

Psychotropic Pharmacogenomics Gene Panel Prior Authorization Ordering Instructions

Mayo Clinic Laboratories is pleased to offer prior authorization services and third party billing on our Psychotropic Pharmacogenomics Gene Panel, Varies (PSYQP). 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 PSYQP with prior authorization services, complete this document as instructed below by insurance type. You must order test code PSYQP 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 PSYQP 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 PSYQP 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: MC2934-285)
- 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 Numb	oer							
Patient Demograp	hics and	Insurance Ir	nformation					
Patient Name (Last, First, Mid			- Indimidation	Sex	Sex		Birth Date (mm-dd-yyyy)	
, , ,	,			□ Male □	Female		, , , , , , , , , , , , , , , , , , , ,	
Patient Mailing Address				City	City		ZIP Code	
Primary Insurance Company Name			Insurance Subscriber	ID No. / Policy No.	Insura	ince Group	No. (if applicable)	
				•		·	, ,,	
Primary Insurance Company Mailing Address				City		State	ZIP Code	
Primary Insurance Compar	nv Phone		Subscriber Name (if o	ifferent than patient) a	nd Relatio	nship to Pa	tient	
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Order Information								
MCL Test ID PSYQP		ired MCL test	enomics Gene Pane	I Varios				
			monnes dene i ane	., varies				
ICD-10 Codes (use number	r codes to higl	nest specificity)				Service Da	ate (Collection Date)	
Referring Provider Name			Referring Pr	Referring Provider's National Provider ID (NPI)				
Client Account and	d Client (Soutoot Info	um ation	'				
MCL Client Account Number		Referring Client						
	- (- ,	3	,					
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: MC2934-285
 - Templates provided on the following pages
- · Copy of Front and Back of patient's insurance card (if available)

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Letter of Medical Necessity for Psychotropic Pharmacogenomics Gene Panel Testing Patient Name (Last, First, Middle) Birth Date (mm-dd-yyyy) Member Number ICD-10 Codes To Whom It May Concern: We are requesting preauthorization for the Psychotropic Pharmacogenomics Gene Panel, Varies (PSYQP) 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: Many FDA-approved drugs used to treat depression and other psychiatric disorders provide genotype-based guidance or information on the drug label aimed at assisting with determination of appropriate usage and/or dosage of the drug. The Clinical Pharmacogenomics Implementation Consortium (CPIC) and other professional organizations provide clinicians with additional assistance to effectively utilize pharmacogenomic test results.^{1,2} This test provides comprehensive analysis for multiple genes that have strong pharmacogenomics associations with medications used in the treatment of psychiatric disorders, including depression. Test results will thereby have the potential to impact the patient's medical management and treatment.

Results from this test may assist with individualized selection and dosage of medications, avoidance of drugs associated with adverse response or toxicity risk, or selection of alternative medication. In addition, this test assists with the evaluation of patients who have failed therapy with selective serotonin reuptake inhibitors (SSRIs) and patients with treatment-resistant depression. Results from this test may help to predict response time to improvement with SSRIs, and may also reduce the amount of time required to achieve response and/or remission.³

Test requested: PSYQP / Psychotropic Pharmacogenomics Gene Panel, Varies is a cost-effective test that utilizes next-generation sequencing (NGS), and other technologies to evaluate for common chromosomal aneuploidies affecting the fetus via a maternal blood specimen.

Laboratory information: Testing would be performed at Mayo Clinic Laboratories (TIN# 411346366 / NPI# 1093792350), a CAP-accredited and CLIA-certified laboratory, using CPT code: 81479, 81226, 81225, 81227, 81230, 81231, 81291, 81381 x2, 0071U-0076U (if appropriate).

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

Sincerely,

Ordering Clinician Name ______Contact information _____

- 1. Relling MV and Klein TE: CPIC: Clinical Pharmacogenetics Implementation Consortium of the Pharmacogenomics Research Network. Clin Pharmacol Ther. 2011 Mar;89(3):464-7
- 2. Swen JJ, Nijenhuis M, de Boer A, et al: Pharmacogenetics: from bench to byte--an update of guidelines. Clin Pharmacol Ther. 2011 May;89(5):662-73
- 3. Singh AB: Improved Antidepressant Remission in Major Depression via a Pharmacokinetic Pathway Polygene Pharmacogenetic Report. Clin Psychopharmacol Neurosci. 2015 Aug 31;13(2):150-6

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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 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
PSYQP / Psychotropic Pharmacogenomics Gene Panel, Varies	Patient's personal and family history of cancer does not meet Medicare's medical necessity coverage criteria for this laboratory test.	\$1,700.00

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: Chec	ck 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 Info	

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.

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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. 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.

Form CMS-R-131 (Exp. 06/30/2023)

Form Approved OMB No. 0938-0566