



Senate Bill (SB) 961 Required Coverage for Pharmacogenomic Testing

Lisa Kennedy, ASA, MAAA, FCA

Principal | Berry, Dunn, McNeil & Parker, LLC

Dina Nash, MPH

Manager | Berry, Dunn, McNeil & Parker, LLC

November 20, 2025

Agenda

- I. Overview and Legislation**
- II. Social Evaluation**
- III. Medical Evaluation**
- IV. Financial Evaluation**

Overview and Legislation

Pharmacogenomic Testing

Definition

- Pharmacogenomic (PGx) testing is defined in SB961 as “laboratory genetic testing, including single-gene and multigene panel testing, constructed to evaluate how an individual’s genetic profile may impact the efficacy, safety, or toxicity of medications.”
 - PGx tests identify genetic variations that affect how individuals metabolize and respond to medications, which can influence treatment outcomes and side effects.
 - PGx test results are used by providers to guide prescription of antidepressants, such as SSRIs and SNRIs, to align with an individual’s genetic makeup.

Overview and Legislation

Senate bill 961 introduced during the 2025 session

- **The bill would require commercial insurers and Maryland Medicaid to cover PGx testing for individuals with diagnosed anxiety and depression.**
- Chapter 322 of the Laws of 2023 requires coverage of biomarker testing used to guide diagnosis, treatment, or monitoring when supported by evidence.
 - Effective January 1, 2024 (commercial) and July 1, 2025 (Medicaid Fee-for-Service [FFS] and Managed Care Organizations [MCOs]).
- PGx testing for anxiety and depression is often not considered medically necessary by insurers and thus not covered under existing biomarker legislation.
- SB 961 has explicit coverage requirements for PGx testing for individuals with anxiety and depression.

