



Options for CYP2C9 genotype testing

Novartis covers the cost of the test for all patients being considered for MAYZENT® (siponimod) tablets*



Independent of the MAYZENT Start Form

Providers can order testing directly from LabCorp via their EMR, a routine LabCorp test request form, or any other existing process used for ordering tests via LabCorp using test code **512215 CYP2C9 Testing for Siponimod**. The cost of the test will be covered by Novartis on behalf of the patient.

- Walk-ins are welcome, or patients can make an appointment at one of more than 1900 LabCorp Patient Service Centers online at LabCorp.com/labs-and-appointments
- You can also request a blood specimen pickup at your office from LabCorp online at LabCorp.com, or by phone at 1-855-LABCORP (1-855-522-2677). If you do not have an existing LabCorp account, please contact your local LabCorp representative or sign up online at LabCorp.com/provider-services
- Test results will be reported to the provider according to their LabCorp account setup (see example on page 2)

***A blood draw fee of no more than \$10 may apply and be billed by LabCorp to the patient or the patient's health insurance when using a LabCorp Patient Service Center.**

OR



Using the MAYZENT Start Form

Providers can request CYP2C9 genotype testing when completing the Start Form by checking the box next to “Genotype CYP2C9” in Section 5.


- Complete the Start Form on CoverMyMeds.com, or fax it to the number at the top of the form. Do not submit the Start Form to LabCorp
- A Program coordinator will help to schedule the blood draw at a Program-sponsored medical facility or at the patient's home
- Test results will be reported to the provider via fax and uploaded to the [CoverMyMeds®](http://CoverMyMeds.com) portal, as authorized by the patient on the Start Form (see example on page 2)


CYP2C9 genotype testing is required to determine candidacy and the appropriate maintenance dosage for MAYZENT before treatment initiation. MAYZENT is contraindicated in patients who have a CYP2C9*3/*3 genotype.

*A CYP2C9 genotype blood test is available at no cost to any patient who is being considered for treatment with MAYZENT. Limitations may apply. The cost of the test may not be billed to any third-party payer. Providers are responsible for obtaining patient consent for genetic testing in accordance with all applicable laws. This Program is not contingent on any orders or purchase of products or services from LabCorp or Novartis. This Program is subject to termination or modification at any time.

Reviewing results

Test results will provide information to help you determine candidacy for treatment with MAYZENT® (siponimod) tablets and the appropriate dosage.





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Patient Name	DOB	Patient ID/Medical Record #	Gender	Monogram Accession #
Date Collected	Date Received	Date Reported	Mode	Report Status
Referring Physician			Reference Lab ID/Order #	
Comments				

Cytochrome P450 2C9 Genotyping - Siponimod

Test result

2C9 Genotype: *1/*1

CYP2C9 Genotype	Prescribing Information for Siponimod ±
*1/*1 *1/*2 *2/*2	The standard maintenance dose (2 mg once daily) is recommended.
*1/*3 *2/*3	A modification of the maintenance dose is recommended. The recommended dose is 1 mg once daily (4 x 0.25 mg) to avoid an increased exposure to siponimod.
*3/*3	Siponimod should not be used in patients with a CYP2C9*3*3 genotype. Use of siponimod in these patients results in substantially elevated siponimod plasma levels.

Director Review: Weidong Huang, MD, PhD
Director, Monogram Biosciences

Methodology:
DNA analysis is performed by allele-specific real-time polymerase chain reaction (PCR) to detect the *2 and *3 alleles in the CYP2C9 gene. No other variants in this gene are detected by this assay. Molecular-based testing is highly accurate, but as in any laboratory test, rare diagnostic errors may occur.

CYP2C9 Information:
Cytochrome P450 CYP2C9 is involved in the metabolism of several clinically important drugs in addition to siponimod including warfarin and some anti-diabetic drugs. Individuals with CYP2C9 *2 or *3 alleles may experience a reduced therapeutic response and may be at increased risk for side effects from drugs that are metabolized by CYP2C9. The exact effect of a particular genotype on individual drugs can vary. About 20% of the Caucasian population have at least one *2 or *3 variant. These variants are rare in African and Asian populations. The metabolism of drugs is also influenced by race, ethnicity, diet and other medications and all factors should be considered prior to initiating new therapy. All results must be interpreted in the context of other test results and clinical findings. This result does not rule out the possibility of variant alleles in other drug metabolism pathways. Patients should speak with their health care provider about the individual results of this test.
± Mayzent (siponimod) [package insert]. East Hanover, NJ: Novartis Pharmaceutical Corporation; 2019.

For more information on interpreting this report, please visit www.MonogramBio.com or call Customer Service at 800-777-0177 between the hours of 6:30am to 5:00pm PT Monday through Friday.

This assay meets the standards for performance characteristics and all other quality control and assurance requirements established by CLIA. The results should not be used as the sole criteria for patient management. This test was developed and its performance characteristics determined by Monogram Biosciences. It has not been cleared or approved by the FDA. This document contains private and confidential health information protected by state and federal law. If you have received this document in error, please call 800-777-0177. The provision of this free test is not contingent on any requirement to utilize or purchase this test, or any other product or service, in the future. Additionally, provision of this free test by Novartis Pharmaceutical Corporation is a form of patient support with no independent value and is not intended to influence the independent medical judgment of any health care provider. Because this test is being provided to the patient free of charge to determine the clinical appropriateness and/or appropriate dosing of siponimod, a claim for reimbursement may not be submitted for this test to any insurer, including commercial insurers or federal health care programs such as Medicare and Medicaid.

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Test result

Recommended maintenance dosage according to the full Prescribing Information

See the full Prescribing Information for additional considerations to determine appropriate dosage

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