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SONIC HEALTHCARE USA

Client Communication

Medicare Local Coverage Determination Policy: CGS

Coverage Policy

L35984 – MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR)

CPT: 81240, 81241, 81291

Revision Effective Date: 07/20/2023

Coverage Indications, Limitations, and/or Medical Necessity

Indications

This is a non-coverage policy for genetic testing for thrombophilia testing for the Factor V Leiden (FVL) variant in the F5 gene, the G20210G>A (G20210A) variant in the F2 gene, and the MTHFR gene which encodes the 5,10-methylenetetrahydrofolate reductase enzyme. Genetic testing for these genes for all risk factors, signs, symptoms, diseases, or conditions, including cardiovascular risk assessment, are non-covered except for pregnant patients.

Testing for FVL and F2 G20210A mutations is indicated for pregnant patients who have a history of personal venous thromboembolism (VTE) associated with a non-recurrent (transient) risk factor who are not otherwise receiving anticoagulant prophylaxis. The results of genetic testing can inform risk stratification for VTE recurrence and subsequent need for antenatal prophylaxis. However, Medicare will not add coverage of thrombophilia testing for pregnant women because they likely represent a very small group of potential Medicare (disabled) patients. Claims submitted on this limited Medicare population will deny per the policy, but should be appealed for coverage with submission of medical records supporting the necessity for testing, and specify how testing changed anticoagulant prophylaxis management for the patient.

Non-coverage Summary

Genetic testing for inherited thrombophilias is controversial. While the association between FVL and F2 mutations and increased risk for VTE is apparent, the actual impact of this increased risk on clinical management is less certain. Older professional society guidelines recommend genetic testing for thrombophilia for a wide range of indications, while more

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recent consensus statements and recommendations suggest much more limited clinical utility of testing.

The population for which genetic testing results have direct implications for treatment is pregnant women with a previous history of VTE associated with a transient risk factor (e.g., surgery, trauma). These women would typically not be treated with antepartum anticoagulant prophylaxis unless they were found to have a genotype associated with a high risk of VTE recurrence (FVL homozygosity, F2 G20210A homozygosity, or compound heterozygosity for FVL and F2 G20210A). Genetic testing for these patients is indicated.

There may also be benefit to screening pregnant women with a family history of known thrombophilia, as those women found to have a high risk genotype would be offered antenatal prophylactic anticoagulant therapy even in the absence of a personal history of VTE. However, the Medicare benefit applies only to patients with signs and symptoms of disease and does not include screening in asymptomatic patients.

Finally, despite many earlier publications suggesting a link between MTHFR polymorphisms and a risk for a wide spectrum of obstetric and cardiovascular complications, it is now accepted that MTHFR genotype alone is not associated with VTE. There is no clinical indication for MTHFR genotyping in any population.

There is insufficient evidence in the published peer-reviewed scientific literature to support coverage for genetic testing for inherited thrombophilias outside the pregnant women as described above. Genetic testing for FVL and F2 G20210A is considered investigational for all other indications. However, Medicare may consider coverage for FVL and/or F2 genetic testing in unusual circumstances where testing will change clinical management of the patient. Denied claims can be appealed with supporting evidence of specific medical necessity. Only providers with evidence of formal training with board eligibility or certification in hematology/oncology, hematopathology or coagulation disorders at an accredited program satisfy reasonable and necessary criteria for these tests. There is broad consensus in the medical literature that MTHFR genotyping has no clinical utility in any clinical scenario. This testing is considered investigational and is NOT a Medicare benefit.

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The ICD10 codes listed below are the top 40 diagnosis codes Sonic most commonly receives from ordering physicians for this limited-coverage test. Medicare supports provider utilization of all the diagnosis codes listed below, except those notated in bold. **If you are providing a diagnosis code that is bolded below, please submit a valid ABN form with the order.** To view the complete policy and the full list of medically supported diagnosis codes, please refer to the CMS website for guidance: https://www.cms.gov/medicare-coverage-database/search.aspx

Codes	Description
I10	Essential (primary) hypertension
E78.2	Mixed Hyperlipidemia
I82.401	Acute embolism and thrombosis of unspecified deep veins of right lower extremity
E78.5	Hyperlipidemia, Unspecified
E11.9	Type 2 Diabetes Mellitus without complications
Z86.718	Personal history of other venous thrombosis and embolism
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
E55.9	Vitamin D deficiency, unspecified
I73.9	Peripheral vascular disease, unspecified
G45.9	Transient cerebral ischemic attack, unspecified
R53.83	Other Fatigue
E83.52	Hypercalcemia
I26.99	Other pulmonary embolism without acute cor pulmonale
R04.0	Epistaxis
R73.03	Prediabetes (latent diabetes)
D68.59	Other primary thrombophilia
D68.2	Hereditary deficiency of other clotting factors
Z36.9	Antenatal screening, unspecified
Z79.899	Other long-term (current) drug therapy
Z83.2	Family history of diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
E89.0	Post procedural hypothyroidism

R41.0	Disorientation, unspecified
R09.02	Hypoxemia
I50.22	Chronic systolic (congestive) heart failure
R53.82	Chronic fatigue, unspecified
D68.51	Activated protein C resistance
Z85.3	Personal history of malignant neoplasm of breast
E78.49	Other hyperlipidemia
R22.32	Localized swelling, mass and lump, left upper limb
I82.729	Chronic embolism and thrombosis of deep veins of unspecified upper extremity
R41.3	Other amnesia
D89.9	Disorder involving the immune mechanism, unspecified
D51.0	Vitamin B deficiency anaemia due to intrinsic factor deficiency
D68.9	Coagulation defect, unspecified
N95.2	Postmenopausal atrophic vaginitis
E72.12	Methylenetetrahydrofolate reductase deficiency
G47.8	Other sleep disorders
K58.0	Irritable bowel syndrome with diarrhea
N40.0	Benign prostatic hyperplasia without lower urinary tract symptoms
D50.9	Iron deficiency anaemia, unspecified