FLORIDA HOUSE OF REPRESENTATIVES
BILL ANALYSIS

This bill analysis was prepared by nonpartisan committee staff and does not constitute an official statement of legislative intent.

BILL #: CS/HB 1335	**COMPANION BILL:** None
TITLE: Biomarker Testing	**LINKED BILLS:** None
SPONSOR(S): Gonzalez Pittman, Owen	**RELATED BILLS:** None

Committee References

Health Care Facilities & Systems	➤	Budget	➤	Health & Human Services
16 Y, 0 N, As CS		24 Y, 0 N		

SUMMARY

Effect of the Bill:

CS/HB 1335 authorizes the Medicaid program to cover medically necessary blood-based biomarker tests for colorectal cancer screening. The bill's requirements apply to both traditional Medicaid and Medicaid managed care. The bill sunsets the coverage requirements on July 1, 2031. The bill requires AHCA to contract for a five-year cost-benefit analysis study to calculate the return-on-investment to the state for covering blood-based biomarker tests for colorectal cancer screening.

The bill requires the Agency for Health Care Administration (AHCA) to establish billing codes and reimbursement schedules for biomarker testing services by August 1, 2025.

Fiscal or Economic Impact:

The requirement to establish Proprietary Laboratory Analyses codes for biomarker testing will have an indeterminate, but significant, negative fiscal impact on the state Medicaid program. The bill has an indeterminate fiscal impact on the state Medicaid program relating to colorectal cancer screening because it is uncertain whether Medicaid currently covers blood-based biomarker tests for colorectal cancer screening. The cost-benefit analysis required by the bill will cost $1.25 million over five years; however, AHCA can absorb these costs with existing contractual services funds.

JUMP TO SUMMARY ANALYSIS RELEVANT INFORMATION BILL HISTORY

ANALYSIS

EFFECT OF THE BILL:

Medicaid Coverage of Blood-Based Biomarker Tests for Colorectal Cancer Screening

Current law requires Medicaid to cover medically necessary physician services and medically necessary diagnostic laboratory procedures. Current law also authorizes Medicaid to cover biomarker testing services for diagnosis, treatment, appropriate management, and ongoing monitoring of a recipient's disease or condition, provided that medical and scientific evidence indicates that the specific biomarker test provides clinical utility to the recipient. However, current law does not allow Medicaid to cover biomarker testing for screening, rather than diagnostic, purposes.

CS/HB 1335 requires traditional Medicaid and Medicaid managed care to cover medically necessary blood-based biomarker tests for colorectal cancer screening. (Section 2).

Cost-Benefit Analysis

The bill requires AHCA to contract for an independent, actuarially sound, five-year comparative cost-benefit analysis. The purpose of the study is to measure the cost-effectiveness of covering blood-based biomarker tests for colorectal cancer in the Medicaid program.

The contractor must analyze the following, at a minimum:

- Medicaid recipient utilization of blood-based biomarker tests, fecal immunochemical tests, fecal occult blood tests, fecal DNA tests, colonoscopies, and inpatient and outpatient treatment of colorectal cancer.
- Medicaid reimbursement to providers who appropriately billed for blood-based biomarker tests, fecal immunochemical tests, fecal occult blood tests, fecal DNA tests, colonoscopies, and inpatient and outpatient treatment of colorectal cancer (including the total costs of other related medically necessary care).
- Medicaid recipient deaths from colorectal cancer (or complications from colorectal cancer).

The contractor must calculate, if feasible, how blood-based biomarker tests for colorectal cancer screening decreases Medicaid program spending on more costly tests and treatments.

AHCA must submit an interim report by November 30, 2028, and a final report by November 30, 2030, to the Governor, the President of the Senate, and the Speaker of the House. (Section 3).

Repeal

The bill requires an automatic repeal of the provisions of the bill that authorize Medicaid coverage of necessary blood-based biomarker tests for colorectal cancer screening. Those provisions will be repealed July 1, 2031, unless a subsequent legislative enactment reenacts this coverage authority. (Section 4).

Biomarker Testing

As of 2024, current law s. 409.906(29), F.S., requires Medicaid to cover biomarker testing services for diagnosis, treatment, appropriate management, and ongoing monitoring of a recipient's disease or condition, provided the available medical and scientific evidence indicates that the specific biomarker test provides clinical utility to the recipient.

