Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

January 2, 2024

The Honorable Pamela Beidle
Chair, Senate Finance Committee
3 East Miller Senate Office Bldg.
Annapolis, MD 21401-1991

The Honorable Joseline A. Peña-Melnyk
Chair, House Health and Government Operations Committee
241 Taylor House Office Building
Annapolis, MD 21401-1991

RE: Report pursuant to Chapters 322 and 323 of the Acts of 2023, *Maryland Medical Assistance Program and Health Insurance – Required Coverage for Biomarker Testing* (MSAR #14913)

Dear Chairs Beidle and Peña-Melnyk:

Pursuant to the requirements of Chapters 322 and 323 of the Acts of 2023, *Maryland Medical Assistance Program and Health Insurance – Required Coverage for Biomarker Testing* (Senate Bill (SB) 805/House Bill (HB) 1217), the Maryland Department of Health (the Department) respectively submits this report on Medicaid coverage of biomarker testing.

This report includes information on the fiscal impact of the biomarker testing coverage pertaining to the Maryland Medical Assistance Program's policy on biomarker testing coverage for specific cancers during fiscal year 2024; available data on use of biomarker testing by race and ethnicity in the Program; and the anticipated fiscal and access impacts of expanding the coverage in fiscal year 2026.

If further information is needed please contact Sarah Case-Herron, Director, Office of Governmental Affairs, at sarah.case-herron@maryland.gov.

Sincerely,

Laura Herrera Scott, M.D., M.P.H.
Secretary

cc: Ryan Moran, Deputy Secretary, Health Care Financing and Medicaid
Tricia Roddy, Deputy Medicaid Director
Alyssa Brown, Director, Office of Innovation, Research, and Development
Sarah Case-Herron, Director, Office of Governmental Affairs
Sarah Albert, Department of Legislative Services (5 copies)

Report on Senate Bill 805/House Bill 1217, *Maryland Medical Assistance Program and Health Insurance – Required Coverage for Biomarker Testing,*
(Chapters 322 and 323 of the Acts of 2023)

Introduction

As defined in §15–859 of the Maryland Insurance Article, a biomarker is "a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention…[and] includes gene mutations, characteristics of genes, or protein expression." Biomarker testing may be used for the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition. Biomarker testing includes tests that are single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

This report includes information on the fiscal impact of the biomarker testing coverage pertaining to the Maryland Medical Assistance Program's (Medical Assistance) policy on biomarker testing coverage for specific cancers during fiscal year (FY) 2024; available data on use of biomarker testing by race and ethnicity in the Program in FY 2024; and the anticipated fiscal and access impacts of expanding the coverage in FY 2026, pursuant to the requirements established in Chapters 322 and 323 of the Acts of 2023, *Maryland Medical Assistance Program and Health Insurance – Required Coverage for Biomarker Testing* (Senate Bill (SB) 805/House Bill (HB) 1217).[1]

Fiscal Impact of Covering Cancer Biomarker Testing

Effective August 1, 2023, Medical Assistance expanded coverage of biomarker testing to include cancer biomarker tests that are utilized as a companion diagnostic test to direct specific cancer treatments.[2] The Department already covered certain cancer screening tests that fall under the definition of biomarkers such as Cologuard for colorectal cancer screening, prostate-specific antigen (PSA) testing for prostate cancer screening, and BRCA gene testing for breast cancer screening. These biomarker tests are covered for individuals who meet clinical risk-based criteria such as family history or age in alignment with medical society guidelines.

A companion diagnostic test is used to determine if a specific medication or therapy will be effective for treatment. The test must be approved by the United States Food and Drug Administration (FDA) and be classified as a Category 2A or above by the National Comprehensive Cancer Network (NCCN) to be covered by the Medical Assistance program.[3] Medical Assistance does not cover instances where a companion diagnostic test is conducted for screening purposes on asymptomatic patients or their relatives. This coverage policy applies to all participants, both those enrolled in the fee-for-service (FFS) program and those enrolled in the managed care program, HealthChoice.