Social Evaluation

**Prevalence, Utilization, Coverage, and
Access**

Social Evaluation

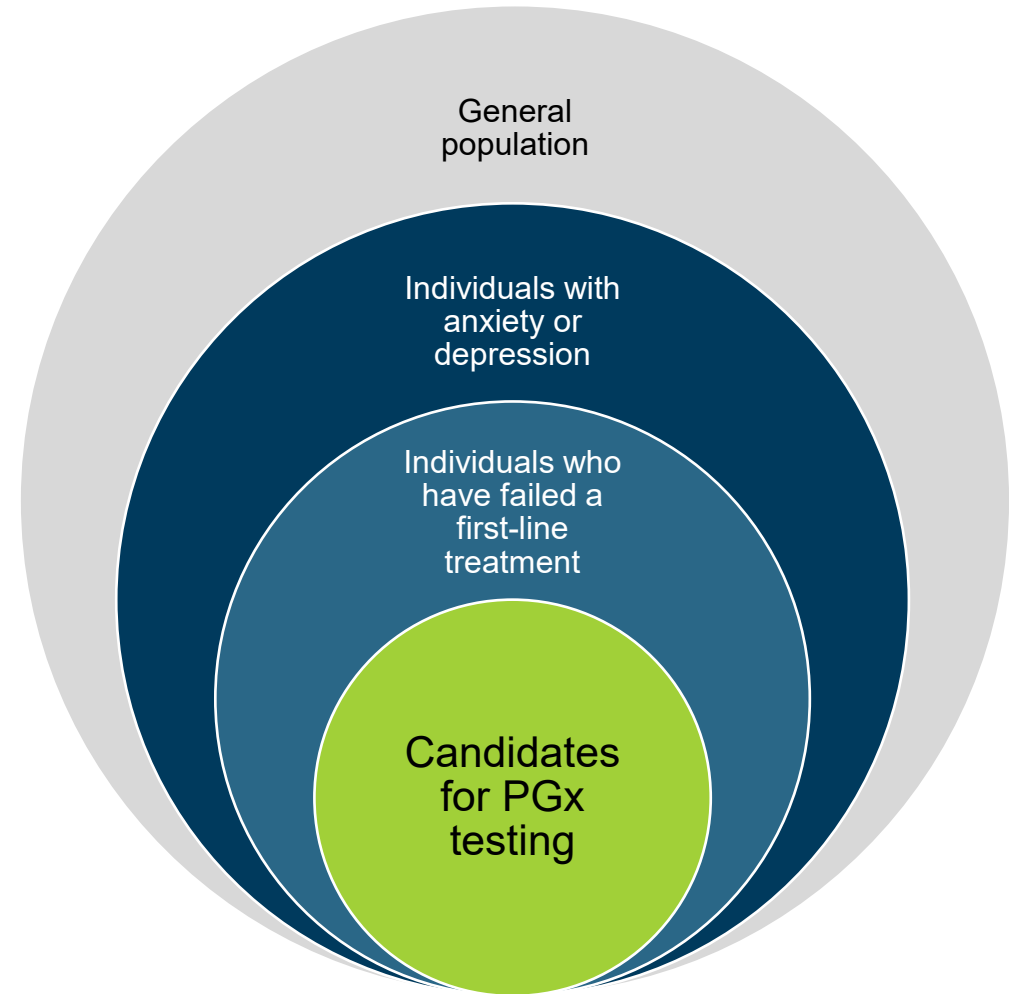
Background

- Anxiety and depression are common mental health conditions that can interfere with daily activities and quality of life if untreated.
- Antidepressants such as SSRIs and SNRIs are first-line treatments for anxiety and depression as well as many other mental health issues.
- PGx testing uses information about a person's genetic makeup to help determine which medications, and at what doses, are likely to be the most effective and safe.

Social Evaluation

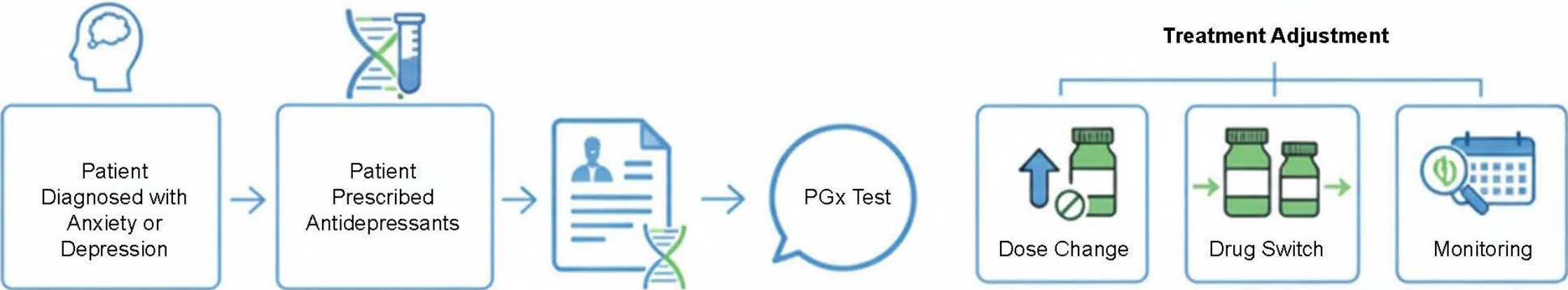
Use Cases

- PGx testing is primarily utilized for individuals who have unsuccessfully tried at least one medication.
- According to responses from expert interviews, PGx testing is most effective when used with patients who are unresponsive or have had adverse responses to medications.



Social Evaluation

Integration of PGx Testing in Treatment Plans



Social Evaluation

Utilization and Demand

- In February 2023, 27.3% of adults in Maryland reported experiencing symptoms of anxiety or depression.
 - Anxiety and depression are more common among certain populations, such as individuals insured via Medicaid.
- Individuals with anxiety or depression are more likely to miss workdays or be less productive while at work.
 - Effective treatment can alleviate symptoms, improve health outcomes, and reduce absenteeism.
- PGx testing is rarely used nationwide; according to a 2022 survey, less than 1% of patients who experienced depressive episodes received PGx testing.

Social Evaluation

ACA and Existing Coverage

In Scope

- Commercial coverage remains limited and variable across insurers – most large insurers do not cover.
- Medicaid coverage is not required and is on a case-by-case basis.

Out of Scope

- Medicare covers PGx testing when prescribing drugs with known drug-gene interactions (including many common SSRIs) under the Molecular Diagnostic Services Program (MoIDX®).

Social Evaluation

Access

- Access to PGx testing is highly variable across insurers.
 - Several insurers considered PGx testing to be “experimental” and “not medically necessary” and thus do not cover.
 - Some insurers who do cover PGx testing impose prior authorization requirements or only cover a subset of available tests.
- Access is limited by provider knowledge and experience with PGx testing.
 - Demand and utilization for PGx testing could increase with more widespread provider and patient knowledge.

