The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Banking and Insurance

BILL:	CS/SB 964
INTRODUCER:	Banking and Insurance Committee and Senator Calatayud
SUBJECT:	Coverage of Biomarker Testing
DATE:	February 8, 2024 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Fav/CS**
2.			AHS	
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 964 requires Florida's Medicaid program and the Division of State Group Insurance program to provide coverage for biomarker testing for the diagnosis, treatment, management, and ongoing monitoring of disease or condition of an enrollee or insured, respectively to guide treatment decisions when the following conditions are met:

- Such testing provides clinical utility to the insured or subscriber; and
- The testing is demonstrated by medical and scientific evidence, including but not limited to specified criteria in the bill.

Biomarker testing is a method to look for genes, proteins, and other substances (biomarkers or tumor markers) that can provide information about cancer and other conditions. Biomarker testing is a component of precision medicine, also known as personalized medicine, which is an approach to medical care in which disease prevention, diagnosis, and treatment are tailored to the genes, proteins, and other substances that are unique to a patient. Such testing may significantly improve health outcomes and prolong patient survival, particularly for those with advanced forms of cancer.

The bill may have a significant operational and fiscal impact on the Medicaid Program. The impact on the Division of State Group Insurance is unknown.

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

II. Present Situation:

Biomarkers[1] and Tumor Markers[2]

A biomarker is a biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition. A biomarker is also called molecular marker and a signature molecule. Biomarker testing is a method to look for genes, proteins, and other substances (biomarkers or tumor markers) that can provide information about cancer and other conditions.

A tumor marker is anything present in or produced by cancer cells or other cells of the body in response to cancer or certain benign (noncancerous) conditions that provides information about a cancer, such as how aggressive it is, what kind of treatment it may respond to, or whether it is responding to treatment.

Tumor markers have traditionally been proteins or other substances that are made at higher amounts by cancer cells than normal cells. These can be found in the blood, urine, tumors, or other tissues or bodily fluids of some patients with cancer. Increasingly, however, genomic markers (such as tumor gene mutations, patterns of tumor gene expression, and nongenetic changes in tumor DNA) are being used as tumor markers. These markers are found both in tumors themselves and in tumor fragments shed into bodily fluids. Many different tumor markers have been characterized and are in clinical use.[3] Some are associated with only one type of cancer, whereas others are associated with multiple cancer types.

Application of Tumor Markers in Cancer Care[4]

Tumor markers that indicate whether someone is a candidate for a particular targeted therapy[5] are sometimes referred to as biomarkers for cancer treatment. Tumor markers can provide a wide variety of information that is important for cancer care, such as:

- Helping to diagnose cancer. However, having an elevated level of a tumor marker does not mean that someone has cancer. Noncancerous conditions can sometimes cause an increase in the level of a tumor marker. In addition, not everyone with a particular type of cancer will have a higher level of a tumor marker associated with that cancer. Therefore, measurements of tumor markers are usually combined with the results of other tests, such as biopsies or imaging, to diagnose cancer.
- The type of cancer.
- The stage of the cancer.

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[1] Biomarker Testing for Cancer Treatment - NCI (last visited Jan. 25, 2024).
[2] Tumor Markers - NCI (cancer.gov) (last visited Jan. 28, 2024).
[3] Tumor Marker Tests in Common Use - NCI (cancer.gov) (last visited Jan. 24, 2024).
[4] *Supra* at 2.
[5] This is a type of treatment that uses drugs or other substances to target specific molecules that cancer cells need to survive and spread. Targeted therapies work in different ways to treat cancer. Some stop cancer cells from growing by interrupting signals that cause them to grow and divide, stopping signals that help form blood vessels, delivering cell-killing substances to cancer cells, or starving cancer cells of hormones they need to grow. Other targeted therapies help the immune system kill cancer cells or directly cause cancer cell death. Most targeted therapies are either small-molecule drugs or monoclonal antibodies. Also called molecularly targeted therapy. *See* Definition of targeted therapy - NCI Dictionary of Cancer Terms - NCI (last visited Jan. 27, 2024).

