



Mayo Clinic Laboratories is pleased to offer prior authorization services and third party billing on our Inflammatory Bowel Disease Primary Immunodeficiency (PID) Panel, Varies (IBDGP). 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 IBDGP with prior authorization services, complete this document as instructed below by insurance type. **You must order test code IBDGP 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 IBDGP 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 IBDGP 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: MC2934-124)
- 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 <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 IBDGP	Name of desired MCL test Inflammatory Bowel Disease Primary Immunodeficiency (PID) Panel, 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: MC2934-124
 - Templates provided on the following pages
- Copy of Front and Back of patient's insurance card (if available)

Letter of Medical Necessity for Inflammatory Bowel Disease Primary Immunodeficiency (PID) Panel 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 Inflammatory Bowel Disease Primary Immunodeficiency (PID) Panel, Varies (IBDGP) performed by

Mayo Clinic Laboratories for (insert patient name) _____

Patient's personal medical history is significant for _____

Patient's family history is significant for _____

Rationale: Inflammatory bowel disease (IBD) is a term used to encompass disorders involving chronic intestinal inflammation. It is typically classified as either Crohn's disease or ulcerative colitis based on clinical features, colonoscopy findings, histologic changes, and the anatomical distribution of disease; however, in some cases a definitive classification cannot be made. Over the past few decades, the incidence of inflammatory bowel disease has been rapidly increasing in both children and adults.

While the majority of IBD is thought to be either polygenic or multifactorial, and triggered by an environmental component, recent studies have shown an increase in recognition of monogenic diseases that can present with IBD-like intestinal inflammation. These monogenic cases can be attributed to disease-causing variants in a single gene (monogenic inheritance) which results in a highly penetrant condition.

A substantial proportion of monogenic patients present with onset of intestinal inflammation before the age of six and their monogenic disease often remains undiagnosed, as they frequently have clinical presentation, endoscopic and histologic features, and presence of perianal disease that are indistinguishable from more traditional, or polygenic, forms of IBD.

Additionally, monogenic IBD patients often do not respond to conventional IBD therapies and are associated with a higher morbidity. As such, genetic testing to identify these truly different diagnoses may enable clinicians to optimize patient treatment plans and possibly reduce the high morbidity and mortality associated with these conditions.

Also, while disease onset typically occurs in children, there is also a subgroup of older patients where this testing can be helpful. Specifically, adults who had early onset IBD, but whose diagnosis predated the availability of genetic testing, as well as very severe refractory patients and patients who exhibit other immune-mediated symptoms that are atypical for IBD.

Test requested: IBDGP / Inflammatory Bowel Disease Primary Immunodeficiency (PID) Panel, Varies uses next-generation sequencing to test for variants in the *ADA*, *ADAM17*, *AICDA*, *BTK*, *CD3G*, *CD40LG*, *CTLA4*, *CYBA*, *CYBB*, *DCLRE1C* (Artemis), *DKC1*, *DOCK8*, *FOXP3*, *G6PC3*, *ICOS*, *IKBKG*, *IL10*, *IL10RA*, *IL10RB*, *IL21*, *IL21R*, *IL2RA*, *IL2RG*, *ITGB2*, *LIG4*, *LRBA*, *MEFV*, *MVK*, *NCF2*, *NCF4*, *NLRC4*, *PIK3CD*, *PIK3R1*, *PLCG2*, *RAG1*, *RAG2*, *RTEL1*, *SH2D1A*, *SKIV2L*, *SLC37A4*, *STAT1*, *STAT3*, *STIM1*, *STXBP2*, *TNFAIP3*, *TTC37*, *TTC7A*, *WAS*, *WIPF1*, *XIAP*, and *ZAP70* genes.

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: 81443.

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 (First, Middle, Last)

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
IBDGP / Inflammatory Bowel Disease Primary Immunodeficiency (PID) Panel, Varies	Patient's personal and family history does not meet Medicare's medical necessity coverage criteria for this laboratory test.	\$2,860.00

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.

- 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 also receive a copy.

Signature

Date (mm-dd-yyyy)

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 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.