LETTER OF MEDICAL NECESSITY

**DILATED CARDIOMYOPATHY GENETIC TESTING**

Date: Date of Service/claim

To: Utilization Review Department

Insurance Company Name, Address, City, State

Re: Patient Name, DOB, ID #

ICD-10 Codes:

The ICD-10 codes listed below are commonly received by Ambry from ordering providers for the testing described in this letter. Ambry provides this information as a customer service but makes no recommendations regarding the use of any diagnosis codes. As a reminder, it is the ordering provider’s responsibility to always determine, for the specific date of service, the appropriate diagnostic codes based on the patient’s signs and symptoms.

Code Description

I42.0 DILATED CARDIOMYOPATHY

I42.8 OTHER CARDIOMYOPATHIES

I50.22 CHRONIC SYSTOLIC (CONGESTIVE) HEART FAILURE

I50.9 HEART FAILURE, UNSPECIFIED

Z13.6 ENCOUNTER FOR SCREENING FOR CARDIOVASCULAR DISORDERS

Z82.49 FAMILY HISTORY OF ISCHEMIC HEART DISEASE AND OTHER DISEASES OF THE CIRCULATORY SYSTEM

Z84.81 FAMILY HISTORY OF CARRIER OF GENETIC DISEASE

E78.2 MIXED HYPERLIPIDEMIA

I25.10 ATHEROSCLEROTIC HEART DISEASE OF NATIVE CORONARY ARTERY WITHOUT ANGINA PECTORIS

This letter is regarding my patient and your subscriber, referenced above, to request full coverage of medically indicated genetic testing for dilated cardiomyopathy to be performed by Ambry Genetics Corporation.

Dilated cardiomyopathy (DCM) is characterized by left ventricular enlargement and systolic dysfunction (reduced ejection fractions).  Individuals with DCM can experience symptoms of fatigue; however, many individuals are asymptomatic for years.   Individuals with DCM develop arrhythmias, cardiac conduction disease, and progression to congestive heart failure (which may require a heart transplant).1,2

A genetic etiology of DCM is established in up to one-half of cases and is associated with mutations in a broad number of genes. 3,7 **Significant aspects of my patient’s personal and/or family medical history that suggest hereditary DCM are below:** [check all that apply]

* Cardiac conduction disease (first-, second- or third-degree block)
* Idiopathic dilated cardiomyopathy
* Patient is a candidate for an implantable or wearable cardioverter defibrillator
* Close relative with idiopathic dilated cardiomyopathy
* Close relative with sudden cardiac death at age 50 or younger
* Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Based on their personal and/or family history above, my patient meets the **Heart Failure Society of America/American College of Medical Genetics and Genomics’ (HFSA/ACMG) and/or the Heart Rhythm Society’s (HRS) published guidelines for genetic testing**. 4,5,6

Identification of a mutation through genetic testing confirms a diagnosis of DCM or a predisposition to DCM.  Genetic testing also informs prognosis, screening and treatment options, efforts to prevent complications (such as earlier ICD or pacemaker implantation), and genetic counseling, all of which can vary depending on the specific gene implicated in the disease.2,3,4,7,8 Specifically for this patient, the impact of testing may include: [check all that apply]

* Genetic testing could allow immediate management and treatment to anticipate and control common clinical findings based on the results of the testing
* Genetic testing could assist in long-term management and monitoring of suspected disease progression based on the results of the testing
* Genetic testing could lead to changes in diagnostic procedures such that more potentially invasive alternative procedures could be avoided, reducing unnecessary tests and cost
* Genetic testing could lead to informed decisions for other family members with similar conditions, or that may be at risk for similar conditions
* Genetic testing could alleviate the need for long-term clinical surveillance in individuals who test negative for any disease-causing variants found in my patient
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* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Due to the risks associated with these mutations and the interventions available to reduce these risks, **I am requesting coverage for this testing as medically necessary care and affirm that my patient has provided informed consent for genetic testing.** I recommend that you support this request for coverage of genetic testing for DCM in my patient.

Thank you for your time and please don’t hesitate to contact me with any questions.

Sincerely,

Ordering Clinician Name (Signature Provided on Test Requisition Form)

(MD/DO, Clinical Nurse Specialist, Nurse-Midwives, Nurse Practitioner, Physician Assistant, Genetic Counselor\*)

\*Authorized clinician requirements vary by state

**Test Details**

Test Name:  DCMNext

CPT codes: 81439

Laboratory: Ambry Genetics Corporation (TIN 33-0892453 / NPI 1861568784), a CAP-accredited and CLIA-certified laboratory located at 7 Argonaut, Aliso Viejo, CA 92656

**References**

1. Hershberger RE, et al. Genetic evaluation of cardiomyopathy – a Heart Failure Society of America practice guideline.  [J Card Fail.](https://www.ncbi.nlm.nih.gov/pubmed/?term=29567486) 2018 May;24(5):281-302.
2. Ackerman MJ, 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.](https://www.ncbi.nlm.nih.gov/pubmed/?term=21787999) 2011 Aug;8(8):1308-39.
3. Hershberger RE, et al. Dilated cardiomyopathy: the complexity of a diverse genetic architecture. [Nat Rev Cardiol.](https://www.ncbi.nlm.nih.gov/pubmed/?term=Nature+Reviews+Cardiology+volume+10%2C+pages+531%E2%80%93547+(2013)) 2013 Sep;10(9):531-47.
4. Heidenreich PA, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022;145:e895–e1032.
5. Musunuru K, et al. Genetic Testing for Inherited Cardiovascular Diseases: Scientific Statement from the American Heart Association. Circulation. 2020;13(4):
6. Hershberger RE, et al. ACMG Professional Practice and Guidelines Committee. Genetic evaluation of cardiomyopathy: a clinical practice resource of the American College of Medical Genetics and Genomics (ACMG). Genet Med. 2018;20:899-909.
7. Wilde AAM, et al. European Heart Rhythm Association (EHRA)/Heart Rhythm Society (HRS)/Asia Pacific Heart Rhythm Society (APHRS)/Latin American Heart Rhythm Society (LAHRS) Expert Consensus Statement on the state of genetic testing for cardiac diseases [published correction appears in Europace. 2022 Aug 30;:]. Europace. 2022;24(8):1307-1367. Doi:10.1093/europace/euac030