HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 885 Coverage for Biomarker Testing
SPONSOR(S): Select Committee on Health Innovation, Gonzalez Pittman and othrs
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 964

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Health Innovation	15 Y, 0 N, As CS	Lloyd	Calamas
2) Appropriations Committee	27 Y, 0 N	Smith	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Biomarker testing is a method of looking for any structure, process, genes, proteins, or other substance in the body that can provide information that can be measured in the body or its products and influence or predict the incidence of outcome or disease. It is a type of personalized or precision medicine where medical care is tailored to a person's specific genes, proteins, and other substances which may be present in a person's body. Biomarker testing is not helpful for all kinds of diseases. With cancer, for example, biomarker testing can help show:

- Whether the cancer is likely to grow or spread;
- Whether certain types of cancer treatments may be more likely or unlikely to be helpful; and
- Whether the cancer treatment is working.

Different types of biomarker tests can be done to help determine the best cancer treatment options or what treatment options are not helpful. Many tests look for gene changes in the cancer cells, while some measure certain proteins or other kinds of markers.

Biomarker testing for other diseases may look at just a single biomarker or check for many biomarkers at the same time (such as patterns of certain genes or proteins). Some tests look at all of the genes inside cancer cells. Biomarker tests may be done on tumor samples removed during a biopsy or surgery, but some biomarker tests can be done on samples of blood or other bodily fluids.

CS/HB 885 would require coverage for biomarker testing in Medicaid and the state group health insurance program. A recipient or insured and health care providers must have access to a clear and convenient process to request authorization for such testing through a readily accessible website of the insurer or plan. Coverage would not be required for biomarker testing for screening purposes.

The bill has an indeterminate, insignificant negative fiscal impact on state government. *See* Fiscal Analysis.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Biomarker Testing

Biomarker testing is a way of looking for genes, proteins, and other substances in the body that can provide information about diseases, such as cancer.[1] In 1988, the International Programme on Chemical Safety, led by the World Health Organization (WHO) and in coordination with the United Nations and the International Labor Organization, defined a biomarker as "any substance, structure, or process that can be measured in the body or its products and influence or predict the incidence of outcome or disease".[2]

An even broader definition of biomarker testing considers not just the incidence and outcome of disease, but also the effects of treatments, interventions, and even unintended environmental exposure, such as to chemicals or nutrients. In its report on the validity of biomarkers in environment risk assessment, the WHO has stated that a true definition of biomarkers includes "almost any measurement reflecting an interaction between a biological system and a potential hazard, which may be chemical, physical, or biological.[3] Biomarker testing is also a type of personalized or precision medicine where medical care is tailored to a person's specific genes, proteins, and other substances which may be present in a person's body.[4]

Biomarker testing is not helpful for every kind of disease, but in the example of biomarker testing for cancer, such testing can help show:

- Whether the cancer is likely to grow or spread.
- Whether certain types of cancer treatments may be more likely or unlikely to be helpful.
- Whether the cancer treatment is working.[5]

Studies indicate that currently only half of patients with cancer in the United States for whom biomarker testing is recommended receive biomarker testing.[6] More than a quarter of patients who did not receive recommended biomarker testing reported that it was because insurance was not covering the test at all and/or they would have incurred high out-of-pocket costs.[7]

Different types of biomarker tests can be done to help determine the best cancer treatment options. Many tests look for gene changes in the cancer cells, while some measure certain proteins or other kinds of markers. Other tests may look at just a single biomarker or check for many biomarkers at the same time (such as patterns of certain genes or proteins). Some tests look at all of the genes inside cancer cells.[8]

Biomarker tests may be done on tumor samples removed during a biopsy or surgery, but some biomarker tests can be done on samples of blood or other bodily fluids without being as invasive.[9] For certain types of cancer, biomarker testing is done routinely to assist with treatment decisions. Some

