A STUDY OF NEW JERSEY ASSEMBLY BILL 4163

REQUIRES HEALTH INSURERS TO PROVIDE COVERAGE FOR BIOMARKER TESTING

Report to the New Jersey General Assembly

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Mandated Health Benefits Advisory Commission

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INTRODUCTION

The Mandated Health Benefits Advisory Commission (MHBAC) has been asked to review A4163 (see Appendix I for a copy of the legislation), a bill that requires health insurance carriers to provide coverage for biomarker testing, defines standards that establish clinical evidence, and sets a benefit specific turnaround time for prior authorization review. The bill applies to coverage issued by a health service corporation, hospital service corporation, medical service corporation, commercial individual and group health insurer, health maintenance organization, entities contracted to administer health benefits in connection with the State Health Benefits Program (SHBP) and School Employees' Health Benefits Program (SEHBP), and the State Medicaid program.

Specifically, A4163 would require that "Biomarker testing…be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a subscriber. Importantly, in addition to establishing a mandate for coverage, the bill also sets forth very specific review standards for coverage eligibility, which generally do not exist for other services or supplies under New Jersey law. Specifically, the bill mandates coverage if "the test is supported by medical and scientific evidence, including but not limited to:

(1) labeled indications for an FDA-approved or FDA-cleared test;

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) Nationally-recognized clinical practice guidelines and consensus statements.

The bill also provides that, if a carrier undertakes a utilization management review, a decision must be provided within 72 hours for a non-urgent request or 24 hours for an urgent request, Generally, such review turnaround times are standardized under New Jersey law. These standard times were recently modified by the enactment of P.L. 2023, c.296, which takes effect January 1, 2025. The timeframes established under this bill may not align with standard timeframes governing utilization review, which could present administrative complication to the extent it would establish variable standards for utilization review depending on the specific procedures involved.

The bill applies to the state regulated insurance markets, including the individual market, the small employer market, and the large employer market. It also applies to the Medicaid program and the SHBP and SEHBP.

The Mandated Health Benefits Advisory Commission Act (N.J.S.A. 17B:27D-1 et seq.) tasks the Commission with providing an independent analysis of the social, medical, and financial impact of proposed legislation referred to it for review. The Act does not ask the Commission to recommend whether to enact the legislation, and the Commission does not do so here. The MHBAC prepared this report using its own resources, including staff from the New Jersey Department of Banking and Insurance. Commission members contributed their professional expertise, on a voluntary basis, in helping to shape the presentation of this report, analyzing published research, and drafting and editing its various sections. The MHBAC has sought to include information from a number of reputable sources that it found credible but recognizes that opinions and analyses may differ.

MEDICAL EVIDENCE

The American Cancer Society Cancer Action Network (ACSCAN) defines biomarker testing as an analysis of tissue, blood, or other biospecimen to identify acquired or inherited mutations that impact treatment decisions in patients who have already been diagnosed with a disease or other condition.[i] Biomarker testing is also referred to as genomic testing, molecular testing, molecular profiling, and tumor profiling. According to ACSCAN, biomarker testing can be further subdivided into the following biomarker groups:

- **Diagnostic biomarkers**, used to confirm the presence of a disease or condition, or to identify individuals with a subtype of the disease or condition;
- **Prognostic biomarkers**, used to identify the likelihood of disease recurrence or progression in patients after diagnosis;
- **Pharmacogenomic biomarkers**, used to predict a drug's efficacy or likelihood of toxicity, as the same treatment given to patients with the same disease can produce different responses based on each person's inherited genes;
- **Predictive biomarkers**, used to help medical practitioners identify the most effective treatment for a patient in terms of favorable or unfavorable responses to treatment or therapy; and
- **Monitoring biomarkers**, used to detect signs of disease progression or recurrence, sometimes before those changes are visible through traditional monitoring.[ii]

Biomarker testing can be used in the diagnosis and treatment of various types of cancer, autoimmune diseases, cardiovascular diseases, kidney diseases, infectious diseases, metabolic diseases, and behavioral health conditions. Cancer biomarkers can include proteins or genetic changes such as mutations, rearrangements, or fusions. In cancer treatments, these biomarkers can be used to identify "targeted cancer therapies, which work by interfering with specific

cellular processes involved in the growth, spread, and progression of cancer."[iii] ACSCAN asserts that biomarker testing can save lives, expedite treatment times, avoid ineffective and unnecessary treatments, reduce adverse side effects from treatments, and potentially reduce healthcare costs by matching patients with diagnosed diseases or conditions with the treatments most likely to be effective, also known as precision medicine.[iv]

A study of the impact of biomarker testing on the cost-effectiveness of targeted treatments for metastatic colorectal cancer found a generally positive effect. The authors concluded that the use of biomarkers to select "targeted therapies…were mostly found to be cost-effective; otherwise, they improved the cost-effectiveness of corresponding therapies by saving some costs."[v]

Biomarker testing can be limited to tests for single biomarkers, narrow panel sequencing tests, which look for a limited number of biomarkers from a single sample, or broad panel sequencing, which can look for a larger number of biomarkers from a single sample. There is evidence that more expensive, broad panel sequencing (BPS) biomarker testing results in lower total cancer treatment costs than narrow panel sequencing (NPS) biomarker testing. A study of lung cancer treatment costs, for example, found that while the average cost for the more limited NPS was $719 versus $1977 for BPS, a difference of $1258, the average cost of 6 months of treatment measured per member per month (PMPM) was $11,535 for the BPS patients versus $20,039 PMPM for the NPS patients. While the initial biomarker testing was substantially more expensive for the BPS patients, the targeted treatments indicated by the fuller "genomic landscape of a patient's tumor earlier" resulted in an average monthly treatment cost savings of $8,504.[vi] An expanded discussion of the potential financial impacts of biomarker testing mandates is presented below.

