Letter of Medical Necessity for the Cardiomyopathy Panel

Patient Information

Date: ____/____/_____
Patient Name: _____
Patient DOB: ____/____/_____
Insurance Company Name, Address, City, State: _____
_____
Policy Number: _____
Group Number: _____
ICD10 Codes: _____

Test Information

Test Name: Cardiomyopathy Panel
CPT Codes: 81406x5
Laboratory:
Advanced Lab Solutions LLC
3729 Easton Nazareth Hwy,
Easton, PA,18045
Telephone: 610-438-0919

This letter is in regards to my patient, [_____ _____], to request full coverage for the Cardiomyopathy Panel to be performed by Advanced Lab Solutions LLC. 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 Cardiomyopathy 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.

Cardiomyopathy is defined as disease of the heart muscle and has many different presentations, including hypertrophic cardiomyopathy (HCM), dilated cardiomyopathy (DCM), left ventricular noncompaction (LVNC), and arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVC). It also occurs in Noonan syndrome and other RASopathies, which can also include hematologic disorders and increased cancer risk. There is a broad range of clinical severity, from asymptomatic disease to progressive deterioration of cardiac function and even sudden cardiac death.

Diagnosis of cardiomyopathy 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. Hereditary cardiomyopathy 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 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 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. [6]
- 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.[7]
- 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 genetic testing can be useful for patients satisfying task force diagnostic criteria LVNC.[8]

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 surveillance for progression is critical and is strongly influenced by knowledge of the underlying genetic cause.[1-5] Cardiomyopathies are medically actionable disorders with well-established treatments and interventions that can reduce morbidity and improve survival.[1-5] 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 cardiomyopathies 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 Failure Society of America (HFSA).[6,7,9-12]

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

Summary
The Cardiomyopathy Panel at Advanced Lab Solutions LLC 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 (_____) ____-_____..

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. Hershberger RE, Morales A. Dilated Cardiomyopathy Overview. 2007 Jul 27 [Updated 2018 Aug 23]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2018. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1309/

5. Callis et al. (2010) Evolving molecular diagnostics for familial cardiomyopathies: at the heart of it all. *Expert Review Of Molecular Diagnostics* 10 (3):329-51 (PMID: 20370590) 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/

6. 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)

7. 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)

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). *Europace* 13 (8):1077-109 (PMID: 21810866)

9. Yancy et al. (2013) 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J. Am. Coll. Cardiol.* 62 (16):e147-239 (PMID: 23747642)

10. Yancy et al. (2016) ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation 134 (13):e282-93 (PMID: 27208050)

11. Ponikowski et al. (2016) ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC). Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. Eur. J. Heart Fail. 18 (8):891-975 (PMID: 27207191)

12. Corrado et al. (2015) Treatment of arrhythmogenic right ventricular cardiomyopathy/dysplasia: an international task force consensus statement. Eur. Heart J. 36 (46):3227-37 (PMID: 26216920)