The bill requires AHCA to establish reimbursement schedules and billing codes for biomarker testing services by August 1, 2025. Specifically, AHCA must establish billing codes under the Current Procedural Terminology (CPT) codes or Proprietary Laboratory Analysis (PLA) codes. (Section 1).

The effective date of the bill is upon becoming a law. (Section 5).

RULEMAKING:

The bill modifies provisions of law that are already under the AHCA's existing rulemaking authority, relating to payments for covered services, pursuant to s. 409.908, F.S. and s. 409.961, F.S.

Lawmaking is a legislative power; however, the Legislature may delegate a portion of such power to executive branch agencies to create rules that have the force of law. To exercise this delegated power, an agency must have a grant of rulemaking authority and a law to implement.

FISCAL OR ECONOMIC IMPACT:

STATE GOVERNMENT:

According to AHCA, the bill's requirement to establish Proprietary Laboratory Analyses codes for biomarker testing will have a significant, negative fiscal impact on the state Medicaid program;[1] however, this impact is currently unknown.

The bill's colorectal cancer screening coverage requirements may have an indeterminate fiscal impact on the state Medicaid program. According to AHCA, Medicaid currently covers colorectal cancer screening tests. However, it is unclear whether Medicaid covers blood-based biomarker colorectal cancer screening tests. To the extent Medicaid does not, the bill will have an indeterminate negative fiscal impact on the Medicaid program.[2]

According to AHCA, the bill's requirement to contract for a cost-benefit analysis of colorectal cancer screening coverage will cost a total of $1.25 million;[3] however, AHCA has sufficient contractual services funds to absorb this impact.

PRIVATE SECTOR:

To the extent blood-based biomarker testing services for colorectal cancer screening are not already covered by Medicaid, the bill may have a positive economic impact on the manufacturers of these tests, due to increased Medicaid utilization.

RELEVANT INFORMATION

SUBJECT OVERVIEW:

Colorectal Cancer

In 2025, the American Cancer Society (ACS) estimates that there will be 171,960 new cancer cases and 49,040 deaths from cancer in Florida alone. From these totals, ACS projects 12,330 new colorectal cancer cases in Florida and believes 3,970 Floridians may die from colorectal cancer complications.[4]

The colon and the rectum, two parts of the large intestine, are common places for cancer to occur. Colorectal cancer is an uncontrolled growth of abnormal cells in the colon and, or rectum. Colorectal tumors often begin as small growths (polyps) on the inside of the large intestine. Polyps that are not removed eventually can become cancerous.[5]

[1] Email from Jim Browne, Legislative Affairs Director, Agency for Health Care Administration, RE: HB 1335 Fiscal Questions, (Mar. 28, 2025), on file with the Health and Human Services Committee.
[2] Email from Jim Browne, Legislative Affairs Director, Agency for Health Care Administration, RE: HB 1335 Fiscal Questions, (Mar. 25, 2025), on file with the Health and Human Services Committee. The Statewide Medicaid Managed Care plans also waive copayments and coinsurance requirements for all services under their expanded benefits.
[3] Email from Jim Browne, Legislative Affairs Director, Agency for Health Care Administration, RE: HB 1335 Fiscal Questions, (Mar. 28, 2025), on file with the Health and Human Services Committee.
[4] American Cancer Society, Cancer Facts & Figures: 2025, https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2025/2025-cancer-facts-and-figures-acs.pdf (last visited April 3, 2025); *See* Rebecca Siegel, Tyler Kratzer, Angela Giaquinto, Hyuna Sung, and Ahmedin Jemal, "Cancer Statistics, 2024," CA: A Cancer Journal for Clinicians, Vol. 75, Issue 1, (Jan. 16, 2025) https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21871 (last visitedApril 3, 2025).
[5] Harvard Health Publishing, Colorectal Cancer, Harvard Medical School (last reviewed Jul. 28, 2023) https://www.health.harvard.edu/cancer/colorectal-cancer-a-to-z (last visited April 3, 2025).

