**New *ALTERNATE* COA for:**

# GENETIC TESTING: PHARMACOGENETICS

## Example Tests and CPT codes

- GeneSight (Assurex Health): 0345U
- Genomind Professional PGx Express (Genomind): 0175U
- NeuroIDgenetix (AltheaDx): 81479
- Neuropharmagen (Precision Molecular Solutions) 81418
- PGXPSYCH (PHD Laboratory LLC) 81418
- Psychotropic Pharmacogenomics Gene Panel (Mayo): 81418
- Focused Pharm Panel (Mayo): 0029U
- Personalised RX (Lab Genomics, Agena Biosciences): 0380U
- IDgenetix (Castle): 0411U
- Tempus nP (Tempus): 0419U

# NEW COVERAGE CRITERIA

## Pharmacogenetic Panel Tests

I. Pharmacogenetic panel tests (0029U, 0175U, 0345U, 0380U, 0411U, 0419U, 81418, 81479) 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, **AND**

D. The pharmacogenetic panel test being considered has proven clinical utility, **AND**

E. The member has a diagnosis of any of the following for which a treatment medication is being considered:

1. Major depressive disorder, **OR**

2. Generalized anxiety disorder.

II. Pharmacogenetic panel tests (0029U, 0175U, 0345U, 0380U, 0411U, 0419U, 81418, 81479) 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

2. **Clinical utility** refers to the risks and benefits resulting from genetic test use. The most important considerations in determining clinical utility are: (1) whether the test and any subsequent interventions lead to an improved health outcome among people with a positive test result; and (2) what risks occur as a result of testing.

# BACKGROUND AND RATIONALE

*Centers for Medicare and Medicaid Services*

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…"

The CMS local coverage determination (LCD) reference article entitled "Billing and Coding: MolDX: Pharmacogenomics Testing" lists several panels it considers "covered multigene panels with intended uses" for major depressive disorder (MDD) and several neuropsychiatric disorders. This reference article also outlines specific multigene panels covered for neuropsychiatric indications, included in the "covered multigene panels with intended uses" table as well as the Group 1 Codes table.

*Bunka et al*

In their 2023 rapid review and meta-analysis, Bunka et al state the following regarding the age of patients who have participated in studies related to the use of pharmacogenetic panels: "The only RCT [randomized controlled trials] including adolescents (Vande Voort et al., 2021) found no significant differences between groups in symptom improvement (that is, change in depression scale score), response, or remission at week 8 or at any point throughout the study as measured with the Children's Depression Rating Scale-Revised (CDRS-R) or the Quick Inventory of Depressive Symptomatology (QIDS). There was no statistically significant difference in the number of adverse events or side effects between groups. While there was a statistically significant improvement in patient and parent satisfaction with care in the overall study population, it was not significantly different between the treatment arms. Based on these findings, there is currently no evidence to support the use of PGx tests in depression care for adolescents." (p. 5)

# REFERENCES

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

2. Centers for Medicare & Medicaid Services. Medicare Coverage Database: Billing and Coding Article. Billing and Coding: MolDX: Pharmacogenomics Testing (A58324) Available at: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58324&ver=30&
3. 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.