

February 10th, 2023

From:
Global Market Access Team,
Invitae Corporation

To:
Medical Policy,
MoDX Program

Dear Sir/Madam,

Through this cover letter and its attachments, Invitae requests coverage for genetic testing for Medicare cardiology and neurology patients in two separate clinical areas.

Background on Cardiovascular Genetic Testing

It is now well established that inherited genetic changes make a contribution to the clinical presentation and diagnostic work-up of several cardiologic conditions. Availability of genetic testing can directly assist clinicians treating patients to make decisions that can improve outcomes including reducing mortality. The American Heart Association's current clinical guidance statement¹, indicates that genetic testing is recommended for patients with a confirmed or suspected diagnosis of an inherited cardiovascular disease. In the statement, the American Heart Association summarized best practices for genetic testing and the role of this information in the diagnosis and management of cardiovascular conditions, including arrhythmias, aortopathies, cardiomyopathies, and lipid disorders.

To determine which cardiovascular diseases most strongly support a MoDX Local Coverage Determination, we identified gene-disease associations that fulfill the following criteria:

- A. There are a considerable **number of individuals** impacted by the disease that are age 65 and over.
- B. Genetic testing is consistent with **current guidelines and statements** by relevant professional societies.
- C. There is a significant **diagnostic yield** in patients over age 65.
- D. Understanding the genetic etiology of disease in a patient has **high clinical utility** (impacts clinical decision-making and is associated with improved outcomes).

The gene-disease associations that we found fulfill these criteria are:

1. Heritable thoracic aortic disease (HTAD) and
2. Hereditary transthyretin amyloidosis (hATTR)

Given that these diseases have clinically distinct intended use populations, we are submitting two requests for Local Coverage Determination, one for HTAD and one for hATTR.

Best,

Niranjan Shekar

Encl: HTAD LCD submission, hATTR LCD submission, associated published articles

1. Musunuru K, Hershberger RE, Day SM, Klinedinst NJ, Landstrom AP, Parikh VN, et al. Genetic Testing for Inherited Cardiovascular Diseases: A Scientific Statement From the American Heart Association. *Circ Genom Precis Med.* 2020 Aug;13(4):e000067.