BerryDunn

Maryland Health Care Commission

Maryland Medical Assistance Program and Health Insurance – Pharmacogenomic Testing – Required Coverage – Senate Bill 961

MARYLAND Health Care Commission

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Highlights

Senate Bill 961 Required Coverage for Pharmacogenomic Testing

The Maryland Health Care Commission (MHCC) is required to evaluate the medical, social, and financial impact of a proposed health insurance services mandate. Senate Bill 961 would have required Maryland's state-regulated commercial insurers and the Maryland Medical Assistance Program (Medicaid) to provide coverage for pharmacogenomic (PGx) testing for individuals with diagnosed anxiety and depression. PGx testing uses genetic information to guide medication choice and dosing for more personalized care.

Social Evaluation

- Anxiety and depression affect a significant portion of the population, both nationwide and in Maryland.
- These conditions can negatively impact individuals' quality of life and daily functioning, underscoring the value of effective treatment.
- Researchers found anxiety and depression impose large economic costs through absenteeism, reduced productivity, and lost household income.
- Insurance coverage for PGx testing is inconsistent across states and insurers; Medicare offers relatively broad coverage, while commercial coverage is often limited.
- When coverage is unavailable, patients may forgo PGx testing, limiting access to potentially beneficial precision-guided treatment options.

Medical Evaluation

- Standard treatments (e.g., therapy, lifestyle interventions, medications) are widely available and clinically recognized as effective, though responses vary by individual.
- PGx testing is recognized in the medical community as a tool that can modestly improve short-term treatment outcomes by informing antidepressant selection and dosing, though long-term benefits remain uncertain.
- Clinical guidelines support PGx-informed prescribing in certain contexts, but evidence remains mixed, and adoption is uneven due to limited independent research and provider familiarity.

Financial Evaluation

BerryDunn estimates that the proposed mandate requiring coverage of PGx testing for anxiety and depression would result in increases in health insurance costs[i] across all market segments. For fully insured health plans, the projected premium increase ranges from $0.01 (or 0.002%) to $0.07 (or 0.012%) per member per month (PMPM). For self-insured State of Maryland employee health benefit plans (State Health Plan), the projected premium equivalent increase ranges from $0.01 (or 0.002%) to $0.09 (or 0.011%) PMPM. The projected Medicaid program cost increase is

[i] The term "health insurance costs" is used to describe premiums in the fully insured market, premium equivalents in the self-insured market, and program costs for Medicaid. Health insurance cost components vary by market segment but refer to projected funding to cover any fee-for service claims, non-claim expenses, capitation, administrative expenses, fixed fees, assessments, taxes, contribution to reserve/profit margin, cost of capital, and risk and contingency margin. Member cost-sharing (e.g., deductible, copay, and coinsurance) is not included in health insurance costs.

$0.02 (or 0.006%) to $0.16 (or 0.037%) PMPM. Table 1 below summarizes the projected incremental cost of the proposed mandate by market segment.

Table 1: PGx Testing Projected Incremental Cost Summary by Market Segment

Range of Estimates	Low	Middle	High
Fully Insured Individual			
% of Fully Insured Individual Market Population Receiving PGx Tests	0.05%	0.09%	0.13%
Fully Insured Individual Premium PMPM Increase	$0.01	$0.05	$0.08
Fully Insured Individual Premium PMPM % Increase	0.003%	0.010%	0.018%
Fully Insured Individual Premium Increase	$42,274	$162,049	$281,824
Fully Insured Small Group			
% of Fully Insured Small Group Population Receiving PGx Tests	0.07%	0.11%	0.16%
Fully Insured Small Group Premium PMPM Increase	$0.01	$0.03	$0.06
Fully Insured Small Group Premium PMPM % Increase	0.001%	0.006%	0.010%
Fully Insured Small Group Premium Increase	$21,369	$81,915	$142,460
Fully Insured Large Group			
% of Fully Insured Large Group Population Receiving PGx Tests	0.15%	0.24%	0.34%
Fully Insured Large Group Premium PMPM Increase	$0.01	$0.03	$0.06
Fully Insured Large Group Premium PMPM % Increase	0.001%	0.005%	0.009%
Fully Insured Large Group Premium Increase	$44,594	$170,942	$297,290
Total Fully Insured Commercial (Individual, Small Group, Large Group)			
% of Total Fully Insured Population Receiving PGx Tests	0.10%	0.17%	0.23%
Total Fully Insured Premium PMPM Increase	$0.01	$0.04	$0.07
Total Fully Insured Premium PMPM % Increase	0.002%	0.007%	0.012%
Total Fully Insured Premium Increase	$108,236	$414,905	$721,574
Self-Insured State Health Plan			
% of Self-Insured State Health Plan Population Receiving PGx Tests	0.06%	0.09%	0.13%
Self-Insured State Health Plan Premium Equivalent PMPM Increase	$0.01	$0.05	$0.09
Self-Insured State Health Plan Premium Equivalent PMPM % Increase	0.002%	0.007%	0.011%
Self-Insured State Health Plan Premium Equivalent Increase	$31,391	$120,332	$209,273
Medicaid			
% of Medicaid Population Receiving PGx Tests	0.71%	1.18%	1.64%
Medicaid Program Cost PMPM Increase	$0.02	$0.09	$0.16
Medicaid Program Cost PMPM % Increase	0.006%	0.021%	0.037%
Medicaid Program Cost Increase	$466,361	$1,787,718	$3,109,075

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1.0 Executive Summary

1.1 Background

Insurance Article §15-1501, Annotated Code of Maryland, requires the Maryland Health Care Commission (MHCC) to evaluate the medical, social, and financial impact of proposed mandated health insurance services.[1] This report is in response to Senate Bill 961 (SB 961), introduced during the 2025 legislative session. The legislation would have required Medicaid and other state-regulated health insurers[ii] to provide coverage of PGx testing for individuals with diagnosed anxiety and depression.[2]

PGx testing is a laboratory test used to assess how an individual's genetic makeup influences metabolism, efficacy, and potential side effects of various medications. In the context of this bill, PGx testing is specifically used to inform medication selection and dosing for treatment of anxiety and depression (e.g., antidepressants), with the goal of improving treatment outcomes and reducing adverse effects.[3]

The requirements include both single-gene and multi-gene[iii,4] PGx testing when: the individual has a diagnosis of anxiety or depression, a provider is considering a medication change or augmentation, gene-drug interactions are known, and the test is ordered by the provider. The bill establishes limits to prior authorization requirements and permits the provider to submit prior authorization requests with minimum necessary documentation.