During FY 2024, cancer biomarker coverage is expected to have a fiscal impact amounting to $921,766 ($571,144 federal funds, $350,622 state general funds). Due to claims runout, in which providers have up

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[1] Chapter 322 of the Acts of 2023: https://mgaleg.maryland.gov/2023RS/chapters_noln/Ch_322_sb0805E.pdf; Chapter 323 of the Acts of 2023: https://mgaleg.maryland.gov/2023RS/chapters_noln/Ch_323_hb1217E.pdf

[2] Provider Transmittal 13-24: https://health.maryland.gov/mmcp/provider/Documents/Transmittals_FY2024/PT%2013-24%20Expanded%20Coverage%20of%20Cancer%20Biomarkers%20for%20Companion%20Diagnostic%20Testing%20and%20Targeted%20Drug%20Therapies%20sk%20signed%207.24.2023.pdf

[3] Maryland Medical Assistance Criteria for Coverage Determination: https://health.maryland.gov/mmcp/Documents/BioMarkers%20for%20Companion%20Diagnostic%20Testing%20&%20Target%20Drug%20Therapy%20-%20Clinical%20Criteria.pdf

to 12 months after rendering the service to submit a claim to the Medical Assistance FFS program, the Department does not have finalized claims and encounter data at this time.

Utilization of Cancer Biomarker Testing

Maryland Medical Assistance analyzed available claims and encounter data to examine utilization of cancer biomarker tests during FY 2024. Overall, 4,428 participants had a cancer biomarker test during FY 2024. Table 1, below, depicts utilization by race and ethnicity, as well as the fiscal impact of each group's utilization. The table also includes the make-up of the Medical Assistance program as a whole.

Table 1. Utilization of Cancer Biomarker Testing by Race/Ethnicity, FY 2024

Race/Ethnicity	Claims Cost	Number of Participants	Percent of Total Claims Cost	Percent of Total Participants	Overall Enrollment
Asian	$ 63,364	220	6.9%	5%	5.6%
Black	$ 384,726	1,701	41.7%	38.4%	43.4%
Black and White	$0.00	0	0.0%	0.0%	1.5%
Hispanic	$98,493	470	10.7%	10.6%	18.3%
Native American/Alaskan	$9,690	47	1.1%	1.1%	0.9%
Pacific Islander	$0.00	0	0.0%	0.0%	0.1%
Two or More Races	$7,743	43	0.8%	1.0%	1.1%
Missing/Other/Unknown	$37,937	160	4.1%	3.6%	3.6%
White	$319,078	1,784	34.6%	40.3%	25.4%
Total	**$921,766**	**4,428**			

Financial Modeling & Rate Setting Assumptions

The Maryland Department of Health (the Department) partnered with the Hilltop Institute at the University of Maryland, Baltimore County (Hilltop) to conduct an analysis of the fiscal impact of implementing SB 805/HB 1217. Beginning with FY 2024, the Department and the Hilltop's Rate Setting team modeled the fiscal impact for coverage of biomarkers from FY 2026 to FY 2030 as outlined below.

Biomarker tests were categorized into the following disease groups:

- Behavioral Health: Tests used for the diagnosis and/or treatment of certain behavioral health diseases such as major depression, bipolar disorder, and schizophrenia.

- Metabolic: Tests used for the diagnosis and/or treatment of metabolic diseases, including, but not limited to, metabolic syndrome, diabetes, and haemochromatosis.
- Infectious Disease: Tests used for the diagnosis and/or treatment of infectious disease such as sepsis and other bacterial diseases, tuberculosis, fungal diseases, and viral diseases.
- Autoimmune: Tests used for the diagnosis and/or treatment of diseases such as lupus, Crohn's & ulcerative colitis, and Grave's disease.
- Kidney: Tests used for the diagnosis and/or treatment of kidney disease.
- Cardiovascular: Tests used for the diagnosis and/or treatment of heart disease.
- Cancer: Tests used for the diagnosis and/or treatment of cancer. (Coverage implemented effective August 1, 2023.[4])
- Expanded Carrier Testing (ECT): Testing panels that move beyond the standard carrier testing that are routinely performed on reproductive age individuals to identify potential inherited genetic disorders. ECT identifies genes associated with genetic disorders and is often performed before or during pregnancy to screen for potential inherited disorders.

