Policy: MP336
Section: Medical Benefit Policy
Subject: Genetic Testing for Inherited Thrombophilia/ Hypercoagulability

I. Policy: Genetic Testing for Inherited Thrombophilia/ Hypercoagulability

II. Purpose/Objective:
To provide a policy of coverage regarding Genetic Testing For Inherited Thrombophilia/ Hypercoagulability

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.
DESCRIPTION: Inherited thrombophilia is a genetic predisposition to develop a group of clinical conditions caused by associated gene variants and defects. Common causes include Factor V Leiden, a prothrombin gene variation, and deficiencies in protein S, protein C, and antithrombin.

INDICATIONS: Genetic testing for Factor V and/or Factor II Blood Clotting Protein mutations may be considered medically necessary for any of the following conditions in members without recurrent VTE risk factors (e.g., recent surgery, prolonged immobilization, collagen vascular disease, malignancy, certain hematologic disorders):

- Age less than 50, any venous thrombosis; or
- Myocardial infarction in female smokers less than age of 50; or
- Recurrent venous thrombosis; or
- First or second degree relative of individuals with venous thrombosis less than age of 50; or
- Relative with confirmed Factor V or Factor II mutation; or
- Venous thrombosis and a first or second degree relative with venous thrombosis; or
- Venous thrombosis in pregnant women or women taking oral contraceptives; or
- Venous thrombosis in unusual sites (such as hepatic, mesenteric and cerebral veins)
- Prior to administration of oral contraceptives in women with a personal or family history of venous thrombosis
- Preeclampsia or hemolysis, elevated liver enzymes, low platelets (HELLP) syndrome

EXCLUSIONS: The Plan considers the use of genetic testing for hereditary thrombophilia for ANY of the following indications to be experimental, investigational or unproven and NOT COVERED:

- General population screening
- Routine initial testing in an individual with arterial thrombosis
- Routine screening of asymptomatic women during pregnancy or prior to the use of oral contraceptives, hormone replacement therapy (HRT), or selective estrogen receptor modulators
- Newborn testing, or routine testing in an asymptomatic child
- Prenatal or preimplantation testing

The Plan considers the use of genetic testing for Factor V and Factor II mutations for all other indications not listed above to be considered experimental, investigational or unproven and NOT COVERED.

The Plan considers the use of genetic testing for MTHFR for diagnosis or management of all indications, including but not limited to, inherited thrombophilia, infertility, recurrent pregnancy loss, coronary artery disease, vascular disease, congenital heart defects, hepatitis, stroke, Parkinson’s, peripheral neuropathy, cancer, migraine headache, Alzheimer’s disease, dementia, autism spectrum disorder, depression, or schizophrenia to be considered experimental, investigational or unproven and NOT COVERED.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Genetic Testing For Inherited Thrombophilia/ Hypercoagulability

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

81291 MTHFR (5,10-methylene tetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, common variants
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
81400 MOLECULAR PATHOLOGY PROCEDURE LEVEL 1
81401 MOLECULAR PATHOLOGY PROCEDURE LEVEL 2

ELIGIBILITY AND CONTRACT SPECIFIC BENEFITS, LIMITATIONS AND/OR EXCLUSIONS WILL APPLY. COVERAGE STATEMENTS FOUND IN THE LINE OF BUSINESS SPECIFIC BENEFIT DOCUMENT WILL SUPERSEDE THIS POLICY. FOR MEDICARE, APPLICABLE LCD’S AND NCD’S WILL SUPERSEDE THIS POLICY. FOR PA MEDICAID BUSINESS SEGMENT, THIS POLICY APPLIES AS WRITTEN.

REFERENCES:


LOCAL COVERAGE DETERMINATION (LCD): MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) (L36159)


AMERICAN COLLEGE OF MEDICAL GENETICS PRACTICE GUIDELINES: LACK OF EVIDENCE FOR MTHFR POLYMORPHISM TESTING. Scott E. Hickey, M.D., FACMG, Cynthia J. Curry, M.D., FACMG and Helga V. Toriello, PhD, FACMG, Genetics in Medicine 2013:15(2):153-156.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 6/20

Reviewed: