GENETIC TESTING FOR FACTOR V LEIDEN
HS-056

Easy Choice Health Plan, Inc.
Harmony Health Plan of Illinois, Inc.
Missouri Care, Inc.
‘Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona, Inc.
WellCare Health Insurance of Illinois, Inc.
WellCare Health Plans of New Jersey, Inc.
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WellCare of South Carolina, Inc.
WellCare Prescription Insurance, Inc.
Windsor Health Plan
Windsor Rx Medicare Prescription Drug Plan

Genetic Testing for Factor V Leiden

Policy Number: HS-056

Original Effective Date: 11/6/2008


APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.
BACKGROUND

Factor V Leiden thrombophilia is an inherited disorder of blood clotting. Factor V Leiden is the name of a specific mutation that results in thrombophilia, or an increased tendency to form abnormal blood clots in blood vessels. People who have the factor V Leiden mutation are at somewhat higher than average risk for a type of clot that forms in veins, such as the deep veins of the legs (deep venous thrombosis), or a clot that travels through the bloodstream and lodges in the lungs (pulmonary embolism). Most people with the factor V Leiden mutation never develop abnormal blood clots, however. Factor V Leiden is the most common inherited form of thrombophilia. Between 3 percent and 8 percent of the Caucasian (white) population in the United States and Europe carry one copy of the factor V Leiden mutation in each cell, and about 1 in 5,000 people have two copies of the mutation. The mutation is less common in other populations.¹

Mutations in the F5 gene cause factor V Leiden thrombophilia. The F5 gene plays a critical role in the formation of blood clots in response to injury. The protein made by the F5 gene, coagulation factor V, is involved in a series of chemical reactions that hold blood clots together. A molecule called activated protein C (APC) prevents blood clots from growing too large by inactivating factor V. The term "factor V Leiden" refers to the specific G-to-A substitution at nucleotide 1691 in the gene for factor V that predicts a single amino acid replacement (R506Q) at one of three APC cleavage sites in the factor Va molecule. In people with the factor V Leiden mutation, APC is unable to inactivate factor V normally. As a result, the clotting process continues longer than usual, increasing the chance of developing abnormal blood clots. Other factors also increase the risk of blood clots in people with the factor V Leiden mutation. These factors include increasing age, obesity, trauma, surgery, smoking, the use of oral contraceptives (birth control pills) or hormone replacement therapy, and pregnancy. The combination of the factor V Leiden mutation and mutations in other genes involved in blood clotting can also influence risk.²,³,⁴

POSITION STATEMENT

Applicable To:

- Medicaid – Hawaii, Kentucky*
- Medicare – Easy Choice Health Plan, Hawaii, Kentucky*

For markets noted below, please refer to Care Core National Lab Management criteria (program effective August 2014) available at www.wellcare.com/provider/CCGs.

- Medicaid – Florida, Georgia, Illinois, Missouri, New Jersey, New York, South Carolina
- Medicare – Arizona, Connecticut, Florida, Georgia, Illinois, Louisiana, Missouri, New Jersey, New York, Ohio, Texas, Windsor

* Kentucky (Medicaid and Medicare) pending state approval; CCG to be used until Care Core is effective in late 2014.

Genetic Testing for Factor V Leiden thrombophilia is considered medically necessary if ANY of the following criteria are met:

- Members are aged < 50 years with any venous thrombosis; OR,
- Member has venous thrombosis in unusual sites (such as hepatic, mesenteric, and cerebral veins); OR,
- Member has recurrent venous thrombosis; OR,
- Member has venous thrombosis and a strong family history of thrombotic disease; OR,
• Member is female, has venous thrombosis and is pregnant or taking oral contraceptives; OR,
• Member has relatives with venous thrombosis under age 50; OR,
• Member is a female smoker under the age of 50 with myocardial infarction; OR,
• Female members who have experienced recurrent pregnancy loss

Genetic Testing for Factor V Leiden thrombophilia is NOT medically necessary and NOT a covered benefit in the following situations:
• Random screening of the general population; OR,
• Routine screening during pregnancy; OR,
• Routine screening prior to use of oral contraceptives, hormone replacement therapy, or selective estrogen receptor modulators; OR,
• Prenatal or newborn testing; OR,
• Routine testing in asymptomatic children; OR,
• Routine initial testing in members with arterial thrombosis.

CODING

CPT® Codes
81240  F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A Variant
81241  Factor V Leiden gene analysis, (hereditary hypercoagulability)
81291  MTHFR (5,10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, Common variants (eg, 677T, 1298C)

ICD-9-CM Procedure Codes - No applicable codes.

Covered HCPCS Code
S3843* DNA analysis of the F5 gene for susceptibility to Factor V Leiden thrombophilia
*Note: S-Codes are NON COVERED FOR MEDICARE - For Medicare, bill the appropriate CPT code listed above.

Covered ICD-9-CM Diagnosis Codes - This list may not be all inclusive
410.00 - 412  Myocardial infarction (Ischemic heart disease)
415.11 - 415.19  Pulmonary embolism and infarction
434.00 - 434.91  Cerebral artery thrombosis or occlusions
453.0  Hepatic Vein Thrombosis; Budd-Chiari Syndrome
453.2  Vena Cava Thrombosis
453.3  Renal Vein Thrombosis
453.40  DVT - Venous embolism and thrombosis of unspecified deep vessels of lower extremities
453.41  DVT – Venous embolism and thrombosis of deep vessels of proximal lower extremity
453.42  DVT – Venous embolism and thrombosis of deep vessels of distal lower extremity
453.8  DVT of other specified veins
646.33  Habitual Aborter, Complication of Pregnancy Elsewhere classified
671.20 - 671.33  Pregnancy complicated by thrombosis
V12.51 - V12.52, V12.55  Personal history of thrombosis
V17.41 - V17.49  Family history of thrombosis

Covered ICD-10-CM Diagnosis Codes
I21.09 – I25.790  Myocardial infarction (Ischemic heart disease)
I26.01 – I26.99  Pulmonary embolism and infarction
I22.20 - I22.33, O87.0  Pregnancy complicated by thrombosis
I63.30 - I63.39  Cerebral infarction due to thrombosis of cerebral arteries
I81  Portal vein thrombosis
I82.0 Budd Chiari syndrome
I82.210 Acute embolism and thrombosis of superior vena cava
I82.211 Chronic embolism and thrombosis of superior vena cava
I82.220 Acute embolism and thrombosis of inferior vena cava
I82.221 Chronic embolism and thrombosis of inferior vena cava
I82.3 Embolism and thrombosis of renal vein
I82.40 - I82.499 Acute embolism and thrombosis of deep veins of lower extremity
K55.0 Acute vascular disorders of intestine; Mesenteric (artery) (vein) thrombosis
O22.30 - O22.33 Deep phlebothrombosis in pregnancy
O22.50 - O22.53 Cerebral venous thrombosis in pregnancy
O26.20 - O26.23 Pregnancy care of habitual aborter
O87.1 Deep phlebothrombosis in the puerperium
O87.3 Cerebral venous thrombosis in the puerperium
Z86.718, Z86.72, Z86.74 Personal history of thrombosis
Z82.41, Z82.49 Family history of thrombosis


REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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<td>8/7/2014</td>
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<tr>
<td>11/1/2012</td>
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<td>12/1/2011</td>
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<td>10/6/2011</td>
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