MAYO CLINIC LABORATORIES

Hypertriglyceridemia Gene Panel (HYPTG) Prior Authorization Ordering Instructions

Mayo Clinic Laboratories is pleased to offer prior authorization services and third party billing on our Hypertriglyceridemia Gene Panel, Varies (HYPTG). 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 HYPTG with prior authorization services, complete this document as instructed below by insurance type. **You must order test code HYPTG 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 HYPTG 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 HYPTG 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: MC2934-333)
- 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 **HYPTG**	Name of desired MCL test **Hypertriglyceridemia 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: MC2934-333
  - Templates provided on the following pages
- Copy of front and back of patient's insurance card (if available)

Letter of Medical Necessity for Hypertriglyceridemia Gene Panel (HYPTG) 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 Hereditary Hypertriglyceridemia Gene Panel, Varies (HYPTG) 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 an inherited form of hypertriglyceridemia is suspected and genetic testing is recommended.

Rationale: The use of genetic testing to aid in the diagnosis of a hereditary form of primary hypertriglyceridemia is supported by experts in the field.[1–3] Test results will have a direct impact on this patient's medical management, screening, and prevention of potential complications.[1–3]

Genetic testing is used to confirm a diagnosis and/or identify at-risk individuals. This testing would allow for the unequivocal diagnosis 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. For example, identification of a disease-associated variant would confirm a diagnosis of a hereditary form of primary hypertriglyceridemia, and early diagnosis allows for more intensive monitoring and initiation of treatment.

Several inherited conditions present similarly with elevated triglycerides, including chylomicronemia, transient infantile hypertriglyceridemia, and dysbetalipoproteinemia. Monogenic forms of hypertriglyceridemia are treated differently from acquired or polygenic forms of hypertriglyceridemia. For example, while fibrates and omega-3 fatty acids are effective in lowering triglycerides in individuals with acquired/polygenic chylomicronemia, they are not an effective form of treatment for individuals with monogenic forms of chylomicronemia. Additionally, the risk for pancreatitis is up to 70% in individuals with confirmed monogenic forms of chylomicronemia, compared to 10% in other forms of the condition. For these reasons, it is critical that individuals with monogenic forms of chylomicronemia adhere to a strict, low-fat diet. Lastly, there are several emerging treatments for monogenic hypertriglyceridemia conditions that are gene-based, and patients must have genetic testing performed to assess their eligibility for gene-based treatments. 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 a monogenic form of hypertriglyceridemia or, alternatively, it could indicate that additional genetic testing (such as a larger multi-gene dyslipidemia panel, whole exome sequencing, 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 monogenic hypertriglyceridemia, and a positive result may mean family members are at up to a 50% risk of being affected, or of being a carrier for monogenic hypertriglyceridemia. When a familial variant has been identified, genetic testing can identify family members who are not at increased risk to develop for a hereditary form of primary hypertriglyceridemia. 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 dyslipidemia specialist.

Test requested: Hypertriglyceridemia Gene Panel, Varies (HYPTG) is a cost-effective test that utilizes next-generation sequencing (NGS) to evaluate 13 genes for primary hypertriglyceridemia and related condition-associated variants.

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: 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. 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
2. 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
3. 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

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 Non-coverage (ABN)

Medicare doesn't pay for everything, even some care you or your health care provider think you need. **We expect Medicare may not pay for the item, test, service or care listed below.** If Medicare doesn't pay, you may have to pay.

Item, Test, Service or Care	Reason Medicare May Not Pay	Estimated Cost
HYPTG / Hypertriglyceridemia Gene Panel, Varies	Patient's personal and family history of cancer does not meet Medicare's medical necessity coverage criteria for this laboratory test.	$2,400.00

What to do now

- Read this notice to make an informed decision about your care.
- Ask any questions you have.
- Choose one option below to let us know if you still want to get the item, test, service or care.

Choose ONE option below. We can't choose for you.

If you choose Option 1 or 2, we may help you use any other insurance you might have, but Medicare can't require us to do this.

☐ **OPTION 1: I want the item, test, service or care listed above, and I want Medicare to be billed for an official decision on payment, which I'll get on a Medicare Summary Notice (MSN).** You can ask to be paid now. I understand that if Medicare doesn't pay, I'm responsible to pay, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you'll refund any payments I made to you, minus co-pays or deductibles.

☐ **OPTION 2: I want the item, test, service or care listed above, but don't bill Medicare.** You can ask to be paid now and I'm responsible to pay. I understand that I can't appeal, since Medicare isn't billed.

☐ **OPTION 3: I don't want the item, test, service or care listed above.** I understand I'm not responsible for payment and I can't appeal to see if Medicare would pay.

Additional Information:

This notice gives our opinion, not an official Medicare decision. For other questions about this notice or Medicare billing, call 1-800-MEDICARE (1-800-633-4227). TTY users can call 1-877-486-2048. Signing below means you received and understand this notice. You can ask to get 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.

PRA Disclosure Statement: 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. This information collection is for providers, suppliers, Hospice and Religious Non-medical HealthCare Institutes and Home Health Agencies to notify original Medicare beneficiaries of their potential financial liability under specific conditions. The time required to complete this information collection is estimated to average less than 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, to review and complete the information collection. This information collection is mandatory under Section 1879 of the Social Security Act, 42 CFR 411.404(b) and (c) and 411.408(d)(2) and (f). If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.