX: Percepta© Bronchial Genomic Classifier	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36891 MolDX: Percepta© Bronchial Genomic Classifier	A57504 Billing and Coding: MolDX: Percepta© Bronchial Genomic Classifier	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L37195 MolDX: Percepta© Bronchial Genomic Classifier	A57584 Billing and Coding: MolDX: Percepta© Bronchial Genomic Classifier	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L36854 MolDX: Percepta© Bronchial Genomic Classifier	A56849 Billing and Coding: MolDX: Percepta® Bronchial Genomic Classifier	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36908 MolDX: Percepta© Bronchial Genomic Classifier	A56972 Billing and Coding: MolDX: Percepta® Bronchial Genomic Classifier	CGS	KY, OH	KY, OH
L38394 MolDX: Pharmacogenomics Testing	A58324 Billing and Coding: MolDX: Pharmacogenomics Testing	CGS	KY, OH	KY, OH
L38335 MolDX: Pharmacogenomics Testing	A57384 Billing and Coding: MolDX: Pharmacogenomics Testing	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L38337 MolDX: Pharmacogenomics Testing	A57385 Billing and Coding: MolDX: Pharmacogenomics Testing	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L38294 MolDX: Pharmacogenomics Testing	A58318 Billing and Coding: MolDX: Pharmacogenomics Testing	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L38435 MolDX: Pharmacogenomics Testing	A58395 Billing and Coding: MolDX: Pharmacogenomics Testing	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L39073 Pharmacogenomics Testing	A58812 Billing and Coding: Pharmacogenomics Testing	First Coast	FL, PR, VI	FL, PR, VI
L39063 Pharmacogenomics Testing	A58801 Billing and Coding: Pharmacogenomics Testing	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L36665 ProMark® Risk Score	A56957 Billing and Coding: ProMark® Risk Score	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36704 ProMark® Risk Score	A57515 Billing and Coding: MolDX: ProMark® Risk Score	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L37011 ProMark® Risk Score	A57587 Billing and Coding: ProMark® Risk Score	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L36706 ProMark® Risk Score	A57609 Billing and Coding: ProMark® Risk Score	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L36675 ProMark® Risk Score	A57034 Billing and Coding: ProMark® Risk Score	CGS	KY, OH	KY, OH
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54901 Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Next Generation Sequencing Testing in Cancer	CGS	KY, OH	KY, OH
L38158 MolDX: Next-Generation Sequencing for Solid Tumors L38176 MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	A55197 Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Next Generation Sequencing Testing in Cancer	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L38045 MolDX: Next-Generation Sequencing for Solid Tumors L38047 MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	A54795 Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Next-Generation Sequencing Testing in Cancer	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L38119 MolDX: Next-Generation Sequencing for Solid Tumors L38123 MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	A55624 Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Next-Generation Sequencing Testing in Cancer	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L38121 MolDX: Next-Generation Sequencing for Solid Tumors L38125 MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	A56518 Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Next-Generation Sequencing Testing in Cancer	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L38045 MolDX: Next-Generation Sequencing for Solid Tumors	A57831 Billing and Coding: MolDX: Next-Generation Sequencing for Solid Tumors	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L38158 MolDX: Next Generation Sequencing for Solid Tumors	A57858 Billing and Coding: MolDX: Next-Generation Sequencing for Solid Tumors	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L38067 MolDX: Next-Generation Sequencing for Solid Tumors	A57870 Billing and Coding: MolDX: Next-Generation Sequencing for Solid Tumors	CGS	KY, OH	KY, OH
L38121 MolDX: Next-Generation Sequencing for Solid Tumors	A57905 Billing and Coding: MolDX: Next-Generation Sequencing for Solid Tumors	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L38119 MolDX: Next-Generation Sequencing for Solid Tumors	A57901 Billing and Coding: MolDX: Next-Generation Sequencing for Solid Tumors	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L38123 MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	A57891 Billing and Coding: MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L38047 MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	A57837 Billing and Coding: MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L38176 MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	A57878 Billing and Coding: MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L38125 MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	A57892 Billing and Coding: MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L38070 MolDX: Next Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	A57873 Billing and Coding: MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	CGS	KY, OH	KY, OH