1.2 Social Evaluation

Anxiety and depression affect large portions of the population, with higher rates among women, young adults, and individuals identifying as two or more races. These conditions impair daily functioning and have measurable effects on well-being and productivity.[5,6,7]

Coverage for PGx testing varies widely across commercial plans. The proposed PGx testing legislation seeks to create clear, condition-specific requirements for testing when gene-drug interactions are relevant to prescribing decisions.[1] Use of PGx testing for mental health care remains low. National data show that fewer than one percent of patients with depressive episodes received PGx testing, most often after trying at least one medication.[8]

Variation in coverage leads to out-of-pocket costs and administrative hurdles that restrict access.[8] Provider familiarity also remains uneven, limiting broader clinical adoption.[9] States differ in how they regulate biomarker and PGx testing. Many require evidence tied to the Food and Drug Association labeling or Medicare coverage, which limits use for mental health conditions. Only a subset of states

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[ii] Insurers include commercial health insurers, nonprofit health service plans, health maintenance organizations, and managed care organizations.

[iii] Single gene testing analyzes drug gene interactions for one gene. Multi-gene testing, including Myriad's GeneSight test, analyzes several different genes, which can provide more information about potential drug-gene interactions.

explicitly support PGx testing coverage through Medicaid or broader biomarker mandates. This creates inconsistent access across the country and uncertainty for patients and clinicians.[10,11]

1.3 Medical Evaluation

Anxiety and depression are common conditions that significantly affect health, daily functioning, and quality of life, and they carry substantial social and economic costs through absenteeism, reduced productivity, and lost household income.[5,6] Effective treatments such as psychotherapy, lifestyle interventions, and antidepressant medications are widely available and recognized by the medical community, though individual response to treatment varies.[5,6] PGx testing has emerged as a tool to inform antidepressant selection and dosing, with some evidence of modest short-term improvements in treatment response, though long-term benefits remain uncertain. [12,13] Clinical guidelines acknowledge PGx testing in limited circumstances, but adoption is constrained by mixed evidence and limited provider familiarity.[14,15]

Recognizing the complexity of this topic, an overview of key medical terminology is provided in Appendix A.

1.4 Financial Evaluation

BerryDunn conducted a financial evaluation to estimate the potential fiscal impact of mandating insurance coverage of PGx testing for individuals with anxiety and depression under the proposed legislation. The analysis relied on data from Maryland's All Payer Claims Database (APCD), the Medical Care Data Base (MCDB). The MCDB includes enrollment, provider, and claims data for Maryland residents across private insurance (excluding self-insured plans governed by the Employee Retirement Income Security Act of 1974 [ERISA] since 2015), Medicaid fee-for-service (FFS), and Medicaid Managed Care Organizations (MCOs).[16] Data from the MCDB was supplemented by:

- Insurer responses to the survey administered by MHCC in conjunction with BerryDunn.
- Input from medical, pharmacology and therapeutics, and pharmaceutical industry experts.[iv]
- Maryland State Employee Health Benefit Plan (State Health Plan) information.
- Maryland Medicaid financial monitoring reports.
- Related medical literature.

Utilization rates were adjusted to reflect anticipated increases associated with expanded coverage and reduced prior authorization requirements. The cost per test was assumed to be an average of 2022 to 2024 testing costs, and calculated by type of PGx test (i.e., single-gene, multi-gene, or tests categorized as either single- or multi-gene). The health insurance cost impacts associated with the

[iv] Myriad Genetics is the developer and manufacturer of the GeneSight test, which would be required for coverage under this legislation if enacted. Myriad Genetics representatives co-testified at the bill's legislative hearing alongside the bill's sponsor.

passing of the mandate was adjusted for existing coverage, administrative costs, and other retention[v] factors. The modeling indicates that the proposed mandate would result in increases in PMPM insurance costs across market segments: $0.01 (or 0.002%) to $0.07 (or 0.012%) PMPM for fully insured plans, $0.01 (or 0.002%) to $0.09 (or 0.011%) PMPM for the State Health Plan, and $0.02 (or 0.006%) to $0.16 (or 0.037%) PMPM for Medicaid.

These results suggest that while the mandate would broaden access to PGx testing for anxiety and depression, the associated cost increases are relatively small in relation to overall health insurance expenditures. Notably, these estimates are subject to a range of considerations and limitations, including variation in current coverage policies, evolving clinical evidence on PGx testing, differences in provider ordering practices, potential changes in utilization following the mandate, and data constraints within the MCDB. As a result, actual costs could be higher or lower depending on future trends in utilization, coverage policies, and clinical practice.

[v] Depending on the market segment, retention can include administrative expenses, fixed fees, assessments, taxes, contribution to reserve/surplus, cost of capital, and risk margin.

2.0 Social Evaluation

Anxiety and depression are both common mental health conditions that can be influenced by genetics, and environmental and psychological factors. Anxiety and depression, untreated, can interfere with daily activities and quality of life. Standard treatment for both conditions includes medications, psychotherapy, or a combination, along with lifestyle changes including regular exercise and reducing stress.[5,6] Antidepressants are common treatments for anxiety and depression as well as for obsessive-compulsive disorder (OCD), social phobia, panic disorder, and post-traumatic stress disorder (PTSD).[vi,17] Researchers are still studying how antidepressants work. Currently, it is believed that antidepressants target the brain's chemical receptors (neurotransmitters), improving the body's ability to utilize chemicals (e.g., serotonin, dopamine, norepinephrine), alleviating symptoms.[6] According to the National Institute of Mental Health (NIMH), antidepressants take approximately four to eight weeks to demonstrate improvement in mood.[18]

The most commonly prescribed antidepressants include selective serotonin reuptake inhibitors (SSRIs), serotonin/norepinephrine reuptake inhibitors (SNRIs), and tricyclic antidepressants (TCAs).[5,6] Individual experiences of side effects vary. Common antidepressant side effects include "sexual dysfunction, drowsiness, weight gain, insomnia, anxiety, dizziness, headaches, dry mouth, blurred vision, nausea, rash, and tremors."[1917] Increased risk for emerging and worsening suicidal ideation is also associated with antidepressants, especially for youth.[5,6] Appendix B summarizes available antidepressants and their side effects.

Pharmacogenomics involve two key areas: pharmacodynamics, which examines how drugs affect the body at a molecular level, and pharmacokinetics, which focuses on how the body absorbs, distributes, metabolizes, and eliminates drugs. Genetic differences can impact how individuals respond to different medications and doses.[20] 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. PGx testing is used for antidepressants, analgesics (pain relievers), anticoagulants, proton pump inhibitors (PPIs),[vii,21] and cardiovascular medications. PGx testing analyzes genetic variations to help tailor selection and dosing, enabling more personalized and effective treatments in clinical practice.[20] PGx testing is most commonly utilized to tailor prescription and dosing of medications after one or more failures, but can also be used preemptively for a first treatment for anxiety or depression. Figure 1

[vi] Antidepressants also have off-label (non-FDA approved) uses for pain, insomnia, and migraines.
[vii] PPIs are medicines that lower the amount of acid a stomach makes. They are used to treat problems like frequent heartburn, acid reflux, and stomach ulcers. Some PPIs require a prescription, while others are available over the counter.

below demonstrates an example of integrating PGx testing into treatment plans, with the example reflecting the PGx test being implemented reactively.