Risk Factors

The major and potential risk factors for colorectal cancer include:[6]

Major Risk Factors	Potential Risk Factors
• Personal history of colorectal cancer. • Personal history of colon polyps. • Certain inherited genes linked to colon polyps and cancer. • Inflammatory bowel disease, including persistent ulcerative colitis and Crohn's. • Family history of colorectal cancer.	• Cigarette smoking. • Sedentary lifestyle. • Low intake of fruits and vegetables. • High consumption of processed meats. • Low vitamin D levels.

Symptoms

Polyps and early colorectal cancer generally don't cause symptoms. As a result, they are usually caught during screening. More advanced cancer can cause:[7]

- More or less frequent bowel movements than usual.
- Diarrhea or constipation.
- Blood in the stool (bright red, black, or very dark).
- Narrowed stools (about the thickness of a pencil).
- Bloating, fullness, or stomach cramps.
- Frequent gas pains.
- A feeling that the bowel does not empty completely.
- Weight loss without dieting.
- Continuing fatigue.

Preventive Screening

Medical professionals believe the best defense against colorectal cancer is regular screening. Screening tests are designed to find polyps, which are abnormal, noncancerous growths that protrude from mucous membranes in the sinuses and colon lining, so they can be removed before they become cancerous.[8]

The United States Preventative Services Task Force (Task Force), an independent, volunteer panel of experts in prevention, primary care, and evidence-based medicine, recommends that asymptomatic adults at average risk[9] for colorectal cancer being screening at age 45 because of a rising number of younger people diagnosed with the disease.[10] The U.S. Congress created the Task Force through the Patient Protection and Affordable Care Act in 2010 to review scientific evidence relating to the efficacy, appropriateness, and cost-effectiveness of clinical preventative services, and to make periodic recommendations for preventive-care services that most private insurers must

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[6] Harvard Health Publishing, Colorectal Cancer, Harvard Medical School (last reviewed Jul. 28, 2023) https://www.health.harvard.edu/cancer/colorectal-cancer-a-to-z (last visited April 3, 2025).
[7] Harvard Health Publishing, Colorectal Cancer, Harvard Medical School (last reviewed Jul. 28, 2023) https://www.health.harvard.edu/cancer/colorectal-cancer-a-to-z (last visited April 3, 2025).
[8] Harvard Health Publishing, Colorectal Cancer, Harvard Medical School (last reviewed Jul. 28, 2023) https://www.health.harvard.edu/cancer/colorectal-cancer-a-to-z (last visited April 3, 2025); Harvard Health Publishing, Medical Dictionary of Health Terms, Harvard Medical School, https://www.health.harvard.edu/j-through-p#P-terms (last visited April 3, 2025).
[9] The Task Force equates average risk with no prior diagnosis of colorectal cancer, adenomatous polyps, or inflammatory bowel disease; no personal diagnosis or family history of known genetic disorders that predispose them to a high lifetime risk of colorectal cancer. United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19, pp. 1966 (May 18, 2021) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited April 3, 2025).
[10] United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19 (May 18, 2021) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited April 3, 2025).

cover without imposing cost sharing requirements.[11] However, the Supreme Court of the United States is considering the constitutionality of the Task Force this term.[12]

In 2021, the Task Force concluded with high certainty that screening for colorectal cancer in adults aged 50 to 75 years has substantial net benefit, and concludes with moderate certainty that screening for colorectal cancer in adults 45 to 49 years has moderate net benefit. The assessment of net benefits applies only to stool-based tests with high sensitivity, colonoscopy, computed tomography (CT) colonography, and flexible sigmoidoscopy.[13] The 2021 Task Force recommendations did not include serum tests, urine tests, or capsule endoscopy for colorectal screening because of the limited available evidence. The Task Force identified a need for research on the accuracy and efficacy of emerging screening technologies such as serum-and-urine-based colorectal cancer screening tests and capsule endoscopy tests to potentially improve acceptance and adherence to colorectal cancer screening.[14]

Notwithstanding the Supreme Court's impending decision, federal law currently requires the Task Force to review interventions and update recommendations relating to colorectal cancer screening in 2026.[15]