SOCIAL IMPACT

ACSCAN asserts, "Timely access to…comprehensive biomarker testing can help achieve the triple aim of health care including better health outcomes, improved quality of life, and reduced costs."[vii] Utilizing biomarker testing can result in treatments with fewer side effects, longer patient survival times, and avoiding ineffective or unnecessary treatments that can worsen the physical, emotional, and economic burdens of disease.[viii]

There are disparities, however, in access to biomarker testing. A 2022 study reported, "currently only half of patients with cancer in the United States for whom biomarker testing is recommended are receiving the tests." The authors also found the patients least likely to receive biomarker testing are older, Black, uninsured, or covered by Medicaid.[ix] That is consistent with an ACSCAN statement, "Communities that have been excluded, including communities of color, individuals with lower socioeconomic status, rural communities and those receiving care in non-academic medical centers are less likely to receive biomarker testing."[x]

A recent study examined outcomes for patients diagnosed with advanced non-small cell lung cancer, comparing Medicaid patients and patients with commercial insurance. The Medicaid patients were less likely to have received any biomarker testing than commercially insured patients (57% vs. 71%) and had a 23% higher risk of mortality than the patients with commercial insurance. Looking only at Medicaid patients with lung cancer, those who had no biomarker testing had a 27% higher risk of mortality than those Medicaid patients who had at least one biomarker test.[xi]

A Milliman study, commissioned by ACSCAN, estimated the impact on premiums of expanding biomarker testing coverage in the commercial self-insured large group, small group, individual, and Medicaid market segments to the coverage standards of the 50th and 75th percentiles of the respective groups. The authors found that raising Medicaid biomarker testing coverage would increase premiums by a range of $0.05 to $0.09 PMPM, raising biomarker testing coverage in the large group segment would increase premiums from $0.14 to $0.23 PMPM, small group premiums would rise between $0.18 and $0.30 PMPM as a result of increased testing coverage, and individual insurance premiums would rise from $0.31 to $0.51 PMPM with increased biomarker testing coverage.[xii] This study made no assessment of the potential cost savings resulting from using expanded biomarker testing to improve the delivery of healthcare services. A more detailed discussion of the potential financial impacts of biomarker testing mandates as assessed by other states appears below.

One study described the current situation with differences in insurance coverage and access to biomarker testing this way, "The existing racial, ethnic, and socioeconomic disparities in access to and utilization of guideline-indicated [comprehensive biomarker testing] and appropriate treatment with targeted therapies …contribute to disparities in patient outcomes."[xiii] A brief by the National Conference of State Legislatures suggests that some lawmakers consider mandating insurance coverage as one way to address these disparities in access to biomarker testing and resulting health outcomes.[xiv] For example, in describing California's new law mandating insurance coverage for biomarker testing for cancer, University of California Health suggested, "Now, people covered by Medi-Cal and private insurers will be able to take advantage of the newest advances in genomics and precision medicine to gain equitable access to effective, life-changing treatments."[xv]

OTHER STATES

A study recently published in JAMA identified 15 states that have passed biomarker testing laws since 2021.[xvi] The authors indicated that, for all 15 states, biomarker testing coverage mandates apply to commercial payers; the authors noted that the laws also apply to state Medicaid programs in 12 states, explicitly do not apply to Medicaid in one state (Louisiana), and that the applicability of Medicaid coverage was not addressed in two other state laws. The laws in 11

states mandate biomarker testing coverage for all conditions, while in 4 states coverage is limited to testing for cancer biomarkers; for California, that cancer biomarker coverage is limited to testing for stage III or IV cancer only. Fourteen of the 15 state mandates reviewed in the JAMA study cover biomarker testing for diagnosis, management, and monitoring of a covered person's condition or disease.[xvii] The standards and criteria used to "trigger" mandatory biomarker testing were fairly uniform across the 15 state laws, with minor exceptions or differences noted. These measures of medical and scientific evidence were consistent with those named in A4163.

After the JAMA study was published, Colorado, Connecticut, Florida, Indiana, Iowa, and Pennsylvania became 16th, 17th, 18th, 19th, 20th, and 21st states to pass biomarker testing laws. It should be noted that the specific requirements of the mandates adopted in these states can vary, and those differences can potentially affect the prospective medical, social, or financial effects of those mandates. Interestingly, Connecticut's biomarker testing law applies only to the state's Medicaid program, while Florida's law extends biomarker testing coverage to its Medicaid program and state employee health insurance plans, but not to those covered by state-regulated private health insurance plans. A summary of the data on states with biomarker testing mandates is presented in Table 1, with an overview of the diseases covered by those mandates and whether the mandate applies to the state's Medicaid program; it may be noted that this report does not attempt a more comprehensive review of the provisions of those other state laws.