- An estimate of prognosis.
- Determination of what treatment may be effective. Biomarkers are generally measured in samples of tumor tissue. However, tumors can shed cells or bits of biological material into blood, and these can be measured by tests called liquid biopsies.
- How well the treatment is working. Periodic measurements of a marker made while someone is undergoing treatment can indicate whether the tumor is responding to treatment.
- Whether cancer has returned. Measuring tumor markers periodically after treatment has ended may be used to check for recurrence.

Types of Tumor Marker Tests

A number of tumor marker tests are currently being used for a wide range of cancer types.[6] Many tumor marker tests are conducted by commercial and academic laboratories. Sometimes cancer centers use a tumor marker test developed within a single clinical laboratory to meet a specific medical need. All tumor markers are tested in laboratories that meet standards set by the Clinical Laboratory Improvement Amendments program.[7]

State Regulation of Insurance

Office of Insurance Regulation

In Florida, the Office of Insurance Regulation (OIR) licenses and regulates insurers, HMOs, and other risk-bearing entities.[8] To operate in Florida, an insurer or HMO must obtain a certificate of authority from the OIR.[9] The agency regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Prior to receiving a certificate of authority[10] from the OIR, an HMO must receive a Health Care Provider Certificate from the agency. As part of the certification process used by the agency, an HMO must provide information to demonstrate that the HMO has the ability to provide quality of care consistent with the prevailing standards of care.[11]

Division of State Group Insurance

Under the authority of s. 110.123, F.S., the Department of Management Services, through the Division of State Group Insurance, administers the state group health insurance program under a cafeteria plan consistent with s. 125, Internal Revenue Code. To administer the state group health insurance program, DMS contracts with third party administrators for self-insured health plans and insured (HMOs), as well as a pharmacy benefits manager for the state employees' self-insured prescription drug program pursuant to s. 110.12315, F.S.

Florida's Medicaid Program

Administration of the Program

The Agency for Health Care Administration (Agency) is the single state agency responsible for the administration of the Florida Medicaid program, authorized under Title XIX of the Social

[6] Tumor Marker Tests in Common Use - NCI (cancer.gov) (last visited Jan. 23, 2024).
[7] Clinical Laboratory Improvement Amendments (CLIA) | CDC (last visited Jan. 23, 2024).
[8] Section 20.121(3)(a)1., F.S.
[9] Section 641.21(1), F.S.
[10] Sections 624.401 and 641.49, F.S.
[11] Section 641.495, F.S.

Security Act (SSA). This authority includes establishing and maintaining a Medicaid state plan approved by the Centers for Medicare and Medicaid Services (CMS) and maintaining any Medicaid waivers needed to operate the Florida Medicaid program as directed by the Florida Legislature.

A Medicaid state plan is an agreement between a state and the federal government describing how that state administers its Medicaid programs; it establishes groups of individuals covered under the Medicaid program, services that are provided, payment methodologies, and other administrative and organizational requirements. State Medicaid programs may request a formal waiver of the requirements codified in the SSA. Federal waivers give states flexibility not afforded through their Medicaid state plan.

In Florida, most Medicaid recipients receive their services through a managed care plan (Plan) contracted with the Agency under the Statewide Medicaid Managed Care (SMMC) program. The SMMC program has three components: Managed Medical Assistance (MMA), Long-Term Care (LTC), and Dental. Florida's SMMC program benefits are authorized through federal waivers and are specifically required by the Florida Legislature in ss. 409.973 and 409.98, F.S.