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[1] National Cancer Institute, *Biomarker Testing for Cancer,* Biomarker Testing for Cancer Treatment - NCI (last visited February 6, 2024).
[2] Kyle Strimbu and Jorge Tavel, M.D., *What are biomarkers?* Curr Opin HIV AIDS. 2010 Nov; 5(6): 463–466, available at doi: 10.1097/COH.0b013e32833ed177 (last visited February 6, 2024).
[3] *Id*.
[4] American Cancer Society, *Biomarker Tests and Cancer Treatment,* available Biomarker Tests and Cancer Treatment | American Cancer Society (last visited February 6, 2024).
[5] *Id*.
[6] Chawla A, Peeples M, Li N, Anhorn R, Ryan J, Signorovitch J., *Real-world utilization of molecular diagnostic testing and matched drug therapies in the treatment of metastatic cancers*, *J Med Econ*. 2018; 21:543-552, available at Real-world utilization of molecular diagnostic testing and matched drug therapies in the treatment of metastatic cancers - PubMed (nih.gov) (last visited February 6, 2024).
[7] Improving access to biomarker testing. American Cancer Society Cancer Action Network. Published September 28, 2020, available at Improving Access to Biomarker Testing | American Cancer Society Cancer Action Network (fightcancer.org) (last visited February 6, 2024).
[8] *Supra,* note *4.*
[9] *Id*.

cancer treatments, such as targeted therapies and immunotherapies, may only work for individuals with certain type of cancers.[10] However, biomarker testing may not be appropriate or helpful in all such situations. Using cancer as an example, the most common types of cancer for biomarker testing include cancers where there are changes in designated genes for:

- Non-small cell lung cancer;
- Breast cancer;
- Colorectal cancer; and
- Melanoma skin cancer.[11]

Biomarker testing is conducted using a sample of an individual's cancer cells, where the cells are analyzed to identify the specific biomarkers. The lab's report on the specific biomarkers will also identify the treatments that may be helpful for the cancer or the cancer strains identified. Some biomarker tests also require a testing of healthy cells for comparison of a person's healthy cells to his or her cancer cells for different mutations.[12]

One type of biomarker that can be identified is a driver mutation, which is a change in the DNA of a cancer cell and can cause a cancer cell to overgrow or a normal cell to become a cancer cell. The other type of biomarker is an immunotherapy biomarker, which may be found on the surface of a cancer cell and impacts how the cancer cells interact with the immune system. Knowing the types of biomarkers an individual has aids in the individual's plan of care.[13]

A number of types of biomarker tests for molecularly targeted therapies are in clinical use, ranging from single-gene tests to guide the use of a single class of therapy to a suite of multiple, but separate, tests for single analytes to guide the use of multiple therapy options in a specific clinical context for something like breast cancer treatment.[14] Multiple-gene panels include additional analytes for other clinical or research purposes, including assessing secondary response or resistance to targeted therapies, multiplex panel tests, protein express, and whole exome, whole genome, and whole transcriptome sequencing.[15]

Growth in this area of medicine has grown exponentially. For genome-informed therapy, the number of tests available or eligible for testing since 2018 has increased from 16 percent to 27 percent in 2020.[16] From January 1, 2006, when tracking of such approval began at the federal Food and Drug Administration (FDA), through June 30, 2020, 51 different drugs had been approved for 36 genomic indications covering 18 cancer types.[17]

Results of a biomarker test can help an individual find different options for treatment through the FDA-approved treatment regimens, off-label treatments, or clinical trials. Knowing that a cancer does not have certain biomarkers can also save a patient from undergoing unnecessary treatment or treatment that has not been as successful in a particular diagnosis or not have a long-term result leading to the return of the cancer.[18]

Waiting for results from biomarker tests before determining treatment options can provide patients and their providers more information on which to make decisions. Results from testing can take up to four