Table 1. States with Laws Mandating Biomarker Testing and Characteristics of the Laws

State	Bill Number/Year	Diseases Covered	Medicaid Included
Arizona	HB2144 (2022)	All	Yes
Arkansas	HB1121 (2023)	Cancer	No
California	SB496 (2023)	Cancer	Yes
Colorado	SB24-124 (2024)	All	No
Connecticut	SB307 (2024)	All	Yes
Florida	SB885 (2024)	All	Yes
Georgia	HB85 (2023)	All	Yes
Illinois	HB1779 (2021)	All	Yes
Indiana	SB273 (2024)	All	Yes
Iowa	HF2668 (2024)	All	Yes
Kentucky	HB180 (2023)	NS	Yes
Louisiana	SB84 (2021)	Cancer	Not Stated
Maryland	SB805 (2023)	All	Yes
Minnesota	HF1978 (2023)	All	Yes
Nevada	AB155 (2023)	Cancer	Yes
New Mexico	HB73 (2023)	All	Yes

New York	S1196A (2023)	All	Yes
Oklahoma	SB513 (2023)	All	Yes
Pennsylvania	HB1754 (2024)	All	Yes
Rhode Island	S2201 (2022)	All	Not Stated*
Texas	SB989 (2023)	All	Yes

Sources: Lin, Grace A., Coffman, Janet M., and Phillips, Kathryn A., "The State of State Biomarker Testing Insurance Coverage Laws," JAMA, Published online May 13, 2024. Accessed 6/12/24. The State of State Biomarker Testing Insurance Coverage Laws | Cancer Biomarkers | JAMA | JAMA Network

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American Cancer Society Cancer Action Network, "'Game-Changing' Bill Becomes Law in Iowa, Opening Door to Precision Medicine for More Patients," May 1, 2024. Accessed 6/11/24. 'Game-Changing' Bill Becomes Law in Iowa, Opening the Door to Precision Medicine for More Patients | American Cancer Society Cancer Action Network (fightcancer.org)

Pennsylvania General Assembly, "Bill Information – History: House Bill 1754; Regular Session 2023-2024." Accessed 8/26/24. Bill Information (History) - House Bill 1754; Regular Session 2023-2024 - PA General Assembly (state.pa.us)

* *N.B.,* a press release from the American Cancer Society Cancer Action Network states that the Rhode Island law includes those covered by Medicaid. "Rhode Island Senate Votes to Remove Barriers to Biomarker Testing," May 19, 2022. Accessed 6/11/22. Rhode Island Senate Votes to Remove Barriers to Biomarker Testing | American Cancer Society Cancer Action Network (fightcancer.org)

A biomarker testing bill (LD1577) passed both houses in Maine this year but was not signed by the Governor.[xviii] In Washington, HB1450 failed to advance in the House Appropriations Committee.[xix] Advocates in Maine and Washington indicated they would introduce biomarker testing legislation in the next legislative sessions in their respective states.

DISCUSSION

While the empirical evidence for the cost savings resulting from the broader use of biomarker testing is limited, the early results from targeted treatments tied to biomarker testing for some specific diseases and conditions are promising. Several researchers have focused on the need to use biomarker testing more widely to address disparities in treatment and health outcomes for underserved populations. ACSCAN points out the direct connection between payments to providers and the availability of healthcare: "[I]nsurer coverage is an important factor in provider uptake and patient access. Without coverage, patients will not have access."[xx] Because a large number of states have considered or adopted laws expanding insurance coverage for biomarker testing, it is useful to examine the fiscal notes and financial analyses prepared by those states to see what they estimated the cost of the mandate would be to their states.

FINANCIAL IMPACT

Many of the states that have adopted biomarker testing coverage mandates have issued fiscal notes or fiscal impact statements analyzing the laws' impact on state spending or healthcare costs. Some estimates found that a biomarker testing coverage mandate could result in significant increases in premiums or costs to state budgets, while many analyses concluded that any increases were likely to be minimal. Other estimates suggested that cost increases might be or would be offset by cost savings resulting from earlier diagnosis and treatment and by efficiencies resulting from targeted treatments specific to a given patient and the patient's specific health issues. Where fiscal analyses concluded the financial impact of the mandate would be more significant, it was frequently noted that the costs of the mandate might need to be covered through a state budgetary appropriation. Notwithstanding these attempts to assess the costs of proposed biomarker testing mandates, it may be noted that there do not appear to be any comprehensive or definitive analyses of actual financial impact of such mandates in the states where mandates have been adopted, which may reflect that most of the mandates have been only recently adopted.

Set forth below are some examples of cost impact analyses conducted by other states that have considered or enacted legislation similar to A4163. In reviewing these analyses, it should be noted that bills mandating biomarker testing coverage may differ significantly from state to state. Moreover, most state analyses look at state costs, usually from public employee coverage or Medicaid. As such, the size of the markets under discussion and the scope of existing coverage requirements will have an impact on each state's impact analysis and may prevent one-to-one comparisons with the potential costs and impact if a comparable measure were adopted in New Jersey. Lastly, the depth and quality of the analysis may differ from state to state.