Figure 1: Integration of PGx Testing in Treatment Plans

Certain genes influence how individuals metabolize common antidepressants[22] Variants in these genes can lead to poor, intermediate, or ultra-rapid metabolism, which in turn may negatively impact drug efficacy and increase the risk of side effects.[23] Single-gene tests examine one gene, often CYP2D6 or CYP2C19, while panel tests, such as GeneSight, examine a panel of genes examine relevant drug gene interactions across multiple genes.[24,25]

2.1 Prevalence

According to the National Alliance on Mental Illness (NAMI), one in five adults in the U.S. experiences a mental health condition each year, including an estimated 781,000 adults in Maryland.[26] Nationally, the NIMH reported that in 2021, 21 million adults (8.3% of the population) experienced at least one major depressive episode. Depression prevalence was higher among females (10.3%), young adults ages 18 – 25 (18.6%), and individuals identifying as two or more races (13.9%).[27] The COVID-19 pandemic further exacerbated the prevalence of mental health concerns, particularly during the first year. In Maryland, 40.3% of adults reported anxiety or depressive symptoms in November 2020, compared to 27.3% in February 2023. While these rates declined as the pandemic progressed, KFF noted that prevalence may have been influenced by pandemic-related stressors that exacerbated underlying conditions.[28]

Anxiety and depression not only affect millions of Americans each year, but they also have substantial consequences for the workforce and the broader economy. A 2022 review of studies found that individuals with anxiety or depression are more likely to miss workdays or be less productive while at work.[29] While some studies suggest earlier research may have overstated the magnitude of this impact, the relationship remains significant. For example, one study cited in the review found that after adjusting for unobserved factors, women and men with depression still had 10% and 13% higher rates of illness-related absence, respectively.[30] A 2023 study estimated that in 2019, major depressive

disorder (MDD),[viii] a type of depression, cost the U.S. an estimated $334 billion, or nearly $382 billion in 2023 dollars. Most of this burden was attributed to lost work and reduced productivity rather than direct medical expenses. Families also incurred a notable share of costs through reduced household income. Modeling suggested that if faster, more effective treatments were available, the overall economic burden could be reduced by almost 8%, demonstrating the value of improving access to timely and effective care.[31] The World Health Organization (WHO) estimates that anxiety and depression together account for 12 billion lost workdays annually, representing nearly $1 trillion (U.S. currency) in productivity losses worldwide. Importantly, economic modeling shows that scaling up access to evidence-based treatment for individuals with anxiety or depression could yield substantial returns, with every dollar invested generating an estimated five dollars in improved health and productivity.[32]

2.2 Coverage of Services

The Affordable Care Act (ACA) includes required coverage for laboratory testing services as an Essential Health Benefit (EHB) for non-legacy plans.[33] Within this framework, Maryland's recently enacted biomarker legislation requires commercial insurers (beginning January 1, 2024) and Medicaid plans (beginning July 1, 2025) to cover biomarker testing when supported by medical and scientific evidence. Biomarker testing includes analyses used to inform diagnosis, treatment, management, or monitoring and encompasses tests referenced in FDA-approved drug labeling or supported by Medicare coverage determinations or major clinical guidelines.[34]

Although PGx testing scientifically falls within the broader biomarker category, insurers have not consistently interpreted PGx testing for anxiety and depression as meeting the evidence thresholds or medical necessity standards set out in the biomarker legislation. Many antidepressants and anxiolytics with gene-drug interactions do not carry FDA-required genomic testing and are not uniformly addressed in national clinical guidelines. As a result, coverage of PGx testing varies widely across insurers, and many large commercial carriers deny coverage for anxiety and depression. Maryland's EHB benchmark plan similarly does not list PGx testing as a covered benefit.[35,36]

The proposed PGx testing legislation (SB 961) sought to address this gap by establishing clear, condition-specific coverage requirements. Under SB 961, insurers would be required to cover single-gene and multi-gene PGx testing when ordered for an individual with diagnosed anxiety or depression and when a provider is considering a medication change, dose adjustment, or augmentation involving a drug with a known gene-drug interaction. The legislation also outlines prior authorization standards designed to ensure timely access and minimize administrative burden.[2]

While outside the scope of SB 961, Medicare already provides coverage for PGx testing under federal diagnostic testing regulations when prescribing medications with known gene-drug interactions, including several commonly prescribed SSRIs. Medicare covers both single-gene and multi-gene tests.[37]

[viii] Major depressive disorder is a psychological condition characterized by a persistently depressed mood and long-term loss of pleasure or interest in life, often accompanied by disturbed sleep, feelings of guilt or inadequacy, and suicidal thoughts.

Commercial coverage for PGx testing in Maryland varies by insurer but is generally limited. Several respondents to the insurer survey indicated that they do not cover PGx testing. Two insurers do not provide coverage for any PGx testing related to anxiety and depression.[ix] An additional insurer currently covers single-gene testing, but as of January 1, 2025, no longer covers multi-gene panel testing related to anxiety and depression due to a new interpretation of medical evidence.[x] One insurer reported covering PGx testing with prior authorization when there is a known interaction or black box warning related to prescribing. [xi,38] Another insurer reported coverage contingent on meeting medical necessity criteria, though cost sharing requirements and test volume information was unavailable at the time of writing this report. Among insurers that commented on self-funded employer groups, most indicated that coverage policies for PGx testing in these populations align with those applied to fully insured groups. Therefore, the service is generally not covered by self-funded employer groups, including those employing at least 500 employees.

2.3 Utilization

According to a 2022 review of PGx testing among patients with depression, PGx testing is rarely used in nationwide treatment of depression. Less than one percent of the 438,534 patients surveyed who experienced depressive episodes each year received PGx testing. Of those, 57% had been prescribed an antidepressant before receiving PGx testing, indicating that most testing was done reactively. Less than one-third (30%) started taking an antidepressant after receiving PGx testing.[8] In Maryland in 2024, 83% of patients who received GeneSight[xii] testing had a diagnosis of depression and/or anxiety.[xiii]

While PGx testing for anxiety and depression is infrequently utilized for any population, it is more frequently covered and used through public insurance programs than through private insurance. Individuals enrolled in managed Medicare and Medicaid programs were 2.9 times more likely to receive PGx testing than individuals enrolled in commercial health insurance plans.[8] This difference may reflect both coverage patterns and higher rates of psychological distress among publicly insured populations: adults aged 18 – 64 with public insurance had a higher mean Kessler Psychological Distress Scale (K6)[xiv] score of 4.5, compared to 2.0 among those with private insurance. Consistent with this, KFF claims data from 2021 – 2022, demonstrated that the prevalence of any mental illness among people with Medicaid was 31.7% nationwide (36.7% in Maryland) versus 21.3% among those with private insurance (20.4% in Maryland).[8] According to the 2022 review, individuals who received PGx testing

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[ix] One of these insurers referred to PGx testing as “experimental, investigational, and unproven”, while the other indicated that PGx testing “did not meet the criteria per Carelon evidence-based coverage decisions (…) and is not considered medically necessary.”