Rates of colorectal cancer screening are among the highest of the cancers for which screening is recommended. Even so, according to recent data, 30% of eligible adults are not up to date with any type of recommended colorectal cancer screening, and the disease remains the second leading cause of cancer deaths in the United States.[16] Medical professionals recommend various screening methods to detect colorectal cancer. In addition to the digital rectal examination, sigmoidoscopy, colonoscopy, and virtual colonoscopy screening tests, manufacturers produce less invasive and more convenient screenings tests. The table below indicates the Task Force recommendations for each type of colorectal cancer screening test.[17]

Screening Test	Description	Recommended Screening Intervals
Blood-Based Biomarker Tests[18]	Blood-based biomarker tests, also known as liquid biopsy tests, use a blood sample, from blood collected from a vein in an arm, to identify signs of cancer-specific markers in the body, such as cancer cell waste or antibodies in response to cancer in the bloodstream.	No Recommendation

[11] 42 U.S.C. §§ 299b-4, 300gg-13.

[12] The Court will issue this opinion during the first half of 2025. The debate turns on whether Task Force members are principal officers, which must be appointed by the President and confirmed by the Senate, or inferior officers, which are under the direct supervision of a duly confirmed presidential appointee. Task Force members have attributes of both principal and inferior officers, according to the U.S. Court of Appeals for the Fifth Circuit. Since the Task Force recommends colorectal cancer screening as preventive-service that private insurers must cover, the market for colorectal cancer screening tests may face a period of adjustment if the Supreme Court agrees with the U.S. Court of Appeals for the Fifth Circuit and invalidates the Task Force. *See Braidwood Management Inc. v. Becerra*, 104 F.4th 930 (5th Cir. 2024); *see* SCOTUSblog, *Kennedy v. Braidwood Management, Inc.*, (current through Mar. 22, 2025) https://www.scotusblog.com/case-files/cases/becerra-v-braidwood-management-inc/ (last visited April 3, 2025).

[13] United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19, 1966 (May 18, 2021) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited April 3, 2025).

[14] United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19, pp. 1966, 1976 (May 18, 2021) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited April 3, 2025).

[15] *See* 42 U.S.C. § 299b-4(2)(B).

[16] Alyssa Voss, "Colorectal Cancer Screening: Where Does the Shield Liquid Biopsy Fit In?", National Cancer Institute, (Oct. 11, 2024) https://www.cancer.gov/news-events/cancer-currents-blog/2024/shield-blood-test-colorectal-cancer-screening (last visited April 3, 2025).

[17] United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19, pp. 1969 (May 18, 2021) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited April 3, 2025).

[18] Jill Seladi Schulman, "How is Blood-Based Biomarker Testing Used for Colorectal Cancer?", Healthline, (Jul. 25, 2022) https://www.healthline.com/health/colorectal-cancer/blood-based-biomarker-test-for-colorectal-cancer (last visited April 3, 2025); Alyssa Voss, "Colorectal Cancer Screening: Where Does the Shield Liquid Biopsy Fit In?", National Cancer Institute, (Oct. 11, 2024) https://www.cancer.gov/news-events/cancer-currents-blog/2024/shield-blood-test-colorectal-cancer-screening (last visited April 3, 2025); Julie Utterback and Aaron Degagne, "A New Frontier in Cancer Screening and Treatment," Morningstar, (Feb. 11, 2021)

Fecal Immunochemical Tests (FIT)[19]	A fecal immunochemical test detects blood in the stool using antibiotics.	Every Year
Fecal Occult Blood Test (FOBT)[20]	A fecal occult blood test detects blood in the stool based on high-sensitivity chemical detection of blood.	Every Year
Stool DNA Tests[21]	A stool DNA test detects DNA biomarkers for cancer in cells shed from the lining of the colon and rectum into the stool.	Every 1-3 Years

In 2024, the worldwide market capitalization for colorectal cancer screening and diagnostic products was $40 billion and may reach $46.1 billion by 2029. North America holds a 60.8% market share.[22]

The table below depicts a sample of colorectal cancer screening tests available in the U.S.

