# Pharmacogenomics Testing

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➲ Terms and Conditions

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## Policy Summary

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### Overview

This is a limited coverage policy for pharmacogenomics testing (PGx) including single gene, multi-gene panels, and combinatorial tests. These tests are generally covered (with a few exceptions) as described in further detail below to improve safety in the use of specific medications by avoiding potentially harmful medications, doses and/or adverse reactions known to occur with certain genotypes.

PGx testing is considered reasonable and necessary in limited circumstances as described below as an adjunctive personalized medical decision-making tool once a treating clinician has narrowed treatment possibilities to specific medications under consideration for use, or is already using a specified medication, based on other clinical considerations including the patient's diagnosis, the patient's other medical conditions, other medications, professional judgment, clinical science and basic science pertinent to the drug, and the patient's preferences and values.

PGx tests must demonstrate analytical validity, clinical validity, and clinical utility to be considered reasonable and necessary for coverage. PGx tests are considered germline tests and must adhere to other relevant germline testing policies.

It is understood that some panel/combinatorial tests may include content that has demonstrated clinical utility and some that has not. In such circumstances, may provide coverage for the components of tests that have demonstrated clinical utility when used in the proper clinical context described below.

## Guidelines

### *Clinical Indications*

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.

### *Coverage information*

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 identified above) that have different relevant genes. A multi-gene panel is not considered reasonable and necessary if only a single gene on the panel is considered reasonable and necessary.

If two or more single genes are tested, rather than a multi-gene panel, then the record must reflect that a clinician individually ordered each gene, and each single gene must individually be reasonable and necessary at the time they are ordered.

The ordering provider of a PGx test is restricted to providers who have the licensure, qualifications, and necessary experience / training to both diagnose the condition being treated and also to prescribe medications (the provider must be able to do both) for the condition either independently or in an arrangement as required by all the applicable state laws.

### *Test components that are not 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.

### *Noncovered Indications*

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.

### *Special Documentation Requirements*

In order for any of the above services to be covered, the patient's medical record must clearly reflect the following:

- 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.

### *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".

## 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 |
|---|---|
| Provisional | |
| 0029U | Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis (i.e., CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, SLCO1B1, VKORC1 and rs12777823) |
| 0030U | Drug metabolism (warfarin drug response), targeted sequence analysis (i.e., CYP2C9, CYP4F2, VKORC1, rs12777823) |
| 0034U | TPMT (thiopurine S-methyltransferase), NUDT15 (nudix hydroxylase 15)(e.g., thiopurine metabolism) gene analysis, common variants (i.e., TPMT *2, *3A, *3B, *3C, *4, *5, *6, *8, *12; NUDT15 *3, *4, *5) (Effective 01/01/2022) |
| 0070U | CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, common and select rare variants (i.e., *2, *3, *4, *4N, *5, *6, *7, *8, *9, *10, *11, *12, *13, *14A, *14B, *15, *17, *29, *35, *36, *41, *57, *61, *63, *68, *83, *xN) |
| 0071U | CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, full gene sequence (List separately in addition to code for primary procedure) |
| 0072U | CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, targeted sequence analysis (i.e., CYP2D6-2D7 hybrid gene) (List separately in addition to code for primary procedure) |
| 0073U | CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, targeted sequence analysis (i.e., CYP2D7-2D6 hybrid gene) (List separately in addition to code for primary procedure) |
| 0074U | CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, targeted sequence analysis (i.e., non-duplicated gene when duplication/multiplication is trans) (List separately in addition to code for primary procedure) |
| 0075U | CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, targeted sequence analysis (i.e., 5' gene duplication/multiplication) (List separately in addition to code for primary procedure) |

| CPT Code | Description |
|---|---|
| Provisional | |
| 0076U | CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, targeted sequence analysis (i.e., 3' gene duplication/multiplication) (List separately in addition to code for primary procedure) |
| 0286U | CEP72 (centrosomal protein, 72-KDa), NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (e.g., drug metabolism) gene analysis, common variants (Effective 1/1/2022) |
| 81220 | CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; common variants (e.g., ACMG/ACOG guidelines) |
| 81225 | CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (e.g., drug metabolism), gene analysis, common variants (e.g., *2, *3, *4, *8, *17) |
| 81226 | CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism), gene analysis, common variants (e.g., *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN) |
| 81227 | CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (e.g., drug metabolism), gene analysis, common variants (e.g., *2, *3, *5, *6) |
| 81231 | CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (e.g., drug metabolism), gene analysis, common variants (e.g., *2, *3, *4, *5, *6, *7) |
| 81232 | DPYD (dihydropyrimidine dehydrogenase) (e.g., 5-fluorouracil/5-FU and capecitabine drug metabolism), gene analysis, common variant(s) (e.g., *2A, *4, *5, *6) |
| 81247 | G6PD (glucose-6-phosphate dehydrogenase) (e.g., hemolytic anemia, jaundice), gene analysis; common variant(s) (e.g., A, A-) |
| 81283 | IFNL3 (interferon, lambda 3) (e.g., drug response), gene analysis, rs12979860 variant |
| 81306 | NUDT15 (nudix hydrolase 15) (e.g., drug metabolism) gene analysis, common variant(s) (e.g., *2, *3, *4, *5, *6) |
| 81328 | SLCO1B1 (solute carrier organic anion transporter family, member 1B1) (e.g., adverse drug reaction), gene analysis, common variant(s) (e.g., *5) |
| 81335 | TPMT (thiopurine S-methyltransferase) (e.g., drug metabolism), gene analysis, common variants (e.g., *2, *3) |
| 81350 | UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (e.g., drug metabolism, hereditary unconjugated hyperbilirubinemia [Gilbert syndrome]) gene analysis, common variants (e.g., *28, *36, *37) |
| 81355 | VKORC1 (vitamin K epoxide reductase complex, subunit 1) (e.g., warfarin metabolism), gene analysis, common variant(s) (e.g., -1639G>A, c.173+1000C>T) |

