**Letter of Medical Necessity for the Combined Cardiac Panel**

**Patient Information**

**Date:**

**Patient Name:**

**Patient DOB:**

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

**Policy Number:**

**Group Number:**

**ICD10 Codes:**

**Test Information**

**Test Name:** Combined Cardiac Panel

**CPT Codes:** 81413x1, 81414x1

**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 Combined Cardiac 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 Combined Cardiac Panel includes 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.

This test includes genes that cause both cardiac arrhythmias, which occur due to disruption of the heart’s natural rhythm, and cardiomyopathy, which is a disease of the heart muscle. In some individuals or families, the clinical picture is complex and features of both of these conditions can be present, in which case a broader approach to genetic testing is imperative. Both conditions are genetically heterogeneous and have many different clinical presentations.

Diagnosis of cardiomyopathy can most often be established with noninvasive cardiac imaging, including echocardiography and/or cardiac magnetic resonance imaging (cardiac MRI). Similarly, the diagnosis of arrhythmias can often be established by noninvasive electrophysiological studies, including electrocardiogram, cardiac stress test, Holter and other event monitoring. However, when imaging results are absent, subtle, or non-specific, molecular diagnosis with genetic testing aids in diagnosis and management. Additionally, confirmation of the molecular diagnosis assists in establishing recurrence risk and facilitating the option of cascade testing for family members. Molecular genetic testing is critical to aid patient management in a cost-effective way and to minimize morbidity and mortality.7-10

Multiple national and international medical societies have published guidelines that recommend genetic testing for cardiac disorders:

* 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.7 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.7
* The 2011 American College of Cardiology Foundation / American Heart Association (ACCF/AHA) guideline for the diagnosis and treatment of hypertrophic cardiomyopathy recommends genetic testing for HCM and other genetic causes of unexplained cardiac hypertrophy in patients with an atypical clinical presentation of HCM or when another genetic condition is suspected to be the cause.8
* 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 cascade genetic screening of their relatives, by a certified diagnostic laboratory with expertise in the interpretation of cardiomyopathy-related variants.9
* 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 and DCM genetic testing is recommended, and comprehensive or targeted ARVC genetic testing can be useful for patients satisfying task force diagnostic criteria for ARVC and LVNC.10
* The HRS/EHRA Expert Consensus Statement states that genetic testing is recommended with patients with clinical suspicion of LQTS, or asymptomatic patients with primary QT prolongation, is recommended for patients with clinical suspicion of CPVT and can be useful for patients with clinical suspicion of BrS.10

**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. Treatment for cardiomyopathy and arrhythmia and surveillance for progression is critical and is strongly influenced by knowledge of the underlying genetic cause.1-6

Management for cardiomyopathies and arrhythmias is summarized in specific consensus documents from the American College of Cardiology Foundation / American Heart Association (ACCF/AHA), the European Society of Cardiology (ESC), the Heart Rhythm Association (HRS), the European Heart Rhythm Association (EHRA), and the Heart Failure Society of America (HFSA).8-17

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

**Summary**

The Combined Cardiac 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:

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