MAYO CLINIC LABORATORIES

Comprehensive Arrhythmia and Cardiomyopathy Gene Panel (CACMG) Prior Authorization Ordering Instructions

Mayo Clinic Laboratories is pleased to offer prior authorization services and third party billing on our Comprehensive Arrhythmia and Cardiomyopathy Gene Panel, Varies (CACMG). To utilize our prior authorization services on this test, you must follow the process as outlined below.

Ordering and Prior Authorization Process

Mayo Clinic Laboratories utilizes an extract and hold process for prior authorization. To order CACMG with prior authorization services, complete this document as instructed below by insurance type. **You must order test code CACMG and send the completed paperwork in with the sample**. The receipt of the paperwork and sample at Mayo Clinic Laboratories will trigger the extract and hold process and generate a request to the MCL Business Office to verify your patient's insurance coverage for the testing and begin any additional prior authorization services.

If the expected patient out-of-pocket expense is $200 or less after prior authorization services, Mayo Clinic Laboratories will automatically proceed with CACMG testing. If the expected patient out-of-pocket expense is greater than $200, Mayo Clinic Laboratories will seek approval from the client contact listed on the Patient Demographics and Third Party Billing Information form **before proceeding** with CACMG testing. The MCL Business Office offers interest-free payment plans on balances over $200.

Commercial Insurance

For patients with commercial insurance, complete the following, staple them together and send with the specimen:

- Patient Demographics and Third Party Billing Information form (required)
- Letter of Medical Necessity (required)
- Copy of front and back of insurance card (if available)

Note: The Advanced Beneficiary Notice of Noncoverage (ABN) form is not required for commercial insurance-covered patients.

Medicare

For patients with Medicare, complete the following, staple them together and send with the specimen:

- Patient Demographics and Third Party Billing Information form (required)
- Advanced Beneficiary Notice of Noncoverage (ABN) form (required – see separate ABN form: MC2934-320)
- Copy of front and back of secondary insurance card (if applicable)

Attach the ABN form and copy of the secondary insurance card to the Patient Demographics and Third Party Billing Information form and send with the specimen.

Note: The Letter of Medical Necessity and a copy of the Medicare card are not required for Medicare-covered patients.

Medicaid

Mayo Clinic Laboratories may be able to file claims for your Medicaid-covered patients. Before ordering, contact the MCL Business Office at 800-447-6424 to discuss. Have the patient's Medicaid information available when calling.

Note: These instructions are subject to change at any time. Call the MCL Business Office at 800-447-6424 with any questions.

Complete and print.

Reset Form

MAYO CLINIC LABORATORIES

Prior Authorization Patient Demographics and Third Party Billing Information

Client Order Number

Patient Demographics and Insurance Information

Patient Name *(Last, First, Middle)*		Sex ☐ Male ☐ Female	Birth Date *(mm-dd-yyyy)*
Patient Mailing Address		City	State / ZIP Code
Primary Insurance Company Name	Insurance Subscriber ID No. / Policy No.		Insurance Group No. (if applicable)
Primary Insurance Company Mailing Address		City	State / ZIP Code
Primary Insurance Company Phone	Subscriber Name (if different than patient) and Relationship to Patient		

Order Information

MCL Test ID **CACMG**	Name of desired MCL test **Comprehensive Arrhythmia and Cardiomyopathy Gene Panel, Varies**
ICD-10 Codes (use number codes to highest specificity)	Service Date (Collection Date)
Referring Provider Name	Referring Provider's National Provider ID (NPI)

Client Account and Client Contact Information

MCL Client Account Number (if known)	Referring Client Facility Name
Contact Name	Contact Phone
Contact Email	Date Today *(mm-dd-yyyy)*

Attach the Following to This Completed Form

- Letter of Medical Necessity (required except for Medicare patients) – template provided on page 3
- Advanced Beneficiary Notice of Noncoverage (ABN) form (required for Medicare patients only) – see separate form: MC2934-320
  - Templates provided on the following pages
- Copy of Front and Back of patient's insurance card (if available)

Letter of Medical Necessity for Comprehensive Arrhythmia and Cardiomyopathy Gene Panel (CACMG) Testing

Patient Name *(Last, First, Middle)*

Birth Date *(mm-dd-yyyy)*

Member Number

Group

ICD-10 Codes

To Whom It May Concern:

We are requesting preauthorization for the Comprehensive Arrhythmia and Cardiomyopathy Gene Panel, Varies (CACMG) performed by

Mayo Clinic Laboratories for (insert patient name)

Patient's personal medical history is significant for

Patient's family history is significant for

Due to the patient's medical history, a diagnosis of and inherited cardiomyopathy and/or arrythmia is suspected and genetic testing is recommended.

Rationale: The Heart Rhythm Society (HRS), European Heart Rhythm Association (EHRA), Asia Pacific Heart Rhythm Society (APHRS), Latin American Hearth Rhythm Society (LAHRS), and the Heart Failure Society of America (HFSA) support the use of genetic testing in individuals with suspected inherited forms of cardiomyopathy and cardiac arrhythmias.[1-4] Test results will have a direct impact on this patient's medical management, screening, and prevention of potential complications, including sudden cardiac arrest and sudden cardiac death.[1-4] The clinical diagnosis of cardiomyopathies and cardiac arrhythmias can be difficult to establish due to uncertain or borderline results from routine diagnostic tests such as electrocardiogram (EKG) and echocardiogram. Additionally, in a patient presenting with both cardiomyopathy and arrhythmia, it can be difficult to distinguish the primary condition. Furthermore, some affected individuals can be asymptomatic, with sudden cardiac death being the first presentation of the condition in some individuals. Thus, genetic testing is used to confirm a diagnosis and/or identify at-risk individuals.

