Effective: 07/01/2025
Last Revision: 02/25/2025
Last Clinical Review: 02/24/2025

ALTERNATE **COA for:**

SPECIALTY TESTING: TOXICOLOGY AND PHARMACOGENETICS

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

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

REFERENCES

1. Centers for Medicare & Medicaid Services. Medicare Coverage Database: Local Coverage Determination. MolDX: 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&