



Mayo Clinic Laboratories is pleased to offer prior authorization services and third party billing on our Primary Ciliary Dyskinesia Gene Panel, Varies (PCDGG). 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 PCDGG with prior authorization services, complete this document as instructed below by insurance type. **You must order test code PCDGG 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 PCDGG 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 PCDGG 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: MC2934-341)
- 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> | | Sex <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 PCDGG | Name of desired MCL test Primary Ciliary Dyskinesia Gene 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: MC2934-341
 - Templates provided on the following pages
- Copy of Front and Back of patient's insurance card (if available)

Letter of Medical Necessity for Primary Ciliary Dyskinesia Gene Panel (PCDGG) 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 Primary Ciliary Dyskinesia Gene Panel, Varies (PCDGG) 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 primary ciliary dyskinesia (PCD) is suspected and genetic testing is recommended.

Rationale: The use of genetic testing to aid in the diagnosis of primary ciliary dyskinesia is supported by experts in the field.¹⁻² Test results will have a direct impact on this patient's medical management, screening, and prevention of potential complications.

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 pathogenic variant would confirm a diagnosis of PCD, and warrant ongoing multidisciplinary care to prevent exacerbations and slow the progression of lung disease. Additionally, identification of a pathogenic variant would warrant therapeutic airway clearance and prompt aggressive administration of antibiotics. 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 PCD 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 PCD, and a positive result may mean family members are at up to a 50% risk of being affected, or of being a carrier for PCD. When a familial variant has been identified, genetic testing can identify family members who are not at increased risk to be a carrier of PCD or develop PCD-related symptoms. 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 pulmonologist.

Test requested: Primary Ciliary Dyskinesia Gene Panel, Varies (PCDGG) is a cost-effective test that utilizes next-generation sequencing (NGS) to evaluate 40 genes for pathogenic variants associated with primary ciliary dyskinesia (PCD).

Laboratory information: Testing would be performed at Mayo Clinic Laboratories (TIN# 411346366 / NPI# 1093792350), a CAP-accredited and CLIA-certified laboratory, using 2022 CPT code: 81479.

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

Sincerely,

Ordering Clinician Name _____

Contact information _____

References

1. van Dijk FS, Byers PH, Dalgleish R, et al. EMQN best practice guidelines for the laboratory diagnosis of osteogenesis imperfecta. *Eur J Hum Genet.* 2012;20(1):11-19. doi:10.1038/ejhg.2011.141

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 |
|--|--|----------------|
| PCDGG/Primary Ciliary Dyskinesia Gene Panel, Varies | Patient's personal and family history of cancer does not meet Medicare's medical necessity coverage criteria for this laboratory test. | \$2,600.00 |

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.