



Medica Central Coverage Policy

Policy Name: Genetic Testing - Specialty Testing: Toxicology and Pharmacogenomics MP9602

Effective Date: July 01, 2025

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. <https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers>

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Validated Tests

- GeneSight (Assurex Health): 0345U
- Neuropharmagen (Precision Molecular Solutions) 81418
- PGXPSYCH (PHD Laboratory LLC): 81418
- Psychotropic Pharmacogenomics Gene Panel (Mayo): 81418
- Focused Pharm Panel (Mayo): 0029U
- IDgenetix (Castle): 0411U
- Tempus nP (Tempus): 0419U
- Mental Health Panel (Exceltox Laboratories LLC): 81418
- PGX (PHD Laboratory LLC): 81418
- PGS SHORT COMP (PHD Laboratory LLC): 81418
- Sinochips PGx Comprehensive (Sinochips Kansas LLC): 81418
- Carolina Comprehensive PGx (Carolina Diagnostics Lab): 81418
- COR120 - Comprehensive Pharmacogenetic Test (Quantigen LLC): 81418
- PCL PGX+ Comprehensive Report (Patients Choice Laboratories of Indiana, LLC): 81418
- PharmGx Comprehensive PGx Panel (Dxome Clia Laboratory, Inc): 81418
- PsychPainMakers Panel (Genemarkers): 81418
- PredictScript Poly (Phenomics Health Inc): 81418
- PredictScriptCNS (Phenomics Health Inc): 81418



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COVERAGE CRITERIA

Pharmacogenetic Panel Tests

- I. Pharmacogenetic panel tests are considered **medically necessary** when:
 - A. The member is age 18 years or older, **AND**
 - B. The member is being considered for, or is already being treated with, one or more specific medication(s) related to their diagnosis that is known to have a gene-drug interaction, **AND**
 - C. The pharmacogenetic panel test being considered has proven [clinical validity](#), as demonstrated through independent evaluation from a recognized third-party source, including but not limited to MoLDx, ECRI, Hayes, Optum Genomics or FDA, **AND**
 - D. The member has a diagnosis of any of the following for which a treatment is being considered:
 1. Major depressive disorder, **OR**
 2. Generalized anxiety disorder.
- II. Pharmacogenetic panel tests are considered **investigational** for all other indications, including:
 - A. As an initial screening test for medication selection.

DEFINITIONS

1. **Clinical validity**, according to the National Institutes of Health-Department of Energy (NIH-DOE) Task Force on Genetic Testing, describes the accuracy with which a test identifies a particular clinical condition. The components of measuring clinical validity are:
 - a. **Sensitivity**: among people with a specific condition, the proportion who have a positive test result
 - b. **Specificity**: among people who do not have the condition, the proportion who have a negative test result
 - c. **Positive predictive value**: among people with a positive test result, the proportion of people who have the condition
 - d. **Negative predictive value**: among people with a negative test result, the proportion who do not have the condition

PRIOR AUTHORIZATION

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.



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BACKGROUND AND RATIONALE

Pharmacogenetic Panel Tests

Centers for Medicare and Medicaid Services

The CMS local coverage determination (LCD) entitled “MoIDX: Pharmacogenomics Testing” states the following: “PGx tests are indicated when medications are being considered for use (or already being administered) that are medically necessary, appropriate, and approved for use in the patient’s condition and are known to have a gene(s)-drug interaction that has been demonstrated to be clinically actionable...”

Bunka et al

In their 2023 rapid review and meta-analysis, Bunka et al discuss the age of patients who have participated in studies related to the use of pharmacogenetic panels. The authors note that there is currently insufficient evidence to support ordering PGx tests for adolescents as a part of their treatment for depression (p. 5).

REFERENCES

1. Centers for Medicare & Medicaid Services. Medicare Coverage Database: Local Coverage Determination. MoIDX: Phenotypic Biomarker Detection in Circulating Tumor Cells (L38294). Revision Effective Date: 08/24/2024. Available at: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38294&ver=19&>
2. Bunka M, Wong G, Kim D, et al. Evaluating treatment outcomes in pharmacogenomic-guided care for major depression: A rapid review and meta- analysis. *Psychiatry Res.* 2023;321:115102.

Note: The Health Plan uses the genetic testing clinical criteria developed by Concert Genetics, an industry-leader in genetic testing technology assessment and policy development.



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	Committee/Source	Date(s)
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Administrative Update:

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