**LETTER OF MEDICAL NECESSITY**

**HYPERTROPHIC 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

I42.2 OTHER HYPERTROPHIC CARDIOMYOPATHY

I42.1 OBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY

I47.20 VENTRICULAR TACHYCARDIA, UNSPECIFIED

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

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

Z95.810 PRESENCE OF AUTOMATIC (IMPLANTABLE) CARDIAC DEFIBRILLATOR

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

Hypertrophic cardiomyopathy (HCM) occurs at a prevalence of 1 in 500 and is characterized by changes in the structure of the heart including thickening of the left ventricular wall (LVH).   Individuals with HCM can experience symptoms of exercise fatigue and syncope; however, some individuals present with sudden cardiac death with no prior symptoms.  Some individuals with HCM develop arrhythmias and congestive heart failure (which may require a heart transplant).1

The genetic etiology of HCM is established and is most often associated with mutations in sarcomeric genes.  **Significant aspects of my patient’s personal and/or family medical history that suggest inherited HCM are below:** [check all that apply]

* HCM known family mutation in 1st or 2nd degree biologic relative
* Personal or family history of sudden or unexplained death, especially in individuals under 40 yo
* Personal or family history of HCM, heart failure, cardiac transplantation, cardiac conduction system disease or arrhythmia, unexplained stroke or other thromboembolic disease, syncope, and/or exercise fatigue
* Echocardiogram demonstrating LVH without obvious cause
* LVH with a maximum wall thickness of > 15mm (1.5cm) in adults, or > 2 standard deviations for age in children
* Left ventricular wall thickness of > 13mm with a family history of HCM
* Presence of the following pathognomonic histopathologic features of HCM:
  + Myocyte disarray
  + Hypertrophy
  + Increased myocardial fibrosis
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**The American College of Cardiology (ACC), the American Heart Association (AHA),** **the** **Heart Failure Society of America (HFSA), and the Heart Rhythm Society (HRS) have all recognized the clinical utility of genetic testing for hypertrophic cardiomyopathy and support it as standard of care**. 1,2,3,,5

Identification of a mutation through genetic testing confirms a diagnosis of HCM or a predisposition to HCM.  Genetic testing also informs prognosis, risk stratification, screening and treatment options, prevention efforts and genetic counseling, which can vary depending on the specific gene implicated in the disease.2,6 Specifically for this patient, the impact of testing may include2,3,4: [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 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 HCM 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:  HCMNext

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. 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.
3. 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.
4. 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.
5. 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.
6. 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