L37733 Biomarker Testing for Prostate Cancer Diagnosis **Retired 03/01/2024**	A56609 Billing and Coding: Biomarker Testing for Prostate Cancer Diagnosis	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55137 Billing and Coding: MolDX 4q25-AF Risk Genotype Testing	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
N/A	A53457 Billing and Coding: MolDX: 4q25-AF Risk Genotype	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55090 Billing and Coding: MolDX: 4q25-AF Risk Genotype	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55091 Billing and Coding: MolDX: 4q25-AF Risk Genotype	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54241 Billing and Coding: MolDX: 4q25-AF Risk Genotype Guidelines	CGS	KY, OH	KY, OH
N/A	A53657 Billing and Coding: MolDX: 9p21 Genotype Test	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54242 Billing and Coding: MolDX: 9p21 Genotype Test	CGS	KY, OH	KY, OH
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55092 Billing and Coding: MolDX: 9p21 Genotype Test	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55093 Billing and Coding: MolDX: 9p21 Genotype Test	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)	A55138 Billing and Coding: MolDX: 9p21 Genotype Test	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55088 Billing and Coding: MolDX: Aspartoacyclase 2 Deficiency (ASPA) Testing	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55089 Billing and Coding: MolDX: Aspartoacyclase 2 Deficiency (ASPA) Testing	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)	A55142 Billing and Coding: MolDX: Aspartoacyclase 2 Deficiency (ASPA) Testing	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
N/A	A53602 Billing and Coding: MolDX: Aspartoacyclase 2 Deficiency (ASPA) Testing	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54253 Billing and Coding: MolDX: Aspartoacyclase 2 Deficiency (ASPA) Testing	CGS	KY, OH	KY, OH
N/A	A53550 Billing and Coding: MolDX: ATP7B Gene Tests	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54254 Billing and Coding: MolDX: ATP7B Gene Tests	CGS	KY, OH	KY, OH
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55097 Billing and Coding: MolDX: ATP7B Gene Tests	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	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
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55143 Billing and Coding: MolDX: ATP7B Gene Tests	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
N/A	A53484 Billing and Coding: MolDX: BluePrint® Test	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54257 Billing and Coding: MolDX: BluePrint® Test	CGS	KY, OH	KY, OH
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55115 Billing and Coding: MolDX: BluePrint® Test	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55116 Billing and Coding: MolDX: BluePrint® Test	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)	A55146 Billing and Coding: MolDX: BluePrint® Test	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
N/A	A53565 Billing and Coding: MolDX: CHD7 Gene Analysis	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55085 Billing and Coding: MolDX: CHD7 Gene Analysis	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55157 Billing and Coding: MolDX: CHD7 Gene Analysis	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54243 Billing and Coding: MolDX: CHD7 Gene Analysis Guidelines	CGS	KY, OH	KY, OH
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55086 Billing and Coding: MolDX: CHD7 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	A53536 Billing and Coding: MolDX: ENG and ACVRL1 Gene Tests	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54262 Billing and Coding: MolDX: ENG and ACVRL1 Gene Tests	CGS	KY, OH	KY, OH
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55159 Billing and Coding: MolDX: ENG and ACVRL1 Gene Tests	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55181 Billing and Coding: MolDX: ENG and ACVRL1 Gene Tests	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	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	A53619 Billing and Coding: MolDX: HAX1 Gene Sequencing	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54266 Billing and Coding: MolDX: HAX1 Gene Sequencing	CGS	KY, OH	KY, OH
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55165 Billing and Coding: MolDX: HAX1 Gene Sequencing	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55249 Billing and Coding: MolDX: HAX1 Gene Sequencing	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV

