LOUISIANA DEPARTMENT OF INSURANCE
TIMOTHY J. TEMPLE
COMMISSIONER

BULLETIN 2025-05

TO: **ALL HEALTH INSURANCE ISSUERS, HEALTH MAINTENANCE ORGANIZATIONS, AND SELF–INSURERS**

FROM: **TIMOTHY J. TEMPLE, COMMISSIONER OF INSURANCE**

RE: **COVERAGE REQUIREMENTS FOR BIOMARKER TESTING**

DATE: **SEPTEMBER 5, 2025**

The purpose of Bulletin 2025-05 is to explain and promote uniformity in the application of coverage requirements under 2023 Act 324 as amended by 2024 Act 160 (The Biomarker Law), relating to coverage for biomarker testing.[1]

This Bulletin provides guidance to any health insurance issuers, health maintenance organizations, and self-insurers (issuers) subject to the Biomarker Law pursuant to La. R.S. 22:1028.5.

The Biomarker Law was enacted in 2023, and requires issuers to provide coverage for biomarker testing. “Biomarker testing” is defined as an “analysis of a patient’s tissue, blood, or other biospecimen for the presence of a biomarker. ‘Biomarker testing’ includes but is not limited to single-analyte tests, multi-plex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.”[2] “Biomarker” is defined to mean “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 medication being considered for use or currently administered. A ‘biomarker’ includes but is not limited to gene mutations, characteristics of genes, or protein expression.”[3]

The Biomarker Law requires coverage for biomarker testing that is used “for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of an individual’s disease or condition” to guide treatment.[4] Coverage is required when the test provides clinical utility as demonstrated by medical and scientific evidence, including the following items:

[1] Codified at La. R.S. 22:1028.5.
[2] La. R.S. 22:1028.5(E)(2).
[3] La. R.S. 22:1028.5(E)(1).
[4] La. R.S. 22:1028.5(B)(2)

1. Labeled indications for diagnostic tests approved or cleared by the United States Food and Drug Administration or indicated diagnostic tests for a drug approved by the United States Food and Drug Administration;
2. Warnings and precautions listed on a United States Food and Drug Administration approved drug label;
3. National Coverage Determinations of the Centers for Medicare and Medicaid Services or Local Coverage Determinations of Medicare Administrative Contractors; or
4. Nationally recognized clinical practice guidelines."[5]

In order to promote uniformity in application of the Biomarker Law's coverage requirements, the Louisiana Department of Insurance (LDI) offers four clarifications regarding interpretation of the Biomarker Law.

First, the Biomarker Law requires coverage for a biomarker test that is used "for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition" to guide treatment decisions if the biomarker test provides clinical utility. "Clinical utility" is defined to mean that a biomarker test result provides "information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision. The most appropriate test may include both information that is actionable and some information that cannot be immediately used in the formulation of a clinical decision."[6]

The Biomarker Law makes clear that a biomarker test's clinical utility may be "demonstrated" by any one of the categories of "medical and scientific evidence" listed in the Biomarker Law. Accordingly, when a biomarker test satisfies any one of the following four categories of "medical and scientific evidence" listed by the Biomarker Law, clinical utility is "demonstrated" for the test for purposes of the Biomarker Law:

1. Labeled indications for diagnostic tests approved or cleared by the United States Food and Drug Administration or indicated diagnositc tests for a drug approved by the United States Food and Drug Administration;
2. Warnings and precautions listed on a United States Food and Drug Admnistration approved drug label;
3. National Coverage Determinations of the Centers for Medicare and Medicaid Services or Local Coverage Determinations of Medicare Adminstrative Contractors; or
4. Nationally recognized clinical practice guidelines.

[5] La. R.S. 22:1028.5(B)(2).
[6] La. R.S. 22:1028.5(E)(3)

An Insurer therefore must cover a biomarker test if it is satisfied by medical and scientific evidence, as well as by any one of the items listed in the categories of and aforementioned. However, the test must be used "for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition" to guide treatment decisions.[7]

It is important to note that issuers do not have discretion to apply additional or different coverage criteria. For example, where a biomarker test is covered under Local Coverage Determinations of Medicare Administrative Contractors (LCD), an Insurer may not apply coverage criteria additional to or different from those included in the LCD to determine clinical utility. Furthermore, an Insurer shall ensure that coverage be provided in a manner that limits disruption in care, including the need for mutilple biopsies or biospecimens samples.

Second, because medical and scientific evidence or any one of the items listed in the categories is sufficient to demonstrate clinical utility under the Biomarker Law, issuers may not require multiple categories of evidence to provide coverage, and issuers must apply the least restrictive coverage criteria if multiple categories of medical and scientific evidence are satisfied by the biomarker test. For example, if a biomarker test has a labeled indication approved by the FDA and a LCD MAC that imposes coverage criteria more restrictive than the labeled indication, issuers must cover the biomarker test in accordance with its labeled indication, i.e., the less restrictive coverage criteria.

Third, in the absence of medical and scientific evidence or any of the included items listed in the Biomarker Law, issuers may make determinations as to whether a test provides clinical utility in accordance with their judgment, applicable medical policies, and available evidence.

Fourth, in formulating any medical policy used to make coverage decisions for biomarker tests, issuers should explicitly state the requirements of the Biomarker Law and follow those requirements. Insofar as an Insurer utilizes a medical policy that is intended to be generally applicable in multiple jurisdictions, such policy must explicitly provide that the Biomarker Law governs insurance policies to which it applies, and that the coverage requirements of Biomarker Law prevail over any other more general or different requirements. The LDI emphasizes that clear medical policy provisions that faithfully reflect the requirements of the Biomarker Law are critical to effectuating access to biomarker testing.

[7] La. R.S. 22:1028.5(B)(2).

If there are any questions or concerns regarding Bulletin 2025-05, please contact the Deputy Commissioner for the Office of Health, Life, and Annuity at (225) 342-1355 or electronically at public@ldi.la.gov.

Baton Rouge, Louisiana this 5th day of September 2025.

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