Medical Evaluation

Efficacy

Medical Evaluation

Efficacy

- Efficacy has been shown to be limited and variable across studies.
 - Short-term symptomatic remission has been consistently demonstrated but long-term impact is unclear.
 - Limitations to study conclusions include lack of rigorous experimental design, bias, and variable/conflicting outcomes between studies.
 - Insurers mostly indicated that PGx testing for mental health does not meet their criteria for medical effectiveness.

Financial Evaluation

Public and Commercial Insurance Cost Analysis

Financial Evaluation

Overview and Methodology

- Applicable population divided into market segments: fully insured (individual, small group, large group); Medicaid; State Employee Health Plan
- Multi-step modeling process
 - Data sources included claims and enrollment data from the MCDB, information from the carrier survey, and literature
 - Claims data were analyzed to estimate the current number of PGx test users
 - A range of utilization increase factors were developed to capture the potential impacts of relaxed prior authorization requirements
 - Ranges for the cost of PGx tests were developed from the base period claim data

Financial Evaluation

Utilization

- Medicaid utilization is higher than commercial
- Relatively low utilization overall as PGx tests for anxiety and depression are still deemed experimental by most insurers

Current PGx Testing Utilization

	Three-Year Average PGx Users	% of Population Receiving PGx Tests
Individual	116	0.04%
Fully Insured Small Group	102	0.05%
Fully Insured Large Group	495	0.11%
Totally Fully Insured Commercial	713	0.08%
State Employee Health Plan	89	0.04%
Medicaid	9,077	0.55%

Projected PGx Testing Utilization

	Mid-Range Projected PGx Users	% of Population Receiving PGx Tests
Individual	249	0.09%
Fully Insured Small Group	219	0.11%
Fully Insured Large Group	1,065	0.24%
Totally Fully Insured Commercial	1,532	0.17%
State Employee Health Plan	192	0.09%
Medicaid	19,516	1.18%

Financial Evaluation

Considerations and Limitations

The incremental insurance cost impact estimates rely on a series of assumptions relating to utilization, cost of services, retention, and population estimation. Notable limitations and considerations related to the mandate study include:

- Base period claims were limited due to variations in carrier coverage decisions and the continuing evolution of PGx testing
- The potential effect of increasing awareness of PGx testing is unknown, which could drive utilization higher than projected
- The Medicaid continuous eligibility coverage during the COVID-19 public health emergency, and subsequent continuous coverage unwinding may have impacted utilization and enrollment across the market segments during the base period

Financial Evaluation

PGx Testing Commercial Cost Estimate

Total Fully Insured Commercial (Individual, Small Group, Large Group)

Range of Estimates	Low	Middle	High
% of Population Receiving PGx testing	0.10%	0.17%	0.23%
Increase to Premium* PMPM	\$0.01	\$0.04	\$0.07
% Increase to Premium	0.002%	0.007%	0.012%
Total Increase to Premium	\$108,236	\$414,905	\$721,574

*Premiums in the fully insured market refer to projected funding to cover any fee-for-service claims, non-claim expenses, administrative expenses, fixed fees, contribution to reserve/profit, and state/federal taxes and assessments. Member cost-sharing (e.g., deductibles, copays, and coinsurance) is excluded.

Financial Evaluation

PGx Testing Medicaid Cost Estimate

Medicaid			
Range of Estimates	Low	Middle	High
% of Population Receiving PGx Testing	0.71%	1.18%	1.64%
Increase to Program Costs* PMPM	\$0.02	\$0.09	\$0.16
% Increase to Program Costs	0.006%	0.021%	0.037%
Total Increase to Program Costs	\$466,361	\$1,787,718	\$3,109,075

*Program costs for Medicaid refer to projected funding to cover any fee-for service claims, non-claim expenses, capitation, administrative expenses, fixed fees, contribution to reserve/surplus, and/or risk margin, and state taxes, fees, and assessments.

Financial Evaluation

PGx Testing State Employee Health Plan Cost Estimate

State Employee Health Plan			
Range of Estimates	Low	Middle	High
% of Population Receiving PGx Testing	0.06%	0.09%	0.13%
Increase to Premium Equivalent* PMPM	\$0.01	\$0.05	\$0.09
% Increase to Premium Equivalent	0.002%	0.007%	0.011%
Total Increase to Premium Equivalent	\$31,391	\$120,332	\$209,273

*Premium equivalent refers to projected funding to cover any fee-for service claims, non-claim expenses, administrative expenses, fixed fees, contribution to reserve/surplus, and/or risk margin. Member cost-sharing (e.g., deductibles, copays, and coinsurance) is excluded.

