MEDICAL POLICY	Genetic Testing: Inherited Thrombophilias (Medicare Only)
Effective Date: 10/1/2021  10/1/2021 Medical Officer Date	Medical Policy Number: 116 Medical Policy Committee Approved Date: 10/17; 12/18; 12/19; 3/2020; 05/2021; 9/2021

See Policy CPT 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

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.

Service	Medicare Guidelines
Genetic testing for hypercoagulability / thrombophilia	• Local Coverage Determinations (LCD): MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) (L36159) • • For Versiti tests performed in Wisconsin (0278U): 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 may have individual clinical utility and analytical validity, several genes that make up these Versiti panel tests are non-covered. All other genes that make up these panel tests are not addressed by this LCD at all, nor are they addressed in the LCD L35062. Finally, tests performed to

	determine risk of illness or disease are not covered under the LCD or Medicare, unless specifically identified by the law as a Medicare covered preventive benefit. Therefore, 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, and non-coverage of screening tests, the entire panel test will be considered **not medically reasonable or necessary** for Medicare under *Social Security Act, §1862(a)(1)(A).*

BILLING GUIDLEINES

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

- LCA: Billing and Coding: MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) (A57424)

CPT CODES

Medicare Only	
Prior Authorization Required	
0278U	Hematology (genetic thrombosis), genomic sequence analysis of 12 genes, blood, buccal swab, or amniotic fluid *(Versiti™ Thrombosis Panel, by Versiti™ Diagnostic Laboratories; Wisconsin)*
81400	Molecular pathology procedure, Level 1 (e.g., identification of single germline variant [eg, SNP] by techniques such as restriction enzyme digestion or melt curve analysis) – when used for [N48K variant F2 (coagulation factor 2) (eg, hereditary hypercoagulability), 1199G>A variant F5 (coagulation factor V) (eg, hereditary hypercoagulability)]
Medicare Only	
Not Covered	
81240	F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant

81241	F5 (coagulation factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant
81291	MTHFR (5,10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C)

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. Centers for Medicare & Medicaid Services. LCD L36159. LCD Title: MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR). Revision Effective Date: For services performed on or after 11/01/2019. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36159. Accessed 04/02/2021.
2. Centers for Medicare & Medicaid Services. Local Coverage Article (LCA): A57424. LCA Title: Billing and Coding: MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR). Revision Effective Date: 11/01/2019. https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57424. Accessed 04/02/2021.