| CPT Code | Description |
|---|---|
| Non-Covered | |
| 0031U | CYP1A2 (cytochrome P450 family 1, subfamily A, member 2)(e.g., drug metabolism) gene analysis, common variants (i.e., *1F, *1K, *6, *7) |
| 0032U | COMT (catechol-O-methyltransferase)(drug metabolism) gene analysis, c.472G>A (rs4680) variant |
| 0033U | HTR2A (5-hydroxytryptamine receptor 2A), HTR2C (5-hydroxytryptamine receptor 2C) (e.g., citalopram metabolism) gene analysis, common variants (i.e., HTR2A rs7997012 [c.614-2211T>C], HTR2C rs3813929 [c.-759C>T] and rs1414334 [c.551-3008C>G]) |
| 0117U | Pain management, analysis of 11 endogenous analytes (methylmalonic acid, xanthurenic acid, homocysteine, pyroglutamic acid, vanilmandelate, 5-hydroxyindoleacetic acid, hydroxymethylglutarate, ethylmalonate, 3-hydroxypropyl mercapturic acid (3-HPMA), quinolinic acid, kynurenic acid), LC-MS/MS, urine, algorithm reported as a pain-index score with likelihood of atypical biochemical function associated with pain |
| 0173U | Psychiatry (i.e., depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes |

| CPT Code | Description |
|---|---|
| Non-Covered | |
| 0175U | Psychiatry (e.g., depression, anxiety), genomic analysis panel, variant analysis of 15 genes |
| 0289U | Neurology (Alzheimer disease), mRNA, gene expression profiling by RNA sequencing of 24 genes, whole blood, algorithm reported as predictive risk score (Effective 1/1/2022) |
| 0290U | Pain management, mRNA, gene expression profiling by RNA sequencing of 36 genes, whole blood, algorithm reported as predictive risk score (Effective 1/1/2022) |
| 0291U | Psychiatry (mood disorders), mRNA, gene expression profiling by RNA sequencing of 144 genes, whole blood, algorithm reported as predictive risk score (Effective 1/1/2022) |
| 0292U | Psychiatry (stress disorders), mRNA, gene expression profiling by RNA sequencing of 72 genes, whole blood, algorithm reported as predictive risk score (Effective 1/1/2022) |
| 0293U | Psychiatry (suicidal ideation), mRNA, gene expression profiling by RNA sequencing of 54 genes, whole blood, algorithm reported as predictive risk score (Effective 1/1/2022) |
| 0294U | Longevity and mortality risk, mRNA, gene expression profiling by RNA sequencing of 18 genes, whole blood, algorithm reported as predictive risk score (Effective 1/1/2022) |
| 81230 | CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (e.g., drug metabolism), gene analysis, common variant(s) (e.g., *2, *22) |
| 81346 | TYMS (thymidylate synthetase) (e.g., 5-fluorouracil/5-FU drug metabolism), gene analysis, common variant(s) (e.g., tandem repeat variant) |

| Diagnosis Code | Description |
|---|---|
| For CPT Code 81335 | |
| C91.00 | Acute lymphoblastic leukemia not having achieved remission |
| C91.01 | Acute lymphoblastic leukemia, in remission |
| C91.02 | Acute lymphoblastic leukemia, in relapse |
| C91.12 | Chronic lymphocytic leukemia of B-cell type in relapse |
| C91.30 | Prolymphocytic leukemia of B-cell type not having achieved remission |
| C91.40 | Hairy cell leukemia not having achieved remission |
| C91.50 | Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission |
| C91.60 | Prolymphocytic leukemia of T-cell type not having achieved remission |
| C91.A0 | Mature B-cell leukemia Burkitt-type not having achieved remission |
| C91.Z0 | Other lymphoid leukemia not having achieved remission |
| C92.00 | Acute myeloblastic leukemia, not having achieved remission (Effective 12/12/2021) |
| C92.01 | Acute myeloblastic leukemia, in remission (Effective 12/12/2021) |
| C92.02 | Acute myeloblastic leukemia, in relapse (Effective 12/12/2021) |
| K50.00 | Crohn's disease of small intestine without complications |
| M06.89 | Other specified rheumatoid arthritis, multiple sites (Effective 12/12/2021) |
| M06.8A | Other specified rheumatoid arthritis, other specified site (Effective 12/12/2021) |
| Z94.0 | Kidney transplant status (Effective 12/12/2021) |
| Z94.84 | Stem cells transplant status |

| Non-Covered Diagnosis Code |
|---|
| Non-Covered Diagnosis Codes List<br>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. |