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L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55252 Billing and Coding: MolDX: HAX1 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	A53480 Billing and Coding: MolDX: HTTLPR Gene Testing	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54269 Billing and Coding: MolDX: HTTLPR Gene Testing	CGS	KY, OH	KY, OH
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55169 Billing and Coding: MolDX: HTTLPR Gene Testing	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55264 Billing and Coding: MolDX: HTTLPR Gene Testing	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55265 Billing and Coding: MolDX: HTTLPR 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	A53576 Billing and Coding: MolDX: KIF6 Genotype	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54272 Billing and Coding: MolDX: KIF6 Genotype	CGS	KY, OH	KY, OH
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55171 Billing and Coding: MolDX: KIF6 Genotype	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55272 Billing and Coding: MolDX: KIF6 Genotype	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55273 Billing and Coding: MolDX: KIF6 Genotype	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A53467 Billing and Coding: MolDX: LPA-Aspirin Genotype	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54275 Billing and Coding: MolDX: LPA-Aspirin Genotype	CGS	KY, OH	KY, OH
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55173 Billing and Coding: MolDX: LPA-Aspirin Genotype	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55279 Billing and Coding: MolDX: LPA-Aspirin Genotype	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55280 Billing and Coding: MolDX: LPA-Aspirin Genotype	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A53468 Billing and Coding: MolDX: LPA-Intron 25 Genotype	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54276 Billing and Coding: MolDX: LPA-Intron 25 Genotype	CGS	KY, OH	KY, OH
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55174 Billing and Coding: MolDX: LPA-Intron 25 Genotype	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55281 Billing and Coding: MolDX: LPA-Intron 25 Genotype	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55282 Billing and Coding: MolDX: LPA-Intron 25 Genotype	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A53574 Billing and Coding: MolDX: MECP2 Genetic	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54278 Billing and Coding: MolDX: MECP2 Genetic Testing	CGS	KY, OH	KY, OH
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55189 Billing and Coding: MolDX: MECP2 Genetic Testing	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55285 Billing and Coding: MolDX: MECP2 Genetic Testing	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55286 Billing and Coding: MolDX: MECP2 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	A53669 Billing and Coding: MolDX: Mitochondrial Nuclear Gene Tests	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55190 Billing and Coding: MolDX: Mitochondrial Nuclear Gene Tests	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55290 Billing and Coding: MolDX: Mitochondrial Nuclear Gene Tests	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55291 Billing and Coding: MolDX: Mitochondrial Nuclear Gene Tests	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54288 Billing and Coding: MolDX: Mitochondrial Nuclear Gene Tests Guidelines	CGS	KY, OH	KY, OH
N/A	A53585 Billing and Coding: MolDX: NSD1 Gene Tests	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54291 Billing and Coding: MolDX: NSD1 Gene Tests	CGS	KY, OH	KY, OH
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55198 Billing and Coding: MolDX: NSD1 Gene Tests	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55609 Billing and Coding: MolDX: NSD1 Gene Tests	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	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	A53664 Billing and Coding: MolDX: PAX6 Gene Sequencing	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55199 Billing and Coding: MolDX: PAX6 Gene Sequencing	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54293 Billing and Coding: MolDX: PAX6 Gene Sequencing Guidelines	CGS	KY, OH	KY, OH
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55625 Billing and Coding: MolDX: PAX6 Gene Sequencing	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55632 Billing and Coding: MolDX: PAX6 Gene Sequencing	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L37260 MolDX: Prometheus IBD sgi Diagnostic® Policy	A56933 Billing and Coding: MolDX: Prometheus® IBD sgi Diagnostic Policy	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L37352 MolDX: Prometheus IBD sgi Diagnostic Policy	A56940 Billing and Coding: MolDX: Prometheus IBD sgi Diagnostic Policy	CGS	KY, OH	KY, OH
L37299 MolDX: Prometheus IBD sgi Diagnostic® Policy	A57516 Billing and Coding: MolDX: Prometheus IBD sgi Diagnostic Policy	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L37313 MolDX: Prometheus IBD sgi Diagnostic® Policy	A57517 Billing and Coding: MolDX: Prometheus IBD sgi Diagnostic Policy	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L37539 MolDX: Prometheus IBD sgi Diagnostic® Policy	A57588 Billing and Coding: MolDX: Prometheus® IBD sgi Diagnostic® Policy	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
N/A	A53567 Billing and Coding: MolDX: PTCH1 Gene Testing	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54297 Billing and Coding: MolDX: PTCH1 Gene Testing	CGS	KY, OH	KY, OH
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55203 Billing and Coding: MolDX: PTCH1 Gene Testing	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55608 Billing and Coding: MolDX: PTCH1 Gene Testing	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55618 Billing and Coding: MolDX: PTCH1 Gene Testing	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L38288 MolDX: Repeat Germline Testing	A57141 Billing and Coding: MolDX: Repeat Germline Testing	CGS	KY, OH	KY, OH
L38351 MolDX: Repeat Germline Testing	A57331 Billing and Coding: MolDX: Repeat Germline Testing	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L38353 MolDX: Repeat Germline Testing	A57332 Billing and Coding: MolDX: Repeat Germline Testing	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L38274 MolDX: Repeat Germline Testing	A58017 Billing and Coding: MolDX: Repeat Germline Testing	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L38429 MolDX: Repeat Germline Testing	A57100 Billing and Coding: MolDX: Repeat Germline Testing	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
N/A	A53587 Billing and Coding: MolDX: RPS19 Gene Tests	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54299 Billing and Coding: MolDX: RPS19 Gene Tests	CGS	KY, OH	KY, OH
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55205 Billing and Coding: MolDX: RPS19 Gene Tests	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55610 Billing and Coding: MolDX: RPS19 Gene Tests	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	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	A53538 Billing and Coding: MolDX: SULT4A1 Genetic Testing	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54283 Billing and Coding: MolDX: SULT4A1 Genetic Testing	CGS	KY, OH	KY, OH
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55210 Billing and Coding: MolDX: SULT4A1 Genetic Testing	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55596 Billing and Coding: MolDX: SULT4A1 Genetic Testing	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55601 Billing and Coding: MolDX: SULT4A1 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	A53589 Billing and Coding: MolDX: TERC Gene Tests	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54282 Billing and Coding: MolDX: TERC Gene Tests	CGS	KY, OH	KY, OH
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55211 Billing and Coding: MolDX: TERC Gene Tests	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55611 Billing and Coding: MolDX: TERC Gene Tests	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55616 Billing and Coding: MolDX: TERC 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	A53548 Billing and Coding: MolDX: VEGFR2 Tests	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54279 Billing and Coding: MolDx: VEGFR2 Tests	CGS	KY, OH	KY, OH

