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BULLETIN 2026-03

The following Bulletin is to inform the reader of the current position of the Kentucky Department of Insurance on the specified issue. The Bulletin is not legally binding on either the Department or the reader.

TO: **ALL INSURERS ISSUING HEALTH BENEFIT PLANS WITHIN THE COMMONWEALTH OF KENTUCKY**

FROM: **SHARON P. CLARK, COMMISSIONER KENTUCKY DEPARTMENT OF INSURANCE**

DATE: **APRIL 28, 2026**

RE: **BIOMARKER TESTING**

Purpose

The Kentucky Department of Insurance ("Department") is issuing this Bulletin to provide information regarding the regulation and enforcement of House Bill 180 (HB 180), passed during the 2023 Regular Session of the Kentucky General Assembly.

Background

HB 180 became effective January 1, 2024, and has been codified as KRS 304.17A-263. Therefore, any health benefit plan issued, delivered, amended, or renewed on or after January 1, 2024, must satisfy the biomarker coverage requirements mandated by KRS 304.17A-263.

KRS 3014.17A-263(1)(a) defines "biomarker" as, "…a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered." This definition includes gene mutations and protein expression.

KRS 304.17A-263(1)(b) defines "biomarker testing" as, "…the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker." This definition includes single-analyte tests, multiplex panel test, and whole genome sequencing.

KRS 304.17A-263(2) requires a health benefit plan to cover biomarker testing when it is ordered by a qualified health care provider practicing within the provider's scope of practice. The test must be ordered for the purpose of diagnosis, treatment, appropriate management or ongoing monitoring of the insured's disease or condition. The ordered test must be supported by medical and scientific evidence. The statute identifies seven (7) instances when a test is considered to meet the medical and scientific standard, although this list is not exhaustive: 1) Labeled indications for an FDA-approved or FDA-cleared test; 2) indicated tests for an FDA-approved drug; 3) warnings and precautions on FDA-approved drug labels; 4) Centers for Medicare and Medicaid Services national coverage determinations; 5) Medicare Administrative Contractor local coverage determinations; 6) nationally recognized clinical practice guidelines; or 7) consensus statements. *See* KRS 304.17A-263(2)(a)-(g).

Prior authorization requirements for biomarker testing coverage must comply with any existing prior authorization statutes, including KRS 304.17A-607. *See* KRS 304.17A-263(5). Pursuant to KRS 304.17A-263(5), the insured and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception on the insurer's website should the test be denied.

Regulation and Enforcement

The language of KRS 304.17A-265(2) is unambiguous. A health benefit plan shall cover biomarker testing when: (1) it is ordered by a qualified health provider operating within the provider's scope of practice; and (2) the purpose for ordering the test is to diagnose, treat, or perform appropriate management or ongoing monitoring of an insured's disease or condition. Additionally, the test must be supported by medical and scientific evidence.

KRS 304.17A-263(2)(a)-(g) lists specific examples of what is statutorily considered medical and scientific evidence. The coverage requirements of KRS 304.17A-263 are met if the provider or the insured can demonstrate that any one of the examples listed are met.

Insurers do not have discretion to require additional or different coverage criteria. For example, if the provider or insured demonstrates that a test meets the Centers for Medicare and Medicaid Services national coverage determinations, an insurer cannot require additional documentation in furtherance of the claim for services.

Furthermore, this is not an exhaustive list. If the provider or insured can demonstrate by other means that a biomarker test is supported by medical and scientific evidence that is not enumerated in KRS 304.17A-263(2)(a)-(g), the test must be covered by the plan.

If an insurer denies a biomarker test, the insurer's website shall offer a clear, readily accessible, and convenient exception and appeal process to both providers and insureds. Finally, insurers shall ensure that any prior authorization requirements applied to biomarker testing services comply with all applicable prior authorization requirements in the Kentucky Insurance Code (Code). Insurers are not permitted to employ prior authorization requirements upon biomarker testing coverage that do not meet the provisions in the Code. For example, prior authorization denials of biomarker claims shall be in writing and include an explanation of the appropriate medical or scientific reason for denial, which aligns with current standards of practice.

For any question regarding the content of this bulletin, please contact the Kentucky Department of Insurance, Health and Life and Managed Care Division at Health.Mail@ky.gov or at (502) 564-6088.

Sharon P. Clark

Sharon P. Clark, *Commissioner*
Kentucky Department of Insurance
On this 28th day of April 2026