INVITAE

Medicare Ordering Form - Cardiology

A TOOL FOR GUIDELINES-BASED ORDERING

CARDIOLOGY PANEL TESTING

Patient name	Patient DOB (MM/DD/YYYY)

In order to send a claim to Medicare, Invitae requires that:

- ☐ This patient is currently enrolled in Medicare, is affected, and **has not** had previous genetic testing covered by Medicare for this condition.
- ☐ Although Medicare has not yet established genetic testing guidelines for the hereditary cardiovascular disorder(s) that I suspect my patient may have, I have determined this testing is medically necessary. I will provide supporting documentation (e.g., ICD-10 codes, letter of medical necessity, medical records).

If you have not checked both boxes above, please stop and contact Client Services at clientservices@invitae.com or 800-436-3037.

In addition to the criteria above, I suspect that my patient has at least one of the following conditions, and testing will include a cardiovascular genetic test. Select all that apply.

- ☐ 1 Long QT Syndrome (LQTS)
- ☐ 2 Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT)
- ☐ 3 Transthyretin (TTR) Amyloidosis
- ☐ 4 Hypertrophic Cardiomyopathy (HCM)
- ☐ 5 Dilated Cardiomyopathy (DCM) with:
  - ☐ a Conduction disease
  - ☐ b Family history of dilated cardiomyopathy (DCM)
  - ☐ c Family history of sudden cardiac death
  - ☐ d Systemic skeletal myopathy
- ☐ 6 Thoracic Aortic Aneurysms and/or Dissections (TAAD)
- ☐ 7 Marfan Syndrome (MFS)
- ☐ 8 Loeys-Dietz Syndrome (LDS)
- ☐ 9 Vascular Ehlers-Danlos Syndrome (VEDS)
- ☐ 10 Familial Pulmonary Arterial Hypertension (FPAH)
- ☐ 11 Hereditary Hemorrhagic Telangiectasia (HHT)
- ☐ 12 Brugada Syndrome (BrS) with a Type 1 wave
- ☐ 13 Left Ventricular Non-Compaction Cardiomyopathy (LVNC)
- ☐ 14 Familial Dyslipidemia (including Hypercholesterolemia (FH))
- ☐ 15 Unexplained ventricular fibrillation or sudden cardiac death when there is suspicion of a specific inherited disease in the patient or a first degree relative

EXCLUDED MolDx has determined that testing for Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C) is statutorily excluded. Invitae **will not** submit claims to Medicare for ARVD/C. Please consider our patient-pay alternative; contact Client Services at 800-436-3037 for more information.

FOR THIS MEDICARE ORDER, PLEASE SUBMIT:

1. This completed form
2. A letter of medical necessity (LMN)
3. Pedigree (or fill in the family history section on the Invitae requisition form)

HEADQUARTERS & LABORATORY | 1400 16th Street, San Francisco, CA 94103 | www.invitae.com | IN THE US | clientservices@invitae.com | p: 800-436-3037 | f: 415-276-4164
OUTSIDE THE US | globalsupport@invitae.com or visit www.invitae.com/contact | P/N FM132-7

Letter of Medical Necessity

DATE:

PATIENT NAME:

PATIENT DOB (MM/DD/YYYY):

INSURANCE COMPANY NAME:

SUBSCRIBER NAME:

POLICY #:

GROUP #:

Dear Medical Director,

I am writing this letter on behalf of my patient and your subscriber to request full coverage for genetic testing performed by Invitae Corporation, a CAP-accredited and CLIA-certified clinical diagnostic laboratory located at 1400 16th Street, San Francisco, CA 94103.

IN ADDITION TO THE INFORMATION ON SUBMITTED ORDER FORMS, MY PATIENT HAS THE FOLLOWING SYMPTOMS, CLINICAL FINDINGS, AND/OR FAMILY HISTORY:

Knowledge of the patient's genetic information is important for me to more accurately assess my patient's condition and will guide my recommendations for care. Results from Invitae's genetic test will have a direct impact on my patient's treatment and management.

I am specifying the Invitae genetic test because it is a highly sensitive, cost effective, and clinically relevant.

Thank you for your review and consideration. I hope you will support this request for genetic testing coverage for my patient. If you have questions, or if I can be of further assistance, please do not hesitate to contact me.

