MAYO CLINIC LABORATORIES

Brugada Syndrome, SCN5A Full Gene Analysis (SCN5A) Prior Authorization Ordering Instructions

Mayo Clinic Laboratories is pleased to offer prior authorization services and third party billing on our our Brugada Syndrome, *SCN5A* Full Gene Analysis, Varies (SCN5A). 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 **SCN5A** with prior authorization services, complete this document as instructed below by insurance type. **You must order test code SCN5A 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 SCN5A 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 SCN5A 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: MC2934-347)
- 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)			Birth Date (mm-dd-yyyy)
Sex Assigned at Birth ☐ Male ☐ Female ☐ Unknown ☐ Choose not to disclose		Legal/Administrative Sex ☐ Male ☐ Female ☐ Nonbinary	
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 **SCN5A**	Name of desired MCL test **Brugada Syndrome, *SCN5A* Full Gene Analysis, Varies**
ICD-10 Codes (use number codes to highest specificity)	Service/Collection Date (mm-dd-yyyy)
Referring Provider Name (Last, First)	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: MC2934-347
  - Templates provided on the following pages
- Copy of front and back of patient's insurance card (if available)

Letter of Medical Necessity for Brugada Syndrome, *SCN5A* Full Gene Analysis (SCN5A) 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 Brugada Syndrome, *SCN5A* Full Gene Analysis, Varies (SCN5A) 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 Brugada syndrome (BrS) 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 genetic testing for individuals with a strong clinical suspicion for Brugada syndrome.[1,2] Test results may have a direct impact on this patient's medical management and screening for Brugada syndrome, a condition which is associated with sudden cardiac arrest and sudden cardiac death.[3] The clinical diagnosis of Brugada syndrome can be difficult to establish due to uncertain or borderline results from routine diagnostic tests such as electrocardiogram. Furthermore, some affected individuals can be asymptomatic, with sudden cardiac death being the first presentation of the condition in some individuals.

Genetic testing is used to confirm a diagnosis and/or identify at-risk individuals. This testing would allow for identification of a gene variant causative of the patient's medical history and would have significant implications for the patient's clinical management regarding decision making and medical management. Brugada syndrome is associated with a high risk for ventricular arrhythmias that can result in sudden cardiac death. Management recommendations for Brugada syndrome often involve consideration of implantable cardioverter defibrillator (ICD) placement to prevent sudden cardiac death.[3] However, implantation of an ICD is costly and involves the potential for surgical and/or device complications and may have important psychological implications for the patient. In cases where the clinical diagnosis of Brugada syndrome is uncertain, confirmation of a genetic variant by molecular testing can be an important factor in the decision whether to proceed with ICD therapy. 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.

Brugada syndrome is inherited in an autosomal dominant fashion, and each child is at a 50% risk to inherit a causative variant from an affected parent. Therefore, genetic testing can be a critical step to provide informed risk assessment, and appropriately identify family members who are at increased risk for Brugada syndrome-related cardiac arrythmias and sudden cardiac death. 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: SCN5A / Brugada Syndrome, *SCN5A* Full Gene Analysis, Varies is a cost-effective test that utilizes next-generation sequencing (NGS), to evaluate the *SCN5A* gene for Brugada syndrome-associated variants.

Laboratory information: Testing would be performed at Mayo Clinic Laboratories (TIN# 411346366 / NPI# 1093792350), a CAP-accredited and CLIA-certified laboratory, using 2023 CPT code: 81407.

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

Sincerely,

Ordering Provider 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(8):1307-1367
2. Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 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 [published correction appears in J Am Coll Cardiol. 2018 Oct 2;72(14):1760]. J Am Coll Cardiol. 2018;72(14):e91-e220. doi:10.1016/j.jacc.2017.10.054
3. Zeppenfeld K, Tfelt-Hansen J, de Riva M, et al. 2022 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. Eur Heart J. 2022;43(40):3997-4126. doi:10.1093/eurheartj/ehac262

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
SCN5A / Brugada Syndrome, SCN5A Full Gene Analysis, Varies	Patient's personal and family history of cancer does not meet Medicare's medical necessity coverage criteria for this laboratory test.	$2,446.70

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 may ask to receive a copy.

Signature ▶	Date *(mm-dd-yyyy)*

You have the right to get Medicare information in an accessible format, like large print, Braille, or audio. You also have the right to file a complaint if you feel you've been discriminated against. Visit Medicare.gov/about-us/accessibility-nondiscrimination-notice.