[x] This insurer noted that they reversed coverage for multi-gene panel tests because in their view these tests currently “do not demonstrate clinical utility and can inflict patient harm with patients avoiding medications that may otherwise work despite what the test report says.”

[xi] Black box warning, or “boxed warning” refers to drugs that the U.S. Food & Drug Administration (FDA) has found leads to death or serious injury.

[xii] GeneSight is a pharmacogenomic panel test produced by Myriad Genetics for use in the treatment of anxiety and depression.

[xiii] Email communication with representatives from Myriad Genetics, September 15, 2025.

[xiv] The K6 scale measures psychological distress with a survey comprising 24 questions relating to nervousness, hopelessness, restlessness, and depression. K6 scores are often used as a proxy for depression or anxiety.

were 20% more likely to be prescribed an antidepressant, and twice as likely to be prescribed another psychotropic than those who did not receive testing.[8] Of those patients already taking an antidepressant who received testing, 60% did not continue the same medication after the test. Importantly, while this review used a robust sample size, the data period ended in 2017.[8] Since then, innovations in multi-gene panel testing and new research have advanced the field, and significant changes in the prescribing of PGx testing might have occurred. During the period of the study, however, PGx testing was rarely used, likely due to a combination of lack of coverage, limited physician knowledge, and mixed results in clinical trials.[8] **Error! Bookmark not defined.**

A 2022 study found that although participants had limited knowledge of PGx testing their interest in it was high. On a five-point scale, the average self-rated knowledge score was 2.09, compared to an average interest level of 4.16. As PGx testing for mental health becomes more common and insurance coverage expands, patient interest is likely to increase further.[39]

2.4 Access

Inconsistent coverage of PGx testing can lead to substantial out-of-pocket costs for prospective patients, potentially hindering access. Patients who are commercially insured may face out-of-pocket costs of $200 to $500 or more, along with complex and unclear prior authorization requirements.[40] For the GeneSight test, Medicare reimburses $1,569. Patient out-of-pocket costs typically range from $0 to $330 depending on insurance and financial assistance policies.[48] Separately, the test's manufacturer, Myriad Genetics, offers an income-based financial assistance program that caps patient responsibility at $200 or less for households earning below four times the federal poverty level.[25]

A 2025 review of publicly available coverage policies from 14 major insurers in the U.S. found notable variation in coverage decisions for PGx testing, and in the evidence cited to support these decisions. Real world evidence was referenced across coverage policies, but ultimate coverage decisions depended on how insurers interpreted that evidence, which remains inconclusive.[41] As a result, coverage is currently fragmented, especially in the commercial market, despite growing clinical and consumer demand.**Error! Bookmark not defined.**[Error! Bookmark not defined.]

Access is also influenced by providers' clinical knowledge and their understanding of coverage. Studies show many clinicians, especially in primary care,[9] are unfamiliar with how to interpret or apply PGx results for psychiatric medications. Even among psychiatrists, views are mixed, with concerns about the strength of evidence, cost-effectiveness, and ethical responsibilities.[42]

One expert noted that access to the PGx testing for anxiety and depression may depend on the availability of providers who are familiar with PGx testing and can interpret results, as well as whether a patient's insurance plan covers the test and the participating network of labs. PGx tests can be ordered by a qualified healthcare provider or directly by an individual and can be completed at a clinic or at home. For the GeneSight test, most insurers require that the ordering provider be a physician, psychiatrist, or other licensed clinician, and coverage is often linked to network participation with Myriad Genetics or approved laboratories.

While future utilization is unknown, currently, individuals can mail the sample directly from home or a provider's office streamlines access, minimizing the need for in-person lab visits. Patients may still need

follow-up with a clinician to interpret results and adjust medications. According to responses from a Myriad Genetics representative, the GeneSight test will only be processed at the Myriad laboratory in Ohio for the foreseeable future because the test is proprietary. Myriad's representatives additionally reported that their lab does have substantial capacity to process tests, and they do not foresee demand for testing exceeding their capacity to process tests should this legislation pass.[xv]

2.5 Comparison to Other States

The American Cancer Society reports that 18 states have passed laws requiring state-regulated plans to provide coverage for biomarker testing.[xvi,43] A 2024 review examining biomarker legislation that passed after January 1, 2021 found that 15 states have laws that broadly address biomarker testing, but do not explicitly include coverage for depression or anxiety. Most laws defined biomarker testing generally, with 11 states covering testing for any condition and four are limited to cancer. Fourteen of the 15 states required FDA approval of a test and most also used Medicare national coverage and clinical guidelines as criteria.[44]

The ACA and state insurance laws prohibit commercial insurers from denying coverage for services based on specific health conditions. However, insurers' medical policies often consider genetic testing for anxiety and depression as experimental and investigational and therefore do not routinely cover it.[45] Nationally, the evidence for PGx testing for depression and anxiety remains mixed and as a result, many insurers deny coverage for broad use of PGx testing for depression and anxiety, categorizing it as experimental or investigational.

A June 2025 article by the American Pharmacogenomics Association (Association) outlined the PGx testing coverage landscape across public and private insurance. The Association reported that the overall reimbursement rate is roughly 46%, but that rate varies widely depending on the type of insurance coverage. Medicaid reimbursement is reported to range from 36% – 48% depending on the state. Some states, such as Illinois, Arizona, and Rhode Island, have passed legislation mandating Medicaid coverage for biomarker testing that includes PGx testing. However, other states have limited coverage and impose prior authorization requirements resulting in restricted access to this testing.[46]

While state biomarker testing mandates have expanded access in some areas, coverage for PGx testing for anxiety and depression remains inconsistent. The prevailing approach among insurers relies on medical necessity determinations and evidence thresholds, resulting in routine denials when PGx testing is deemed investigational. This patchwork of state laws, medical policies, and evidentiary requirements underscores the uncertainty facing patients and providers seeking coverage for PGx testing in mental health care.

[xv] Information from oral communication with Myriad Genetics representatives on September 5, 2025.
[xvi] Eighteen states require all state-regulated plans to provide biomarker testing coverage. Nebraska's coverage is limited to certain conditions, not including anxiety and depression.