Screening Test	Products (FDA Approval Date)	Manufacturer
Blood-Based Biomarker Test	Epi proColon (2016)[23]	Epigenomics
	Shield (2024)[24] Guardant 360 CDx (2020)[25]	Guardant Health
	PREEMPT CRC Study (*Clinical Trials*)[26]	Freenome
FIT	InSure ONE (2017)[27]	Clinical Genomics
	OC-Light (2015)[28]	Eiken Chemical
FOBT	ColoSense (2024)[29]	Geneoscopy

[19] United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19, pp. 1966 (May 18, 2021) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited April 3, 2025).
[20] United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19, pp. 1966 (May 18, 2021) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited April 3, 2025).
[21] United States Preventative Services Task Force, Screening for Colorectal Cancer: U.S. Preventative Services Task Force Recommendation Statement, JAMA, Vol. 325, No. 19, pp. 1966 (May 18, 2021) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening (last visited April 3, 2025).
[22] Research and Markets, "Colorectal Cancer Screening Diagnostics Market Report 2025, with Profiles of Fujim, Olympus, Exact Sciences, Danaher, Guardant Health, Diacarta, Mainz Biomed, Novigenix, and more," Globe Newswire, (Mar. 20, 2025) https://www.globenewswire.com/news-release/2025/03/20/3046315/0/en/Colorectal-Cancer-Screening-and-Diagnostics-Market-Report-2025-with-Profiles-of-Fujifilm-Olympus-Exact-Sciences-Danaher-Guardant-Health-Diacarta-Mainz-Biomed-Novigenix-and-more.html (last visited April 3, 2025).
[23] United States Food and Drug Administration, Epi proColon – P130001 Approval Letter, United States Department of Health and Human Services (Apr. 12, 2016) https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130001A.pdf (last visited April 3, 2025)
[24] United States Food and Drug Administration, Shield – P230009 Approval Letter, United States Department of Health and Human Services (Jul. 26, 2025) https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230009A.pdf (last visited April 3, 2025).
[25] United States Food and Drug Administration, Guardant 360 CDx – P200010, United States Department of Health and Human Services (Aug. 7, 2020) https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200010A.pdf (last visited April 3, 2024).
[26] Rachel Facci, "Blood Test Could Provide Colonoscopy Alternative for Colorectal Cancer Screening," American Society of Clinical Oncology, (Jan. 21, 2025) https://www.asco.org/about-asco/press-center/news-releases/study-evaluates-new-blood-based-test-colorectal-cancer (Last visited April 3, 2025).
[27] United States Food and Drug Administration, 510(k) Substantial Equivalence Determination Decision Summary: InSure ONE, (Oct. 5, 2017) https://www.accessdata.fda.gov/cdrh_docs/reviews/K170548.pdf (last visited April 3, 2025).
Press Release, "Clinical Genomics and Quest Diagnostics announce FDA 510(K) clearance of InSure ONE," (Nov. 13, 2017) https://newsroom.questdiagnostics.com/press-releases?item=137050 (last visited April 3, 2015).
[28] United States Food and Drug Administration, 510(k) Substantial Equivalence Determination Decision Summary: OC-Light, (Aug. 20, 2015) https://www.accessdata.fda.gov/cdrh_docs/reviews/K143325.pdf (last visited April 3, 2025).
[29] United States Food and Drug Administration, ColoSense-P230001 Approval Letter, United States Department of Health and Human Services (May 3, 2024) https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230001A.pdf (last visited April 3, 2025).

Screening Test	Products (FDA Approval Date)	Manufacturer
	Instant-view-plus (2018)[30]	Alfa Scientific Designs
Stool DNA Tests	Cologuard Plus (2024)[31]	Exact Sciences Corp.
	Cologuard (2014)[32]	

Biomarker testing 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.[33] 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 cancer or another disease does not have certain biomarkers can also save a patient from undergoing unnecessary treatment, treatment that has not been as successful in a particular diagnosis, or treatment which may not have a long-term result leading to the return of the cancer.[34]

Medicaid

Evaluation and Management Services Coverage Policy

Medicaid covers medically necessary services rendered to a recipient by, or under the personal supervision of, a licensed medical or osteopathic physician for the treatment of an injury, illness, or disease, provided that the services rendered are within the physician's scope of practice. These services may be furnished in the physician's office, the Medicaid recipient's home, a hospital, a nursing facility, or elsewhere. However, Medicaid does not cover physician services that are clinically unproven, experimental, or for purely cosmetic purposes.[35]

Florida Medicaid evaluation and management services provide for physician visits to maintain a recipient's health, prevent disease, and treat illness. The Medicaid Evaluation and Management Services Coverage Policy[36] delineates the reimbursement policy for preventative services, including:

- One adult health screening every 365 days, for recipients age 21 years and older.
- Preventative medicine services for recipients under the age of 21 years.
- One evaluation and management visit per month, per recipient of custodial care facility services or nursing facility services.
- Unlimited office visits, as medically necessary, for recipients under the age of 21 years and pregnant recipients age 21 years and older.
- Two office visits per month, per specialty, for recipients age 21 years and older.

