**LETTER OF MEDICAL NECESSITY**

**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

I42.2 OTHER HYPERTROPHIC CARDIOMYOPATHY

I42.8 OTHER CARDIOMYOPATHIES

I42.9 CARDIOMYOPATHY, UNSPECIFIED

I50.42 CHRONIC COMBINED SYSTOLIC (CONGESTIVE) & DIASTOLIC (CONGESTIVE) HEART FAILURE

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

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

Hereditary cardiomyopathies are a group of disorders (including arrhythmogenic right ventricular, dilated, and hypertrophic cardiomyopathies) that can present as arrythmias, cardiac conduction disease, congestive heart failure, fatigue, syncope and/or tachycardia.1,2,3 **However, some individuals present with sudden cardiac death with no prior symptoms**. Given the clinical and genetic overlap between the different cardiomyopathies,3,4,5 a single comprehensive inherited cardiomyopathy test can be the most effective means of identifying at-risk individuals or confirming a diagnosis.

Hereditary cardiomyopathies are caused by mutations in a large number of different genes.  **Significant aspects of my patient’s personal and/or family medical history that suggest inherited CM are below:** [check all that apply]

* Personal or family history of sudden or unexplained death, especially under 40 yo
* Personal or family history of CM, heart failure, cardiac transplantation, cardiac conduction system disease or arrhythmia, unexplained stroke or other thromboembolic disease, syncope, and/or exercise fatigue
* Personal or family history of idiopathic dilated cardiomyopathy
* Cardiac conduction disease
* Patient is a candidate for an implantable or wearable cardioverter defibrillator
* Echocardiogram demonstrating LVH without obvious cause
* Left ventricular wall thickening
* Clinical suspicion for ventricular arrhythmia based on ECG, stress test, or Holter monitor results
* Personal or family history of palpitations, syncope, stress and/or exercise intolerance
* Clinical suspicion for ARVC based on structural cardiac abnormalities
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**The American College of Cardiology (ACC), the American College of Genetics and Genomics (ACMG), the American Heart Association (AHA)** **and the** **Heart Failure Society of America (HFSA), the Heart Rhythm Society (HRS) have all recognized the clinical utility of genetic testing for hereditary cardiomyopathy and support it as standard of care**. 1,3,4,5,7,9,11

Identification of a mutation through genetic testing confirms a diagnosis of hereditary CM or a predisposition to hereditary CM.  Genetic testing also informs risk stratification, prognosis, screening and treatment options, prevention efforts and genetic counseling, which can vary depending on the specific gene implicated in the disease.Specifically for this patient, the impact of testing may include1,6,7,8,9,10,11 : [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 inform lifestyle modifications for the patient
* Genetic testing could assist in long-term management and monitoring of suspected disease progression based on the results of the testing
* Genetic testing will lead to changes in diagnostic procedures such that more potentially invasive alternative procedures could be avoided, reducing unnecessary tests and cost
* Genetic testing will 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
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Based on the screening, lifestyle, and treatment modifications indicated above, this test has clinical utility for my patient. Due to the **risk of sudden cardiac death** 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 hereditary cardiomyopathy 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: CMNext

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. Gersh BJ, et al. 2011 ACCF/AHA guideline for the diagnosis and treatment of hypertrophic cardiomyopathy: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. [J Thorac Cardiovasc Surg.](https://www.ncbi.nlm.nih.gov/pubmed/?term=22093712) 2011 Dec;142(6):1303-38.
2. 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.
3. 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.
4. 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;20:899-909Hershberger 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.
5. Musunuru K, et al. Genetic Testing for Inherited Cardiovascular Diseases: A Scientific Statement From the American Heart Association. Circ Genom Precis Med*.* 2020 Aug;13(4):e000067.
6. Al-Khatib SM, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2018;72:e91–e220.
7. Priori SG, et al. HRS/EHRA/APHRS expert consensus statement on the diagnosis and management of patients with inherited primary arrhythmia syndromes. Heart Rhythm. 2013a;10:1932–63.
8. 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.
9. Ommen SR, et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy. A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation 2020;145:e558-e631.
10. Ho CY, Day SM, Ashley EA, et al. Genotype and Lifetime Burden of Disease in Hypertrophic Cardiomyopathy: Insights from the Sarcomeric Human Cardiomyopathy Registry (SHaRe). Circulation. 2018;138(14):1387-1398. doi:10.1161/CIRCULATIONAHA.117.033200
11. Wilde AAM, et al. EHRA/HRS/APHRS/LAHRS expert consensus statement on the state of genetic testing for cardiac diseases. Heart Rhythm. 2022 Jul;19(7):e1-e60.