Mandatory Medicaid Coverage for Biomarker Testing

Section 409.905, F.S., relating to mandatory Medicaid services, provides that the Agency may make payments for delineated services, which are required of the state by Title XIX of the Social Security Act. Currently, Florida fee for service (FFS) Medicaid and SMMC cover biomarker testing under s. 409.905(7), F.S., as a mandatory service under the category of "Independent Laboratory Services." Florida Medicaid reimburses eligible providers for biomarker testing services in accordance with Rule 59G-4.190, F.A.C., the Laboratory Services and Coverage Policy, and Rule 59G-4.002, F.A.C., the Independent and Practitioner Laboratory Fee Schedules. An eligible recipient must be enrolled in the Florida Medicaid program on the date of service, and the services provided must be determined medically necessary, not duplicative of another service, and meet the criteria of the policy. When determining coverage or if it is appropriate to add a code to a FFS Medicaid fee schedule, the Agency considers clinical and practice guidelines as well as costs and maintaining budget neutrality.

The SMMC plans have the flexibility to cover services above and beyond the Agency's coverage policies, but they may not be more restrictive than Agency policy.

Medically Necessary or Medical Necessity.[12] Under Florida's Medicaid program, for a medical or allied care, goods, or services furnished or ordered to be considered medically necessary or a medical necessity, it must meet the following conditions:

- Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain.
- Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs.

[12] Agency for Health Care Administration, Florida Medicaid, Definitions Policy (Aug. 2017) Definitions of commonly used terms that are applicable to all sections of Rule 59G, F.A.C., unless otherwise specified.

- Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational.
- Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide.
- Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.
- The fact that a provider has prescribed, recommended, or approved medical or allied care, goods, or services does not, in itself, make such care, goods or services medically necessary or a medical necessity or a covered service.
- Medically necessary or medical necessity for inpatient hospital services requires that those services furnished in a hospital on an inpatient basis could not, consistent with the provisions of appropriate medical care, be effectively furnished more economically on an outpatient basis or in an inpatient facility of a different type.

Federal and State Insurance Coverage for Biomarker Testing

In 2020 and 2022, the Centers for Medicare & Medicaid Services (CMS) issued a national coverage determination[13] and local coverage determination[14] that increased access to comprehensive biomarker testing and next-generation sequencing for Medicare beneficiaries.[15] Since 2021, some states have enacted laws mandating coverage of testing, diagnosis, treatment, management, or monitoring of a medical condition, including the following states:

- Louisiana Senate Bill 84 requires broad health insurance coverage for genetic and molecular testing for cancer only.[16]
- Illinois House Bill 1779 requires state-regulated insurance and managed care plans to cover biomarker testing for the purposes of diagnosis, treatment, management, or monitoring of any medical condition.[17]
- Arizona House Bill 2144 requires health insurance coverage for biomarker testing for the purposes of diagnosis, treatment, management, or monitoring of any medical condition.[18]
- Rhode Island Senate Bill 2201 requires state-regulated individual and group health insurance plans to cover biomarker testing for the purposes of diagnosis, treatment, management, or monitoring of any medical condition.[19]

Recent Studies on the Cost of Biomarker Testing

A 2022 study found the addition of biomarker testing (liquid biopsy) for non-small cell lung cancer resulted in incremental cost savings of $3,065 per patient compared to tissue biopsy alone. Increased detection of actionable alterations, using liquid biopsy, was also associated with

[13] NCD - Next Generation Sequencing (NGS) (90.2) (cms.gov) (last visited Jan. 20, 2024).
[14] LCD - Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (L37810) (cms.gov) (last visited Jan 20, 2024).
[15] State Legislation Requiring Coverage of Biomarker Testing Gains Momentum (accc-cancer.org) (Sep. 30, 2022) (last visited Jan. 24, 2024).
[16] LA SB84 | 2021 | Regular Session | LegiScan (last visited Jan. 24, 2024).
[17] IL HB1779 | 2021-2022 | 102nd General Assembly | LegiScan (last visited Jan. 24, 2024).
[18] AZ HB2144 | 2022 | Fifty-fifth Legislature 2nd Regular | LegiScan (last visited Jan. 24, 2024).
[19] RI S2201 | 2022 | Regular Session | LegiScan (last visited Jan. 24, 2024).

