Policy Name: Genetic Testing for Cardiac Channelopathies
Effective Date: 3/20/2019

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

Genetic testing for long QT syndrome (LQTS), catecholaminergic polymorphic ventricular tachycardia (CPVT), Brugada syndrome (BrS), and short QT syndrome (SQTS) is COVERED when the test results will directly impact the treatment of the member and/or at-risk blood relatives who have undergone genetic counseling.

Genetic testing for cardiac channelopathies is investigative and unproven and therefore NOT COVERED for all other indications. 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: This policy is no longer scheduled for routine review of the scientific literature.

Description

Cardiac arrhythmias are disturbances in the heart’s natural rhythm. These disturbances result from a disruption in the normal conduction of electrical signals within the heart. For various reasons, electrical signals may be detoured, slowed or blocked while traveling through certain parts of the heart. This can cause the heart’s natural rhythm to speed up or slow down, affecting the flow of blood to the body’s internal organs.

A number of cardiac arrhythmias result from heritable disorders. Single gene mutations may be directly responsible for a family of diseases called cardiac channelopathies. Cardiac channelopathies are rare genetic conditions that affect electrical activity within the heart by disrupting the flow of ions in and out of the cells of the heart. Examples of cardiac channelopathies, include but are not limited to, long QT syndrome (LQTS), Brugada syndrome (BrS), short QT syndrome (SQTS), and catecholaminergic polymorphic ventricular tachycardia (CPVT). Some people with these conditions remain asymptomatic. However, the disorders can produce an irregular heart rhythm that may result in fainting, seizures, and sudden death.

Scientists have identified hundreds of specific gene mutations associated with cardiac arrhythmias and multiple laboratories have developed in-house tests (i.e., homebrew tests) for detecting ion channel mutations. Common techniques used in these tests include, but are not limited to, polymerase chain reaction (PCR), denaturing high-performance liquid chromatography, and DNA sequencing.
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. The Familion® test (Transgenomic®, Inc., Omaha, NE) is an example of a genetic test for cardiac channelopathies. Transgenomic is a CLIA certified reference laboratory specializing in molecular diagnostics.

Prior Authorization
Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

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:
- 81413 - Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); genomic sequence analysis panel, must include sequencing of at least 10 genes, including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A
- 81414 - Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); duplication/deletion gene analysis panel, must include analysis of at least 2 genes, including KCNH2 and KCNQ1
- S3861 - Genetic testing, sodium channel, voltage-gated, type V, alpha subunit (SCN5A) and variants for suspected Brugada Syndrome
- 0237U - Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia), genomic sequence analysis panel including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions

Original Effective Date: 3/20/2019
Re-Review Date(s): 2/10/2020 – administrative update; format
1/1/2021 – administrative update; code update