3.0 Medical Evaluation

3.1 Efficacy

PGx testing has emerged as a potential tool to improve antidepressant selection and dose adjustment, particularly given the high rates of non-response to first-line treatments for MDD, which is its most common clinical use. While some evidence links PGx testing to key measures of success such as symptomatic remission, and symptom improvement, the clinical utility of PGx testing remains debated. Several randomized controlled trials (RCTs) report meaningful improvements in response and remission rates among patients receiving PGx-guided care compared to treatment as usual (TAU). However, the evidence is mixed, and limitations include a lack of consideration for MDD clinical subtypes (e.g., severity, anxiety, suicidality), limited demographic diversity (predominantly white populations), and potential bias due to industry funding and financial conflicts of interest.[47]

PGx tests are generally accurate in finding the relevant genes, showing strong reliability. However, this does not mean the test can always predict how well a medication will work for each patient. PGx testing may be helpful for patients who do not experience improvement of symptoms after trying several different medications. PGx testing is not recommended as a routine test before starting treatment. A patient's medical history and symptoms should remain the main guide when a provider evaluates which medication to prescribe first.[48]

While not directly tied to symptomatic remission outcomes, a 2024 study on PGx testing and medication switches in patients with MDD found that patients utilizing PGx testing were significantly more likely to adhere to their prescribed medication and were significantly less likely to switch medications. 64.52% of patients utilizing PGx testing demonstrated "good adherence" to their medication, compared to only 50.32% of patients undergoing TAU.[49]

Evidence from RCTs and meta-analyses suggests that PGx-guided care may modestly improve short-term outcomes compared to TAU. For example, a 2022 large (n=1,944) randomized clinical trial demonstrated a 16.5% symptom remission rate at 12 weeks for patients using PGx-guided prescriptions, compared to an 11.2% remission rate using TAU. This improvement in remission is implied to be due to a reported 45% of PGx-guided patients receiving medication with no gene-drug interaction, compared to 18% of those undergoing TAU.[50] Another study conducted in 2022 on older (65+) adults with depression showed higher rates of response and remission at week eight for patients with PGx-guided treatment.[51] A 2023 systematic review and meta-analysis of 11 randomized control trials found that PGx-guided treatment was associated with significantly improved response and remission rates at weeks eight and twelve. However, these effects were not sustained at 24 weeks, and authors characterized PGx testing as having "small and nonpersistent effects on symptom remission."[52] A 2025 Myriad Genetics funded meta-analysis of six studies on PGx testing concluded that utilization of PGx for patients with MDD can lead to significantly improved clinical outcomes.[53] This meta-analysis indicates that PGx-guided care may improve short-term outcomes in depression, but several limitations should be considered. Most of the data came from a single large study, and outcomes were only assessed at 8 – 10 weeks, with no discussion of longer-term results such as remission at 24 weeks.[53]

PGx testing can help guide antidepressant selection and dosing, improving short-term treatment response and reducing trial-and-error prescribing. Evidence shows modest benefits in the first 8 – 12 weeks and some reductions in side effects, but long-term outcomes and effects across diverse populations remain unclear.[54] The 2019 large industry-sponsored randomized control Genomics Used to Improve Depression Decisions (GUIDED) trial of difficult to treat MDD found nonsignificant effects of symptom changes after eight weeks using PGx testing (GeneSight) and usual MDD care. However, among patients taking medications with predicted gene-drug interactions who were switched to "congruent"[xvii] medications, response improved, and remission improved. Participants receiving PGx-guided care showed modestly greater symptom improvement compared to usual care, this finding was not statistically significant.[55]

Several issues complicate the interpretation of PGx testing evidence. Study populations were predominantly white and included only patients with prior antidepressant treatment, which may limit generalizability. In addition, several trials were industry-funded or lacked full blinding, and the analysis did not evaluate the potential impact of medication changes or augmentation strategies.**Error! Bookmark not defined.** Moreover, PGx test results may not remain static over time. For example, when results from 143 patients who underwent PGx testing between 2014 and 2021 were reinterpreted using the 2024 Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines, more than half (57%) required updated interpretation, with notable changes in CYP2C19 and CYP2D6 classifications. PGx testing may help guide medication choices now, yet its usefulness later depends on how well the results are kept up to date and referenced as new drugs, evidence, or health conditions arise. While the test results remain valid indefinitely, their clinical value depends on whether healthcare providers continue to apply them in future treatment decisions. These findings suggest that PGx results may evolve as scientific standards change, an important consideration for both clinical practice and policy development.[56]

There is also emerging evidence that PGx testing may affect health system utilization. A 2025 study using claims data from Optum Labs Data Warehouse reported that patients whose care was guided by PGx testing had 34.4% reduction in psychiatric emergency department (ED) visits, and a further 38.6% reduction in psychiatric hospitalizations.[57] While these findings are promising, they are subject to potential confounding factors and conflicts of interest, as the study was industry-sponsored and did not directly measure clinical outcomes.

3.2 PGx Testing Guidelines

The FDA recognizes that genetic variations, particularly in the CYP2D6 and CYP2C19 genes, can affect how the body processes certain medications used to treat anxiety and depression. People with certain CYP2D6 genetic variants may be poor metabolizers of some antipsychotics, antidepressants, and stomach medications, leading to higher drug levels in the blood. Elevated drug levels can increase the risk of side effects, so lower doses or dosage adjustments may be recommended. Similarly, people who are poor metabolizers due to CYP2C19 variants may have higher drug levels of some

[xvii] In this context, a "congruent" medication refers to a drug whose selection or dosing aligns with a patient's genetic profile.

antidepressants and sleep medicines, which can also raise side effect risks.[xviii] In these cases, providers may lower the dose or monitor patients closely. PGx testing can help guide safer and more effective prescribing, but the FDA emphasizes that it is only one factor in clinical decision-making. Providers should also consider the patient's overall health and treatment context when prescribing. FDA labeling provides specific dosing guidance for many medications based on genetic results.[58]

The CPIC develops peer-reviewed guidelines to help providers use PGx test results.[59] According to CPIC,[xix,15] results for CYP2D6 and/or CYP2C19 can help identify individuals who may face higher risks of side effects or treatment failure. This can support dose changes, switching to a different drug, or close monitoring. However, limitations remain as many commercial PGx tests do not include rare or newly discovered gene variants, which can create uncertainty about how well the results predict drug response. CPIC states that testing is generally reliable when performed in qualified laboratories, though errors are still possible and may affect treatment decisions.[42] **Error! Bookmark not defined.**

4.0 Financial Evaluation

BerryDunn conducted a financial evaluation to estimate the potential fiscal impact of mandating insurance coverage of PGx testing for individuals with anxiety and depression. The analysis focused on the incremental, or marginal, costs associated with expanding coverage, recognizing that current insurer policies vary, with some providing limited coverage for PGx testing and others not covering these services. The evaluation incorporated data on the population who are eligible for testing under the mandate, current utilization of PGx testing, and expected changes in utilization if coverage were expanded and prior authorization requirements were reduced. Costs were estimated by test type (single-gene, multi-gene, or either single- or multi-gene[xx]) and adjusted to reflect current levels of coverage, with premiums, administrative costs, and retention factors incorporated to project PMPM impacts. This approach provides an evidence-based estimate of the range of costs that health insurers and public programs may experience if the mandate is implemented.

4.1 Methodology

To estimate the financial impact of mandating coverage of PGx testing for individuals with anxiety and depression, BerryDunn conducted a multi-step modeling process. First, insurer responses to the survey were reviewed, which indicated that coverage for PGx testing has notable variations across Maryland's insurance market. For this analysis, the marginal cost of the bill was defined as the cost of PGx testing under the mandate minus the cost of PGx tests absent the mandate.