Sincerely,

PHYSICIAN NAME:

PHONE:

Informed Consent for Panel Genetic Testing

FM104-7

I, _____, request and permit Invitae to analyze the gene(s) indicated on the test requisition form in: ◯ My sample ◯ My child's sample

I UNDERSTAND THAT:

1. More information about _____ (condition tested) is available from my healthcare provider and can also be found on the Invitae website (www.invitae.com).
2. The results of this DNA test could be:
   a. Positive, and may:
      i. contribute to the diagnosis of a genetic condition.
      ii. reveal carrier status for a genetic condition.
      iii. reveal a predisposition or an increased risk for developing a genetic disease in the future.
      iv. have implications for other family members.
   b. Negative, and may:
      i. reduce but not eliminate the possibility that my condition has a genetic basis.
      ii. reduce but not eliminate my predisposition or risk for developing a genetic disease in the future.
      iii. be uninformative.
      iv. not remove the need for additional testing.
   c. Of uncertain significance and may:
      i. lead to a suggestion that testing additional family members may be helpful.
      ii. remain uncertain for the foreseeable future.
      iii. be resolved over time. My healthcare provider will be notified of any changes to the classification of previously-reported variants that relate to my (my child's) result.
3. Molecular genetic tests may not be diagnostic for the selected condition(s) in all individuals. This test may or may not provide actionable information or have an implication on my medical management.
4. Some types of DNA changes that could cause a specific genetic disorder may not be detected by this test. As with most molecular genetic tests, Invitae's test has technical limitations that may prevent detection of specific rare variants due to poor DNA quality, inherent DNA sequence properties, or other types of limitations.
5. There may be possible sources of error including, but not limited to, trace contamination, rare technical errors in the laboratory, rare DNA variants that compromise data analysis, inconsistent scientific classification systems, and inaccurate reporting of family relationships or clinical diagnosis information.
6. Invitae will only interpret the parts of the DNA sequence of gene(s) indicated on the requisition form by my or my child's physician. However, the technology obtains the DNA sequence information related to a broad range of genetic conditions and interpretation and release of other parts of the remaining genetic data can be requested through my healthcare provider (additional charges may apply).
7. Invitae's clinical reports are released only to the certified healthcare professional(s) listed on the test requisition form. Clinical reports are confidential and will only be released to other medical professionals with my explicit written consent. It has been explained to me that my clinical report is available for me to view or download at the Invitae website (www.invitae.com) after it has been released by my healthcare professional(s). Alternatively, my clinical report can be made immediately available upon completion of the test with the prior approval of my healthcare professional, as indicated on the test requisition form.
8. It is my responsibility to consider the possible impact of my or my child's test results as they relate to insurance rates, obtaining disability or life insurance and employment. The Genetic Information Nondiscrimination Act (GINA), a federal law, provides some protections against genetic discrimination. For information on GINA visit http://www.genome.gov/10002328.
9. Results from the Invitae test are analyzed with the assumption that correct information on family relationships has been provided. Due to the type of test performed there is the possibility that inconsistencies in information on family relationships could be identified if multiple family members are tested. For example, this test may detect misattributed paternity, where the stated father of an individual is found to not be the true biological father. It may be necessary to report these findings to an individual who requested testing.

10. I will be offered genetic counseling with a geneticist, genetic counselor or other qualified healthcare provider who can answer questions, provide information and advise about alternatives before and after having this test. Further testing or additional physician consults may be warranted.
11. My (my child's) data and personal information will be stored and protected in strict confidence complying with regulatory requirements (e.g. HIPAA and equivalent protections), and acknowledge that I have read and understand Invitae's Privacy Policy and Notice of Privacy Practices. My (my child's) individually identifiable health information (i.e., "Protected Health Information" under HIPAA) will NOT be used in FOR PROFIT research without my additional, explicit consent.
12. Because the understanding of genetic information will improve over time, Invitae may notify me of clinical updates related to my (my child's) genetic profile (in consultation with my primary clinician as indicated). I may request additional notifications and resources relevant to my genetic profile by creating an account at www.invitae.com/patients.
13. I have the right to receive a copy of this consent form.
14. New York residents only: My (or my child's) sample can be retained for greater than 60 days after completion of the test in the event that additional genetic analysis is necessary. _____ INITIAL HERE

BY SIGNING BELOW, I ATTEST TO THE FOLLOWING:

1. I have been informed of the likelihood of finding a change in the gene(s) for which I, or my child, am being tested and have received test-specific clinical information.
2. I have read and understand the information provided on this form and have had an opportunity to have any questions answered by my healthcare provider.

Patient signature	Date
Patient name (please print)	Email address
Signature of parent/guardian, if patient is a minor	Date
Parent's/guardian's name (please print)	Email address

HEALTHCARE PROVIDER STATEMENT

By signing below, I attest that I am the referring physician or authorized healthcare professional. I have explained the purpose of test described above. The patient has had the opportunity to ask questions regarding this test and/or seek genetic counseling. The patient has voluntarily decided to have this test performed by Invitae.

Healthcare provider signature	Date