Certain categories of biomarker testing, such as biomarker testing related to behavioral health, are not considered as effective compared to others at this time.[5] However, efficacy of a test was not taken into account in this analysis. In the process of developing the study, a comprehensive review of existing biomarker coverage in the Medical Assistance program was conducted. The Department identified many biomarkers already covered by the Medical Assistance program.

This analysis captures historic utilization data from 2022 through August 2024 to determine the actual experience of the Medical Assistance program to date. Certain biomarker tests within each disease category are already covered by Medical Assistance, including expanded coverage of cancer biomarkers for companion diagnostic testing and targeted drug therapies. This informed the baseline for the analysis.

The Department notes that expanded carrier testing (ECT) is included in the analysis as its own category to demonstrate its fiscal impact separately. Stakeholders have previously sought coverage for this service type through the Clinical Coverage Committee. ECT identifies genes associated with genetic disorders and is often performed before or during pregnancy to screen for potential inherited disorders.

Average Participants

Hilltop reviewed FY 2024 enrollment data for both the FFS program and HealthChoice's nine managed care organizations (MCOs). The projections for FY 2025 through FY 2030 reflect both projected

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[4] Provider Transmittal 13-24: https://health.maryland.gov/mmcp/provider/Documents/Transmittals_FY2024/PT%2013-24%20Expanded%20Coverage%20of%20Cancer%20Biomarkers%20for%20Companion%20Diagnostic%20Testing%20and%20Targeted%20Drug%20Therapies%20sk%20signed%207.24.2023.pdf

[5] *See, e.g.,* García-Gutiérrez MS, Navarrete F, Sala F, Gasparyan A, Austrich-Olivares A, Manzanares J. Biomarkers in Psychiatry: Concept, Definition, Types and Relevance to the Clinical Reality. Front Psychiatry. 2020 May 15;11:432. doi: 10.3389/fpsyt.2020.00432. PMID: 32499729; PMCID: PMC7243207.

enrollment decline due to the sunset of public health emergency (PHE) unwinding authorities, as well as estimates of future enrollment stabilization and general population enrollment growth.

In FY 2024, 1,774,477 participants were enrolled in the program.

Eligible Participants

To determine participants who would most benefit from use of biomarker testing for early detection and/or targeting treatment, Hilltop analyzed three years of utilization data from their "Chronic Conditions Data Warehouse" (CCW). The CCW captures Medical Assistance data only, enabling Hilltop to account for various demographic differences such as age, sex, and disease prevalence.

Based on 2023 CCW data, the number of FY 2024 Medical Assistance participants who were treated for a condition in one or more of the defined disease categories (excluding expanded carrier testing) was 1,023,128 or 57.7 percent. The top three disease categories were 1) behavioral health (340,305 participants), 2) cardiovascular (314,817 participants), and 3) autoimmune (198,873 participants).

Uptake

Hilltop modeled a linear, gradual increase in uptake such that the defined diseases (excluding expanded carrier testing) realized a composite 45 percent uptake by FY 2030 (426,046 participants). Comprehensive coverage for cancer biomarkers was implemented on August 1, 2023. Projections for future costs for these tests were also included to realize a 45 percent uptake by FY 2030. The model assumes the other categories become effective on July 1, 2025. The analysis on ECT realized a 55 percent uptake by FY 2030.

Cost Per Test

The universe of biomarker tests available on the market is substantial. As such, the Department focused its efforts to develop a comprehensive list of biomarker tests to those currently covered by Medical Assistance in order to inform the baseline. For future projections, the Department and Hilltop identified seven other states that have enacted biomarker legislation: Arizona, California, Illinois, Indiana, Louisiana, Rhode Island, and Texas. Illinois implemented coverage for biomarkers effective January 1, 2022, and currently has the most robust fee schedule data. For the majority of the included diseases, Illinois fee schedule data was used. Maryland Medical Assistance data was used for cancer. In addition, Hilltop used Turquoise Health, which allows for a search for each biomarker disease and yielded over 250 costs from various providers and Function Health, a healthcare technology company, specifically for infectious disease and behavioral health biomarker costs. Hilltop then used the average cost per test for each disease

For expanded carrier tests, the cost per test was determined using information from Lumi Health and Sonic Genetics.

