**Letter of Medical Necessity for the Hypertrophic Cardiomyopathy (HCM) Panel**

**Patient Information**

**Date:**

**Patient Name:**

**Patient DOB:**

**Insurance Company Name, Address, City, State:**

**Policy Number:**

**Group Number:**

**ICD10 Codes:**

**Test Information**

**Test Name:** Hypertrophic Cardiomyopathy Panel

**CPT Codes:** 81405x1, 81406x1, 81407x2

**Laboratory:**

GeneDx, Inc.

(NPI#1487632998 / TAXID#205446298 / CLIA#21D0969951)

207 Perry Parkway

Gaithersburg, MD 20877

Telephone: (301) 519-2100

Fax: (201) 421-2010

This letter is in regards to my patient, [FIRST NAME LAST NAME], to request full coverage for the Hypertrophic Cardiomyopathy Panel to be performed by GeneDx. It is my professional determination that testing is medically necessary and will have a direct impact on this patient’s treatment and management.

**Patient Clinical and Family History**

This testing is requested due to this patient’s personal medical history, which includes the following clinical findings:

* Add Phenotype
* Add Phenotype
* Add Phenotype

The patient’s family history is negative for related conditions / unknown / remarkable for the following related clinical features:

The patient has previously had the following uninformative genetic and other testing:

* Add test
* Add test
* Add test

**Clinical Evidence and Guidelines for Testing**

The HCM Sequencing and Deletion/Duplication Panel include germline analysis of genes involved in conditions that include severe cardiovascular manifestations, including sudden cardiac arrest and sudden cardiac death. Panel testing includes both sequencing and deletion/duplication analysis of multiple genes simultaneously.

HCM is a disease of the cardiac muscle and is characterized by left ventricular hypertrophy (LVH), myocyte disarray, and fibrosis. Signs and symptoms may include dyspnea, chest pain, palpitations, fatigue, syncope, and heart failure. HCM is the most common cause of sudden cardiac death in the young (<30 years of age) and in athletes.1,2 Age of onset spans childhood to adulthood, and the clinical phenotype is variable, even within the same family. HCM is caused by pathogenic variants in genes that result in sarcomere dysfunction as well as some genes associated with metabolic or syndromic forms of HCM.1,2,3 The condition occurs in approximately 1 in 500 individuals.1 Diagnosis of HCM can most often be established with noninvasive cardiac imaging, including echocardiography and/or cardiac magnetic resonance imaging (cardiac MRI). However, when imaging results are absent, subtle, or non-specific, molecular diagnosis with genetic testing aids in diagnosis, management and establishing recurrence risk for family members. HCM can be inherited in an autosomal dominant, autosomal recessive, X-linked, or mitochondrial manner.

Multiple national and international medical societies have published guidelines that recommend genetic testing for HCM and other cardiomyopathies:

* In 2018, the Heart Failure Society of America (HFSA) published a guideline in conjunction with the American College of Medical Genetics and Genomics (ACMG) that recommends genetic testing for cardiomyopathies using multi-gene testing panels. The recommendation cites studies demonstrating the cost-effectiveness of genetic testing, the importance of results in determining specific interventions that can improve survival and reduce morbidity, and the benefits of cascade screening for family members.3
* The Task Force for the Diagnosis and Management of Hypertrophic Cardiomyopathy of the European Society of Cardiology (ESC) recommends genetic testing in patients fulfilling diagnostic criteria for HCM, including to enable genetic testing of at-risk relatives, by a certified diagnostic laboratory with expertise in the interpretation of cardiomyopathy-related variants.4
* The Task Force for the Diagnosis and Management of Hypertrophic Cardiomyopathy of the European Society of Cardiology (ESC) recommends genetic testing in patients fulfilling diagnostic criteria for HCM, including to enable genetic testing of at-risk relatives, by a certified diagnostic laboratory with expertise in the interpretation of cardiomyopathy-related variants.5
* The Heart Rhythm Society / European Heart Rhythm Association (HRS/EHRA) Expert Consensus Statement on the State of Genetic Testing for the Channelopathies and Cardiomyopathies states that comprehensive or targeted HCM genetic testing is recommended.6

**Patient Clinical Utility and Medical Management Implications**

The results of this testing will guide appropriate medical management for this patient, including surveillance, preventive measures, and medical and surgical treatment. HCM and other cardiomyopathies are medically actionable disorders with well-established treatments and interventions that can reduce morbidity and improve survival.1,2,3 Furthermore, cardiomyopathy may have a syndromic cause, such as in Danon disease, Fabry disease, mitochondrial myopathy, or muscular dystrophy.1,3 These disorders, which may be subtle or difficult to diagnose without genetic testing, require further condition-specific medical management, screening, and diagnosis, which is imperative for appropriate treatment.

Management for hypertrophic cardiomyopathy is summarized in specific consensus documents from the American College of Cardiology Foundation / American Heart Association (ACCF/AHA), and the European Society of Cardiology (ESC).4,5 Treatment for cardiomyopathy and surveillance for progression is critical and is strongly influenced by knowledge of the underlying genetic cause.1,2,3 Patients with HCM can be offered pharmacological treatments such as beta-blockers and L-type calcium channel blockers, surgical interventions such as through surgical myectomy and alcohol septal ablation, and prevention of primary manifestations such as via ICD therapy for patients at increased risk for sudden cardiac death.1,2,3

Specifically for this patient, the results of this test will also {ADD ADDITIONAL INFORMATION}

**Summary**

The Hypertrophic Cardiomyopathy Panel at GeneDx is a highly sensitive and cost-effective genetic test. I am requesting coverage for this medically necessary test in order to establish appropriate medical management for this patient. Without testing, treatment would be suboptimal, subjecting this patient to increased morbidity and potentially early mortality.

Thank you for your review and consideration. If you have questions, or if I can be of further assistance, please do not hesitate to call me at (XXX) XXX-XXXX.

Sincerely,

Signature

Ordering Provider’s Name

References:

1. Cirino AL, Ho C. Hypertrophic Cardiomyopathy Overview. 2008 Aug 5 [Updated 2014 Jan 16]. In: Pagon RA, Adam MP, Ardinger HH, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2017. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK1768/>
2. Maron et al. (2003) Relationship of race to sudden cardiac death in competitive athletes with hypertrophic cardiomyopathy. J. Am. Coll. Cardiol. 41 (6):974-80 (PMID: 12651044)
3. Hershberger et al. (2018) Genetic Evaluation of Cardiomyopathy-A Heart Failure Society of America Practice Guideline. J. Card. Fail. 24 (5):281-302 (PMID: 29567486)
4. Gersh et al. (2011) 2011 ACCF/AHA guideline for the diagnosis and treatment of hypertrophic cardiomyopathy: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J. Thorac. Cardiovasc. Surg. 142 (6):e153-203 (PMID: 22093723)
5. Elliott et al. (2014) 2014 ESC Guidelines on diagnosis and management of hypertrophic cardiomyopathy: the Task Force for the Diagnosis and Management of Hypertrophic Cardiomyopathy of the European Society of Cardiology (ESC). European Heart Journal 35 (39):2733-79 (PMID: 25173338)
6. Ackerman et al. (2011) 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). *Europace* 13 (8):1077-109 (PMID: 21810866)