more patients being treated with targeted therapy. Major drivers of cost-effectiveness were drug acquisition costs and prevalence of actionable alterations.[20]

A 2018 study, found that biomarker testing for non-small cell lung cancer, instead of single-gene testing, decreased expected testing procedure related costs to the health plan payer by $24,651. First-line and maintenance treatment costs increased by $842,205, offset by a $385,000 decrease in second-line treatment and palliative care costs. Over 5 years, total budget impact was $432,554 ($0.0072 per member per month).[21]

III. Effect of Proposed Changes:

The bill creates the following definitions:

- "Biomarker" means a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. The term includes, but is not limited to, molecular, histologic, radiographic, and physiologic characteristics but does not include an assessment of how a patient feels, functions, or survives.
- "Biomarker testing" means an analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. The term includes, but is not limited to, single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing performed at a participating in-network laboratory facility that the Centers for Medicare and Medicaid Services has either certified pursuant to the federal Clinical Laboratory Improvement Amendments (CLIA) or that has obtained a CLIA certificate of waiver by the United States Food and Drug Administration for the tests.
- "Clinical utility" means that the test result provides information used in the formulation of a treatment or in a monitoring strategy that impacts a patient's outcome and informs the clinical decision.
- "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. Clinical practice guidelines establish standards of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options and include recommendations intended to optimize patient care.

State Group Insurance Program

Section 1 amends s. 110.12303, F.S., relating to the State Group Insurance program (program) to mandate coverage of biomarker testing for policies issued on or after January 1, 2025. This

[20] Ezeife DA, Spackman E, Juergens RA, Laskin JJ, Agulnik JS, Hao D, Laurie SA, Law JH, Le LW, Kiedrowski LA, Melosky B, Shepherd FA, Cohen V, Wheatley-Price P, Vandermeer R, Li JJ, Fernandes R, Shokoohi A, Lanman RB, Leighl NB. The economic value of liquid biopsy for genomic profiling in advanced non-small cell lung cancer. Ther Adv Med Oncol. 2022 Jul 26;14:17588359221112696. doi: 10.1177/17588359221112696. PMID: 35923926; PMCID: PMC9340413. The economic value of liquid biopsy for genomic profiling in advanced non-small cell lung cancer - PubMed (nih.gov) (last visited Jan. 27, 2024).

[21] 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. doi: 10.1016/j.jval.2018.04.1372. Epub 2018 Jun 8. PMID: 30442274. https://pubmed.ncbi.nlm.nih.gov/30442274/ (last visited Jan. 28, 2024).

coverage would include the diagnosis, treatment, management, or ongoing monitoring of an insured's disease or condition to guide treatment decisions when such testing provides clinical utility to the insured and is demonstrated by medical and specified medical and scientific evidence, including but not limited to, any of the following:

- Labeled indications for a test approved or cleared by the United States Food and Drug Administration (FDA) or indicated tests for an FDA-approved drug.
- Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations.
- Nationally recognized clinical practice guidelines.

The program is required to outline a process for insureds and providers to access a process to request an authorization for biomarker testing.

The biomarker testing services may not be construed to require coverage of biomarker testing for screening purposes.

Medicaid Program

Optional Medicaid Services

Section 2 amends s. 409.906, F.S., relating to optional Medicaid services. Subject to specific appropriations, this section currently authorizes the Agency for Health Care Administration (Agency) to make payments for services which are considered optional under federal Medicaid law. However, such services must be medically necessary and in accordance with state and federal law.

The bill amends this section by providing that the Agency may pay for biomarker testing for diagnosis, treatment, management, or ongoing monitoring of a recipient's disease or condition to guide treatment decisions when such testing provides clinical utility to the recipient and is demonstrated by medical and specified medical and scientific evidence, including but not limited to, any of the following:

- Labeled indications for a test approved or cleared by the United States Food and Drug Administration (FDA) or indicated tests for an FDA-approved drug.
- Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations.
- Nationally recognized clinical practice guidelines.