[xviii] For CYP2D6, this includes drugs such as aripiprazole, atomoxetine, brexpiprazole, clozapine, iloperidone, metoclopramide, pimozide, pitolisant, tetrabenazine, valbenazine, venlafaxine, and vortioxetine. For CYP2C19, examples include citalopram, clobazam, and flibanserin.

[xix] CPIC guidelines are expert consensus based on current evidence to assist clinical decision-making but do not replace individualized patient care. They are voluntary and limited to specific interventions and populations. The final treatment decision rests with the clinician and patient.

[xx] A subset of procedure codes could correspond with either a single-gene or a multi-gene PGx test.

The Medicaid, individual, and fully insured small and large employer group populations were identified in the MCDB using market segment codes. The State Health Plan population, identified via employer identification number (EIN), was assumed to be only those that were classified as self-insured.[2] BerryDunn assumed the State Health Plan would voluntarily adopt these mandated benefits, so the same impact assumptions as the fully insured population were applied.[xxi]

Current PGx testing users of single-gene tests, multi-gene panel tests, and tests that could be categorized as either single- or multi-gene tests, were pulled from the MCDB. The historical number of PGx testing users was relatively small and decreased from 2023 to 2024 in all populations studied. A three-year average of user counts, from 2022 to 2024, were used as a base due to volatility in the user counts and the mix of the users for different test types across the three years. For the Maryland Medicaid population, the historical utilization of PGx tests was higher than in commercial market segments. This likely reflects both higher rates of mental health conditions among Medicaid enrollees, 31.7% nationwide and 36.7% in Maryland, compared to 21.3% and 20.4% among those with private insurance.[8] Consistent with KFF findings, adults with public insurance also tend to have higher levels of psychological distress, which may contribute to greater demand for testing once individuals seek care.[60] The baseline PGx testing user counts by market segment are summarized in Table 2 below.

Table 2: Summary of Assumed Current PGx Testing Utilization

	Three-Year Average PGx Testing 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 Health Plan	89	0.04%
Medicaid	9,077	0.55%

If the mandate were to go into effect, prior authorization requirements are expected to ease, and utilization is expected to increase. BerryDunn applied adjustment factors to account for the anticipated impacts of expanded coverage and reduced prior authorization restrictions. Based on insurer survey data regarding PGx testing denial rates, projected utilization increase factors were developed ranging from a low factor of 1.3, a middle factor of 2.2, and a high factor of 3.0. These utilization increase factors were applied to the three-year average current users to represent claims that would have previously been denied but would become covered under the mandate. Denial rates included all causes, not limited to prior authorization; therefore, a range of utilization increase factors was developed to capture the potential mandate impact of relaxed prior authorization requirements.

The utilization increase factors were applied to the current PGx testing user counts. To capture the range of potential utilization under a coverage mandate, multiple scenarios for increases in PGx testing utilization were developed and multiplied by the assumed baseline PGx testing user counts among

[xxi] This assumption is commonly used in actuarial reviews to estimate the broader cost impacts of state insurance mandates on self-insured public employee coverage.

individuals with anxiety and depression diagnoses. These PGx testing utilization scenarios, using the 2024 populations as a base, are captured in Table 3.

Table 3: Estimated Percentage of PGx Testing Users within the Sample Population

Estimated Percentage of PGx Testing Users within the Sample Population						
	Individual	**Fully Insured Small Group**	**Fully Insured Large Group**	**Totally Fully Insured Commercial**	**State Health Plan**	**Medicaid**
Low	0.05%	0.07%	0.15%	0.10%	0.06%	0.71%
Middle	0.09%	0.11%	0.24%	0.17%	0.09%	1.18%
High	0.13%	0.16%	0.34%	0.23%	0.13%	1.64%

The paid costs per user from MCDB were volatile over the three-year period of 2022 to 2024, thus BerryDunn calculated a three-year weighted average of 2022 to 2024 for the cost estimates under the mandate (Table 4).

Table 4: Paid Costs Per User by Market Segment

Three-Year Average Paid Cost per User	
Individual	$974.61
Fully Insured Small Group	$560.50
Fully Insured Large Group	$255.08
Totally Fully Insured Commercial	$415.43
State Health Plan	$995.61
Medicaid	$145.57

To calculate the marginal cost of the mandate, the costs of PGx tests currently covered absent the mandate were subtracted from the total projected costs under mandated coverage. For the carrier who ended coverage of multi-gene testing in 2025, BerryDunn assumed the base period utilization would have aligned with the carriers who did not cover PGx testing. Retention assumptions were then applied to the marginal claim costs PMPM to derive the corresponding premium PMPM impacts for each market segment.[61,62]

To derive the percentage increase in insurance costs under mandated coverage, premiums for fully insured individual, small group, and large group were taken from the carrier survey responses. For total fully insured, the average premium PMPM reflects a weighted average using the carrier survey responses' reported enrollees for the fully insured individual, small group, and large group segments. The premium equivalent for the State Health Plan was derived using the Maryland State Health Plan benefits information[63] and subscriber relationships from the MCDB. A Maryland Department of Health financial monitoring report included an average program cost for Medicaid MCOs, which make up 88% of Medicaid in Maryland.[64] For simplicity, the program cost for Medicaid FFS was assumed to be the same as for Medicaid MCOs.

4.2 Results

BerryDunn's modeling indicates that the proposed mandate would result in increases in PMPM costs across market segments. For fully insured plans, the estimated insurance cost increase ranges from $0.01 (or 0.002%) to $0.07 (or 0.012%) PMPM. For the State Health Plan, the estimated increase ranges from $0.01 (or 0.002%) to $0.09 (or 0.011%) PMPM. For the Maryland Medicaid, which includes Medicaid and MCOs, the projected increase is $0.02 (or 0.006%) to $0.16 (or 0.037%) PMPM. Table 5 below shows the results in detail.

Table 5: PGx Testing Estimated Cost Summary Due to Legislation by Market Segment

Range of Estimates	Low	Middle	High
Individual			
% of Individual Market Population Receiving PGx Tests	0.05%	0.09%	0.13%
Individual Premium PMPM Increase	$0.01	$0.05	$0.08
Individual Premium PMPM % Increase	0.003%	0.010%	0.018%
Individual Premium Increase	$42,274	$162,049	$281,824
Fully Insured Small Group			
% of Small Group Population Receiving PGx Tests	0.07%	0.11%	0.16%
Small Group Premium PMPM Increase	$0.01	$0.03	$0.06
Small Group Premium PMPM % Increase	0.001%	0.006%	0.010%
Small Group Premium Increase	$21,369	$81,915	$142,460
Fully Insured Large Group			
% of Fully Insured Large Group Population Receiving PGx Tests	0.15%	0.24%	0.34%
Fully Insured Large Group Premium PMPM Increase	$0.01	$0.03	$0.06
Fully Insured Large Group Premium PMPM % Increase	0.001%	0.005%	0.009%
Fully Insured Large Group Premium Increase	$44,594	$170,942	$297,290
Totally Fully Insured Commercial (Individual, Small Group, Large Group)			
% of Total Fully Insured Population Receiving PGx Tests	0.10%	0.17%	0.23%
Total Fully Insured Premium PMPM Increase	$0.01	$0.04	$0.07
Total Fully Insured Premium PMPM % Increase	0.002%	0.007%	0.012%
Total Fully Insured Premium Increase	$108,236	$414,905	$721,574
State Health Plan			
% of State Health Plan Population Receiving PGx Tests	0.06%	0.09%	0.13%
State Health Plan Premium Equivalent PMPM Increase	$0.01	$0.05	$0.09
State Health Plan Premium Equivalent PMPM % Increase	0.002%	0.007%	0.011%
State Health Plan Premium Equivalent Increase	$31,391	$120,332	$209,273
Medicaid			
% of Medicaid Population Receiving PGx Tests	0.71%	1.18%	1.64%
Medicaid Program Cost PMPM Increase	$0.02	$0.09	$0.16
Medicaid Program Cost PMPM % Increase	0.006%	0.021%	0.037%
Medicaid Program Cost Increase	$466,361	$1,787,718	$3,109,075