Claims Trend

The analysis uses an annual claims trend of 4.15 percent based on historic HealthChoice data.

Fiscal Impact

New Claims Costs

Hilltop modeled two different scenarios, a best estimate/expected scenario and a worst case/highest cost scenario. Data was parsed by FFS and HealthChoice/MCO. Federal Medical Assistance Percentage (FMAP) rates were also projected. The Department's estimates are broken out by disease state to better illustrate the cost of potential incremental expansions in coverage. There is variation between the different disease types with respect to average test cost, expected number of members who would need these tests based on disease prevalence, and uptake. The projections for cancer biomarkers are listed separately as coverage is already implemented. See Appendix A, Tables 1 through 4.

In the expected scenario, Hilltop assumes that 1) uptake plateaus at 45 percent by FY 2030 (55 percent for expanded carrier testing), and 2) the annual trend of the costs per test is 4.15 percent. Once the pool reaches a mature state in 2030, the total annual cost could be $119 million in claims costs. The most costly category is cardiovascular tests at $38 million. The least costly is infectious disease at $587,000. The highest number of impacted participants is for cardiovascular at 131,384 participants. The lowest number of impacted participants is infectious disease at 4,240 participants. See Appendix A, Tables 1 and 2.

A sensitivity analysis was done in the form of the worst case/highest cost scenario. Under this scenario, Hilltop assumes that 1) uptake plateaus at a higher level and more quickly at 67 percent by FY 2028, 2) costs per test start 25 percent higher, and 3) the annual trend of the cost per test is 5.65 percent. Under this scenario, annual claims cost amounts to over $225 million. See Appendix A, Tables 3 and 4.

The Department notes that the anticipated fiscal impact is below original projections provided during the 2024 Maryland legislative session. The biggest driver in the cost difference was average test cost and prevalence estimates used to inform uptake. The Department reviewed actual test costs along with data from other states and incorporated additional assumptions on disease prevalence, which was not feasible previously due to the fast turnaround time during the session.

Conclusion

The Department will continue to monitor utilization and the fiscal impact of providing coverage of cancer biomarker coverage. The fiscal impact associated with comprehensive expansion of coverage for biomarkers is projected to be substantial. Incremental expansions by disease state present an opportunity to mitigate the costs associated with broadened coverage while ensuring Medicaid participants can access these services. The Maryland Health Care Commission shall report to the Senate Finance Committee and the House Health and Government Operations Committee no later than December 1, 2025, on the impact of providing biomarker testing coverage, including an analysis of the impact of providing access to biomarker testing to individuals based on race, gender, age, and public or private insurance.

Appendix A. Summary Tables

Table 1. Anticipated Fiscal Impact, Expected Scenario, FY 2026-FY 2030

Uptake Plateaus at 45% by FY 2030; Annual Cost Trend = 4.15%; Average cost per test across all disease types: $158 (Range: $4-$6,651)

	FY 2026	FY 2027	FY 2028	FY 2029	FY 2030	Total Funds	Members Expected to Benefit Annually (FY 2030)
Behavior Health	$ 16,682,623	$ 20,982,736	$ 25,684,368	$ 30,817,619	$ 36,414,631	**$ 130,581,976**	126,270
Metabolic	$ 4,732,661	$ 5,775,329	$ 6,913,502	$ 8,154,286	$ 9,505,267	**$ 35,081,046**	44,315
Infectious Disease	$ 298,102	$ 361,180	$ 430,004	$ 505,001	$ 586,625	**$ 2,180,913**	4,240
Autoimmune	$ 5,995,364	$ 7,123,123	$ 8,351,820	$ 9,688,893	$ 11,142,286	**$ 42,301,486**	94,962
Kidney	$ 2,781,795	$ 3,335,147	$ 3,938,457	$ 4,595,419	$ 5,309,979	**$ 19,960,798**	16,865
Cardiovascular	$ 19,129,479	$ 23,343,957	$ 27,944,467	$ 32,959,732	$ 38,420,417	**$ 141,798,051**	131,384
Expanded Carrier Testing	$ 12,759,631	$ 13,422,048	$ 14,118,853	$ 14,851,833	$ 15,622,866	**$ 70,775,232**	18,212
Total Funds	**$ 62,379,655**	**$ 74,343,521**	**$ 87,381,471**	**$ 101,572,783**	**$ 117,002,071**	**$ 442,659,503**	
Federal Funds	**$ 38,649,879**	**$ 46,062,583**	**$ 54,140,781**	**$ 62,933,591**	**$ 72,493,441**	**$ 274,280,273**	
State General Funds	**$ 23,729,778**	**$ 28,280,939**	**$ 33,240,691**	**$ 38,639,193**	**$ 44,508,632**	**$ 168,399,230**	

