**Letter of Medical Necessity for the 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:** Arrhythmia 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 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 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.

Cardiac arrhythmias occur due to disruption of the heart’s natural rhythm, and have many different presentations, including arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVC), Brugada syndrome (BrS), Catecholaminergic polymorphic ventricular tachycardia (CPVT), and Long QT syndrome (LQTS). 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.

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, Holter and other event monitoring.1,2,3,4 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.5-8

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 for this patient, 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.1,2,3,4,5,6,7,9

Management for arrhythmias is summarized in specific consensus documents from the American College of Cardiology Foundation / American Heart Association (ACCF/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.5,6,8,9

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

**Summary**

The 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:

1. McNally E, MacLeod H, Dellefave-Castillo L. Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy. 2005 Apr 18 [Updated 2014 Jan 9]. 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/NBK1131/>
2. Brugada, Campuzano, Brugada, et al. Brugada Syndrome. 2005 Mar 31 [Updated 2014 Apr 10]. In: Pagon RA, Adam MP, Ardinger HH, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2014. Available from: http://www.ncbi.nlm.nih.gov/books/NBK1517/
3. Napolitano C, Priori SG, Bloise R. Catecholaminergic Polymorphic Ventricular Tachycardia. 2004 Oct 14 [Updated 2014 Mar 6]. In: Pagon RA, Adam MP, Ardinger HH, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2015. Available from: http://www.ncbi.nlm.nih.gov/books/NBK1289/
4. Alders M, Christiaans I. Long QT Syndrome. 2003 Feb 20 [Updated 2015 Jun 18]. In: Pagon RA, Adam MP, Ardinger HH, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2016. Available from: http://www.ncbi.nlm.nih.gov/books/NBK1129/
5. Priori et al. (2013) Executive summary: HRS/EHRA/APHRS expert consensus statement on the diagnosis and management of patients with inherited primary arrhythmia syndromes. *Europace* 15 (10):1389-406 (PMID: 23994779)
6. 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)
7. Brugada & Fernandez-Armenta (2012) E-Journal of Cardiology Practice. 10(25) Available from: https://www.escardio.org/Journals/E-Journal-of-Cardiology-Practice/Volume-10/Arrhythmogenic-right-ventricular-dyplasia (Accessed 4/14/2017)
8. 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). Heart Rhythm : The Official Journal Of The Heart Rhythm Society 8 (8):1308-39 (PMID: 21787999)
9. Epstein et al. (2013) 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. Journal Of The American College Of Cardiology. J. Am. Coll. Cardiol. 61 (3):e6-75 (PMID: 23265327)