Several states issued analyses asserting that the new coverage mandate would have no impact on existing costs or coverage, or that healthcare savings from utilizing biomarker testing were likely

to offset any costs of the mandate. Connecticut's Office of Fiscal Analysis, for example, reported that the law "is not anticipated to result in a fiscal impact as such testing is currently covered."[xxi]

New York's analysis of fiscal implications found, "Any cost of enacting this legislation is far overshadowed by ensuring that the course of treatment used in testing an individual patient's cancer is the most effective and cost-effective treatment."[xxii] In a similar finding in a Fiscal Note from Nevada's Department of Health and Human Services, Health Care Financing and Policy, the agency reported that Nevada's bill would require no additional funding and that, "[A]ny additional costs for biomarker testing related to only cancer would be offset by any savings related to more effective treatment and earlier diagnosis."[xxiii] Kentucky's Financial Impact Statement, produced by the Kentucky Department of Insurance, focused exclusively on commercial health insurance policies, excluding state employee programs and Medicaid. The statement asserted that the biomarker testing mandate was not expected to "materially increase premiums" or "materially increase the total cost of health care" in Kentucky.[xxiv]

A fiscal note produced by Arizona's Joint Legislative Budget Committee (JLBC) also focused on the state's Medicaid program, even though the mandate also applies to commercial health insurance plans and the state's employee health plan. JLBC reported that the current Medicaid program already covered a large number of biomarker tests, so the new law "would not present an immediate and substantial increase in the number of tests" the program covered and, therefore, the JLBC "does not expect the bill would yield a significant fiscal impact" on the Medicaid program.[xxv] Finally, the California Health Benefits Review Program (CHBRP), analyzing a similar biomarker testing bill in the last legislative session, reported that the state's Medi-Cal program currently provided coverage for such testing. As a result, the report estimated the new mandate would have no financial impact. If a new mandate were to expand biomarker testing, CHBRP found "it might increase costs of health coverage, but could also decrease costs if it results in more effective, targeted care."[xxvi]

Other state fiscal analyses found there would be small costs incurred in implementing a biomarker testing mandate. Arkansas, for instance, issued an actuarial statement that examined the cost of its cancer biomarker testing mandate on self-insured health plans. The analysis assumed a weighted average cost of testing of $1,700 and a utilization rate of 0.5% of members, arriving at a cost estimate of $369,000 per year for the new mandate. The analysis did not provide a count of covered lives in Arkansas' self-insured plans.[xxvii] Colorado's Legislative Council Staff issued a fiscal note advising that the new biomarker testing mandate could result in higher costs for the state employee health program. The fiscal note downplayed the extent of such cost increases, arguing, "[I]t is assumed that any cost increase in the state share of employee health insurance premiums will be addressed through the annual budget process."[xxviii] The fiscal analysis also pointed out that the new mandate would apply to individual and small group plans only after it was determined that no state defrayal was necessary.[xxix]

New Mexico's Legislative Finance Committee prepared a Fiscal Impact Report of legislation mandating comprehensive biomarker testing for New Mexico's entire insured population. The cost estimates ranged from $97,200 to $3.9 million or roughly 30 cents to $12 per member per year.[xxx] The New Mexico report also noted that, "This legislation would be a newly mandated benefit for individual and small group plans regulated by the federal Affordable Care Act under the New Mexico health insurance exchange." Federal cost-defrayal requirements would mean the state would be required to pay for higher premiums resulting from adding biomarker testing benefits to health coverage sold through New Mexico's insurance marketplace.[xxxi]

Iowa's Legislative Services Agency produced a fiscal note that estimated a new coverage mandate in Iowa would result in an annual cost to the General Fund of $171,000 for the Department of Health and Human Services' Medicaid program. The analysis also advised that biomarker testing could "generate savings in the long term as a result of earlier intervention," but due to the unavailability of data, such potential cost savings could not be estimated.[xxxii] Indiana's Legislative Services Agency, Office of Fiscal and Management Analysis, wrote an analysis with no cost or savings estimates. The analysis did state that expanding biomarker testing coverage would lead to an increase in the utilization of such tests under Indiana's State Employee Health Plans (SEHP) and the state Medicaid program. The analysis found that, "Any resulting impact to the SEHP is expected to be minimal," as the program already covers a number of biomarker tests.[xxxiii] As for the impact on state Medicaid costs, the analysis did not offer an estimate, reporting only that, "[M]edicaid expenditures resulting from this bill will ultimately depend on the utilization of biomarker testing, the cost of the testing, and the impact that such testing may have on the care regime of covered individuals."[xxxiv]

Pennsylvania's Senate Appropriations Committee issued a Fiscal Note that found its proposed biomarker testing mandate would have no impact on state general funds until FY 2026-27. In FY 2026-27, the fiscal note estimated that the mandate would cost Pennsylvania's Department of Human Services $530,000, divided into $318,000 in federal funds and $212,000 in state funding. These costs would apply to both Pennsylvania's Medicaid Medical Assistance program and its Children's Health Insurance Program.[xxxv]