The Agency is also required to outline a process for enrollees and providers to access a process to request an authorization for biomarker testing.

The biomarker testing services may not be construed to require coverage of biomarker testing for screening purposes.

Medicaid Managed Care Plans

Section 3 creates s. 409.9745, F.S., to require managed care plans to provide coverage for biomarker testing for enrollees, as authorized under s. 409.906, F.S., at the same scope, duration, and frequency as the Medicaid program provides for other medically necessary treatments.

Managed care plans are required to outline a process for enrollees and providers to access a process for requesting authorization of biomarker testing.

The bill provides that this provision may not be construed to require coverage of biomarker testing for screening purposes.

Effective Date

Section 4 provides that the bill has an effective date of July 1, 2024.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

The bill requires the Medicaid fee for service and the Medicaid managed care plans and the State Group Insurance program to cover biomarker testing for diagnosis, treatment, management, and ongoing monitoring of a disease or condition of an enrollee to guide treatment decisions when such testing provides clinical utility to the recipient and must be demonstrated by medical and scientific evidence, *including but not limited* to:

- Labeled indications for a test approved or cleared by the United States Food and Drug Administration (FDA) or indicated tests for an FDA-approved drug.
- Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations.
- *Nationally recognized clinical practice guidelines*.

Use of the term "including but not limited to" indicates that the bill does not provide an all-inclusive list for medical and scientific evidence, and it is unclear who would determine the credibility or admissibility of it. Further, the term, "nationally recognized

clinical practice guidelines," does not provide specific named guidelines or examples. The bill provides no rulemaking authority, guidance or standards for the Agency for Health Care Administration or the State Group Insurance program to use for establishing this additional criteria. Thus, this additional, unspecified medical and scientific evidence or guidelines for determining coverage may be an unlawful delegation of legislative authority.

The Legislature may not delegate its constitutional duties to another branch of government.[22] While the Legislature must make fundamental policy decisions, it may delegate the task of implementing that policy to executive agencies with "some minimal standards and guidelines ascertainable by reference to the enactment establishing the program."[23] Moreover, the Legislature can permit "administration of legislative policy by an agency with the expertise and flexibility to deal with complex and fluid conditions."[24]

Florida courts have found an unlawful delegation of legislative authority in the following instances:

- Where the Legislature allowed the Department of State to "in its discretion allow such a candidate to withdraw…";[25] and
- Where the Legislature created a criminal penalty for escape from certain classifications of juvenile detention facilities, but delegated the classification (or determination whether to classify at all) to an agency.[26]

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Indeterminate. The mandated coverage is anticipated to reduce the overall costs of care of an enrollee, insured, or subscriber as a result of the use of a more targeted, optimal treatment protocol.

C. Government Sector Impact:

Florida's Medicaid Program[27]

The bill would limit the Agency's ability to determine coverage of biomarker testing using the current Agency's established process. The bill could have both a significant

[22] See FLA. CONST. art. II, s. 3.
[23] Askew v. Cross Key Waterways, 372 So.2d 913, 925 (Fla. 1978).
[24] Microtel, Inc. v. Fla. Public Serv. Comm'n., 464 So.2d 1189, 1191 (Fla. 1991).
[25] Fla. Dep't. of State, Div. of Elections v. Martin, 916 So.2d 763 (Fla. 2005).
[26] D.P. v. State, 597 So.2d 952 (Fla. 1st DCA, 1992)(disapproved on other grounds).
[27] Correspondence from Patrick Steele, Legislative Affairs Director, Agency for Health Care Administration (Feb. 1, 2024). On file with Senate Banking and Insurance Committee staff.

operational and fiscal impact on the Medicaid Program as it would require the Agency to cover all codes that meet the clinical criteria defined by the bill.