Laboratory Services Coverage Policy

Medicaid covers medically necessary diagnostic laboratory procedures ordered by a licensed physician or other licensed practitioner of the healing arts for a Medicaid recipient in a federally certified laboratory.[37] Florida Medicaid laboratory services provide clinical testing of bodily fluids, tissues, or other substances. Laboratory

[30] United States Food and Drug Administration, 510(k) Substantial Equivalance Determination Decision Summary: Instant-View-PLUS Immunochemical Fecal Occult Blood Test, (Feb. 15, 2018) https://www.accessdata.fda.gov/cdrh_docs/reviews/K173212.pdf (last visited April 3, 2025).
[31] United States Food and Drug Administration, Cologuard Plus – P230043 Approval Letter, (Oct. 3, 2024) https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230043A.pdf (last visited April 3, 2025).
[32] United States Food and Drug Administration, Cologuard – P130017 Approval Letter, United States Department of Health and Human Services, (Aug. 11, 2014) https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130017A.pdf (last visited April 3, 2025).
[33] American Cancer Society, *Biomarker Tests and Cancer Treatment,* available Biomarker Tests and Cancer Treatment | American Cancer Society (last visited April 3, 2025).
[34] American Cancer Society, *Biomarker Tests and Cancer Treatment,* available Biomarker Tests and Cancer Treatment | American Cancer Society (last visited April 3, 2025).
[35] S. 409.905(9), F.S.
[36] Rule 59G-4,087, Evaluation and Management Services Coverage Policy, (Effective Jun. 29, 2016) https://ahca.myflorida.com/medicaid/rules/adopted-rules-service-specific-policies (last visited April 3, 2025).
[37] S. 409.905(7), F.S.

services rendered to an eligible recipient must not be duplicative of another service and comply with the American Medical Association's Current Procedural Terminology and the Florida Medicaid fee schedule.[38]

The Medicaid Laboratory Services Coverage Policy[39] delineates the reimbursement policy for genetic and biomarker testing, including:

- *Clinical cytogenetics* which studies a patient's chromosomes looking for changes, including broken, re-arranged, or extra chromosomes which may be the sign of a disease or a condition.[40]
- *Genetic carrier screening* occurs when an individual is thinking of starting a family and wants to know if he or she carries a specific gene, usually an inherited genetic condition; or testing a sibling for an inherited trait.[41]
- *Histocompatibility* is a chromosomal complex and relates to the compatibility or incompatibility of tissue types for tissue grafting, and also influences an individual's resistance and susceptibility to a range of infectious diseases.[42] Biomarker testing is conducted primarily for donor matching.[43]
- *Whole genome sequencing* is a process in which an individual's chromosomal DNA is sequenced or put in order to identify variants or mutations among chromosomes.[44] Targeted sequencing may be used for disease identification and treatment options.

Medicaid specifically excludes testing for multiple organ and disease panels that contain duplicate components or are repeat tests as a result of provider error.[45] Medicaid managed care plans have the flexibility to cover services above and beyond Medicaid Coverage Policies, but they may not be more restrictive.[46]

Biomarker Testing Services

As of 2024, current law requires Medicaid to cover biomarker testing services for diagnosis, treatment, appropriate management, and ongoing monitoring of a recipient's disease or condition, provided the available medical and scientific evidence indicates that the specific biomarker test provides clinical utility to the recipient. However, current law does not expressly authorize traditional Medicaid and Medicaid managed care to cover biomarker testing when its purpose is for screening services. [47]

According to AHCA, Medicaid currently covers colorectal cancer screening tests in general. However, it is unclear whether Medicaid covers blood-based biomarker colorectal cancer screening tests.[48]

