Medica Coverage Policy

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<th>Policy Name:</th>
<th>Methylenetetrahydrofolate Reductase (MTHFR) Gene Mutation Testing</th>
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<td>Effective Date:</td>
<td>8/21/2017</td>
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Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Methylenetetrahydrofolate reductase (MTHFR) gene mutation testing is investigative and unproven and therefore NOT COVERED. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description

MTHFR gene mutation testing is a genetic laboratory test performed on a blood sample to evaluate the presence or absence of a gene mutation involved in folic acid (i.e., vitamin B9) metabolism. Presence of MTHFR mutation variants have been suggested to be associated with increased risk of cardiovascular disease, thrombosis, stroke, hypertensive preeclampsia, neural tube birth defects, and toxicity to certain medications (e.g., methotrexate).

Two common MTHFR mutation variants tested are C677T and A1298C. Results are reported as ‘present’ or ‘absent’ for an MTHFR mutation. Mutation expression (i.e., homozygosity or heterozygosity) may also be reported.

FDA Approval

Genetic tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) Act of 1988. Premarket approval from the FDA is not required as long as the assay is performed in a laboratory facility that observes CLIA regulations and the test is not marketed for general distribution.

Many university-associated and private reference laboratories offer MTHFR gene mutation testing, including but not limited to:
1. ARUP Laboratories Molecular Genetics Laboratory (Salt Lake City UT)
2. BloodCenter of Wisconsin Hemostasis Reference Laboratory (Milwaukee WI)
3. Genzyme Genetics Molecular Diagnostic Laboratory (Westborough MA)
4. Laboratory Corporation of America (LabCorp) Molecular Biology Laboratory (Research Triangle Park NC)
5. Quest Diagnostics Molecular Genetics Laboratory (San Juan Capistrano CA; Chantilly VA)
6. University of Minnesota Physicians Outreach Laboratory (Minneapolis MN)
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Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:

81291 - MTHFR (5, 10-methylenetetrahydrofolate reductase) (e.g., hereditary hypercoagulability) gene analysis, common variants (e.g., 677T, 1298C)

Original Effective Date: 8/1/2011

Re-Review Date(s): 4/16/2014
6/21/2017
2/20/2020 – administrative update; format