304.17A-263 Coverage under health benefit plan for biomarker testing.

(1) As used in this section:

(a) "Biomarker":

1. Means 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; and

2. Includes but is not limited to gene mutations and protein expression;

(b) "Biomarker testing":

1. Means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker; and

2. Includes but is not limited to single-analyte tests, multiplex panel tests, and whole genome sequencing;

(c) "Consensus statements" means statements that are:

1. Developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure with a conflict of interest policy;

2. Aimed at specific clinical circumstances; and

3. Based on the best available evidence for the purpose of optimizing the outcomes of clinical care;

(d) "FDA" means the United States Food and Drug Administration; and

(e) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that:

1. Are developed by an independent organization or medical professional society utilizing a transparent methodology and reporting structure with a conflict of interest policy;

2. Establish standards of care informed by:

a. A systematic review of evidence; and

b. An assessment of the benefits and risks of alternative care options; and

3. Include recommendations intended to optimize care.

(2) A health benefit plan shall provide coverage for biomarker testing when ordered by a qualified health care provider operating within the provider's scope of practice for the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of an insured's disease or condition when the test is supported by medical and scientific evidence, including but not limited to:

(a) Labeled indications for an FDA-approved or FDA-cleared test;

(b) Indicated tests for an FDA-approved drug;

(c) Warnings and precautions on FDA-approved drug labels;

(d) Centers for Medicare and Medicaid Services national coverage

determinations;

(e) Medicare Administrative Contractor local coverage determinations;

(f) Nationally recognized clinical practice guidelines; or

(g) Consensus statements.

(3) The coverage required under this section shall be provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(4) When coverage for biomarker testing is restricted by an insurer or a third party acting on behalf of the insurer, the insured and prescribing practitioner shall have access to a clear, readily accessible, and convenient process on the insurer's website to request an exception to the coverage policy.

(5) Any prior authorization requirement applicable to coverage required under this section shall comply with any existing prior authorization laws, including but not limited to KRS 304.17A-607.

(6) Nothing in this section shall be construed to:

(a) Require coverage of biomarker testing for screening purposes; or

(b) Limit coverage required under:

1. KRS 304.17A-259;

2. KRS 205.522; or

3. Any other law.

Effective: January 1, 2024

History: Created 2023 Ky. Acts ch. 77, sec. 1, effective January 1, 2024.

Legislative Research Commission Note (1/1/2024). 2023 Ky. Acts ch. 77, sec. 3, provides that this statute applies to health benefit plans issued, delivered, amended, or renewed on or after January 1, 2024.