Biomarker Testing Billing Codes

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[38] Rule 59G-4.190, *Laboratory Services and Coverage* Policy (Jan. 2024; Effective Apr. 3, 2024), available at Reference Material Home - Florida Administrative Rules, Law, Code, Register - FAC, FAR, eRulemaking (flrules.org) (last visited April 3, 2025).
[39] Rule 59G-4.190, *Laboratory Services and Coverage* Policy (Jan. 2024; Effective Apr. 3, 2024), available at Reference Material Home - Florida Administrative Rules, Law, Code, Register - FAC, FAR, eRulemaking (flrules.org) (last visited April 3, 2025).
[40] National Human Genome Research Institute, *Cytogenetics* (updated Mar. 22, 2024), available at https://www.genome.gov/genetics-glossary/Cytogenetics (last visited April 3, 2025).
[41] National Human Genome Research Institute, *Carrier Screening* (updated Mar. 22, 2024), available at https://www.genome.gov/genetics-glossary/Carrier-Screening (last visited April 3, 2025).
[42] Dustin J. Penn, *Major Histocompatibility Complex, Encyclopedia of Life Sciences (2002),* available at https://www.researchgate.net/publication/228038374_Major_Histocompatibility_Complex_MHC (last visited April 3, 2025).
[43] Eric Epierings, Katharina Fleischhauer, *Chapter 9: Histocompatibility,* National Library of Medicine, The EBMT Handbook: Hematopoietic Stem Cell Transplantation and Cellular Therapies (2019), available at https://www.ncbi.nlm.nih.gov/books/NBK553927/ (last visited April 3, 2025).
[44] van El CG, Cornel MC, et al, ESHG Public and Professional Policy Committee. *Whole-genome sequencing in health care. Recommendations of the European Society of Human Genetics,* Eur J Hum Genet. 2013 Jun;21 Suppl 1(Suppl 1):S1-5, available at . https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3660957/ (last visited April 3, 2025).
[45] Rule 59G-4.190, *Laboratory Services and Coverage* Policy (January 2024; Effective April 3, 2024), available at Reference Material Home - Florida Administrative Rules, Law, Code, Register - FAC, FAR, eRulemaking (flrules.org) (last visited April 3, 2025).
[46] Agency for Health Care Administration, *2024 Agency Legislative Bill Analysis – SB 964/HB* 885, pp. 2 (January 17, 2024) (on file with the Select Committee on Health Innovation).
[47] S. 409.906(29), F.S.
[48] Email from Jim Browne, Legislative Affairs Director, Agency for Health Care Administration, RE: HB 1335 Fiscal Questions, (Mar. 25, 2025), on file with the Health and Human Services Committee. The Statewide Medicaid Managed Care plans also waive copayments and coinsurance requirements for all services under their expanded benefits.

The American Medical Association's Current Procedural Terminology (CPT) codes offer physicians and health care practitioners a uniform language for coding medical services and procedures to streamline reporting, with the intention to increase accuracy and efficiency. Proprietary Laboratory Analysis (PLA) codes are a subset of CPT codes, which describe the proprietary clinical laboratory analyses that certain laboratories can provide.[49]

RECENT LEGISLATION:

YEAR	BILL #	HOUSE SPONSOR(S)	SENATE SPONSOR	OTHER INFORMATION
2024	CS/CS/HB 885	Gonzalez Pittman	Calatayud	Became law on July 1, 2024.

BILL HISTORY

COMMITTEE REFERENCE	ACTION	DATE	STAFF DIRECTOR/ POLICY CHIEF	ANALYSIS PREPARED BY
Health Care Facilities & Systems Subcommittee	16 Y, 0 N, As CS	3/27/2025	Calamas	DesRochers
THE CHANGES ADOPTED BY THE COMMITTEE:	Click or tap here to enter text.			
Budget Committee	24 Y, 0 N	4/8/2025	Pridgeon	Smith
Health & Human Services Committee				

THIS BILL ANALYSIS HAS BEEN UPDATED TO INCORPORATE ALL OF THE CHANGES DESCRIBED ABOVE.

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[49] American Medical Association, "CPT overview and code approval," https://www.ama-assn.org/practice-management/cpt/cpt-overview-and-code-approval#what-is-a-cpt-code (last visited April 3, 2025).