Genetic Testing for Dilated Cardiomyopathy

Introduction

Dilated cardiomyopathy is a condition in which the left ventricle (the main pumping chamber of the heart) becomes enlarged and can no longer pump effectively. This can lead to heart failure, as well as cause an abnormal rhythm of the heart. It has been found that sometimes dilated cardiomyopathy seems to run in families, and in these cases it may be caused by a genetic problem. Doing genetic tests to see if a genetic problem has caused a person’s dilated cardiomyopathy is still investigational. Testing people who do not have any known heart problems to see if they are at risk for developing dilated cardiomyopathy is also investigational. Medical studies have not shown that this type of testing helps to manage the care of patients. For this reason, genetic testing for dilated cardiomyopathy is still considered to be unproven (investigational).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Testing

<table>
<thead>
<tr>
<th>Genetic testing for dilated cardiomyopathy</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genetic testing for dilated cardiomyopathy is considered investigational in all situations.</td>
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</table>

Coding

There are several listings of genetic tests performed for dilated cardiomyopathy in the CPT Tier 2 molecular pathology codes listed below.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</table>
| 81403 | Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)  
–Includes: PLN (phospholamban) (eg, dilated cardiomyopathy, hypertrophic cardiomyopathy), full gene sequence |
| 81405 | Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)  
–Includes: ANKRD1 (ankyrin repeat domain 1) (eg, dilated cardiomyopathy), full gene sequence; TPM1 (tropomyosin 1 [alpha]) (eg, familial hypertrophic cardiomyopathy), full gene sequence; TNNC1 (troponin C type 1 [slow]) (eg, hypertrophic cardiomyopathy or dilated cardiomyopathy), full gene sequence |
| 81406 | Molecular pathology procedure, Level 7 (eg, analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia)  
–Includes: LDB3 (LIM domain binding 3) (eg, familial dilated cardiomyopathy, myofibrillar myopathy), full gene sequence; LMNA (lamin A/C) (eg, Emery-Dreifuss muscular dystrophy; [EDMD1, 2 and 3] limb-girdle muscular dystrophy; [LGMD] type 1B, dilated cardiomyopathy; [CMD1A], familial partial lipodystrophy; [FPLD2]), full gene sequence; TNNT2 (troponin T, type 2 [cardiac]) (eg, familial hypertrophic cardiomyopathy), full gene sequence |
<p>| 81407 | Molecular pathology procedure, Level 8 (eg, analysis of 26-50 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of &gt;50 exons, sequence |</p>
<table>
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<th>Code</th>
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<tr>
<td></td>
<td>analysis of multiple genes on one platform)</td>
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<tr>
<td></td>
<td>–Includes: MYH6 (myosin, heavy chain 6, cardiac muscle, alpha) (eg, familial dilated cardiomyopathy), full gene sequence; MYH7 (myosin, heavy chain 7, cardiac muscle, beta) (eg, familial hypertrophic cardiomyopathy, Liang distal myopathy), full gene sequence; SCN5A (sodium channel, voltage-gated, type V, alpha subunit) (eg, familial dilated cardiomyopathy), full gene sequence</td>
</tr>
<tr>
<td>81439</td>
<td>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</td>
</tr>
</tbody>
</table>

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If a genetic sequencing panel (GSP) is performed that does not meet the criteria in code 81439, the relevant tier 2 codes above would be reported for the specific genes tested, and the unlisted molecular pathology code would be reported 1 time for the remaining genes in the panel that lack a specific CPT.

**Related Information**

**Genetic Counseling**

Genetic counseling is primarily aimed at patients who are at risk for inherited disorders, and experts recommend formal genetic counseling in most cases when genetic testing for an inherited condition is considered. The interpretation of the results of genetic tests and the understanding of risk factors can be very difficult and complex. Therefore, genetic counseling will assist individuals in understanding the possible benefits and harms of genetic testing, including the possible impact of the information on the individual's family. Genetic counseling may alter the utilization of genetic testing substantially and may reduce inappropriate testing. Genetic counseling should be performed by an individual with experience and expertise in genetic medicine and genetic testing methods.

