



Mayo Clinic Laboratories is pleased to offer prior authorization services and third party billing on our MLH1 Gene, Full Gene Analysis, Varies (MLH1Z). 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 MLH1Z with prior authorization services, complete this document as instructed below by insurance type. **You must order test code MLH1Z 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 MLH1Z 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 MLH1Z 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: MC2934-192)
- 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

--

Patient Demographics and Insurance Information

Patient Name <i>(Last, First, Middle)</i>		Gender <input type="checkbox"/> Male <input type="checkbox"/> Female		Birth Date <i>(mm-dd-yyyy)</i>	
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 MLH1Z	Name of desired MCL test MLH1 Gene, Full Gene Analysis, 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 <i>(mm-dd-yyyy)</i>		

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: MC2934-192
 - Templates provided on the following pages
- Copy of Front and Back of patient's insurance card (if available)

Letter of Medical Necessity for Lynch Syndrome (MLH1) Full Gene Analysis Genetic 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 genetic testing of the MLH1 gene associated with Lynch syndrome: MLH1 Gene, Full Gene Analysis, Varies (MLH1Z) 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 absence of MLH1 protein expression previously detected in this patient's tumor, Lynch syndrome is suspected and genetic testing of the MLH1 gene is recommended (National Comprehensive Cancer Center Guidelines – Genetic/Familial High-Risk Assessment: Colorectal Version 2.2014).

Rationale: The American Society of Clinical Oncology recommends that genetic testing be offered to individuals with suspected inherited cancer risk in which test results will aid in medical management decision-making (ASCO Policy Statement Update: genetic testing for cancer susceptibility. J Clin Oncol 2003;21(12):2397-2406). Because an aggressive approach to medical management is necessary for individuals identified as having a genetic mutation, test results are important in reducing cancer risk and promoting early cancer detection.

A positive result would indicate that the patient has an inherited predisposition to cancer and could help guide treatment strategies and allow for surveillance of associated organ systems known to be of increased risk for cancer (colorectal, endometrial, ovarian, bladder, bile duct, gastric, and other cancers). Specific screening recommendations are dependent on the gene implicated. A positive test result would therefore allow the utilization of appropriate screening guidelines (ie, National Comprehensive Cancer Center Clinical Practice Guidelines in Oncology) and help guide decisions toward possible preventative measures, such as colectomy, hysterectomy, and oophorectomy as relevant.

Tests requested: MLH1Z / MLH1 Gene, Full Gene Analysis, Varies uses Sanger sequencing and multiplex ligation-dependent probe amplification to evaluate this gene for pathogenic mutations and deletions associated with Lynch syndrome.

Laboratory information: Testing would be performed at Mayo Clinic Laboratories (TIN# 411346366 / NPI# 1093792350), a CAP-accredited and CLIA-certified laboratory, using 2020 CPT codes: 81228 and 81292.

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

Sincerely,

Ordering Clinician Name _____

Contact information _____

Patient Name <i>(First, Middle, Last)</i>	Mayo Clinic 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
MLH1Z / MLH1 Gene, 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.	\$1433.40

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 also receive a copy.

Signature ▶	Date <i>(mm-dd-yyyy)</i>
----------------	--------------------------

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.

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.