CS/HB 885 (companion to SB 964) mandates specific criteria by which biomarker testing must be evaluated for coverage by Florida Medicaid. Currently, the Agency does not define "specific nationally recognized clinical practice guidelines" that are referenced in CS/HB 885 and SB 964 in rule for determining coverage. Covered services must be medically necessary as defined by Rule 59G-1.010, F.A.C., not duplicate another service, and meet the criteria in the service specific coverage policy. When determining coverage or if it is appropriate to add a code to a FFS Medicaid fee schedule, the Agency considers clinical and practice guidelines as well as costs and maintaining budget neutrality.

Typically, the Agency does not cover every code designated by the American Medical Association for a covered service. For example, the Agency covers integumentary and wound care supplies under s. 409.906 F.S., Optional Medicaid services. There are a total of 87 skin substitute procedure codes listed in the AMA CPT codebook. Of these, Florida Medicaid covers a total of 26 CPT codes.

There are numerous biomarker tests that are Propriety Laboratory Analyses (PLA) Current Procedural Terminology (CPT) codes. A PLA code is a code set approved by the American Medical Association (AMA) CPT Editorial Panel. These codes are corresponding descriptors for labs or manufactures that want to identify their proprietary test more specifically. Florida Medicaid currently covers 46 non-PLA biomarker CPT codes under the Laboratory Services Fee Schedule that are listed on the CMS List for Billing and Coding: Biomarkers for Oncology. Florida Medicaid does not typically include PLA codes on FFS fee schedules when determining coverage based on the Agency's current coverage determination process.

Currently, managed care plans have the flexibility to cover services above and beyond the Agency's fee schedules and coverage policies, as well as reimburse providers mutually agreed upon rates. Plans may not be more restrictive in coverage than the Agency and promulgated rule, as detailed in their contract.

As currently written, the bill requires the Agency to cover every biomarker test when the medical and scientific evidence, as outlined in the bill, indicates clinical utility to the recipient. This requirement will have a significant fiscal impact to the Medicaid program which is indeterminate and on-going as the number of PLA and non-PLA codes that could meet this criteria is unknown. The impact will be ongoing as the bill will require the Agency to cover a biomarker test every time a new test meets the criteria outlined in the bill.

State Group Insurance

The fiscal impact of the mandated coverage on the State Group Insurance is indeterminate. It is unclear what particular biomarker tests are currently covered and the criteria that is used to determine coverage of such testing.

VI. Technical Deficiencies:

The additional coverage mandates and criteria for coverage created in ss. 409.906 and 409.9745, F.S. appear to conflict with current coverage requirements of s. 409.905, F.S. Currently, s. 409.905, F.S., relating to the federal mandatory services, requires Florida's fee for service and SMMC to provide coverage for biomarker testing, subject to medical necessity and other requirements. However, the bill requires Medicaid to provide coverage for biomarker testing under the optional services required by the state but subject to an appropriation, pursuant to s. 409.906, F.S. This would apply to fee for service, as well as managed care plans. Like mandatory federal services, optional services under the Medicaid program are subject to medical necessity and other requirements. However, the bill requires coverage of biomarker testing when the testing provides *clinical utility*, which appears to be a different standard than medical necessity.

The bill provides that the medical and scientific evidence that may be used to determine if biomarker testing provides clinical utility "includes, but is not limited to" certain specified items. The use of the phrase "includes, but is not limited to" results in the bill being unclear what the additional medical and scientific evidence would be that would require the coverage of a biomarker test.

VII. Related Issues:

The bill takes effect on July 1, 2024. However, the Medicaid managed care program rates are set on a plan year beginning October 1.

VIII. Statutes Affected:

This bill substantially amends sections 110.12303 and 409.906 of the Florida Statutes.
This bill creates section 409.9745 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Banking and Insurance on February 6, 2024:
The CS excludes commercial policies and contracts from the coverage mandate. Such coverage is mandated for the Medicaid fee for service program and the managed care plans and State Group Insurance.

B. Amendments:

None.