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 Clinic Laboratories): 81418
- Focused Pharm Panel (Mayo Clinic Laboratories): 0029U
- IDgenetix (Castle Biosciences): 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 has previously been treated with at least one medication related to their diagnosis that was ineffective, **AND**

C. The member is being considered for one or more specific medication(s) related to their diagnosis that is known to have a gene-drug interaction, **AND**

D. 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**

E. 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

RATIONALE AND REFERENCES

Pharmacogenetic Panel Tests

Centers for Medicare and Medicaid Services (CMS)

The CMS local coverage determination (LCD) entitled “MolDX: 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…”

Centers for Medicare & Medicaid Services. Medicare Coverage Database: Local Coverage Determination. MolDX: Phenotypic Biomarker Detection in Circulating Tumor Cells (L38294). Revision Effective August 24, 2023.
https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38294&ver=19&

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).

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. doi:10.1016/j.psychres.2023.115102

Concert Note

Without clear guidance from professional society guidelines or other comparable resources, Concert maintains the position of coverage for this testing contingent on the member failing at least one medication in keeping with mainstream clinical practice and the practical realities of needing to treat patients prior to return of test results.