4.3 Considerations and Limitations

When evaluating the potential financial impact of mandating coverage for PGx testing for individuals with anxiety and depression, several considerations and limitations should be noted. Many PGx tests for patients with anxiety and depression are relatively new, with evolving procedure codes that may not

be consistently captured in claims data, limiting the accuracy of base period utilization and cost estimates. Provider knowledge, comfort, and preferences also influence when, and whether tests are ordered, creating uncertainty in future utilization trends under the mandate.

The potential effect of increased awareness of PGx testing for anxiety and depression, either due to the passage of the mandate itself or from targeted outreach and canvassing by manufacturers such as Myriad, is unknown, which could drive utilization higher than projected. Denial rate data was available from only two insurers. BerryDunn developed a wider-than-typical range of utilization increase factors, which is expected to capture some of the uncertainties and to account for potential variances in utilization across the broader market.

The COVID-19 Public Health Emergency Medicaid continuous coverage and subsequent continuous coverage unwinding (MCCU) impacted enrollment and utilization from 2020 to 2024. Medicaid enrollees who had coverage extended (March 2020 to March 2023) and were disenrolled during the MCCU (April 2023 to June 2024) likely had other insurance coverage that was primary, thus lowering their Medicaid claims. Including the MCCU disenrolled in this analysis might be a contributing factor for the low observed PGx testing utilization. In addition, for simplicity, members eligible for a partial month were counted as eligible for the entire month, which may slightly overstate the total member months.

Finally, insurance cost and retention levels are uncertain, and actual retention levels may differ from the simplified assumptions used in these insurance cost PMPM estimates. Deviations from these factors could materially affect the projected PMPM cost impacts.

These limitations suggest that while the modeling results provide a useful estimate of the potential financial impact of the mandate, actual costs could be either higher or lower depending on future utilization patterns, insurer policies, and evolving clinical evidence. Rising mandate-related costs may constrain some employers, particularly small firms, from offering comprehensive benefits or may lead to increased employee cost sharing. Over the past five years, the average annual premium for family coverage has increased by 24%,[65] reflecting continued upward pressure on employer-sponsored health plan costs. However, mandates can improve access to high-value medical services, which may enhance employee health, treatment outcomes, and productivity, potentially offsetting employer cost pressures over time.

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Appendix A

Overview of Medical Terminology

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, SNRIs, and tricyclic antidepressants.[66]
Black Box Warning	A black box warning is the most severe type of warning that the FDA can require for a prescription drug, indicating severe risks associated with taking that drug. In the context of antidepressants, the black box warning refers to the potential increase in suicide risk for patients taking common antidepressants such as SSRIs. These risks and the associated warnings have been a subject of debate since the addition of the black box warning to antidepressants.[67]
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.[68]
Congruent Medication	A congruent medication as it relates to PGx testing is a medication with no known negative gene-drug interactions based on the genetic information gathered from the patient.[69]
CYP2D6	A gene involved in metabolizing a variety of medications, including those used for mental health disorders.[70]
CYP2C19	A gene involved in metabolizing a variety of medications, including those used for mental health disorders.[70][71]**Error! Bookmark not defined.**
Diagnostic Accuracy	Diagnostic accuracy refers to the ability of a test to discriminate between the target condition and normal health (lack of the target condition). A perfect diagnostic procedure can completely separate subjects with and without a given target condition.[72]
Gene-Drug Interaction	A gene-drug interaction refers to the way an individual's genetic makeup influences their response to medications.[73]
Major Depressive Disorder (MDD)	Major depressive disorder is a psychological condition characterized by a persistently depressed mood and long-term loss of pleasure or interest in life, often accompanied by disturbed sleep, feelings of guilt or inadequacy, and suicidal thoughts.[74]
Metabolism	Metabolism refers to how the body processes foreign substances. In the case of antidepressants, several key genes can impact how the body metabolizes the drug, making it either faster, slower, or otherwise different.[75]
Psychotropic	Psychotropic medications are drugs which affect behavior, mood, thoughts, or perception. Medications for anxiety and depression, as well as antipsychotics, are common examples of psychotropics.[76]
Randomized Controlled Trial (RCT)	A randomized controlled trial is a type of experiment that randomly assigns participants to either an experimental or control group to measure the effectiveness of a treatment. RCTs are considered the most rigorous way to

Term	Definition
	determine a cause-effect relationship in a clinical setting in which double-blind studies are not feasible.[77]
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.[78]
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.[79]
Trial-and-Error Prescribing Method	Trial-and-error prescribing is the standard method of prescribing antidepressants such as SSRIs in which the provider starts a patient on a selected dose of one medication and then updates or changes the medication dose based upon patient response.[80]
Treatment as Usual (TAU)	In a clinical trial setting, TAU refers to the standard method of medical or psychological treatment. In the context of PGx testing, TAU refers to the standard trial-and-error prescribing method for treatment of anxiety and depression.[81]
Validity	Validity is the extent to which a test measures what it claims to measure. In the context of PGx, a valid test is one which can accurately determine relevant gene-drug interactions.[82]

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Appendix B

Overview of Antidepressants[1783]

	Medication Type	Medication Names	Potential Side Effects
Commonly Prescribed	Selective serotonin reuptake inhibitors (SSRIs)	Sertraline, fluvoxamine, fluoxetine, paroxetine, citalopram, escitalopram	Sexual dysfunction, headaches, heart rhythm disorder
	Serotonin/norepinephrine reuptake inhibitors	Venlafaxine, desvenlafaxine, duloxetine, milnacipran, levomilnacipran	High blood pressure, headaches, sweating, bone shrinkage/loss
	Tricyclic antidepressants (TCAs)	Amitriptyline, clomipramine, doxepin, imipramine, trimipramine, desipramine, nortriptyline, protriptyline, maprotiline, amoxapine	Dry mouth, urinary retention (unable to fully empty the bladder), constipation, heart rhythm disorder, seizures, low blood pressure when standing up
Other	Atypical antidepressants	Buproprion, mirtazapine, agomelatine	Seizures
		Mirtazapine	Weight gain, drowsiness
		Agomelatine	Liver damage
	Serotonin modulators	Nefazodon	Liver damage
		Trazodone	Drowsiness, prolonged erection
		Vilazodone	Diarrhea
		Vortioxetine	Nausea
	Monoamine oxidase inhibitors (MAOIs)	Selegiline, moclobemide, tranylcypromine, isocarboxazid, phenelzine	Sexual dysfunction, serotonin syndrome (too much serotonin in the body, can be fatal if untreated)
	N-Methyl-D-aspartate (NMDA) receptor antagonists	Esketamine, dextromethorphan/bupropion	Dissociative experiences, perception difficulties, can be misused
		Dextromethorphan/bupropion	Dizziness, headaches, dry mouth, drowsiness