**Evidence Review**
Description

Dilated cardiomyopathy (DCM) is characterized by progressive left ventricular enlargement and systolic dysfunction, leading to clinical manifestations of heart failure. There are a variety of causes of DCM, including genetic and nongenetic conditions. Genetic forms of DCM are heterogeneous in their molecular basis and clinical expression. Genetic testing for DCM has potential utility in confirming a diagnosis of genetic DCM, and as a predictive test in family members when familial DCM is present.

Dilated Cardiomyopathy

Dilated cardiomyopathy (DCM) is defined as the presence of left ventricular enlargement and dilatation in conjunction with significant systolic dysfunction. DCM has an estimated prevalence of 1 in 2700 in the United States. The age of onset for DCM is variable, ranging from infancy to the eighth decade, with most individuals developing symptoms in the fourth through sixth decades.

Primary clinical manifestations of DCM are heart failure and arrhythmias. Symptoms of heart failure, such as dyspnea on exertion and peripheral edema, are the most common presentation of DCM. These symptoms are generally gradual in onset and slowly progressive over time. Progressive myocardial dysfunction also may lead to electrical instability and arrhythmias. Symptoms of arrhythmias may include light-headedness, syncope, or sudden cardiac arrest.

Many underlying conditions can cause DCM, including:

- Ischemic coronary artery disease
- Toxins
- Metabolic conditions
- Endocrine disorders
- Inflammatory and infectious diseases
- Infiltrative disorders
- Tachycardia-mediated cardiomyopathy
Therefore, when a patient presents with DCM, a workup is performed to identify underlying causes, especially those treatable. The standard workup consists of clinical exam, blood pressure monitoring, electrocardiography (ECG), echocardiography, and workup for coronary artery disease as warranted by risk factors. In many cases, a definite underlying cause is not identified. Extensive workup including cardiac magnetic resonance imaging, exercise testing, right-sided catheterization with biopsy, and 24-hour ECG monitoring will uncover only a small number of additional etiologies for DCM. Approximately 35% to 40% of DCM cases are thus determined to be idiopathic after a negative workup for secondary causes. This has traditionally been termed idiopathic dilated cardiomyopathy (IDC).

Clustering of IDC within families has been reported, leading to the conclusion that at least some cases of DCM have a genetic basis. Familial DCM is diagnosed when 2 closely related family members have IDC in the absence of underlying causes. Penetrance of familial DCM is variable and age-dependent, often leading to lack of appreciation of the familial component.

Treatment of DCM is similar to that for other causes of heart failure. This includes medications to reduce fluid overload and relieve strain on the heart, and lifestyle modifications such as salt restriction. Patients with clinically significant arrhythmias also may be treated with antiarrhythmic medications, pacemaker implantation, and/or an automatic implantable cardiac defibrillator (AICD). AICD placement for primary prevention also may be performed if criteria for low ejection fraction and/or other clinical symptoms are present. End-stage DCM can be treated with cardiac transplantation.

**Genetic DCM**

Genetic DCM has been proposed as a newer classification that includes both familial DCM and some cases of sporadic IDC. The percentage of patients with sporadic DCM that has a genetic basis is not well characterized. Most pathologic variants are inherited in an autosomal dominant fashion, but some autosomal recessive, X-linked, and mitochondrial patterns of inheritance may be present.

In general, genotype-phenotype correlations are either not present or not well-characterized. There have been some purported correlations between certain disease-associated variants and the presence of arrhythmias. For example, patients with conduction system disease and/or a family history of sudden cardiac death may be more likely to have disease-associated variants in the LMNA, SCN5A, and DES genes. Kayvanpour et al (2017) performed a meta-analysis of genotype-phenotype associations in DCM. The analysis included 48 studies (total N=8097 patients) and found a higher prevalence of sudden cardiac death, cardiac transplantation, and
ventricular arrhythmias in LMNA and PLN disease-associated variant carriers and increasing penetrance with age of DCM phenotype in subjects with TTN-truncating variants.