# Definitions

Gene: The term "gene" in this document will be used as a term to encapsulate all of the following: gene, pseudogene, and genetic locus.

Single-gene test: A laboratory test to detect relevant genetic variants (alleles) of 1 gene. If two or more different single genes are ordered individually but simultaneously, this is not a panel but rather a couple of or multiple single gene tests.

Multi-gene panel: A laboratory test to detect genetic variants of at least 2 genes, wherein the clinician does not individually order genes, but orders a panel with a specified list of genes.

Combinatorial PGx test: A type of multi-gene panel that requires a proprietary algorithm to evaluate pharmacokinetic or pharmacodynamic relationships resulting in drug recommendations or warnings.

Actionable use: A test is considered to have an actionable use when the genotype information may lead to selection of or avoidance of a specific therapy or modification of dosage of a therapy. The selection, avoidance, or dose change must be based on the FDA-label for the drug, an FDA warning or safety concern, or a CPIC level A or B gene-drug interaction. An intended change in therapy based on the result of a genotyping test that is not supported by one of these sources is not considered an actionable use.

# References

## CMS National Coverage Determinations (NCDs)

Reference NCD: NCD 90.1 Pharmacogenomic Testing for Warfarin Response

## CMS Local Coverage Determinations (LCDs) and Articles

| LCD | Article | Contractor | Medicare Part A | Medicare Part B |
|---|---|---|---|---|
| General Molecular Diagnostic Tests | | | | |
| L36021 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 |
| 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 |

| LCD | Article | Contractor | Medicare Part A | Medicare Part B |
|---|---|---|---|---|
| General Molecular Diagnostic Tests | | | | |
| L36807 MolDX: Molecular Diagnostic Tests (MDT) | A57772 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) | WPS | AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY | IA, IN, KS, MI, MO, NE |
| N/A | A58918 Billing and Coding: Molecular Pathology and Genetic Testing | First Coast | FL, PR, VI | FL, PR, VI |
| N/A | 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 |
| 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 |
| Repeat Germline Testing | | | | |
| 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 |
| 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 | AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY | IA, IN, KS, MI, MO, NE |
| Testing of Multiple Genes | | | | |
| N/A | A57910 Billing and Coding: MolDX: Testing of Multiple Genes | CGS | KY, OH | KY, OH |

| LCD | Article | Contractor | Medicare Part A | Medicare Part B |
|---|---|---|---|---|
| Testing of Multiple Genes | | | | |
| N/A | A58120 Billing and Coding: MolDX: Testing of Multiple Genes | Noridian | AS, CA, GU, HI, MP, NV | AS, CA, GU, HI, MP, NV |
| N/A | A58121 Billing and Coding: MolDX: Testing of Multiple Genes | Noridian | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY |
| N/A | A57503 Billing and Coding: MolDX: Testing of Multiple Genes | Palmetto | AL, GA, NC, SC, TN, VA, WV | AL, GA, NC, SC, TN, VA, WV |
| N/A | A57880 Billing and Coding: MolDX: Testing of Multiple Genes | WPS | AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY | IA, IN, KS, MI, MO, NE |
| Pharmacogenomics Testing | | | | |
| 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 | AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY | IA, IN, KS, MI, MO, NE |
| L39073 Pharmacogenomics Testing Effective 12/12/2021 | A58812 Billing and Coding: Pharmacogenomics Testing Effective 12/12/2021 | First Coast | FL, PR, VI | FL, PR, VI |

| LCD | Article | Contractor | Medicare Part A | Medicare Part B |
|---|---|---|---|---|
| Pharmacogenomics Testing | | | | |
| L39063 Pharmacogenomics Testing<br>Effective 12/12/2021 | A58801 Billing and Coding: Pharmacogenomics Testing<br>Effective 12/12/2021 | 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 |
| L35698 CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing<br>Retired 12/12/2021 | A57704 Billing and Coding: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing<br>Retired 12/12/2021 | First Coast | FL, PR, VI | FL, PR, VI |

### CMS Benefit Policy Manual

Chapter 15; § 80.1–80.1.3 Clinical Laboratory Services

### CMS Claims Processing Manual

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

### UnitedHealthcare Commercial Policy

Pharmacogenetic Testing

### Other(s)

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 |
|---|---|
| 02/09/2022 | • New Policy Guideline |

## 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 below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

# 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.



*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.