Oklahoma's Management and Enterprise Services estimated that an Oklahoma biomarker testing mandate would add approximately $500,000 in total to all non-Medicaid premiums in the state, averaging between 14 and 23 cents per member annually. The Oklahoma Health Care Authority found that the mandate would have no fiscal impact on the state's Medicaid program, as biomarker testing is already covered.[xxxvi] A later bill summary restated the same total cost to premiums ($500,000) as a 0.05% increase in total premium.[xxxvii] Texas' Legislative Budget Board produced an analysis that found the Texas biomarker testing mandate would result in overall costs to General Revenue of $2,687,068 in FY2025, which costs were estimated to rise to $3,161,492 in FY2028. Projected increased expenditures by the Texas Medicaid program were responsible for these estimated increased costs to General Revenue. On the other hand, the

budget analysis stated, "No significant fiscal implication to units of local government is anticipated."[xxxviii]

Minnesota's Health Finance and Policy Committee produced a detailed fiscal analysis of the state's biomarker testing bill. The analysis estimated state costs would increase by $2,851,000 in FY 2026 and $2,863,000 in FY 2027. Estimated total costs to local Minnesota governments would increase by $240,000 in FY 2026 and $252,000 in FY 2027.[xxxix] Minnesota Management and Budget, which administers the State Employee Group Insurance Program, estimated the biomarker testing mandate would increase plan premiums by an average of $0.15 per member per month (PMPM), with a range of $0.10 to $0.20 PMPM, or $0.17 PMPM in future fiscal years to account for anticipated healthcare cost inflation.[xl] The Minnesota fiscal analysis did not attempt to account for potential cost savings resulting from the new mandate.

Maryland's Department of Legislative Services (DLS) produced a fiscal and policy note on the impacts of its biomarker testing bill on local governments, the State Employee and Retiree Health and Welfare Benefits Program, and the state Medicaid program. The analysis estimated the mandate would have no impact on the state employee and retiree health program and, "To the extent the mandate increases the cost of health insurance, expenditures for local governments that purchase fully insured medical plans may increase."[xli] As for the Medicaid program, DLS provided a cost estimate labeled "*For illustrative purposes only*," (italics in the original), with assumptions meant to demonstrate a highest possible annual cost.

The DLS analysis started with a Medicaid population of nearly 1.6 million people, a cost of $1,700 per biomarker test, testing for the widest possible number of diseases and conditions, and an assumption that up to 25% of the adult Medicaid population and 10% of Medicaid enrollees under age 18 presenting at an emergency department would receive a biomarker test. The estimated cost to Medicaid under these assumptions was roughly $460 million per year.[xlii] DLS mitigated the impact of these costs by anticipating that general Federal funding for the program would "increase by an indeterminate but potentially significant amount," and that the costs of biomarker testing were balanced "by savings (or cost avoidance) as the tests are intended to diagnose, treat, and manage diseases and conditions; facilitate the use of more effective and targeted …treatments; and help avoid use of therapies that may be unsafe or ineffective for specific patients." DLS was unable to provide a reliable estimate of such savings or their net impact on Medicaid's overall expenditures, suggesting that, "Expenditures are likely offset by indeterminate savings."[xliv]

Florida's Committee on Fiscal Policy produced an analysis of the impact of its biomarker testing bill on the state's Medicaid program and Florida employees' State Group Insurance program. The analysis was not able to determine the precise impact of the mandate on State Group Insurance but cited an estimate ranging from no impact to $1.6 million per year.[xlv] The analysis found the mandate could have "a significant operational and fiscal impact on the Medicaid Program," as the expanded criteria for coverage contained in the bill could increase the number

of biomarker tests covered by Medicaid. Conversely, the analysis found, "[E]xpanding the number of biomarker tests covered under the Florida Medicaid program may result in future cost savings from the use of more targeted, optimal treatment protocols for diseases."[xlvi]

Summarizing the findings of the state financial and fiscal impact analyses, a few states expected the biomarker testing mandates to have a significant impact on state budgets or insurance premiums (Texas and Minnesota's projected Medicaid costs). On the other hand, many states found that their biomarker testing mandates would have little or no impact on state budgets or insurance premium costs (Connecticut, Nevada, and Kentucky). Indiana's analysis found that future cost effects would depend on the number and combination of biomarker tests found to meet the rigorous criteria for inclusion in the mandate (*e.g.*, FDA approval, approval by the Centers for Medicare and Medicaid Services National Coverage Determinations, and nationally-recognized clinical practice guidelines and consensus statements). Other states' analyses found that while healthcare costs might rise with an expanded testing mandate, even greater cost savings could result from earlier interventions with more targeted and effective treatments that have fewer side effects, reductions in wasted or ineffective healthcare costs, and better health outcomes (New York, Maryland, California, Iowa, and Florida).

It is interesting that for the few states that did provide estimated ranges for the increased costs of biomarker testing mandates on non-Medicaid insurance premiums (Oklahoma, New Mexico, and Minnesota), those states' estimates were remarkably consistent with the premium cost estimates described in the Milliman study cited above. One final item of note is that a number of states that anticipated little-to-no financial impact to a biomarker testing coverage mandate cited the fact that the state already had some form of biomarker testing coverage mandate in place prior to the introduction of legislation establishing a mandate. It is worth noting that New Jersey does not currently have a State-mandated biomarker testing coverage requirement in place, so the potential costs of a mandate would likely not be offset by existing coverage requirements.