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55232 Billing and Coding: MolDX: VEGFR2 Tests	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55468 Billing and Coding: MolDX: VEGFR2 Tests	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55469 Billing and Coding: MolDX: VEGFR2 Tests	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L37725 MolDX: Melanoma Risk Stratification Molecular Testing	A56961 Billing and Coding: MolDX: Melanoma Risk Stratification Molecular Testing	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L38016 MolDX: Melanoma Risk Stratification Molecular Testing	A57165 Billing and Coding: MolDX: Melanoma Risk Stratification Molecular Testing	CGS	KY, OH	KY, OH
L38018 MolDX: Melanoma Risk Stratification Molecular Testing	A56636 Billing and Coding: MolDX: Melanoma Risk Stratification Molecular Testing	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L37750 MolDX: Melanoma Risk Stratification Molecular Testing	A57268 Billing and Coding: MolDX: Melanoma Risk Stratification Molecular Testing	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
	A57417 Billing and Coding: MolDX: DecisionDx - Melanoma **Retired 08/08/2022**			
L37748 MolDX: Melanoma Risk Stratification Molecular Testing	A57290 Billing and Coding: MolDX: Melanoma Risk Stratification Molecular Testing	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L37748 MolDX: Melanoma Risk Stratification Molecular Testing	A57418 Billing and Coding: MolDX: DecisionDx - Melanoma **Retired 08/08/2022**		AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L39389 MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma **Effective 08/06/2023**	A59163 Billing and Coding: MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma **Effective 08/06/2023**	CGS	KY, OH	KY, OH
L39373 MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma **Effective 08/06/2023**	A59179 Billing and Coding: MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma **Effective 08/06/2023**	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L39375 MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma **Effective 08/06/2023**	A59181 Billing and Coding: MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma **Effective 08/06/2023**	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L39345 MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma **Effective 08/06/2023**	A59109 Billing and Coding: MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma **Effective 08/06/2023**	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L39479 MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma **Effective 08/13/2023**	A59261 Billing and Coding: MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma **Effective 08/13/2023**	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
N/A	A55293 Billing and Coding: MolDX: myPap™	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54290 Billing and Coding: MolDX: myPap™	CGS	KY, OH	KY, OH
N/A	A55292 Billing and Coding: MolDX: myPap™	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A53544 Billing and Coding: MolDX: myPap™	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55195 Billing and Coding: MolDX: myPap™	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A55172 Billing and Coding: MolDX: know error®	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A54273 Billing and Coding: MolDX: know error®	CGS	KY, OH	KY, OH
N/A	A53554 Billing and Coding: MolDX: know error®	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A55274 Billing and Coding: MolDX: Know error®	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A55275 Billing and Coding: MolDX: Know error®	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L35025 MolDX: Molecular Diagnostic Tests (MDT)	A56973 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)	CGS	KY, OH	KY, OH
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

