Medica Coverage Policy

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<th>Genetic Testing for Cardiomyopathies</th>
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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

Genetic testing for (1) hypertrophic cardiomyopathy (HCM), (2) arrhythmogenic right ventricular cardiomyopathy (ARVC), (3) dilated cardiomyopathy (DCM), (4) left ventricular non-compaction (LVNC), and (5) restrictive cardiomyopathy (RCM) 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 cardiomyopathies is investigative and therefore NOT COVERED for all other indications. Reliable evidence does not permit conclusions concerning its effectiveness.

Note: This policy is no longer scheduled for routine review of the scientific literature.

Description

Cardiomyopathies are a group of diseases that cause the heart muscle to become abnormally enlarged, thickened, and/or stiffened, diminishing the heart’s ability to function and creating the potential for arrhythmias and sudden cardiac death. The wall thickness, chamber size, contraction, relaxation, conduction and rhythm of the heart may all be affected. Some people with these conditions remain asymptomatic. However, the disorders can produce an irregular heart rhythm that may result in dizziness, palpitations, fainting, seizures, and sudden death. The World Health Organization (WHO) currently recognizes four classes of cardiomyopathy: hypertrophic cardiomyopathy (HCM), arrhythmogenic right ventricular cardiomyopathy (ARVC), dilated cardiomyopathy (DCM), and restrictive cardiomyopathy (RCM). However, other rarer forms of cardiomyopathy have been identified as well. These cardiomyopathies may have overlapping features with any of the previous types described and include, but are not limited to, left ventricular non-compaction (LVNC) and mitochondrial cardiomyopathies.

Cardiomyopathies may be acquired or inherited. Scientists have identified numerous gene mutations associated with inherited cardiomyopathies and are researching or have developed multiple genetic tests to detect the gene mutations potentially associated with these disorders. Some examples of clinically available tests include, but are not limited to, the Familion® test (Transgenomic, Omaha, NE), the CardioChip test (Laboratory for Molecular Medicine, Cambridge, MA), the Cardiomyopathy Panel (Ambry Genetics, Aliso Viejo, CA) and the Hypertrophic Cardiomyopathy (HCM) Panel (Gene Dx, Gaithersburg, MD).
FDA Approval
Multiple laboratories have developed in-house tests for detecting genetic mutations causing cardiomyopathies. Currently, these homebrew tests are not subject to FDA premarket approval or 501(k) clearance. However, the laboratories providing the testing service are regulated under the Clinical Laboratory Improvement Act of 1988. All providers of commercial assays of genetic testing for the cardiomyopathies are CLIA certified.

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:
- S3865 - Comprehensive gene sequence analysis for hypertrophic cardiomyopathy
- S3866 - Genetic analysis for a specific gene mutation for hypertrophic cardiomyopathy (HCM) in an individual with a known HCM mutation in the family
- 81439 - Inherited cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy) genomic sequence analysis panel, must include sequencing of at least 5 genes, including DSG2, MYBPC3, MYH7, PKP2, and TTN

Original Effective Date: 3/20/2019
Re-Review Date(s):