



## BULLETIN 25-EX-7

TO: ALL HEALTH PLANS IN THE STATE OF GEORGIA

FROM: JOHN F. KING  
INSURANCE AND SAFETY FIRE COMMISSIONER

DATE: DECEMBER 31, 2025

RE: MANDATED COVERAGE OF BIOMARKER TESTING

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This Bulletin is intended for all health benefit policies<sup>1</sup> issued for delivery in Georgia, including any plans established under Article 1 of Chapter 18 of Title 45 (Georgia state employee plans).

O.C.G.A. § 33-24-59.33 requires that all health benefit policies include coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when the testing is supported by any of the following five criteria:

- (1) **FDA Approval:** A labeled indication for a test that has been approved or cleared by the United States Food and Drug Administration (FDA).
- (2) **Indicated Test:** A test indicated for an FDA-approved drug or included in the warnings/precautions of an FDA-approved drug label.
- (3) **CMS Determinations:** A national coverage determination made by the federal Centers for Medicare and Medicaid Services or a local coverage determination made by a medicare administrative contractor.
- (4) **Clinical Practice Guidelines:** Nationally recognized clinical practice guidelines and consensus statements.
- (5) **Warnings and precautions on FDA approved drugs.**

Further all health benefit policies shall ensure biomarker testing coverage is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples. The process for requesting an exception to a coverage policy or appealing an adverse

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<sup>1</sup> "Health benefit policy" means any individual or group plan, policy, or contract for healthcare services issued, delivered, issued for delivery, or renewed in this state which provides major medical benefits, including those contracts executed by the State of Georgia on behalf of state employees under Article 1 of Chapter 18 of Title 45, by a health care corporation, health maintenance organization, preferred provider organization, accident and sickness insurer, fraternal benefit society, hospital service corporation, medical service corporation, or other insurer or similar entity. O.C.G.A. § 33-24-59.33(a)(4).

determination must be readily accessible on the plan's website. Further, plans are expected to adhere to the expedited timelines required for urgent medical necessity.

### **Required Coverage: Examples and Medicare LCDs**

To assist in compliance, the Commissioner has identified the following non-exhaustive list of tests and categories that have met the threshold for coverage based on the criteria above, specifically referencing Palmetto GBA (MolDX) determinations for the Georgia jurisdiction:

<b>Test Category</b>	<b>Relevant Evidence / LCD</b>	<b>Application</b>
<b>Comprehensive Genomic Profiling (CGP)</b>	NCD 90.2 / NCCN Guidelines	Advanced/Metastatic solid tumors (Stage III/IV).
<b>Liquid Biopsy</b>	LCD L37870 (InVisionFirst)	Lung cancer patients (NSCLC) where tissue is insufficient.
<b>Pharmacogenomics</b>	FDA Labeled Indications	DPYD/TPMT for chemo toxicity; CYP2C19 for Clopidogrel.
<b>Minimal Residual Disease (MRD)</b>	LCD L38290 (Signatera/Guardant)	Monitoring recurrence in colorectal and other cancers.
<b>Hereditary Cancer Testing</b>	NCCN Guidelines / LCD L38966	BRCA1/2, Lynch Syndrome, and high-risk panel testing.
<b>Neurological/Oncology</b>	LCD L35974	MGMT Promoter Methylation for Glioblastoma.

This Bulletin is intended to remind health plans of their obligation to comply with O.C.G.A. § 33-24-59.33 and the Department of Insurance will take regulatory action as necessary to enforce compliance with such obligation.

  
JOHN F. KING  
INSURANCE AND SAFETY FIRE COMMISSIONER  
STATE OF GEORGIA