Key Takeaways

- Currently, coverage for PGx testing is minimal across most insurers
- The efficacy of PGx testing is limited and uncertain compared to treatment as usual, especially across longer time frames
- Utilization of PGx testing could increase due to external factors, creating uncertainty about the long-term impact of mandated coverage
- Across market segments, the mandate would increase the cost of insurance; biggest impact is for Medicaid

Thank You

Lisa Kennedy, ASA, MAAA, FCA

Principal | Berry, Dunn, McNeil & Parker, LLC

Dina Nash, MPH

Manager | Berry, Dunn, McNeil & Parker, LLC

Appendices

Key Terms, References

Key Terms

Term	Definition
Antidepressant	Antidepressants are drugs designed to alleviate symptoms of depression by altering the levels of certain brain chemicals. Examples of antidepressants include SSRIs, selective/norepinephrine reuptake inhibitors (SNRIs), and tricyclic antidepressants.
Clinical Utility	Clinical utility refers to the risks and benefits resulting from the utilization of a particular method, drug, or service. This includes side effects, cost, patient attrition, quality of life, and any other direct or indirect effects on the patient's life.
Gene-Drug Interaction	A gene-drug interaction refers to the way an individual's genetic makeup influences their response to medications.
Symptomatic Remission	Symptomatic remission is defined differently across studies and illnesses. Full remission means the patient is no longer affected by any symptoms of the condition; however, studies often refer to partial remission. In this context, partial remission often refers to a reduction in severity or number of symptoms.
Statistical Significance	A result is statistically significant if the likelihood of a certain relationship between variables is above a certain level (usually 95%) based on analysis of available data.
Selective Serotonin Reuptake Inhibitor(SSRI) / Selective Norepinephrine Reuptake Inhibitor(SNRI)	Classes of antidepressants commonly used as first-line treatments for a range of mental health conditions including anxiety and depression. SSRIs and SNRIs are the primary drug classes for which PGx testing can be utilized in a mental health context.

References

- Albers RE, Dyer MP, Kucera M, et al. Meta-Analysis of Response and Remission Outcomes With a Weighted Multigene Pharmacogenomic Test for Adults With Depression. *J Clin Psychopharmacol*. 2025. doi: 10.1097/JCP.0000000000002061.
- Anderson HD, Thant TM, Kao DP, Crooks KR, Mendola ND, Aquilante CL. Pharmacogenetic Testing Among Patients With Depression in a US Managed Care Population. *Clin Transl Sci*. 2022;15(7):1644-1653. doi: 10.1111/cts.13279.
- Centers for Medicare & Medicaid Services. Maryland EHB Benchmark Plan (2025-2027). <https://www.cms.gov/files/document/md-bmp-summary-py2025-2027.pdf>. Accessed September 23, 2025.
- Centers for Medicare & Medicaid Services. MolDX: Pharmacogenomics Testing. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=38294&DocID=L38294>. Revised October 2, 2025. Accessed October 8, 2025.
- Chapter 322 (Senate Bill 805) AN ACT concerning Maryland Medical Assistance Program and Health Insurance – Required Coverage for Biomarker Testing. https://mgaleg.maryland.gov/2023RS/Chapters_noln/CH_322_sb0805e.pdf. Accessed October 20, 2025.
- Cleveland Clinic. Proton Pump Inhibitors. <https://my.clevelandclinic.org/health/articles/proton-pump-inhibitors>. Updated September 28, 2023. Accessed September 22, 2025.
- CPIC. Guidelines. <https://cpicpgx.org/guidelines/>. Accessed July 15, 2025. Shi L, Chen ZW, Dotson D, et al. Cost-Effectiveness of Pharmacogenomic Testing: How to Measure the Value of Having the Right Dose of the Right Drug for the Right Patient. <https://blogs.cdc.gov/genomics/2023/05/08/cost-effectiveness/>. Published May 8, 2023. Accessed July 23, 2025.
- Cung M, Loftus J, Marzinke MA, Stevenson JM. Reinterpretation of Pharmacogenomic Phenotypes After Combinatorial Psychiatric Testing. *Pharmacogenomics*. 2025;26(1-2):1-7. doi: 10.1080/14622416.2025.2479409.
- Davis K. Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey. Statistical Brief #418: State Differences in the Cost of Job-Related Health Insurance, 2012. Published July 2013. https://meps.ahrq.gov/data_files/publications/st418/stat418.shtml. Accessed October 20, 2025.
- Del Tredici AL, Johnson HL, DeHart B, et al. Real-World Impact of Pharmacogenomic Testing on Medication Use and Healthcare Resource Utilization in Patients With Major Depressive Disorder. *J Clin Psychopharmacol*. 2025;45(4):320-328. doi: 10.1097/JCP.0000000000001999.
- Forester BP, Parikh SV, Weisenbach S, et al. Combinatorial Pharmacogenomic Testing Improves Outcomes for Older Adults With Depression. *Am J Geriatr Psychiatry*. 2020;28(9):933-945. doi: 10.1016/j.jagp.2020.05.005.
- Gene Interactions on Medication Selection and Remission of Symptoms in Major Depressive Disorder: The PRIME Care Randomized Clinical Trial. *JAMA*. 2022;328(2):151–161. doi: 10.1001/jama.2022.9805.