Identification of a causative gene variant in individuals with suspected inherited forms cardiomyopathies and/or cardiac arrhythmias also contributes to customized management aimed at reducing the risk of sudden cardiac arrest/death. Management recommendations for these conditions may involve consideration of implantable cardioverter defibrillator (ICD) placement to prevent sudden cardiac death.[4] However, the decision to implant an ICD is very expensive and involves the potential for surgical and/or device complications as well as important psychological implications for the patient. Confirmation of the diagnosis of an inherited cardiac arrhythmia by genetic testing is, therefore, an important factor in the decision on whether or not to proceed with ICD therapy. Knowledge of the causative gene also helps to identify the triggers that can cause a cardiac event and allows for patient counseling to avoid these triggers. Lastly, some genes associated with cardiomyopathy and arrhythmia, such as the LMNA, MYH7, LMNA, LAMP2, and DES genes, may involve skeletal muscle weakness or other systemic features. Thus, it is important to assess for a causative genetic variant to provide appropriate medical recommendations. In summary, a positive genetic test result would provide a definitive cause for this patient's medical history and would ensure this patient is being treated appropriately.

A negative genetic test result could also be informative. A negative result may help to reinforce that the patient does not have an inherited form of cardiomyopathy or arrhythmia, or alternatively it could indicate that additional genetic testing (such as whole exome or whole genome sequencing) should be considered to confirm an alternate diagnosis and allow for gene-specific management and screening.

Genetic testing can confirm a diagnosis of an inherited form of cardiomyopathy or arrhythmia, and a positive result may mean family members are at up to a 50% risk of being affected or of being a carrier for an inherited form of cardiomyopathy or arrhythmia. When a familial variant has been identified, genetic testing can identify family members who are not at increased risk of developing symptoms and complications associated cardiomyopathy and arrhythmia. No other test can reliably differentiate unaffected family members, who do not require further health screening, from presymptomatic affected family members, who must be followed closely by a cardiologist.

Test requested: Comprehensive Arrhythmia and Cardiomyopathy Gene Panel, Varies (CACMG) is a cost-effective test that utilizes next-generation sequencing (NGS) to evaluate 105 genes for pathogenic variants associated with inherited forms of cardiomyopathy and/or arrhythmias. Laboratory information: Testing would be performed at Mayo Clinic Laboratories (TIN# 411346366 / NPI# 1093792350), a CAP-accredited and CLIA-certified laboratory, using 2020 CPT code: 81439.

Thank you for your thoughtful consideration of our preauthorization request. We look forward to hearing back from you.

Sincerely,

Ordering Clinician Name

Contact information

References

1. Wilde AAM, Semsarian C, Marquez MF, et al. European Heart Rhythm Association (EHRA)/Heart Rhythm Society (HRS)/Asia Pacific Heart Rhythm Society (APHRS)/Latin American Hearth Rhythm Society (LAHRS) Expert Consensus Statement on the state of genetic testing for cardiac diseases. Europace 2022;24:1307-1367
2. Hershberger RE, Givertz MM, Ho CY, et al. Genetic Evaluation of Cardiomyopathy-A Heart Failure Society of America Practice Guideline. J Card Fail. 2018;24(5):281-302. doi:10.1016/j.cardfail.2018.03.004
3. Al-Khatib: AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Heart Rhythm 2017 Oct;doi: 10.1016/j.hrthm.2017.10.036
4. Priori SG, Blomström-Lundqvist C, Mazzanti A, et al. 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). Eur Heart J. 2015;36(41):2793-2867. doi:10.1093/eurheartj/ehv316

Print

MAYO CLINIC LABORATORIES
200 First Street SW
Rochester, Minnesota 55905
800-447-6424

Patient Name *(First, Middle, Last)*	MCL Order Number

Advance Beneficiary Notice of Noncoverage (ABN)

Note: If Medicare doesn't pay for Items and Services below, you may have to pay.
Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the Items and Services below.

Items and Services	Reason Medicare May Not Pay	Estimated Cost
CACMG/Comprehensive Arrhythmia and Cardiomyopathy Gene Panel, Varies	Patient's personal and family history of cancer does not meet Medicare's medical necessity coverage criteria for this laboratory test.	$2,950.00

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the Items and Services listed above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

Options: Check only one box. We cannot choose a box for you.

☐ **OPTION 1.** I want the Items and Services listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

☐ **OPTION 2.** I want the Items and Services listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed.**

☐ **OPTION 3.** I don't want the Items and Services listed above. I understand with this choice I am **not** responsible for payment, and **I cannot appeal to see if Medicare would pay.**

Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY**: 1-877-486-2048).
Signing below means that you have received and understand this notice. You also receive a copy.

Signature ▶	Date *(mm-dd-yyyy)*

CMS does not discriminate in its programs and activities. To request this publication in an alternative format, please call: 1-800-MEDICARE or email: AltFormatRequest@cms.hhs.gov.