An additional consideration is that the federal Patient Protection and Affordable Care Act requires states to defray the cost of any health insurance benefit mandate enacted after December 31, 2011, that is part of an insurance plan sold on a state exchange that is in addition to the state's essential health benefits (EHBs) and related to specific care, treatment, or services. ((P.L. 111-148 § 1311(d)(3) & 45 CFR 155.170). Federal law requires (1) the state to identify benefit mandates that are in addition to the state's EHB, and (2) insurers to report the cost of those benefits back to the state (i.e., excess cost reports). The state must then defray the cost of the additional mandates by making the appropriate payment directly to an enrollee or to the insurer on the enrollee's behalf (45 CFR 155.170). A 2017 federal final rule (§ 19) changed the entity responsible for identifying mandates and receiving excess cost reports from the state's exchange to the state. Defrayment does not apply to the large group market. For more information on State-required benefits, please refer to this CMS FAQ on Defrayal of State Additional Required Benefits. As part of the HHS Notice of Benefit and Payment Parameters for 2025, which was finalized on April 2, 2024, for plan years beginning on or after January 1, 2027, CMS is revising

the standards for state selection of EHB-benchmark plans to address long-standing requests from states to improve, and reduce the burden of, the EHB-benchmark plan update process.[xlvii] The process of updating the state's EHB-benchmark plan could create a pathway to adding benefits to the benchmark plan that may not trigger defrayal provided certain parameters are met. Thus, although this is a state-by-state analysis and no such analysis has been performed for New Jersey, a biomarker testing mandate may trigger the federal defrayment requirements.

CONCLUSION

A4163 would expand insurance coverage for biomarker testing to those covered by New Jersey health insurance carriers, Medicaid, and the SHBP and SEHBP to the extent that coverage is not already available. Biomarker testing coverage would include testing for diagnosis, treatment, management, and monitoring of a disease or condition, but not for screening purposes. Insurance coverage for biomarker testing would include any tests that have FDA approval, CMS approval, or those included in nationally-recognized clinical practice guidelines.

Biomarker testing coverage has the potential to reduce disparities in healthcare treatments and outcomes by facilitating more expedient access to the treatments most likely to result in the best outcomes for all patients with coverage. As ACSCAN stated, "Improving coverage for and access to biomarker testing across insurance types is key to reducing health disparities."[xlviii] Furthermore, moving more quickly to the targeted treatments most likely to have fewer side effects or result in the best outcomes without wasting resources on less effective or ineffective treatments could result in lower overall healthcare costs. However, ensuring that biomarker testing is actually appropriate and valuable remains important. While the current empirical evidence is too sparse to make a determination, a number of states cited potential overall cost savings as a factor when assessing the fiscal impacts of their biomarker testing bills. Twenty-one states have made expanded biomarker testing part of their insurance laws, in some form, although it may be noted that the specific requirements of those mandates vary, meaning it might not be possible to conduct an apples-to-apples comparison of the provisions of those various laws or compare those laws with the provisions of A4163. No state that has adopted a legislative coverage mandate for biomarker testing found the costs of the mandate to be prohibitive.

ENDNOTES

[i] American Cancer Society Cancer Action Network (ACSCAN), "Biomarker Testing FAQs," January 2023. Accessed 6/17/24. biomarker_testing_faq_.pdf (fightcancer.org)

[ii] *Ibid.*

[iii] American Cancer Society Cancer Action Network, "Improving Access to Biomarker Testing: Advancing Precision Medicine in Cancer Care," September 2020. Accessed 6/25/24. Improving Access to Biomarker Testing.pdf (fightcancer.org)

[iv] *Ibid.*

[v] Seo, Mikyung Kelly and Cairns, John, "Do Biomarkers Make Targeted Therapies Cost-Effective? A Systematic Review in Metastatic Colorectal Cancer," PLoS One, Volume 13(9), published online September 26, 2018. Accessed 6/10/24. Do cancer biomarkers make targeted therapies cost-effective? A systematic review in metastatic colorectal cancer - PMC (nih.gov)

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[vii] American Cancer Society Cancer Action Network, "Biomarker Testing and Cost Savings," January 2023. Accessed 6/10/24. biomarker_testing_costs_and_cost_savings_1.pdf (fightcancer.org)

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[x] Andrea Fox, "Biomarker Legislation Could Improve Patient Access in 2024," Healthcare IT News, December 29, 2023. Accessed 6/10/24. Biomarker legislation could improve patient access in 2024 | Healthcare IT News

[xi] Gross, Cary Philip, Meyer, Craig S., Ogale, Sarika, *et al.*," The Association between Medicaid Insurance, Biomarker Testing, and Outcomes in Patients with Advanced Non-Small Cell Lung Cancer (aNSCLC)," Journal of Clinical Oncology, Vol. 38 (Supplement 29, Abstract 89), 2020. Accessed 6/25/24. Program Guide – ASCO Meeting Program Guide

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ASSEMBLY, No. 4163

STATE OF NEW JERSEY

221st LEGISLATURE

INTRODUCED APRIL 8, 2024

Sponsored by:
Assemblywoman SHAVONDA E. SUMTER
District 35 (Bergen and Passaic)
Assemblyman GARY S. SCHAER
District 36 (Bergen and Passaic)
Assemblywoman SHAMA A. HAIDER
District 37 (Bergen)

