

Test Update 920

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Please be advised that testing for Factor V Leiden Mutation (order code FVMT) and Prothrombin (Factor II) c.*97G>A (20210) (order code PROMT) are **not a covered benefit** under **Medicare** except for pregnant patients.

Requests for these tests referred to MLabs for a Medicare patient must be accompanied by appropriate documentation of medical necessity for pregnant patients or by an ABN signed by the patient and agreeing to payment, or testing will be client billed to the referring facility.

See Medicare LCD L36400 MolDX: Genetic Testing for Hypercoagulability/Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR)

This is a non-coverage policy for genetic testing for thrombophilia testing for the Factor V Leiden (FVL) variant in F5 gene, the 20210G>(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.

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