**LETTER OF MEDICAL NECESSITY FOR GENETIC TESTING FOR**    
**INHERITED CARDIOVASCULAR CONDITIONS (CardioNext, CustomNext-*Cardio*)**

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

I42.9 CARDIOMYOPATHY, UNSPECIFIED

I47.2 VENTRICULAR TACHYCARDIA

I50.22 CHRONIC SYSTOLIC (CONGESTIVE) HEART FAILURE

Z82.41 FAMILY HISTORY OF SUDDEN CARDIAC DEATH

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

Z84.81 FAMILY HISTORY OF CARRIER OF GENETIC DISEASE

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

CardioNext and CustomNext-*Cardio* analyze genes associated with hereditary cardiovascular conditions. These conditions may present with fatigue, syncope, stress and/or exercise intolerance, seizures, ECG abnormalities, arrythmias, palpitations, and/or congestive heart failure.1,3,5 However, **they are often asymptomatic and can result in sudden cardiac death.**3,10Given the clinical and genetic overlap between cardiovascular conditions, a single comprehensive test can be the most effective means of identifying at-risk individuals or confirming a diagnosis.

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

* Clinical suspicion for a hereditary cardiovascular condition based on echocardiogram, stress test, or Holter monitor results
* Clinical suspicion for a hereditary cardiovascular condition based on an identified structural cardiac abnormality
* Patient is a candidate for an implantable or wearable cardioverter defibrillator
* Personal and/or family history of palpitations, syncope, fatigue, seizures, stress and/or exercise intolerance
* Personal and/or family history of cardiomyopathy, heart failure, cardiac transplantation, cardiac conduction system disease or arrhythmia, unexplained stroke or other thromboembolic disease
* Personal and/or family history of sudden cardiac death or near sudden death
* 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**.1,3,4,5,7,9,12,13

Identification of a mutation through genetic testing confirms a diagnosis of a hereditary cardiovascular condition or a predisposition to a hereditary cardiovascular condition. Genetic testing also informs 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 include6-14 : [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 risk stratification, 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 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 a hereditary cardiovascular conditions 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: CardioNext/CustomNext-*Cardio*

CPT codes: 81413, 81414

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. Schwartz PJ, et al. Impact of genetics on the clinical management of channelopathies. J Am Coll Cardiol. 2013;62:169-180.
11. Schwartz PJ and Ackerman MJ. The long QT syndrome: a transatlantic clinical approach to diagnosis and therapy. Eur Heart J. 2013;34:3109-3116.
12. Towbin J, et al. 2019 HRS expert consensus statement on evaluation, risk stratification, and management of arrhythmogenic cardiomyopathy. Heart Rhythm. 2019;16(11):e301-e372.
13. 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.
14. Giudicessi JR and Ackerman MJ. Genotype- and phenotype-guided management of congenital long QT syndrome. Curr Probl Cardiol. 2013;38:417-455.