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L35025 MolDX: Molecular Diagnostic Tests (MDT)	A56853 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A57772 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L39256 MolDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia **Effective 05/14/2023**	A59015 Billing and Coding: MolDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia **Effective 05/14/2023**	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L39356 MolDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia **Effective 05/14/2023**	A59121 Billing and Coding: MolDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia **Effective 05/14/2023**	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L39276 MolDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia **Effective 06/04/2023**	A59051 Billing and Coding: MolDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia **Effective 06/04/2023**	CGS	KY, OH	KY, OH
L39262 MolDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia **Effective 05/28/2023**	A59032 Billing and Coding: MolDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia **Effective 05/28/2023**	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L39264 MolDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia **Effective 05/28/2023**	A59034 Billing and Coding: MolDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia **Effective 05/28/2023**	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY

CMS Claims Processing Manual

Chapter 26; § 10.4-Items 14-33 - Provider of Service or Supplier Information Instructions for Not Otherwise Classified (NOC) Codes

CMS Transmittals

Transmittal 11398, Change Request 12737, Dated May 4, 2022 (Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment)
Transmittal 11453, Change Request 12124, Dated June 10, 2022 (International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)–July 2021)
Transmittal 11460, Change Request 12705, Dated June 17, 2022 (International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)–October 2022 Update)
Transmittal 11461, Change Request 12483, Dated June 21, 2022 (National Coverage Determination (NCD) 90.2, Next Generation Sequencing (NGS))

Transmittal 12207, Change Request 13166, Dated August 11, 2023 (International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)–October 2023 Update)
Transmittal 12021, Change Request 13195, Dated May 4, 2023 (Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment)
Transmittal 12355, Change Request 13278, Dated November 9, 2023 (International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)–January 2024 Update)
Transmittal 12350, Change Request 13391, Dated November 3, 2023 (International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)–April 2024 Update–CR 2 of 2)

Other(s)

Billing and Describing Not Otherwise Classified (NOC) Codes, WPS
CMS Clinical Laboratory Fee Schedule, CMS Website
Palmetto GBA MolDx Website
Palmetto GBA MolDx Manual, 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	Summary of Changes
04/10/2024	**Applicable Codes** ***Non-Covered Diagnosis Codes*** • Added Z02.84 **Administrative** • Archived previous policy version MPG383.18

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 NCDs, LCDs, LCAs, 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 above 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.

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.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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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.