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[10] *Supra*, note 1.
[11] *Supra*, note 4.
[12] *Id*.
[13] Genentech, *Understanding Biomarkers,* available at Learn About Biomarkers And Biomarker Testing in Advanced Non-Small Cell Lung Cancer | MyCareRoadMap By Genentech (last visited February 6, 2024).
[14] Laurene A, Graig, et al, *Biomarker Tests for Molecularly Targeted Therapies, Institute of Medicine, The Nat'l Academies of Science, Engineering & Medicine (2016), available at* Biomarker Tests for Molecularly Targeted Therapies. Key to Unlocking Precision Medicine (nih.gov) (last visited February 6, 2024).
[15] *Id*.
[16] Genomic testing for targeted oncology drugs: hopes against hype, Editorial, *Annals of Oncology*, (Vol. 32, Iss.7, 2021), available at Genomic testing for targeted oncology drugs: hopes against hype (annalsofoncology.org) (last visited February 6, 2024).
[17] A. Haslam, M.S. Kim, & V. Presad, *Updated Estimates of Eligibility for and Responses to Genome Targeted Oncology Drugs Among US Cancer Patients; Annals of Oncoloy* (Vol. 32, Issue 7, July 2021; 926:943), available at Updated estimates of eligibility for and response to genome-targeted oncology drugs among US cancer patients, 2006-2020 - Annals of Oncology (last visited February 6, 2024).
[18] *Supra*, note 4.

weeks or longer to receive.[19] A patient may also have biomarker testing more than once during treatment to determine the efficacy of a treatment or if other options need to be considered.[20]

In 2020, the FDA approved two liquid biopsy tests that help guide treatment therapies for individuals with any solid tumor cancer, but not those with a blood cancer. These two approved tests can check for multiple cancer related mutations and are considered less invasive and quicker than the typical needle biopsy.[21] One test, Guardant360 CDX, checks for changes in more than 60 genes, while the other approved test, FoundationOne Liquid CDx, can identify changes in more than 300 genes.[22] Medicare does provide coverage for two FDA-approved tests, but coverage by private insurance companies for these same tests is not consistent.

Costs of Biomarker Testing

The costs of biomarker testing vary based on the type of testing being conducted and the type of disease being tested. The average allowed unit cost to insurers per biomarker test ranges from $78.71 (Medicaid) to $224.40 (large group self-insured).[23]

One study published in November 2022 found that among those with biomarker tests, the median per-patient total payer lifetime costs of all biomarker testing were $394/$462 (lung/metastatic lung) and $148/$232 (thyroid/metastatic thyroid).[24] In this study, total lifetime biomarker costs for payers ranged from a median of $128 (consumer-driven health plans) to $477 (preferred provider organizations). Median lifetime patient out-of-pocket costs were $0.00 for both tumor types and all payer types except for consumer-driven health plans ($12 for thyroid and $10 for metastatic lung).[25]

Costs vary by type of testing. The FDA has provided marketing approval for the sale of direct to patient biomarker tests. One of these tests, which was approved in 2019, can identify cancer-associated alterations in 324 genes in any type of solid tumor.[26] Different levels of screening tests can be ordered by a patient directly online or by a patient's health care provider for $299 - $350 for the cost of the test – not including the cost of analysis or review by the practitioner.[27]

For new cancer treatments, costs may be covered as part of clinical trials. If an individual participates in a clinical trial, costs of the testing are usually covered as part of participation.[28] Increasingly, clinical trials report the enrollment of individuals based on the specific genetic mutation or alteration and not which organ the cancer originated from.[29]

State Employee Health Plan Coverage

For state employees who participate in the state employee benefit program, the Department of Management Services (DMS) through the Division of State Group Insurance (DSGI) under the authority of section 110.123, F.S., administers the state group health insurance program (Program). The

