



Mayo Clinic Laboratories is pleased to offer prior authorization services and third party billing on our Hypercholesterolemia Gene Panel, Varies (HCHLG). 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 HCHLG with prior authorization services, complete this document as instructed below by insurance type. **You must order test code HCHLG 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 HCHLG 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 HCHLG 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: MC2934-329)
- 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.



**Prior Authorization
Patient Demographics and
Third Party Billing Information**

Client Order Number

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Patient Demographics and Insurance Information

Patient Name (Last, First Middle)		Birth Date (mm-dd-yyyy)	
Sex Assigned at Birth <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown <input type="checkbox"/> Choose not to disclose		Legal/Administrative Sex <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> 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 HCHLG	Name of desired MCL test Hypercholesterolemia Gene Panel, 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: MC2934-329
 - Templates provided on the following pages
- Copy of Front and Back of patient's insurance card (if available)

Letter of Medical Necessity for Hypercholesterolemia Gene Panel (HCHLG) 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 Hypercholesterolemia Gene Panel, Varies (HGHLG) 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 familial hypercholesterolemia, sitosterolemia, lysosomal acid lipase deficiency, or other inherited hypercholesterolemia condition is suspected, and genetic testing is recommended.

Rationale: The use of genetic testing to aid in the diagnosis of monogenic, inherited forms of hypercholesterolemia is supported by experts in the field.¹⁻⁴ Genetic testing is used to confirm a diagnosis and/or identify at-risk individuals. This testing would allow for the unequivocal diagnosis of a genetic 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.¹⁻⁴

Several inherited conditions present similarly with elevated LDL cholesterol, including familial hypercholesterolemia (FH), sitosterolemia, and lysosomal acid lipase deficiency. However, each of these conditions require different medical management, and it is therefore important to identify the specific underlying genetic condition. For example, identification of a causative genetic variant resulting in FH may indicate treatment with dietary changes, statins, PCSK9 inhibitors, or lipoprotein apheresis. A diagnosis of sitosterolemia may indicate treatment with ezetimibe or bile acid sequestrants, and avoidance of plant sterols in the patient's diet. A diagnosis of lysosomal acid lipase deficiency would be treated with enzyme replacement therapy.^{1,2} 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 hypercholesterolemia 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 hypercholesterolemia, 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 hypercholesterolemia condition. When a familial variant has been identified, genetic testing can identify family members who are not at increased risk to develop symptoms and complications associated with hypercholesterolemia. 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 specialist.

Test requested: Hypercholesterolemia Gene Panel, Varies (HGHLG) is a cost-effective test that utilizes next-generation sequencing (NGS) to evaluate 12 genes for disease-associated variants associated with familial hypercholesterolemia, sitosterolemia, and other inherited hypercholesterolemia conditions.

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: 18406 (x2), 81407, and 81479.

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. Sturm AC, Knowles JW, Gidding SS, et al. Clinical genetic testing for familial hypercholesterolemia: JACC Scientific Expert Panel. *J Am Coll Cardiol.* 2018;72(6):662-680. doi: 10.1016/j.jacc.2018.05.044
2. Hegele RA, Borén J, Ginsberg HN, et al. Rare dyslipidaemias, from phenotype to genotype to management: a European Atherosclerosis Society task force consensus statement. *Lancet Diabetes Endocrinol.* 2020;8(1):50-67. doi:10.1016/S2213-8587(19)30264-5
3. Brown EE, Sturm AC, Cuchel M, et al. Genetic testing in dyslipidemia: A scientific statement from the National Lipid Association. *J Clin Lipidol.* 2020;14(4):398-413. doi:10.1016/j.jacl.2020.04.011
4. Handelsman Y, Jellinger PS, Guerin CK, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Management of Dyslipidemia and Prevention of Cardiovascular Disease Algorithm - 2020 Executive Summary. *Endocr Pract.* 2020;26(10):1196-1224. doi:10.4158/CS-2020-0490

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
HCHLG/Hypercholesterolemia Gene Panel, Varies	Patient's personal and family history of cancer does not meet Medicare's medical necessity coverage criteria for this laboratory test.	\$2,500.00

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.
<input type="checkbox"/> 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.
<input type="checkbox"/> 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.
<input type="checkbox"/> 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 <i>(mm-dd-yyyy)</i>
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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.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.