Co-Sponsored by:
Assemblywomen Bagolie, Hall, Donlon, Matsikoudis, Lopez, Pintor Marin, Assemblymen Clifton, Sampson, Karabinchak, Assemblywoman Flynn, Assemblymen Conaway, DePhillips and Calabrese

SYNOPSIS

Requires health insurers to provide coverage for biomarker testing.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 6/3/2024)

AN ACT concerning health insurance coverage for biomarker testing and amending and supplementing various parts of the statutory law.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. a. Each hospital service corporation contract that provides hospital or medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1938, c.366 (C.17:48-1 et seq.) or is approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a subscriber when the test is supported by medical and scientific evidence, including, but not limited to:

(1) labeled indications for an FDA-approved or FDA-cleared test;

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of a subscriber.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the subscriber and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The subscriber and the treating health care provider or treating health care entity prescribing biomarker testing for the subscriber shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The benefits shall be provided to the same extent as for any other medical condition under the contract.

f. The provisions of this section shall apply to all hospital service corporation contracts in which the hospital service corporation has reserved the right to change the premium.

g. As used in this section:

"Biomarker" means 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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

2. a. Each medical service corporation contract that provides hospital or medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1940, c.74 (C.17:48A-1 et seq.) or is approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a subscriber when the test is supported by medical and scientific evidence, including, but not limited to:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of a subscriber.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the subscriber and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The subscriber and the treating health care provider or treating health care entity prescribing biomarker testing for the subscriber shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The benefits shall be provided to the same extent as for any other medical condition under the contract.

f. The provisions of this section shall apply to all medical service corporation contracts in which the medical service corporation has reserved the right to change the premium.

g. As used in this section:

"Biomarker" means 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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The guidelines establish standards of care informed by a systematic review of evidence and an assessment of

the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

3. a. Each health service corporation contract that provides hospital or medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1985, c.236 (C.17:48E-1 et seq.) or is approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a subscriber when the test is supported by medical and scientific evidence, including, but not limited to:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of a subscriber.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the subscriber and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The subscriber and the treating health care provider or treating health care entity prescribing biomarker testing for the subscriber shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The benefits shall be provided to the same extent as for any other medical condition under the contract.

f. The provisions of this section shall apply to all health service corporation contracts in which the health service corporation has reserved the right to change the premium.

g. As used in this section:

"Biomarker" means 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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

4. a. Each individual health insurance policy that provides hospital or medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to chapter 26 of Title 17B of the New Jersey Statutes or is approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of an insured when the test is supported by medical and scientific evidence, including, but not limited to:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of an insured.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the insured and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The insured and the treating health care provider or treating health care entity prescribing biomarker testing for the insured shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The benefits shall be provided to the same extent as for any other medical condition under the contract.

f. The provisions of this section shall apply to all health benefits plans in which the carrier has reserved the right to change the premium.

g. As used in this section:

"Biomarker" means 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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

5. a. Each group health insurance policy that provides hospital or medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to chapter 27 of Title 17B of the New Jersey Statutes or is approved for issuance or renewal in this State by

the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide benefits for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of an insured when the test is supported by medical and scientific evidence, including, but not limited to:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of an insured.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the insured and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The insured and the treating health care provider or treating health care entity prescribing biomarker testing for the insured shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The benefits shall be provided to the same extent as for any other medical condition under the contract.

f. The provisions of this section shall apply to all policies in which the insurer has reserved the right to change the premium.

g. As used in this section:

"Biomarker" means 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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

6. a. Each individual health benefits plan that provides hospital or medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1992, c.161 (C.17B:27A-2 et seq.) or is approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide benefits for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a covered person when the test is supported by medical and scientific evidence, including, but not limited to:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of a covered person.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the covered person and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The covered person and the treating health care provider or treating health care entity prescribing biomarker testing for the

covered person shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The benefits shall be provided to the same extent as for any other medical condition under the health benefits plan.

f. The provisions of this section shall apply to all health benefits plans in which the carrier has reserved the right to change the premium.

g. As used in this section:

"Biomarker" means 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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

7. a. Each small employer health benefits plan that provides hospital or medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1992, c.162 (C.17B:27A-17 et seq.) or is approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide benefits for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a covered person when the

test is supported by medical and scientific evidence, including, but not limited to:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of a covered person.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the covered person and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The covered person and the treating health care provider or treating health care entity prescribing biomarker testing for the covered person shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The benefits shall be provided to the same extent as for any other medical condition under the health benefits plan.

f. The provisions of this section shall apply to all health benefits plans in which the carrier has reserved the right to change the premium.

g. As used in this section:

"Biomarker" means 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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical

circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

8. a. Each health maintenance organization contract for health care services that is delivered, issued, executed, or renewed in this State pursuant to P.L.1973, c.337 (C.26:2J-1 et seq.) or is approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide health care services for biomarker testing, as defined by subsection g. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of an enrollee when the test is supported by medical and scientific evidence, including, but not limited to:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of an enrollee.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the enrollee and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The enrollee and the treating health care provider or treating health care entity prescribing biomarker testing for the enrollee shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. The health care services shall be provided to the same extent as for any other medical condition under the contract.