[19] LUNGevity, *Biomarker testing can help you get the best treatment for your lung cancer,* 353b8753a58e4ebaae940e2d4b95ca49 (d2zd6ny1q7rvh6.cloudfront.net) (last visited February 6, 2024).
[20] *Id*.
[21] National Cancer Institute, *FDA Approves Cancer Test Which Can Help Guide Cancer Treatment (October 15, 2020)* FDA Approves Blood Tests That Can Help Guide Cancer Treatment - NCI (last visited February 6, 2024).
[22] *Id*.
[23] Yu TM, Morrison C, Gold EJ, Tradonsky A, Arnold RJG. *Budget Impact of Next-Generation Sequencing for Molecular Assessment of Advanced Non-Small Cell Lung Cancer,* Value Health. 2018 Nov;21(11):1278-1285, available at doi: 10.1016/j.jval.2018.04.1372, Epub 2018 Jun 8. PMID: 30442274. (last visited February 6, 2024).
[24] Lisa M. Hess, et al., *Costs of biomarker testing among patients with metastatic lung or thyroid cancer in the USA: a real-world commercial claims database study,* J Med Econ 2023 Jan-Dec;26(1):43-50., available at Costs of biomarker testing among patients with metastatic lung or thyroid cancer in the USA: a real-world commercial claims database study - PubMed (nih.gov) (last visted February 6, 2024).
[25] *Id*.
[26] National Cancer Institute, *Genomic Profiling Tests Cleared by FDA Can Help Guide Cancer Treatment, Clinical Trial Enrollment (December 21, 2017)*, https://www.cancer.gov/news-events/cancer-currents-blog/2017/genomic-profiling-tests-cancer, *(last visited February 6, 2024).*
[28] *Id*.
[28] *Supra*, note 4.
[29] National Cancer Institute, *Genomic Profiling Tests Cleared by FDA Can Help Guide Cancer Treatment, Clinical Trial Enrollment (December 21, 2017)* available at FDA Approves Two Genomic Profiling Tests for Cancer - NCI (last visited February 6, 2024).

Program is a cafeteria plan managed consistent with section 125 of the Internal Revenue Code.[30] To administer the program, DSGI contracts with third party administrators for self-insured plans, a fully insured HMO, and a pharmacy benefits manager for the state employees' self-insured prescription drug program, pursuant to s. 110.12315, F.S.

The state group health insurance program delivers benefits to state employees, retirees, and their families through contracts it competitively bids for on regular contract cycles with health insurers, health maintenance organizations, and third party administrators. The current benefits and premium rates for the plan year of January 1, 2024 through December 31, 2024 are established in these contracts and the state's General Appropriations Act. Any additional statutory changes in state employee benefits require a contract amendment to effectuate these benefits.

An online review of the 2024 member benefit handbooks and medical coverage guidelines for the currently contracted state employee insurers indicate that biomarker testing may already be covered within the Program under certain parameters. Based on the diagnosis, additional criteria are usually applied for testing to be covered in some of the coverage guidelines and all of the contracted plans have a general exclusionary coverage statement testing for any testing considered experimental or investigational, unless the testing falls under an allowable clinical trial.[31]

Medicaid Coverage of Biomarker Testing

Florida Medicaid covers biomarker testing under s. 409.905(7), F.S., as a mandatory Medicaid service under independent laboratory services. Eligible providers are reimbursed for biomarker testing under Rule 59G-4.190, Florida Administrative Code (F.A.C.), the Laboratory Services and Coverages Policy and Rule 59G-4.002, F.A.C., the Independent and Practitioner Laboratory Fee Schedules. The services provided to the eligible recipient must be determined to be medically necessary, not duplicative of another service, and meet the criteria of the policy.