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Appendix C

Carrier Survey

Maryland Health Care Commission

Senate Bill (S.B.) 961

An Act concerning Maryland Medical Assistance Program and Health Insurance – Pharmacogenomic Testing – Required Coverage

Questions to Insurance Carriers

July 21st, 2025

Senate Bill (S.B.) 961 An Act concerning Maryland Medical Assistance Program and Health Insurance – Pharmacogenomic Testing – Required Coverage requires commercial health insurers and the Maryland Medical Assistance Program to cover pharmacogenomic (PGx) testing,[xxii,2] including single-gene and multi-gene panel tests, for individuals diagnosed with depression or anxiety when a provider is considering a medication change, dose adjustment, or augmentation involving a drug with known gene-drug interactions. The bill also imposes limits on prior authorization requirements for PGx test by requiring: (1) a clear and timely pathway to coverage; (2) only minimal documentation from the treating provider to confirm eligibility; (3) a sufficient window of time after specimen collection to submit PA requests and related claims; (4) flexibility for either the treating provider or the laboratory to submit the PA request; and (5) no unnecessary administrative burdens or delays that could hinder patient access to care.[2]

The Maryland Health Care Commission (MHCC) has engaged BerryDunn to assist with performing a medical and social evaluation of the mandated services and estimating the bill's impact on cost. Our questions relate to existing coverage and the potential responses by your organization if the legislation were to pass. Neither MHCC nor BerryDunn take any position on whether this bill should reach enactment.

We recognize and appreciate the effort you make to complete this survey. Please respond to Dina Nash at BerryDunn (dina.nash@berrydunn.com) by Friday August 22nd, 2025, and please address questions about the survey to Dina, as well. Thank you for your assistance.

[xxii] The bill defines PGx testing as "laboratory genetic testing, including single-gene and multigene panel testing, conducted to evaluate how an individual's genetic profile may impact the efficacy, safety, or toxicity of medications."

Questions:

1) Please indicate the extent to which pharmacogenomic (PGx) testing related to treatment for anxiety and depression is currently offered or covered in the following markets. If possible, please differentiate between:
    - Single-gene tests (e.g., CYP2D6, CYP2C19)
    - Multi-gene panel tests (e.g., GeneSight, IDgenetix)

    Markets:

    a. Individual market
    b. Small group market
    c. Fully insured group market
    d. Self-insured group market
    e. State employee health plan [State Health Plan]
    f. Medicaid

2) Please complete the following table with how many people are enrolled in the following lines of business as of June 30th, 2025.

Individual Market	Small Group Market	Fully Insured Group Market	Self-insured Group Market	State Employee Health Plan [State Health Plan]	Medicaid

3) Please complete the following table with average monthly premium in the following lines of business as of June 30th, 2025.

Individual Market	Small Group Market	Fully Insured Group Market	Self-insured Group Market	State Employee Health Plan [State Health Plan]	Medicaid

4) Please describe your current policy regarding PGx testing for individuals with anxiety or depression, or if you do not have a specific related policy, please describe the condition-specific policies.

    a. Please provide the procedure (HCPCS/CPT®) codes that are currently covered, including any codes related to administration of the test itself (i.e., obtaining the sample).

b. Please provide a list of PGx tests that are not covered, and their associated procedure codes.
c. Please list the ICD-10 codes you use to determine eligibility for PGx testing.
d. Please indicate if you have cost sharing. If so, how would it change under the proposed legislation.
e. Prior authorizations and associated procedure codes
    i. How do you anticipate the current prior authorization policies changing in response to the legislation?

5) Under what clinical circumstances are the following types of PGx tests covered? Can you please provide the volume of these cases for 2022, 2023, and 2024 by year?

    a. Single gene tests (e.g., CYP2C19, CYP2D6)
    b. Multi-gene panel testing (e.g., GeneSight, IDgenetix)
    c. At-home tests sent to a laboratory
    d. Other (e.g., pharmacodynamic gene panels, bundled psychiatric testing – please specify)

6) Has your coverage for PGx testing changed over the past three years? If so, please describe the nature of these changes and the rationale for them.

7) Are PGx testing benefits administered or coordinated with a pharmacy benefit manager (PBM)? If so, what role do your contracted PBMs play in:

    a. Evaluating the clinical utility of PGx testing
    b. Making coverage or formulary decisions for medications with known gene-drug interactions
    c. Setting prior authorization requirements that may be linked to PGx test results
    d. Proving laboratory tests directly

8) Are there any existing PBM policies that could affect or conflict with the coverage and access requirements outlined in S.B. 961? If so, please describe.

9) Please describe the nature and volume of denied PGx claims (by year: 2022–2024), including:

    a. Denials by procedure code
    b. Denial reason (medical necessity or administrative/other)
    c. Volume and resolution of related grievances or appeals

10) How does your plan define a “medication change, dose adjustment, or augmentation” for the purposes of determining eligibility for pharmacogenomic (PGx) testing under S.B. 961?

    a. How do you identify whether a medication is being prescribed for the first time versus being adjusted or changed?
    b. Would PGx testing be covered when an individual is prescribed an antidepressant or anti-anxiety medication for the first time, assuming the drug has a known gene-drug interaction? If not, please describe how your plan determines that a medication trial has occurred and failed prior to covering PGx testing.
    c. Does your plan require documentation from the provider confirming that the PGx testing is related to a change, adjustment, or augmentation (as opposed to initial prescribing)? If so, what documentation is required?

11) Given your anticipated level of demand, is there adequate availability of providers who perform PGx testing (ordering, interpreting, and delivering results)? If not, what do you anticipate the impact of provider availability will be on implementation or access under the proposed legislation?

12) Do you plan to revise internal policies, workflows, or vendor contracts (including PBMs) in response to this law? If so, please describe any considered revisions.

13) What operational, administrative, or data system changes would be necessary for your organization to comply with this proposed legislation if enacted? Please estimate the anticipated implementation timeframe and cost if possible.
14) As you understand current or soon-to-be-effective federal and Maryland laws and regulations, are there other overlapping or related requirements you are tracking? How do you interpret their interaction with this law?

15) Please provide any general comments, concerns, or questions you have about the implementation of S.B. 961.

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