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BULLETIN NO. 2025-06

TO: **All Health Insurance Companies, HMOs, and Other Interested Parties**

RE: **Coverage Requirements for Biomarker Testing**

FROM: **Glen Mulready, Insurance Commissioner**

DATE: **October 17, 2025**

Disclaimer: The purpose of this bulletin is to inform, clarify, and promote uniformity in the application of the mandated biomarker testing coverage as required by 36 O.S. § 6060.5a. Please refer to the Oklahoma Supreme Court Network (OSCN) webpage to view the complete language of the statute.

The Biomarker Law was enacted by Senate Bill 513 (2023), with an effective date of January 1, 2024, and codified at 36 O.S. § 6060.5a. The statute requires that "[a]ny health benefit plan, including the Oklahoma Employees Insurance Plan, that is offered, issued, or renewed in this state on or after the effective date of this act shall provide coverage for biomarker testing." 36 O.S. § 6060.5a(B).

"Biomarker testing" is defined as an "analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing shall include but not be limited to single-analyte tests, multiplex panel tests, gene or protein expression, and whole exome, whole genome, and whole transcriptome sequencing." 36 O.S. § 6060.5a(A)(2).

"Biomarker" is defined to mean "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 or for other purposes. Biomarkers shall include but are not limited to gene mutation or protein expression." 36 O.S. § 6060.5a(A)(1).

The law requires coverage for biomarker testing "for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of an individual's disease or condition to guide treatment decisions when the biomarker test provides clinical utility as demonstrated by medical and scientific evidence including, but not limited to:

1) Labeled indications for tests that are approved or cleared by the United States Food and Drug Administration ("FDA");

2) Indicated tests for a drug that is approved by the FDA;

3) Warnings and precautions on a FDA approved-drug labels;

4) Centers for Medicare and Medicaid Services ("CMS") national coverage determinations or Medicare administrative contractor local coverage determinations; or

5) Nationally recognized clinical practice guidelines and consensus statement."

36 O.S. § 6060.5a(B)(1)-(5).

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

First, the Biomarker Law requires coverage for a biomarker test that is used for "the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of an insured's disease or condition to guide treatment decisions when the biomarker test provides clinical utility as demonstrated by medical and scientific evidence" 36 O.S. § 6060.5a(B).

"Clinical utility" is defined to mean "the 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." 36 O.S. § 6060.5a(A)(3).

A biomarker test's clinical utility may be "demonstrated" by any one of the categories of "medical and scientific evidence." As such, when a biomarker test satisfies any one of the following five categories of "medical and scientific evidence" listed by the Biomarker Law, clinical utility is "demonstrated":

1) Labeled indications for tests that are approved or cleared by the FDA;

2) Indicated tests for a drug that is approved by the FDA;

3) Warnings and precautions on a FDA approved-drug labels;

4) CMS national coverage determinations or Medicare administrative contractor local coverage determinations; or

5) Nationally recognized clinical practice guidelines and consensus statement."

An Insurer therefore must cover a biomarker test if it is satisfied by medical and scientific evidence, or by any one of the items listed in the categories aforementioned. However, the test must be used for the "purpose of diagnosis, treatment, appropriate management, or ongoing

monitoring of an insured's disease or condition to guide treatment decisions." 36 O.S. § 6060.5a(B).

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, "a health benefit plan shall ensure that coverage is provided in a manner that limits disruption in care, including the need for multiple biopsies and biospecimens samples." 36 O.S. § 6060.5a(C).

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 OID emphasizes that clear medical policy provisions that faithfully reflect the requirements of the Biomarker Law are critical to effectuating access to biomarker testing.

Finally, the Biomarker Law is meant to be applied in conjunction with all other applicable statutorily mandated health benefit coverage provisions.

Questions concerning this bulletin should be directed to the Oklahoma Insurance Department's Legal Division at 405-521-2746 or by email to Tyler Trammell, Assistant General Counsel, at Tyler.Trammell@oid.ok.gov.