The Medicaid Laboratory Services Policy covers reimbursement for:

- Chemistry;
- Clinical cytogenetics;
- Diagnostic immunology;
- Genetic carrier screening;
- Hematology;
- Histocompatibility;
- Immunohematology;
- Microbiology; and
- Pathology.[32]

Medicaid managed care plans have the flexibility to cover services above and beyond Agency for Health Care Administration (AHCA) coverage policies, but they may not be more restrictive than AHCA policy.[33]

Effects of the Bill

CS/HB 885 would require all policies issued under the state group health insurance program on or after January 1, 2025, to provide coverage of biomarker testing as a covered benefit, for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or

[30] A section 125 cafeteria plan is a type of employer offered, flexible health insurance plan that provides employees a menu of pre-tax and taxable qualified benefits to choose from, but employees must be offered at least one taxable benefit such as cash, and one qualified benefit, such as a Health Savings Account.
[31] Department of Management Services, *My Benefits – Health Plans in Your Area,* available at Health Plans in Your Area / Health Insurance Plans / Health - MyBenefits / Department of Management Services (myflorida.com) (last viewed January 23, 2024). A scan of Health Insurance Booklets, Benefits Documents,
[32] Rule 59G-4.190, F.A.C., *Laboratory Services and Coverage Policy,* available at 59G-4.190 Coverage Policy Proposed.pdf (last visited February 6, 2024).
[33] Agency for Health Care Administration, *2024 Agency Legislative Bill Analysis – SB 964/HB 885* (January 17, 2024)(on file with the Select Committee on Health Innovation).

condition if the medical and scientific evidence indicated that the biomarker testing provides clinical utility to the enrollee. Under the bill, such medical and scientific evidence includes, but is not limited to:

- A labeled indication for a test approved or cleared by the FDA;
- An indicated test for a drug approved by the FDA;
- A National Coverage Determination made by the Centers for Medicare and Medicaid Services or a Local Coverage Determination made by the Medicare Administrative Contractor; or
- A nationally recognized clinical practice guideline developed by an independent organization or medical professional society using transparent methodology and reporting structure, and with a conflict of interest policy.

The bill expressly provides that the coverage requirements for biomarker testing services do not include testing for screening purposes.

CS/HB 885 amends s.409.906, F.S., to add biomarker testing services as an optional Medicaid service, if medical and scientific evidence indicate that biomarker testing for the diagnosis, treatment, and appropriate management of a Medicaid recipient's disease provides clinical utility to the Medicaid recipient.

The bill requires Medicaid managed care plans provide coverage for biomarker testing in the same manner and scope as Medicaid provides to other medically necessary treatments. The provision also requires that the recipient and his or her provider have easy access to a clear and convenient authorization process on the managed care plan's website.

The bill further authorizes the agency to seek federal approval, if necessary to implement the coverage requirement.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY

Section 1: Amends s.110.12303, F.S., related to state group health insurance coverage for biomarker testing.
Section 2: Amends s.409.906, F.S., related to optional Medicaid services.
Section 3: Creates s. 409.9745, F.S., related to managed care plan biomarker testing.
Section 4: Providing an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill would have an indeterminate, insignificant negative fiscal impact on the Department of State Group Insurance, if the requirements of the bill result in a higher employer premium. Based on denied claims for biomarker testing from prior years, and with no reasoning provided for the test order, the potential impact may range from $0 to $1.6 million annually.[34]

   It is unclear the extent to which current contractors in the state group insurance program do or do not currently cover biomarker testing; therefore, the potential fiscal impact to the state of the costs of this coverage decision is unknown.

[34] Department of Management Services, *2024 Agency Legislative Bill Analysis: CS/HB 885* (February 5, 2024), (on file with the House Appropriations Committee).

The bill would have no impact on AHCA, as biomarker testing is already a covered service under Florida Medicaid.[35]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

AHCA and the DSGI have sufficient rule-making authority under current law to implement the bill's provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On January 22, 2024, the Select Committee on Health Innovation adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Limits application of the requirement for biomarker testing to the Medicaid program and State Group Health Insurance Plan effective July 1, 2024.
- Removes provisions requiring private health insurers and HMOs to provide coverage for annual skin cancer screenings without cost sharing restrictions.

The analysis is drafted to the committee substitute as passed by the Select Committee on Health Innovation.

[35] *Supra*, note 34.