f. The provisions of this section shall apply to those contracts for health care services by health maintenance organizations under which the right to change the schedule of charges for enrollee coverage is reserved.

g. As used in this section:

"Biomarker" means 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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

9. a. The State Health Benefits Commission shall ensure that every contract providing hospital or medical expense benefits, which is purchased by the commission on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), provides coverage for biomarker testing, as defined by subsection e. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a covered person when the test is supported by medical and scientific evidence, including, but not limited to:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of a covered person.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the covered person and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The covered person and the treating health care provider or treating health care entity prescribing biomarker testing to the covered person shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. As used in this section:

"Biomarker" means 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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

10. a. The School Employees' Health Benefits Commission shall ensure that every contract providing hospital or medical expense benefits, which is purchased by the commission on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), provides coverage for biomarker testing, as defined by subsection e. of this section.

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of a covered person when the test is supported by medical and scientific evidence, including, but not limited to:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of a covered person.

d. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice shall be sent to the covered person and the appropriate health care provider, and if the request is made through a health care entity, to the health care entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The covered person and the treating health care provider or treating health care entity prescribing biomarker testing for the covered person shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

e. As used in this section:

"Biomarker" means 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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

"Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The statement shall be aimed at specific clinical circumstances and be based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

"Nationally-recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy. The guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

11. a. Notwithstanding any State law or regulation to the contrary, the Department of Human Services shall ensure that expenses incurred for biomarker testing shall be provided with no cost-sharing to persons served under the Medicaid program, established pursuant to P.L.1968, c.413 (C.30:4D-1 et seq.).

b. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a disease or condition of an individual when the test is supported by medical and scientific evidence, including, but not limited to:

(1) labeled indications for an FDA-approved or -cleared test;

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally-recognized clinical practice guidelines and consensus statements.

c. Coverage, pursuant to subsection b. of this section, shall be provided in a manner that limits disruption, including multiple biopsies or biospecimen samples, in the care of an individual.

d. If the Division of Medical Assistance and Health Services in the Department of Human Services contracts with a third-party entity to deliver biomarker testing services pursuant to this section to beneficiaries under the Medicaid program, the third-party entity shall provide biomarker testing at the same scope, duration and frequency as the Medicaid program otherwise provides to individuals.

e. (1) Notwithstanding any other law, rule, or regulation to the contrary, if utilization review is required, a decision shall be rendered on a prior authorization request, and notice be sent to an individual, the appropriate health care provider, and, if necessary, the requisite health care entity if the request for prior authorization was

submitted through the entity, within 72 hours for a non-urgent request or 24 hours for an urgent request.

(2) The individual and the treating health care provider or treating health care entity prescribing biomarker testing for the individual shall have access to clear, readily accessible, and conspicuous information on the process to submit an appeal to an adverse determination.

f. As used in this section:

"Biomarker" means 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, including known gene-drug interactions for medications being considered for use or already being administered. Biomarkers shall also include, but not be limited to, gene mutations, characteristics of genes, or protein expression.

"Biomarker testing" means the analysis of tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

12. This act shall take effect on the 90th day next following enactment and shall apply to policies and contracts issued or renewed on or after the effective date.

STATEMENT

This bill requires health insurers to cover biomarker testing. Under the bill, health insurance carriers (including health service corporations, hospital service corporations, medical service corporations, commercial individual and group health insurers, health maintenance organizations, entities contracted to administer health benefits in connection with the State Health Benefits Program and School Employees' Health Benefits Program, and Medicaid) are to cover testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition when the test is supported by medical and scientific evidence. The evidence includes, but is not limited to: (1) labeled indications for an FDA-approved or -cleared test; (2) indicated tests for an FDA-approved drug; (3) warnings and precautions on FDA-approved drug labels; (4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or (5) Nationally recognized clinical practice guidelines and consensus statements. Coverage is to be provided in a manner that limits disruption, including multiple biopsies or biospecimen

samples, in the care of an individual. The bill also stipulates timelines in which a decision on prior authorization is to be made.

Appendix II

NEW JERSEY GENERAL ASSEMBLY

390 Amwell Road, Suite 301
Hillsborough, NJ 08844
Email: asmfreiman@njleg.org
Phone: (908) 829-4191
Fax: (908) 829-4193

Roy Freiman
Assemblyman
16th District

Committees
Chair, Financial Institutions and Insurance
Vice Chair, Oversight, Reform and Federal Relations
Budget

June 5, 2024

NJ Mandated Health Benefits Advisory Commission
P.O. Box 325
Trenton, NJ 08625

Dear Members of the Commission:

As the Chairman of the Assembly Financial Institutions and Insurance Committee, I respectfully request the Commission review and prepare a written report of A4163, which requires health insurers to provide coverage for biomarker testing.

If you have any questions, please do not hesitate to contact Mark Iaconelli, Jr., Esq., Deputy General Counsel, at 609-847-3500.

Thank you for your immediate attention to this matter.

Sincerely,

CC: Mark Iaconelli, Jr., Esq.
Deputy General Counsel
Assembly Majority Office