Factor V Leiden Thrombophilia – F5 Gene

Date of Origin: 08/2019 **Last Review Date: 08/26/2020** **Effective Date: 09/01/2020**

Dates Reviewed: 08/2019, 08/2020

Developed By: Medical Necessity Criteria Committee

I. Description

Thrombophilia is an abnormal blood coagulation condition leading to increased tendency towards coagulation (hypercoagulability). People with hypercoagulability are at risk of developing thrombosis, especially venous thromboembolic (VTE) disorders including deep vein thrombosis (DVT) and pulmonary embolism (PE). Factor V Leiden thrombophilia is an inherited disorder of blood clotting. Factor V Leiden is the specific gene mutation that results in thrombophilia, which is an increased tendency to form abnormal blood clots that can block blood vessels. A variant in the factor V gene (F5), called factor V Leiden (FVL), is the most common genetic risk factor for thrombophilia (hypercoagulability), especially among Caucasians. People with factor V Leiden thrombophilia have a higher than average risk of developing DVT. The most common presentations of venous thromboembolism are DVT of the lower extremity and PE.

II. Criteria: CWQI HCS-0264

A. Moda considers genetic testing for factor V Leiden medically necessary when ANY of the following requirements are met;
   a. Members with an abnormal (low) activated protein C resistance (APC) assay result
   b. Members with their first venous thromboembolism (VTE) before age 50 with no triggering/precipitating factors (e. g. from unknown etiology)
   c. Members who present with a VTE, and have a personal or family history of recurrent VTE (more than two in the same person)
   d. Members less than 50 years of age with a history of venous thrombosis
   e. Members with a history of recurrent venous thrombosis
   f. Presentation of venous thrombosis at unusual sites such as mesenteric, portal, cerebral or hepatic veins
   g. VTE that results with the use estrogen-containing oral contraceptives, selective estrogen receptor modulators (SERMs), or hormone replacement therapy
   h. Diagnostic evaluation of VTE during pregnancy or puerperium
   i. Female members who are smokers, under the age of 50 and have a history of myocardial infarction

B. Genetic testing for coagulation factor V Leiden is considered not medically necessary for ANY of the following;
   i. Routine screening of the general population
   ii. Newborn screening, or routine testing in an asymptomatic child
   iii. Testing of asymptomatic first-degree relative of an individual with proven symptomatic VTE and a proven coagulation factor V Leiden or prothrombin mutation for evaluating primary prophylactic anticoagulation

III. Information Submitted with the Prior Authorization Request:

1. Chart notes that include but not limited to history and physical or exam findings

IV. CPT or HCPC codes covered:

Codes	Description
81241	F5 (Coagulation factor V) (e.g. hereditary hypercoagulability) gene analysis, 20210G>A variant
81400	Molecular pathology procedure, Level 1 (eg, identification of single germline variant [eg, SNP] by techniques such as restriction enzyme digestion or melt curve analysis)
96040	Medical genetics and genetic counseling services, each 30 minutes face to face with patient or family

V. CPT or HCPC codes NOT covered:

Codes	Description

VI. Annual Review History

Review Date	Revisions	Effective Date
08/28/2019	Updated criteria requirements for coverage	09/01/2019
08/26/2020	Annual review: Minor grammar changes	09/01/2020

VII. References

1. Your guide to understanding genetic conditions. Genetics home reference https://ghr.nlm.nih.gov/condition/factor-v-leiden-thrombophilia
2. LaBonte, M. L. (2014). Anticoagulant factor V: Factors affecting the integration of novel scientific discoveries into the broader framework. https://www.sciencedirect.com/science/article/pii/S1369848614000363
3. Jadaon. M. M. (2011). Epidemiology of activated protein C resistance and Factor V Leiden mutation in the Mediterranean region. Mediterranean Journal of Hematology and Infectious diseases. https://www.researchgate.net/publication/221728480_Epidemiology_of_Activated_Protein_C_Resistance_and_Factor_V_Leiden_Mutation_in_the_Mediterranean_Region

Appendix 1 – Applicable Diagnosis Codes:

Codes	Description

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC