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
Apolipoprotein E (APOE) genetic testing for prediction and management of cardiovascular disease 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.

Note: See also related Medica coverage policies, Lipoprotein Subclass Testing for Screening, Evaluation, and Monitoring of Cardiovascular Disease and Genetic Testing for Alzheimer Disease.

Description
APOE gene testing is a genetic laboratory test performed on a blood sample to evaluate the presence or absence of defects in the apolipoprotein E gene. The APOE gene provides instructions for the synthesis of the protein, apolipoprotein E, which combines with lipids within the body to form lipoproteins. APOE is a major component of very low-density lipoproteins, which remove excess cholesterol from the blood and transports cholesterol to the liver for processing. Variants of APOE have been studied in association with cardiovascular disease risk. APOE genetic testing has been proposed for use in predicting risk of cardiovascular disease (e.g., heart attack, stroke), hyperlipoproteinemia type III, and therapy response.

There are at least three alleles of the APOE gene, called e2, e3, and e4. The most common allele is e3, which is found in more than half of the U.S. population. Carriers of at least one copy of the APOE e4 allele have been purported to be at increased risk for development of atherosclerosis, which may lead to heart attack or stroke. The presence of the APOE e2 allele has been purported to increase the risk of hyperlipoproteinemia type III. This condition is characterized by increased blood levels of cholesterol, triglycerides, and beta-very low-density lipoproteins, which may lead to xanthoma skin lesions and atherosclerosis. It has also been suggested that response to statin therapy varies according the APOE genotype. It has been suggested that individuals with the APOE e2 allele show a greater responsiveness to statin therapy than individuals lacking the e2 allele.

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.
Laboratories in the United States that offer APOE testing for prediction and management of cardiovascular disease include, but are not limited to:
1. ARUP Laboratories (Salt Lake City, UT)
2. Athena Diagnostics (Worcester, MA)
3. Laboratory Corporation of America (LabCorp) (Burlington, NC)
4. Mayo Clinic (Rochester, MN)
5. Quest Diagnostics Laboratories (Madison, NJ)

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:
81401: Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)

Original Effective Date: 10/1/2011
Re-Review Date(s): 7/16/2014
8/16/2017
2/10/2020 – administrative update; format