


MEDICAL POLICY	Genetic Testing: Cytochrome P450 and VKORC1 Polymorphisms (Medicare Only)
Effective Date: 10/1/2021	Medical Policy Number: 314
 10/1/2021	Medical Policy Committee Approved Date: 7/2021
Medical Officer	Date

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA	
<p>The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.</p>	
Service	Medicare Guidelines
<p><i>Cytochrome P450 and VKORC1 Pharmacogenetic Testing</i></p>	<ul style="list-style-type: none"> • National Coverage Determination (NCD) for Pharmacogenomic Testing for Warfarin Response (90.1) *Note coverage for • Local Coverage Determination (LCD): MoIDX: Pharmacogenomics Testing (L38337) <p>For Versiti tests performed in Wisconsin (0270U, 0272U): LCD for Molecular Pathology Procedures (L35000) and LCD for Biomarkers Overview (L35062)*According to LCD L35000, “For testing panels...testing would be covered ONLY for the number of genes or test that are reasonable and necessary to obtain necessary information for therapeutic decision making.” While some genes in these panels have individual clinical utility and analytical validity, several genes that make up these Versiti panel tests are non-covered and both <i>CYP2C9</i> and <i>VKORC1</i> have very specific Medicare coverage requirements detailed in NCD 90.1. All other genes that make up</p>

MEDICAL POLICY	Genetic Testing: Cytochrome P450 and VKORC1 Polymorphisms (Medicare Only)
-----------------------	--

	these panel tests are not addressed by this LCD at all, nor are they addressed in the LCD L35062. Due to the single CPT code used to report for the entire panel test, based on the LCD requirement that all gene test components be reasonable and necessary, the entire panel test will be considered not medically reasonable or necessary for Medicare under <i>Social Security Act, §1862(a)(1)(A)</i> .
--	--

BILLING GUIDLEINES

See related local coverage articles (LCAs) for additional coding and billing assistance.

- LCA: Billing and Coding: MolDX: Pharmacogenomics Testing ([A57385](#))

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
0028U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, copy number variants, common variants with reflex to targeted sequence analysis
0030U	Drug metabolism (warfarin drug response), targeted sequence analysis (ie, CYP2C9, CYP4F2, VKORC1, rs12777823)
0070U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, common and select rare variants (ie, *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) (eg, 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) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, CYP2D6-2D7 hybrid gene) (List separately in addition to code for primary procedure)
0073U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, CYP2D7-2D6 hybrid gene) (List separately in addition to code for primary procedure)
0074U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, non-duplicated gene when

MEDICAL POLICY	Genetic Testing: Cytochrome P450 and VKORC1 Polymorphisms (Medicare Only)
-----------------------	--

	duplication/multiplication is trans) (List separately in addition to code for primary procedure)
0075U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, 5' gene duplication/multiplication) (List separately in addition to code for primary procedure)
0076U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, 3' gene duplication/ multiplication) (List separately in addition to code for primary procedure)
0270U	Hematology (congenital coagulation disorders), genomic sequence analysis of 20 genes, blood, buccal swab, or amniotic fluid (<i>Versiti™ Coagulation Disorder Panel, by Versiti™ Diagnostic Laboratories; Wisconsin</i>)
0272U	Hematology (genetic bleeding disorders), genomic sequence analysis of 51 genes, blood, buccal swab, or amniotic fluid, comprehensive (<i>Versiti™ Comprehensive Bleeding Disorder Panel, by Versiti™ Diagnostic Laboratories; Wisconsin</i>)
81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)
81226	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants (eg, *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) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)
81230	CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (eg, drug metabolism), gene analysis, common variant(s) (eg, *2, *22)
81231	CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *7)
81355	VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variant(s) (eg, -1639G>A, c.173+1000C>T)
81401	Molecular pathology procedure level 2
81402	Molecular pathology procedure level 3
81404	Molecular pathology procedure level 5
81405	Molecular pathology procedure level 6
Not Covered	
0029U	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis (ie, CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, SLCO1B1, VKORC1 and rs12777823)
0031U	CYP1A2 (cytochrome P450 family 1, subfamily A, member 2) (eg, drug metabolism) gene analysis, common variants (ie, *1F, *1K, *6, *7)
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then prior-authorization is required.	
81479	Unlisted molecular pathology procedure

MEDICAL POLICY	Genetic Testing: Cytochrome P450 and VKORC1 Polymorphisms (Medicare Only)
-----------------------	--

81599	Unlisted multianalyte assay with algorithmic analysis
-------	---

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

- 1.