There may be interactions between genetic and environmental factors that lead to the clinical manifestations of DCM. A genetic variant alone may not be sufficient to cause DCM, but may influence (predispose) the development of DCM in the presence of environmental factors. Some interactive factors include nutritional deficiencies or viral infections. It also has been suggested that DCM genetics may be more complex than simply single-gene variants, with low-penetrance variants that are common in the population contributing to a cumulative risk of DCM that includes both genetic and environmental factors.

**Genetic Testing for DCM**

Approximately 30% to 40% of patients referred for genetic testing will have a disease-associated variant identified. Disease-associated variants linked to DCM have been identified in more than 40 genes of various types and locations. The most common genes involved are those that code for titin (TTN), myosin heavy chain (MYH7), troponin T (TNNT2), and alpha-tropomyosin (TPM1). These 4 genes account for approximately 30% of disease-associated variants identified in cohorts of patients with DCM. A high proportion of the identified disease-associated variants are rare or novel variants. This rarity creates challenges in assigning the pathogenicity of discovered variants. Some individuals with DCM will have more than 1 DCM-associated variant. The frequency of multiple disease-associated variants is uncertain, as is the clinical significance.

**Summary of Evidence**

For individuals who have signs and/or symptoms of dilated cardiomyopathy (DCM) who receive comprehensive genetic testing, the evidence includes case series reporting analytic and clinical validity. Relevant outcomes are overall survival, change in disease status, test accuracy and validity, symptoms, functional outcomes, quality of life, and treatment-related morbidity. The analytic validity of genetic testing for DCM is expected to be high when testing is performed by direct sequencing or next-generation sequencing. In contrast, there is a large degree of uncertainty with clinical validity. The percentage of patients with idiopathic DCM who have a genetic variant (clinical sensitivity) is relatively low, in the range of 10% to 50%. Clinical specificity of DCM-associated variants is unknown, but DCM-associated variants in the same genes have been reported in 1% to 3% of patients without DCM. Because of the suboptimal clinical validity, the accuracy of assigning variants as disease-associated or benign may also be
The clinical utility of genetic testing for diagnosing DCM has not been demonstrated. For a patient who is diagnosed with idiopathic DCM, the presence of a DCM-associated variant will not change treatment or prognosis. The evidence is insufficient to determine the effect of the technology on health outcomes.

For individuals who are asymptomatic with a first-degree relative who has DCM and a known familial variant who receive targeted genetic testing for a known familial variant, the evidence includes case series reporting analytic and clinical validity. Relevant outcomes are test accuracy and validity, symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. For an individual at risk due to genetic DCM in the family, genetic testing can identify whether a familial variant has been inherited. However, it is uncertain how knowledge of a familial variant improves outcomes for an asymptomatic individual. The uncertain clinical validity of predictive testing makes it unclear whether actions taken as a result of testing will improve outcomes. Early treatment based on a genetic diagnosis is unproven. The evidence is insufficient to determine the effect of the technology on health outcomes.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed below.

### Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT02148926</td>
<td>Clinical and Genetic Examinations of Dilated Cardiomyopathy</td>
<td>480</td>
<td>Mar 2017</td>
</tr>
<tr>
<td>NCT01736566</td>
<td>The MedSeq Project Pilot Study: Integrating Whole Genome Sequencing Into the Practice of Clinical Medicine</td>
<td>220</td>
<td>Aug 2017</td>
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<tr>
<td>NCT01857856</td>
<td>PHOospholamban RElated CARdiomyopathy STudy - Intervention (Efficacy Study of Eplerenone in Presymptomatic PLN-R14del Carriers)</td>
<td>150</td>
<td>Apr 2020</td>
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<tr>
<td><strong>Unpublished</strong></td>
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<td></td>
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<tr>
<td>NCT02057341*</td>
<td>A Study of ARRY-371797 in Patients With LMNA-Related Dilated Cardiomyopathy</td>
<td>12</td>
<td>May 2016 (completed)</td>
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<tr>
<td>NCT01583114</td>
<td>Preventive Effect of ACE Inhibitor Perindopril on the Onset</td>
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<td>Dec 2017</td>
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<td>NCT No.</td>
<td>Trial Name</td>
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<td></td>
<td>or Progression of Left Ventricular Dysfunction in Subjects at a Preclinical Stage From Families With Dilated Cardiomyopathy&lt;sup&gt;44&lt;/sup&gt;</td>
<td></td>
<td>(terminated)</td>
</tr>
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</table>

