**LETTER OF MEDICAL NECESSITY FOR FAMILIAL HYPERCHOLESTEROLEMIA**
**GENETIC TESTING (FHNext)**

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

E78.00 PURE HYPERCHOLESTEROLEMIA, UNSPECIFIED

E78.01 FAMILIAL HYPERCHOLESTEROLEMIA

E78.2 MIXED HYPERLIPIDEMIA

E78.5 HYPERLIPIDEMIA, UNSPECIFIED

Z83.438 FAMILY HISTORY OF OTHER DISORDER OF LIPOPROTEIN METABOLISM AND OTHER LIPIDEMIA

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

Z83.42 FAMILY HISTORY OF FAMILIAL HYPERCHOLESTEROLEMIA

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

Familial hypercholesterolemia (FH) is a hereditary disorder characterized by high cholesterol and an increased risk for coronary artery disease1,4,5,6. FHNext analyzes genes associated with familial hypercholesterolemia. Diagnostic criteria for FH include extreme hypercholesterolemia, premature coronary heart, cerebral, or peripheral vascular disease, tendon xanthomas, corneal arcus; a family history of high cholesterol, heart disease, and/or tendon xanthomas; and a positive genetic test result9. While FH is common, it is under diagnosed; a **significant proportion of affected individuals are missed despite widespread cholesterol screening programs**.1,6,7 Genetic testing is effective in facilitating the diagnosis of FH.1,4,8 The genetic etiology of FH is established and involves genes associated with lipid metabolism. 3

**Significant aspects of my patient’s personal and/or family medical history that suggest familial hypercholesterolemia are below4,5:** [check all that apply]

* Persistent LDL-C levels (>190 mg/dL in adults or >160 mg/dL in children)
* Personal history of premature (age 55 or earlier in males, age 65 or earlier in females) coronary artery disease
* A first degree relative with elevated cholesterol or premature coronary artery disease
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**The FH Foundation and National Lipid Association have recognized the clinical utility of genetic testing for FH and support it as standard of care.** 2,4

Identification of a mutation in one of these genes through genetic testing can confirm a diagnosis of FH.4,5,6,8,9 In many patients genetic testing is essential to diagnosing the disease, as LDL screening is insufficient for elucidating all cases.4 Genetic testing also informs prognosis, patient risk stratification, screening and treatment options (such as high dose statin cocktails or PCSK9 inhibitors), and genetic counseling, which can vary depending on the specific gene implicated in the disease. Timely diagnosis can lead to early initiation of lipid-lowering therapies and the identification of at-risk relatives, thereby reducing morbidity and mortality.2,4,6,7 Specifically for this patient, the impact of testing may include2,4,5: [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 could lead to informed decisions for other family members with similar conditions, or that may be at risk for similar conditions
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Based on the screening and treatment modifications indicated above, this test has clear clinical utility for my patient.** Due to the **risk of early-onset coronary artery disease** 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 diagnostic genetic testing for FHNext for 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: FHNext

CPT codes: 81328, 81405, 81406, 81497, 81479

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. Abdul-Husn N, et al. Genetic identification of familial hypercholesterolemia within a single U.S. health care system. [Science.](https://www.ncbi.nlm.nih.gov/pubmed/?term=Abul-Husn+FH) 2016 Dec 23;354(6319).
2. Watts GF, et al. Integrated guidance on the care of familial hypercholesterolaemia from the International FH Foundation. [Int J Cardiol.](https://www.ncbi.nlm.nih.gov/pubmed/24418289) 2014 Feb 15;171(3):309-25.
3. Paththinige CS, et al. Genetic determinants of inherited susceptibility to hypercholesterolemia- a comprehensive literature review. [Lipids Health Dis.](https://www.ncbi.nlm.nih.gov/pubmed/?term=28577571) 2017 Jun 2;16(1):103.
4. Sturm AC, et al. Convened by the Familial Hypercholesterolemia Foundation. Clinical Genetic Testing for Familial Hypercholesterolemia: JACC Scientific Expert Panel. [J Am Coll Cardiol.](https://www.ncbi.nlm.nih.gov/pubmed/?term=30071997) 2018 Aug 7;72(6):662-680.
5. Musunuru K, et al. Genetic Testing for Inherited Cardiovascular Diseases: Scientific Statement From the American Heart Association. Circulation. 2020 Aug;13(4):e000067.
6. Khera AV, et al. Diagnostic Yield and Clinical Utility of Sequencing Familial Hypercholesterolemia Genes in Patients With Severe Hypercholesterolemia. J Am Coll Cardiol. 2016;67(22):2578-2589.
7. Nordestgaard BG, et al. Familial hypercholesterolaemia is underdiagnosed and undertreated in the general population: guidance for clinicians to prevent coronary heart disease: consensus statement of the European Atherosclerosis Society [published correction appears in Eur Heart J. 2020 Dec 14;41(47):4517]. *Eur Heart J*. 2013;34(45):3478-90a.
8. Brown EE, et al. Genetic testing in dyslipidemia: A scientific statement from the National Lipid Association. *J Clin Lipidol*. 2020;14(4):398-413.
9. Austin MA, et al. Genetic causes of monogenic heterozygous familial hypercholesterolemia: a HuGE prevalence review. Am J Epidemiol 2004. Sep;160(5):407-420.