Table 2. Cancer Biomarkers Anticipated Fiscal Impact, Expected Scenario, FY 2024-FY 2030

	FY 2024*	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029	FY 2030	Total Funds
Cancer	$ 921,766	$ 984,775	$ 1,172,127	$ 1,381,672	$ 1,609,815	$ 1,857,923	$ 2,127,452	**$ 10,055,530**
Federal Funds	$ 571,144	$ 610,185	$ 726,272	$ 856,110	$ 997,472	$ 1,151,205	$ 1,318,210	**$ 6,230,598**
State General Funds	$ 350,622	$ 374,590	$ 445,855	$ 525,562	$ 612,343	$ 706,718	$ 809,242	**$ 3,824,932**

**Claims subject to runout until July 2025; encounters subject to runout until January 2025*

Appendix A. Summary Tables

Table 3. Anticipated Fiscal Impact, Worst Case Scenario, FY 2026-FY 2030

Uptake Plateaus at 67% by FY 2028; Annual Cost Trend = 5.65% (+1.50%); Costs Per Tests Start 25% Higher

	FY 2026	FY 2027	FY 2028	FY 2029	FY 2030	Total Funds
Behavioral Health	$ 37,825,259	$ 50,753,112	$ 65,244,851	$ 69,620,497	$ 74,289,596	**$ 297,733,316**
Metabolic	$ 9,854,689	$ 12,927,163	$ 16,367,425	$ 17,465,107	$ 18,636,404	**$ 75,250,788**
Infectious Disease	$ 607,891	$ 792,699	$ 999,561	$ 1,066,596	$ 1,138,127	**$ 4,604,874**
Autoimmune	$ 11,529,631	$ 14,773,557	$ 18,400,733	$ 19,634,778	$ 20,951,585	**$ 85,290,284**
Kidney	$ 5,498,319	$ 7,104,469	$ 8,901,321	$ 9,498,288	$ 10,135,290	**$ 41,137,686**
Cardiovascular	$ 39,832,782	$ 52,251,765	$ 66,157,349	$ 70,594,192	$ 75,328,592	**$ 304,164,679**
Expanded Carrier Testing	$ 16,179,249	$ 17,264,311	$ 18,422,142	$ 19,657,623	$ 20,975,961	**$ 92,499,285**
Total Funds	**$ 121,327,819**	**$ 155,867,075**	**$ 194,493,383**	**$ 207,537,081**	**$ 221,455,555**	**$ 900,680,912**
Federal Funds	**$ 74,291,246**	**$ 95,440,265**	**$ 119,091,861**	**$ 127,078,756**	**$ 135,601,293**	**$ 551,503,421**
State General Funds	**$ 47,036,574**	**$ 60,426,810**	**$ 75,401,522**	**$ 80,458,325**	**$ 85,854,262**	**$ 349,177,492**

Table 4. Cancer Biomarkers Anticipated Fiscal Impact, Worst Case Scenario, FY 2024-FY 2030

	FY 2024*	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029	FY 2030	Total Funds
Cancer	$ 1,212,263	$ 1,531,966	$ 2,049,731	$ 2,638,853	$ 3,297,947	$ 3,623,065	$ 3,728,560	**$ 18,082,385**
Federal Funds	$751,141	$949,235	$1,270,052	$1,635,084	$2,043,471	$2,244,920	$2,310,287	**$11,204,191**
State General Funds	$ 461,122	$ 582,731	$ 779,679	$ 1,003,769	$ 1,254,476	$ 1,378,145	$ 1,418,273	**$ 6,878,194**

**Claims subject to runout until July 2025; encounters subject to runout until January 2025*