References

- Gene Interactions on Medication Selection and Remission of Symptoms in Major Depressive Disorder: The PRIME Care Randomized Clinical Trial. *JAMA*. 2022;328(2):151–161. doi: 10.1001/jama.2022.9805.
- GeneSight. GeneSight® Tests: Psychotropic and MTHFR. <https://genesight.com/product/>. Accessed September 6, 2025.
- Greden JF, Parikh SV, Rothschild AJ, et al. Impact of Pharmacogenomics on Clinical Outcomes in Major Depressive Disorder in the GUIDED Trial: A Large, Patient- and Rater-Blinded, Randomized, Controlled Study. *J Psychiatr Res*. 2019;111:59-67. doi: 10.1016/j.jpsychires.2019.01.003.
- Grogan S, Preuss CV. Pharmacokinetics. <https://www.ncbi.nlm.nih.gov/books/NBK557744/>. Updated July 30, 2023. Accessed September 10, 2025.
- Hicks JK, Sangkuhl K, Swen JJ, et al. Clinical Pharmacogenetics Implementation Consortium Guideline (CPIC) for CYP2D6 and CYP2C19 Genotypes and Dosing of Tricyclic Antidepressants: 2016 Update. *Clin Pharmacol Ther*. 2017;102(1):37-44. doi: 10.1002/cpt.597.
- Joas E, Jonsson L, Viktorin A, et al. Effect of CYP2C19 polymorphisms on antidepressant prescription patterns and treatment emergent mania in bipolar disorder. *Pharmacogenomics J*. 2023;23(1):28-35. doi: 10.1038/s41397-022-00294-4. U.S. Food & Drug Administration. Table of Pharmacogenetic Associations. <https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations>. Updated October 26, 2022. Accessed July 15, 2025.
- Kastrinos A, Campbell-Salome G, Shelton S, Peterson EB, Bylund CL. PGx in psychiatry: Patients' knowledge, interest, and uncertainty management preferences in the context of pharmacogenomic testing. *Patient Educ Couns*. 2021 Apr;104(4):732-738. doi: 10.1016/j.pec.2020.12.021. Epub 2020 Dec 25. PMID: 33414028; PMCID: PMC9620865.
- KFF. 2024 Employer Health Benefits Survey. Section 3: Employee Coverage, Eligibility, and Participation. Published October 9, 2024. <https://www.kff.org/health-costs/2024-employer-health-benefits-survey/#e3efa8b3-48d2-458b-a2f7-c4d5add1983b--h-section-3-employee-coverage-eligibility-and-participation>. Accessed October 21, 2025.
- KFF. Mental Illness Prevalence by Insurance Coverage. <https://www.kff.org/mental-health/state-indicator/mental-illness-prevalence-by-insurance-coverage/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>. Accessed September 22, 2025.
- Lin GA, Coffman JM, Phillips KA. The State of State Biomarker Testing Insurance Coverage Laws. *JAMA*. 2024;331(22):1885-1886. doi: 10.1001/jama.2024.6058.
- Maryland Department of Budget and Management. 2025 Direct Pay Enrollees Monthly Rates. <https://dbm.maryland.gov/benefits/Documents/CY25%20Direct%20Pay%20Rate%20Sheet.pdf>. Accessed October 20, 2025.
- Maryland General Assembly Department of Legislative Services. Senate Bill 961 Fiscal and Policy Note. Published February 25, 2025. https://mgaleg.maryland.gov/2025RS/fnotes/bil_0001/sb0961.pdf. Accessed October 21, 2025.

