**Letter of Medical Necessity for Sudden Cardiac Arrest Arrhythmia Panel**

**Patient Information**

**Date:**

**Patient Name:**

**Patient DOB:**

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

**Policy Number:**

**Group Number:**

**ICD10 Codes:**

**Test Information**

**Test Name:** Sudden Cardiac Arrest (SCA) Arrhythmia Panel

**CPT Codes:** 81405x1, 81406x2, 81407x1, 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 Sudden Cardiac Arrest (SCA) Arrhythmia 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 Sudden Cardiac Arrest (SCA) Arrhythmia 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.

Sudden cardiac arrest (SCA) is a significant cause (10-15%) of mortality in the United States, as only 3-10% of individuals are successfully resuscitated after an out-of-hospital cardiac arrest.1,2 The majority of sudden cardiac arrest or sudden cardiac death is a result of structural heart disease.1,3 However, unexplained cardiac arrest in the young (<35y) is a less frequent occurrence and more commonly suggests an inherited form of heart disease.1,3 The occurrence of unexplained cardiac arrest or sudden cardiac death with no identifiable cause presents a diagnostic problem. An estimated 1/3 of sudden death cases in individuals younger than 20 years do not have an identifiable cause at autopsy, and arrhythmia should be considered in the differential diagnosis.4 In one study examining 173 individuals with sudden unexplained death and negative autopsy findings, 45 (26%) were subsequently diagnosed with an inherited arrhythmia condition.5

Cardiac arrhythmias occur due to disruption of the heart’s natural rhythm. Long QT syndrome (LQTS), Brugada syndrome (BrS), and catecholaminergic polymorphic ventricular tachycardia (CPVT) are heritable forms of arrhythmia that frequently manifest symptoms before the age of 50, with some cases occurring in infancy. In each of these conditions, a significant proportion of patients present with sudden death as the first symptom. Other symptoms include palpitations, syncope, and dizziness. In some individuals or families, the clinical picture is complex and features of more than one of these conditions can be present, in which case a broader approach to genetic testing is imperative. Cardiac arrhythmias are genetically heterogeneous and have many different clinical presentations. The diseases included in this SCA Panel occur in all ethnicities, and prevalence varies from 1 in 2,000 to 1 in 10,000.6,7,8 Genetic predispositions to arrhythmias can be inherited in an autosomal dominant, autosomal recessive, X-linked, or mitochondrial manner.

The diagnosis of arrhythmias can often be established by noninvasive electrophysiological studies, including electrocardiogram, cardiac stress test, and holter and other event monitoring. 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. Molecular genetic testing is critical to aid patient management in a cost-effective way and to minimize morbidity and mortality.10,11

National and international medical societies have published guidelines that recommend genetic testing for arrhythmias:

* 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 ARVC genetic testing can be useful for patients satisfying task force diagnostic criteria for ARVC and LVNC.8
* Similarly, 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.8

**Patient Clinical Utility and Medical Management Implications**

The results will guide appropriate medical management, including surveillance, preventive measures, and medical and surgical treatment. Treatment for arrhythmia, and surveillance for progression, is critical and is strongly influenced by knowledge of the underlying genetic cause.6-12

Management for arrhythmias is summarized in specific consensus documents from the American College of Cardiology / American Heart Association (ACC/AHA), the Heart Rhythm Association (HRS) and the European Heart Rhythm Association (EHRA), and in the European Society of Cardiology (ESC) guidelines on ventricular arrhythmias.10,11,13,15

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

**Summary**

The Sudden Cardiac Arrest Arrhythmia 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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11. Priori et al. (2015) 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC) Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC). *Europace* 17 (11):1601-87 (PMID: 26318695)
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