NCT: national clinical trial.
<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

**Heart Rhythm Society and European Hearth Rhythm Association**

The Heart Rhythm Society and European Hearth Rhythm Association issued joint guidelines in 2011 on genetic testing for cardiac channelopathies and cardiomyopathies.<sup>38</sup> These guidelines contained the following recommendations on genetic testing for DCM:

**Class I recommendations**

- Comprehensive or targeted (LMNA and SCN5A) DCM genetic testing is recommended for patients with DCM and significant cardiac conduction disease (ie, first-, second-, or third-degree heart block) and/or with a family history of premature unexpected sudden death.

- Mutation-specific testing is recommended for family members and appropriate relatives following the identification of a DCM-causative mutation [variant] in the index case.

**Class IIa recommendations**

- Genetic testing can be useful for patients with familial DCM to confirm the diagnosis, to recognize those who are at highest risk of arrhythmia and syndromic features, to facilitate cascade screening within the family, and to help with family planning.

**Heart Failure Society of America**

The Heart Failure Society of America published a practice guideline in 2009 on the Genetic Evaluation of Cardiomyopathy.<sup>37</sup> The following recommendations for genetic testing for cardiomyopathy (including DCM) were made:
• Evaluation, genetic counseling, and genetic testing of cardiomyopathy patients are complex processes. Referral to centers expert in genetic evaluation and family-based management should be considered (Level of Evidence B).

• Genetic testing should be considered for the one most clearly affected person in a family to facilitate screening and management.

• Genetic and family counseling is recommended for all patients and families with cardiomyopathy (Level of Evidence A).

U.S. Preventive Services Task Force Recommendations

No U.S. Preventive Services Task Force recommendations for cardiomyopathy have been identified.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Regulatory Status

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests (LDTs) must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). No genotyping tests were identified. Laboratories that offer LDTs must be licensed by CLIA for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

References


37. Ackerman MJ, Priori SG, Wilkens S, et al. HRS/EHRA expert consensus statement on the state of genetic testing for the channelopathies and cardiomyopathies this document was developed as a partnership between the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA). Heart Rhythm. Aug 2011;8(8):1308-1339. PMID 21787999


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tr>
<td>03/10/14</td>
<td>New Policy. New policy developed with literature review through December 15, 2013. Genetic testing for dilated cardiomyopathy is considered investigational for all indications.</td>
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<td>07/24/14</td>
<td>Update Related Policies. Remove 12.04.91.</td>
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<td>03/10/15</td>
<td>Annual Review. Policy updated with literature review through December 23, 2014; references 5, 18-19, and 21-25 added. Policy statement unchanged.</td>
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<tr>
<td>04/01/16</td>
<td>Annual Review, approved March 8, 2016. Policy updated with literature review through November 17, 2015; reference 1 updated; references 4 and 24 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Coding update; added new CPT code 81439 effective 1/1/17.</td>
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<tr>
<td>05/01/17</td>
<td>Annual review, approved April 11, 2017. Policy updated with literature review through December 21, 2016; references 6-10, 18-21, 26-27, and 39-43 added. The policy is revised with updated genetics nomenclature – mutation changed to variant when applicable. Policy statement unchanged.</td>
</tr>
<tr>
<td>09/22/17</td>
<td>Policy moved to new format, no changes to policy statement.</td>
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</table>

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ประกาศนี้มีข้อมูลสําคัญต่อคุณ ประกาศนี้อาจมีวันที่สำคัญในกรณีที่คุณต้องการติดต่อเพื่อความช่วยเหลือหรือเพื่อมaintain your health coverage หรือ เพื่อการแจ้งการขอใช้สิทธิ์การประกันสุขภาพของคุณ หรือการบริการที่คุณต้องการที่มีมูลค่า เข้าสู่สิทธิ์คุณ ถึงแม้จะต้องใช้ในสถานการณ์ที่คุณต้องเสียชีวิต หรือ 800-722-1471 (TTY: 800-842-5357).

Український (Ukrainian):
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Tiếng Việt (Vietnamese):