References

- Maryland General Assembly. Maryland Medical Assistance Program and Health Insurance - Pharmacogenomic Testing - Required Coverage. <https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/sb0961>. Updated February 27, 2025. Accessed September 9, 2025.
- Maryland Insurance Administration. Essential Health Benefits Chart: Individual and Small Group Plans. <https://insurance.maryland.gov/consumer/documents/publicnew/essentialbenefitschart.pdf>. Published September 8, 2025. Accessed September 9, 2025.
- MedlinePlus. Anxiety. <https://medlineplus.gov/anxiety.html>. Updated October 17, 2023. Accessed September 8, 2025.
- MedlinePlus. Depression. <https://medlineplus.gov/depression.html>. Updated June 30, 2025. Accessed September 8, 2025.
- Ortaliza J, Cox C. KFF. 2024 Medical Loss Ratio Rebates. <https://www.kff.org/private-insurance/medical-loss-ratio-rebates/>. Published June 5, 2024. Accessed October 9, 2025.
- Ortaliza J, Fuglesten Biniek J, Hinton E, et al. Health Insurer Financial Performance in 2023. KFF. Published July 2, 2024. <https://www.kff.org/medicare/health-insurer-financial-performance/>. Accessed October 21, 2025.
- Palumbo S, Mariotti V, Pellegrini S. A Narrative Review on Pharmacogenomics in Psychiatry: Scientific Definitions, Principles, and Practical Resources. *J Clin Psychopharmacol*. 2024;44(1):49-56. doi: 10.1097/JCP.0000000000001795.
- Patel JN, Chaihorsky L, Dong OM, et al. Medical Policy Determinations for Pharmacogenetic Tests Among US Health Plans. *Am J Manag Care*. 2025;31(2):e47-e55. doi: 10.37765/ajmc.2025.89683.
- Pyzocha N. GeneSight Psychotropic Genetic Testing for Psychiatric Medication Selection. *Am Fam Physician*. 2021;104(1):89-90. <https://pubmed.ncbi.nlm.nih.gov/34264602/>. Accessed July 16, 2025.
- Stevenson JM, Smith DM, Tuteja S, Patel JN. Pharmacogenomics Global Research Network (PGRN) Publications Committee. Navigating Pharmacogenomic Testing in Practice: Who to Test and When to Test. *Clin Pharmacol Ther*. 2025;118(3):561-566. doi: 10.1002/cpt.3704.
- Telcor. UHC Will No Longer Cover Pharmacogenetic Panel Tests for Commercial and Individual Exchange Plans. <https://telcor.com/uhc-will-not-cover-pharmacogenetic-panel-tests-for-commercial-and-individual-exchange-plans/#:~:text=According%20to%20a%20policy%20bulletin%20issued%20by%20UHC,any%20indication%20due%20to%20insufficient%20evidence%20of%20efficacy.%E2%80%9D>. Accessed September 9, 2025.

References

- U.S. Food & Drug Administration. Drug Advertising: A Glossary of Terms. <https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms>. Updated January 19, 2020. Accessed October 6, 2025.
- Vest BM, Wray LO, Brady LA, et al. Primary Care and Mental Health Providers' Perceptions of Implementation of Pharmacogenetics Testing for Depression Prescribing. *BMC Psychiatry*. 2020;20(518). doi: 10.1186/s12888-020-02919-z. Barlati S, Minelli A, Nibbio G, et al. The Role of Pharmacogenetics in the Treatment of Major Depressive Disorder: A Critical Review. *Front Psychiatry*. 2023;14:1307473. doi: 10.3389/fpsy.2023.1307473.
- Wang X, Wang C, Zhang Y, An Z. Effect of Pharmacogenomics Testing Guiding on Clinical Outcomes in Major Depressive Disorder: A Systematic Review and Meta-Analysis of RCT. *BMC Psychiatry*. 2023;23(1):334. doi: 10.1186/s12888-023-04756-2.
- Yankah SE, Nafie M, Hendricks-Sturup RM, Lu CY. An Assessment of Real-World Evidence and Other Sources Supporting Payer Coverage Decisions for Pharmacogenomic Testing in Psychiatry. *J Pers Med*. 2025;15(6):232. doi: 10.3390/jpm15060232.